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# CAPACITY-BUILDING (ARTICLE 22, ARTICLE 28)

*Indicative framework for capacity-building under the Cartagena Protocol on Biosafety*

*Note by the Executive Secretary*

## INTRODUCTION

1. This note from the Executive Secretary provides an initial indicative framework for capacity-building under the Cartagena Protocol on Biosafety. It begins with the nature of capacity-building in an international and national context; presents the mandate for capacity-building under the Protocol and guidance provided by the Parties; outlines the general and specific rights and obligations of the Parties under the Protocol; identifies the types of capacities needed to implement these rights and obligations and potential approaches and options for achieving the required capacities; and, finally provides a summary of lessons learned from past and ongoing capacity-building activities for biosafety including biotechnology.

## I. CAPACITY-BUILDING IN INTERNATIONAL AND NATIONAL CONTEXTS

2. Over the past decade, experience with capacity-building efforts relating to international environmental agreements and other environment and development initiatives has led to the identification of key factors to guide capacity-building efforts. 1/, 2/, 3/ These factors include: the need to consider national capacity-building at the overall "systems" level, not just at the level of separate institutions or individual skills; the importance of basing design and implementation on a detailed assessment of locally identified needs; the need for thorough analysis and understanding of the local and national contexts in environmental, socio-cultural, economic and institutional terms; the need to link environmental priorities to other national priorities; and, the involvement of a broad range of stakeholders, including the private sector, in project design and implementation.

3. It is also widely accepted that capacity-building must go beyond single, short interventions to encompass systematic, longer-term efforts. Consequently, the scope of capacity-building usually includes the assessment of needs, identification of options at the national (and possibly regional) level, the development and strengthening of relevant institutions, the development of skills and expertise in human resources, including through education and training, establishment of necessary scientific and information management facilities, and assessments for technology transfer. These and other areas of capacity-

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building are generally supported through the provision of external technical assistance and financial resources on a bilateral, multilateral or private basis.

4. In the context of the Convention on Biological Diversity, capacity-building is linked to national biodiversity strategies and action plans (NBSAPs) which describe how Parties are responding to or intend to respond to their obligations under the Convention. NBSAPs and national biodiversity reports help countries to identify the requirements for meeting these obligations and provide an indication of priorities for capacity-building. More recently, the UNDP/GEF Capacity Development Initiative is identifying national priorities for implementation of the Convention on Biological Diversity, and other environmental agreements. While these broad approaches to capacity building have included some references to biosafety issues, more focused efforts such as the UNEP/GEF pilot biosafety enabling activity project have begun to assist countries in assessing their biosafety capacity needs and preparing national biosafety frameworks. 4/ With the conclusion of the Cartagena Protocol negotiations, the opportunity and necessity to focus more specifically on capacity-building for biosafety is evident.

5. To assist information-sharing in response to this guidance, the Executive Secretary sent a request on 27 March 2000 to Parties to provide information on their existing programmes for regulating living modified organisms; and to provide related technical assistance, including training, to interested Parties and States. In July, a notice on the website of the Convention on Biological Diversity sought inputs about ongoing capacity-building activities/initiatives in biosafety from Parties and other Governments, international organizations, industry, non-governmental organizations and any other interested experts.

6. The indicative framework on capacity-building outlined in the present document responds to the mandate set out in the decision V/1. Although this framework is being developed prior to entry-into-force of the Protocol, it nonetheless can serve to provide guidance to countries seeking to strengthen their capacities in biosafety, and to other bodies such as bilateral and multilateral cooperation and financing programmes and the engaged private sector which are in a position to cooperate in such efforts. There can be an active period for capacity-building prior to entry-into-force that can also serve to encourage and support Parties in ratification of the Protocol. Further, the guidance on capacity-building prepared by the ICCP can then be considered by the first Meeting of the Parties to the Protocol for further action in the post-entry-into-force period.

## II. PARAMETERS FOR CAPACITY-BUILDING FOR IMPLEMENTATION OF THE CARTAGENA PROTOCOL

7. The rights and obligations of Parties contained in the Cartagena Protocol provide a basis for developing a framework for capacity-building, given that Parties need to have in place or to have access to the necessary capacities to act on and respond to these rights and obligations. * The concept of rights and obligations is important, as it reflects the balance between the right of Parties to protect their environment from potential adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health, and the obligation not to unduly restrict transboundary movements of living modified organisms in taking measures to achieve the necessary protection.

8. The Protocol contains both general and specific rights and obligations. The general rights and obligations relate to biosafety in the context of both domestic use and transboundary movement. The specific rights and obligations focus primarily on measures pertaining to transboundary movement set out in the Protocol. An indicative list of these is provided below.

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

* This section does not provide a legal review or interpretation of the provisions of the Protocol, but identifies indicative rights and obligations as they relate to capacity-building for the implementation of the Protocol.

(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*: endeavour to ensure that any living modified organism whether imported or locally developed, has undergone an appropriate period of observation before it is put to its intended use;

(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.

10. Specific rights and obligations set out in the Protocol most relevant to capacity-building include:

(a) *Article 7*: application of the advanced informed agreement procedure;

(b) *Article 8*: Party of export to notify competent national authority of Party of import prior to the intentional transboundary movement of a living modified organism;

(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.

11. This indicative list of rights and obligations points to an extensive set of institutional capacities and individual expertise and skills that will be needed to effectively implement the Protocol, including those related to legal and administrative measures, policy formulation and decision making, and scientific and technical analysis.

## III. IDENTIFICATION OF THE TYPES OF CAPACITY REQUIRED TO IMPLEMENT THE RIGHTS AND OBLIGATIONS IN THE PROTOCOL

12. Three main categories of capacities can be identified as required for an effective implementation of the Protocol by developing countries and countries with economies in transition: institution-building, risk-management capacity, and risk-assessment capacity. There follows a general description of each of these categories and their interrelationship, along with a description of certain areas where cross-cutting capacities are required in support of these three categories. The table on pages 5 and 6 below provides specific details for each of these categories of capacities, based on the rights and obligations in the Protocol noted above.

13. The first category is institution-building, which encompasses the development of the legal, regulatory and administrative structures and procedures needed for an effective biosafety regime. Experience to date has shown the need for a comprehensive planning process as the first step in building capacities, through the preparation of national biosafety frameworks. The table identifies capacities required for this planning stage, for the development of the biosafety regime itself, and for long-term regime maintenance.

14. The second and third categories of capacities relate to the implementation of the provisions concerning domestic handling and use of living modified organisms, as well as the more specific requirements for the regulation, management and control of living modified organisms subject to intentional transboundary movements. These are the capacities to undertake risk assessments, and to develop and implement appropriate risk management processes. Each of these has a distinct set of requirements that are presented in the table.

15. A number of cross-cutting themes are relevant to all three aspects of capacity-building. Data management and information sharing is one such theme. The Biosafety Clearing-House (BCH), established by Article 20 of the Protocol, is a critical component, including its use to facilitate access to

all types of data and information in the biosafety field. In this regard, the design of the mechanism needs to ensure that it provides a useful resource for capacity-building. Parties will need to have the necessary capacities – e.g. scientific data-gathering and analysis, installation of information technologies and training in their use – to facilitate the exchange of scientific, technical, environmental and legal information, and to report to the Biosafety Clearing-House on measures taken to implement the Protocol.

16. Capacity development for both risk assessment and risk management needs to occur at the level of individuals such as regulators, scientists, and farmers and other potential end users, as well as at the level of institutions. Therefore, a second essential cross-cutting issue is human resources development – through training, education and other means, including training of end-users in all aspects of the handling and use of living modified organisms.

17. A third cross-cutting issue is the need for public awareness building and participation to be actively supported. A fourth is stakeholder involvement – particularly with regard to the private sector, communities and non-governmental organizations.

18. A final cross-cutting issue is regional capacity development, both related to risk assessment and to harmonization of laws and regulatory approaches.

*Table. Preliminary list of key required capacities for implementation of the Cartagena Protocol*

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

| INSTITUTION BUILDING | RISK ASSESSMENT | RISK MANAGEMENT |
|---|---|---|
| ***Long-term regime building/maintenance***<br>(a) Capacity to monitor, review and report on the effectiveness of risk management programme, including legal, regulatory and administrative mechanisms<br>(b) Capacity to monitor longer-term environmental impacts, if any (based on current baselines)<br>(c) Establishment of environmental reporting systems | | |
| **CROSS-CUTTING CAPACITIES** | | |
| ***Data management and information-sharing***<br>(a) Exchange of scientific, technical, environmental and legal information<br>(b) Collection, storage and analysis of scientific, regulatory and administrative data<br>(c) Communication to the Biosafety Clearing-House | | |
| ***Human resources strengthening and development***<br>(a) All aspects of regime development, evaluation and maintenance for risk assessment and risk management<br>(b) Raising awareness of modern biotechnology and biosafety among scientists, government officials<br>(c) Training and longer-term education<br>(d) Procedures for safe handling, use and transfer of living modified organisms | | |
| ***Public awareness and participation***<br>(a) Administer and disseminate information on legal and administrative framework<br>(b) Public awareness of/participation in scientific assessment process<br>(c) Risks associated with handling and use | | |
| ***Involvement of stakeholders e.g. non-governmental organiztions, local communities, private sector***<br>(a) Capacity to negotiate with and provide opportunity for private sector involvement<br>(b) Processes for community, NGO consultation in development of risk assessment and management regimes<br>(c) Processes for community, NGO consultation prior to decisions | | |
| ***Regional capacity development***<br>(a) Scientific assessment of risk<br>(b) Harmonization of legal regimes<br>(c) Training of human resources<br>(d) Information sharing | | |

## IV. POTENTIAL APPROACHES AND OPTIONS FOR ACHIEVING THE REQUIRED CAPACITY TO IMPLEMENT THE CARTAGENA PROTOCOL

### *A. Approaches and options*

19. The capacity needs of each Party to the Protocol, and the approach used to meet them, will need to be defined on a country-by-country basis through the development of national biosafety frameworks. Some of the key factors to be considered in the process of analysing national biosafety needs and developing a framework will include the present and anticipated extent of domestic biotechnology activity, the anticipated levels of imports of living modified organisms, the nature and complexity of the local receiving environment, and the potential for biodiversity impacts, including on centres of species origin and diversity.

20. Different approaches and models can be identified for putting in place, or having access to, the capacities needed to implement the obligations under the Protocol. The approaches and options outlined in this section may be combined according to particular national needs, availability of financial and technical resources, and cost-effectiveness. The majority of the approaches below will likely involve North-South cooperation, at least until national and regional capacities are well developed.

*(a) Comprehensive national capacity*

21. Each country can seek to achieve the full set of capacities necessary to implement the Protocol. For risk assessment and risk management, this approach would be most critical where there is an extensive or growing domestic biotechnology sector that itself requires appropriate biosafety controls, in keeping with the general obligations under the Protocol and the Convention. Developing a comprehensive national capacity for all countries would, however, be costly. Consequently, setting clear priorities among countries and within each country to determine needs will be required for capacity-building programmes, given finite financial and technological resources.

22. Where the domestic sector is not expansive, the requirement for comprehensive national capacity to address imports subject to the Protocol will likely be high only where there is a large existing or anticipated trade in living modified organisms. Here, expected trade may also require differentiation between living modified organisms for direct release into the environment and living modified organisms intended for direct use as food, feed, or for processing , bearing in mind national decisions on whether or how to address the latter.

*(b) Combining national capacity for risk management decisions with the capacity of exporters for risk assessment*

23. This approach applies primarily to transboundary movements of living modified organisms subject to the control regime of the Protocol, or to the import of biotechnologies for domestic application that might trigger the more general provisions on biosafety under the Protocol. This option may be more relevant than the previous one for a country with a less advanced domestic biotechnology sector.

24. This division of responsibilities between risk assessment and risk management reflects the need for decision-making by entities that are independent of the promoters and direct users of biotechnology, including living modified organisms. The Party of import develops and maintains an independent national decision-making function. At the same time, the Protocol provides for the possibility of the exporter or country of export undertaking the risk assessment. The viability of this option may need to be determined on a case-by-case basis, based on the business case for an exporter to either assist the country of import in capacity-building, or itself provide the necessary capacity.

*(c) Combining national capacity for decision-making and risk management with a regionally based capacity for risk assessment*

25. Experience with capacity-building initiatives to date has demonstrated the value of developing effective regional capacities to assist Parties in meeting their obligations under the Protocol. Under this option, national capacity development could focus on risk management capacity, including decision-making and decision implementation. The scientific capacity for risk assessment, however, could be developed on a regional basis, through centres of excellence at universities or agreed regional research centres, for example. This capacity could then be utilized throughout the region to provide consistent scientific analysis. Similarly, the social science capacity that may be required for a risk assessment can be developed and utilized on a regional basis. Regional training centres could also be used for development of national capacities.

26. Placing a regional risk-assessment capacity at the disposal of countries within a given region or subregion would reduce the need to rely on the risk assessment capacity of the exporter, thus increasing the independence of the process. It also has the potential to be more cost-effective than the development of comprehensive national capacities in every country.

*(d) Regional/subregional harmonization*

27. This approach further develops the regional option, potentially to the level of decision-making for risk management. It is doubtful that the administrative and enforcement aspects of risk management could be regionalized in most cases, but in some cases this may be possible.

28. A regional option developed to the fullest extent may be appropriate in some cases where legal and administrative systems between countries are comparable and can be harmonized. Additionally, the similarity of cultural systems, environmental conditions and biosafety needs would be important considerations. Harmonization or integration of legal, regulatory and administrative systems for biosafety would likely achieve greater cost-efficiencies. A less extensive type of regional integration could involve harmonization of regional laws, while leaving decision-making and implementation to individual countries. Experience in such instances may lead to greater integration.

*(e) The role of the private sector in delivering risk assessment and self-enforcement*

29. As already noted, the Protocol provides for the possibility of private-sector exporters delivering the risk-assessment capacity for transboundary purposes. This option potentially can be expanded to include voluntary or self-enforced risk-management processes. Voluntary processes also may be relevant to the general obligation to ensure biosafety in relation to domestic sectors. In such cases, where the private sector is responsible for ensuring the biosafety of its activities, or for undertaking risk assessment, independent third party auditing of the assessment may also be a requirement.

30. Such an approach can be viable in some circumstances. However, experience to date does suggest strongly that the biosafety regulatory function should be separated from the promotion and business ends of the biotechnology sector.

*(f) The development of model legal and administrative regimes and criteria for legal drafting*

31. The development of model legal and administrative regimes could be used to support the above approaches. Such regimes can be developed at the regional level, or at the multilateral level under the direction of the meeting of the Parties, with interim work set out by the ICCP. Such model regimes would help support the institution-building requirements associated with the Protocol.

32. Model legal and administrative regimes, or the development of principles and criteria for drafting elements of legislation, could potentially assist in promoting the effective implementation of the

environmental goals of the Protocol, in a manner that also enhances those provisions that seek to ensure a consistent approach to the international transfers of living modified organisms. A model regime that is consistently applied in domestic law may also better satisfy the needs of importing countries by reducing the risks of compliance challenges under other international dispute resolution processes, and by promoting a consistent high standard for risk assessment and risk management. In addition, consistency between exporter and importer regimes can be fostered by a model law and administrative process, thereby reducing transaction costs for transboundary movements.

*(g) South-South cooperation*

33. In addition to North-South cooperation in support of the approaches outlined above, expanded South-South cooperation in institution-building, as well as in risk assessment and perhaps several aspects of risk-management decision-making, is also an option to be considered. Several developing countries have extensive national biotechnology sectors, which can provide a significant base of experience and expertise upon which other developing countries can draw. Opportunities to promote such avenues should be examined in the context of defining capacity-building programmes.

34. The inclusion of a South-South component may also have significant benefits for the initial analysis of biosafety needs of a Party, and for the development of both national and regional biosafety frameworks. This could be assisted by "mentoring" of certain countries by experts from those countries that have already developed national biosafety frameworks. 4/

*B. Roster of experts*

35. The role of the roster of experts, established by the Parties in decision EM-I/3, is both to support capacity-building efforts in developing countries and countries with economies in transition, and to provide direct advice in the implementation of biosafety measures themselves, where national capacities are insufficient. Parties will be able to make effective use of the roster either directly on a case-by-case basis, or through biosafety capacity-building efforts supported by international organizations, bilateral donors, or private groups.

36. In the former case, experts on the roster can be engaged directly by a Party itself to help it address specific notifications, and in particular to augment the required capacities outlined in the table on pages 5 and 6 above for risk assessment and risk management. Experts from the roster could assist with: reviewing the information provided; identifying information sources and the scientific and other expertise needed to undertake the risk assessment; contributing directly to the conduct of the assessment; advising on the process for decision-making; and, advising on setting in place risk-management follow-up procedures. The provision of such direct expert and technical assistance considered in most cases as an interim approach, providing Parties with necessary external capacities to implement the Protocol until national and regional capacities are in place.

37. In the latter case, the roster will form a useful resource to Parties and to international, bilateral and private organizations in the design and staffing of capacity-building projects in support of the institution-building requirements outlined in the above table, as well as in the development of specific risk-assessment and management capacities. Support provided by experts on the roster could include: assessment of capacity-building needs; development of national biosafety frameworks; development of legal and regulatory structures and administrative procedures; development of information-management systems; and training at the national and regional/subregional levels.

38. The biosafety roster, as a thematic element of the overall roster of experts for the Convention, will most be useful if it contains keywords on expertise organized by categories reflecting the main areas of specialization/key competencies, and the major disciplines, needed to support biosafety capacity-building. These main categories include the following:

(a) *Specialization/key competencies*: e.g. institutional development; risk assessment, risk management, data management and information sharing; human-resources development, including training; public awareness and participation; and stakeholder involvement;

(b) *Disciplines*: e.g. environmental law; environmental and socio-economic impact assessment; biological sciences divided into major sub-disciplines such as botany, molecular biology and toxicology; socio-economic science divided into sub-disciplines such as natural resource economics, and indigenous culture; and biotechnology, divided into subsectors such as agriculture, microbial industrial processes, and environmental remediation.

39. Parties will need to have facilitated access to the experts listed on the roster. For this purpose, they will need a number of capacities in place to access and use the roster effectively including: ability to evaluate types of expertise required, based on the obligations and rights under the Protocol, and on a capacity-building needs assessment; ability to screen and evaluate specific candidates from a technical/scientific perspective; information technology to access the roster, including through the Biosafety Clearing-House; and, financial resources to be able to engage the chosen experts.

40. It also will be important for Parties to develop rosters at the national and regional levels, to which they can refer in the first instance before relying on broader international expertise. This would be an important outcome of effective capacity development programmes. This will help ensure that country- and region-specific knowledge is brought to bear in building institutional capacities, in training legal, scientific and technical personnel, and in carrying out risk assessments.

41. Further, the Secretariat can play a role in facilitating the use of the roster of experts, in particular through review of qualifications of proposed Roster participants, and through use of the Biosafety Clearing-House to provide Parties, international organizations, private organizations and others with ready access to the roster list.

### *C. Financial and technical resources*

42. A range of financial and technical sources can be considered as useful to support biosafety capacity-building. This range includes:

(a) The Global Environment Facility (GEF) as the institutional structure operating the financial mechanism of the Protocol;

(b) Bilateral funding, technology transfer and technological training opportunities, through:

(i) Development cooperation agencies (official development assistance);

(ii) Sector and other ministries responsible for biotechnology and biosafety;

(iii) National research institutions and universities;

(c) Multilateral agencies with relevant mandates and expertise including:

(i) United Nations specialized agencies and programmes;

(ii) Research institutions of the Consultative Group on International Agricultural Research;

(iii) International development research institutes and networks;

(iv) The World Bank group and regional development banks;

(d) Regional economic cooperation organizations;

(e) Biotechnology industries in various sectors:

(i) Individual companies;

(ii) National biotechnology industry associations;

(iii) International business associations;

(f) International research organizations;

(g) Private foundations

(h) Non-governmental organizations and networks.

43. The ability to utilize resources effectively will reflect a combination of creativity, complementarity of uses, commercial factors, historical capacity-building and broader development cooperation patterns, and other factors. Specific capacity-building and resource requirements will need to be identified on a country-by-country basis, using needs assessment undertaken in the preparation of national biosafety frameworks.

44. While it may not be productive to attempt to sum up the potential cost of building in capacity to implement the Biosafety Protocol in all Parties, the UNEP/GEF pilot biosafety enabling activity project evaluation report, and preliminary work by the GEF secretariat in preparing a GEF initial strategy on biosafety capacity development, 4/ have provided some estimates of costs for the initial stages of capacity-building to allow countries to implement the requirements of the Protocol.

45. However, it must be recognized that the differing needs of each country, and the fact that effective biosafety capacity-building efforts may support more than one objective, e.g. meeting obligations under the Protocol, as well as meeting broader national and regional needs, will make such global forecasting difficult beyond these initial stages of capacity-building. More productive will be country-specific estimate of needs, and a clarification of the potential roles of different types of organizations to address them in each case. This will be based on the willingness, expertise and financial and technical resources available through the range of organizations involved in such capacity-building efforts as summarized in section V below.

### *D. Potential roles for organizations providing capacity-building support*

46. In order to better match available resources and the capacities of different organizations providing assistance with the needs of Parties requesting support, the following generic roles can be considered in capacity-building, including through the provision of financial and technical resources to developing countries and countries with economies in transition. These are based on a review of capacity-building initiatives to date and on the requirements of the Protocol.

| **Type of organization** | **Possible roles in biosafety capacity-building** |
|---|---|
| ***International organizations*** | Assistance with needs assessment<br>Support for development and/or strengthening of national biosafety frameworks<br>Short-term human resources training – science, legal, administrative<br>Support for development and/or strengthening of essential scientific assessment and risk management infrastructure |
| ***Bilateral cooperation*** | Long-term institutional capacity development – policy, legal, regulatory, administrative, scientific<br>Long-term human resources development including training<br>Development and/or strengthening of information-management capacities<br>Development and/or strengthening of risk-management oversight, audit capabilities<br>Awareness-raising - health, environmental risks, uses and value of living modified organisms |
| ***Industry*** | Technical input and information on science-based risk assessment<br>Training on safe handling and use of living modified organisms<br>Benefit-sharing |

| Type of organization | Possible roles in biosafety capacity-building |
|---|---|
| ***Scientific research/ academic institutions*** | Science-based risk assessment – living modified organisms and the receiving environment<br>Human resources development, including training |
| ***Labour*** | Training on safe use<br>Awareness raising- health, environmental risks, uses and value of living modified organisms |
| ***Non-governmental organizations*** | Public and community awareness raising including to foster transparent, objective oversight<br>Technical assistance on scientific assessment, legal regulatory regimes |
| ***Foundations*** | Development and/or strengthening of scientific expertise and risk-assessment capabilities<br>Support for initiating innovative capacity-building efforts |

47. These roles are not intended to be exclusive, however it will be useful for international, bilateral and private organizations providing financial and technical support to consider the most effective role they can play in each country and region. Furthermore, experience of the last 10 years has shown substantial opportunity for partnerships to be formed to support biosafety capacity-building between and among international organizations, national agencies and private industry.

48. Beyond these generic roles, the financial mechanism of the Protocol has a specific role, as stated in Article 28, paragraph 3, of the Protocol. In response to this direction, as well as guidance provided by the Conference of the Parties at its fifth meeting, the Council of the Global Environment Facility (GEF) will consider an *Initial Strategy to Assist Countries to Prepare for the Entry into Force of the Cartagena Protoco*l at its sixteenth meeting, in November 2000. It will be important for this *Initial Strategy* to be consistent with the evolving indicative framework for capacity-building under discussion in the ICCP. In addition, GEF has an important role to play, in cooperation with others organizations, to ensure that all Parties that need support have the opportunity to assess their needs, to develop national biosafety frameworks, and to begin to implement such frameworks.

49. The United Nations Environment Programme (UNEP) has a role to play, based on its experience with its International Technical Guidelines for Safety in Biotechnology and the UNEP/GEF pilot biosafety enabling activity project. It could provide a comparative analysis of existing biosafety legislation to inform the design of future capacity-building efforts, develop elements of model or example laws and regulations as a source of information, and continue its support to developing countries in the development of national biosafety frameworks.

### *E. Facilitating consistency, complementarity and partnership*

50. There is a need to facilitate coordination among a broad range of organizations, given the growing level of activity in support of biosafety capacity-building at the international level. Without efforts to foster coordination, there is a risk of inconsistent approaches to capacity development, and an inefficient use of scarce financial resources.

51. There are important roles for the ICCP, the Convention Secretariat and the GEF secretariat, in particular in the period prior to entry into force of the Protocol, to promote consistency in approaches that will help lay a common basis for effective implementation of the Protocol.

52. ICCP can provide useful suggestions to Parties, international organizations and other interests, through its discussions on an initial indicative framework for capacity-building and future iterations that can provide more detailed advice and suggest priorities for follow-up.

53. The Convention Secretariat can promote a common understanding of the needs for capacity-building under the Protocol, based on the provisions of the Protocol itself, guidance provided by the Parties of the Convention, and drawing on deliberations in the ICCP. It can collate and analyse the results

of biosafety capacity needs assessments and information that it has received from international and other organizations, and produce and disseminate a factual package on common approaches to meeting capacity-building requirements, using, among other means, the Biosafety Clearing-House. Further, in collaboration with organizations active in capacity-building, it can produce formats and methodologies for various elements of biosafety capacity-building, from needs assessment to legal drafting. These may be helpful in providing interim guidance to developing countries and countries with economies in transition in setting capacity-building priorities for their cooperation with bilateral, international and private agencies and organizations willing to provide support.

54. Mechanisms to promote coordination could include: strengthening the Inter-Agency Network for Safety in Biotechnology (IANB) and GEF. If IANB were to include the GEF secretariat, as well as all the GEF implementing agencies, it could better aid technical information-sharing on experience from and approaches to capacity-building for the Cartagena Protocol. GEF could play a convening role among finance and development agencies, working closely with the Convention Secretariat to ensure that the results of discussions in the ICCP are well reflected in multi-donor discussions. Periodic meetings and discussions would help limit overlap among development cooperation agencies, encourage partnerships, and promote greater consistency in approaches across agencies supporting capacity-building. It would be useful in such coordination meetings to have the ICCP and the Convention Secretariat provide clear presentation of the Protocol's requirements for capacity development, the results of needs assessments, as well as model approaches.

## V. OVERVIEW OF EXISTING AND COMPLETED CAPACITY-BUILDING ACTIVITIES

55. This section provides a summary of key lessons learned from the existing base of capacity-building programmes for biosafety and biotechnology relevant to biosafety. A summary description of the activities of intergovernmental organizations, regional organizations, bilateral programmes, industry, non-governmental organizations and private foundations will be provided as an information document to the ICCP at its first meeting.

### *A. Characteristics of past activities*

56. Over the past decade, there have been a substantial number of capacity-building activities related to biosafety, through multilateral, bilateral, and private programmes and projects. Most of these efforts, until recently, have been undertaken in the broad context of biotechnology development and transfer, which have included biosafety elements as a recognized part of biotechnology research, development, promotion and use.

57. Early efforts focused mostly on risk assessment, with an emphasis on such assessment techniques as field trials and data analysis; on regulations for risk management of specific types of living modified organisms; and on general awareness-building among government officials. More recently there have been more efforts targeted directly to biosafety regulation, as part of broader biotechnology capacity-building programmes, and as stand-alone initiatives.

58. With the exception of a small number of multilateral and bilateral projects, most initiatives have involved one-off activities such as regulatory workshops or sample field trials, which have developed individual capacities but have not focused on broader institutional needs, which require longer-term support over a number of years.

59. Capacity-building activities for biotechnology, including biosafety, have shown a number of interesting characteristics in comparison to other domains of international capacity development, including:

(a) Strong emphasis on partnerships;

(b) Substantial involvement of the private sector in terms of number of projects, but in most cases with a limited scope based on commercial considerations;

(c) Until recently, self-initiation without an international regime to drive efforts;

(d) Rapid development of international information networks; and

(e) Attention to building capacity at the regional and subregional levels.

60. Innovative partnerships have been used widely, often involving not just two or more bilateral or multilateral agencies, but industry/bilateral agency, and industry/non-governmental organization/multilateral agency collaborations. Other instances have involved private foundations working with multilateral and industry groups, and academic or international research institutions working with a range of private and public partners. There is substantial potential to broaden these collaborative approaches, given the strong interests and multiple motivations demonstrated in the various fields of modern biotechnology.

### *B. Experience from activities to date*

#### *(a) Intergovernmental organizations*

61. A wide range of international organizations have been involved over the past decade in biotechnology capacity-building, including for biosafety: among United Nations programmes and specialized agencies; research institutes in the Consultative Group on International Agricultural Research (CGIAR), with a number of these providing local support to their host countries in developing national biosafety guidelines; specialized networks and services devoted to biotechnology; the multilateral development banks; the European Commission and, the GEF.

62. Within the United Nations system, these have included the Food and Agriculture Organization of the United Nations (FAO), the International Fund for Agricultural Development (IFAD), the International Labour Organization (ILO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP), UNEP; the United Nations Industrial Development Organization (UNIDO), and the World Health Organization (WHO).

63. Some of the key initiatives which are most relevant to the current indicative framework include: 5/

(a) UNIDO bio-informatics networks in Asia and Latin America, and training courses on risk assessment methodologies, including manuals and computer-assisted decision-support systems for risk assessment;

(b) The International Centre for Genetic Engineering and Biotechnology (ICGEB) Biosafety Unit's training on biosafety; and, technical assistance to developing countries in reviewing requests for information on risk assessment and management of living modified organisms;

(c) The International Service for the Acquisition of Agri-biotech Applications (ISAAA) biosafety training workshops and funding of biosafety fellowships in South-East Asia, as well as projects to develop capacity for regulating field trials of living modified organism crops;

(d) The International Service for National Agricultural Research (ISNAR) Biosafety Initiative guide on establishment of national biosafety systems and training workshops for policy makers, scientists and regulators; 6/

(e) The Inter-Agency Network for Safety in Biotechnology (IANB), comprising a number of United Nations and other organizations active on biosafety matters provides a forum for sharing of information on biosafety;

(f) The UNEP/GEF pilot biosafety enabling activity project, which was completed in 1999;

(g) The UNDP/GEF Capacity Development Initiative.

64. The UNEP pilot project proved successful in helping 18 countries to undertake capacity needs assessments for biosafety, and to prepare national biosafety frameworks. It also undertook eight workshops in four regions to build awareness and understanding of biosafety issues. An evaluation of the Pilot Project recommended that the preparation of national biosafety frameworks be extended to a large number of countries and that support be provided for the implementation of these frameworks. 4/

65. Several major conclusions can be drawn from the pilot project, including: 4/, 7/

(a) Many developing countries lack the information, trained people and facilities needed to assess and manage risks of living modified organisms;

(b) The level of preparedness to assess and manage biosafety risks varies considerably between countries, with existing capacities related to the level of domestic development and use of modern biotechnology;

(c) Preparation of national biosafety frameworks is an essential first step in helping countries to identify the adequacy of current laws, institutions and expertise, to identify needed capacities and to provide the basis for establishing or amending laws, regulations and administrative procedures;

(d) Subregional and regional collaboration is essential because of the potential for living modified organisms to cross boundaries, and for efficient sharing of scientific expertise, information and technical support.

66. The UNDP/GEF Capacity Development Initiative is nearing completion of a major survey of experience and lessons learned in capacity-building efforts in support of the GEF focal areas. It includes a series of regional assessments, thematic assessments for each focal area as well as for science and technology capacity, and an overall synthesis report. 3/ It did not assess biosafety capacity in detail but identified the following generic needs: understanding by decision makers of the biosafety concept and the requirements for implementation of the Protocol; filling gaps in the policy and legislative and regulatory frameworks; abilities to assess and manage the risks posed by living modified organisms.

67. A number of current initiatives are targeted specifically to support building of capacity for the Cartagena Protocol, and are in a position to provide on-going support:

(a) The GEF secretariat has prepared an *Initial Strategy to Assist Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety*. The S*trategy*, which draws on the results of the UNEP/GEF pilot project, addresses the following areas for capacity-building: assisting countries to prepare and implement national biosafety frameworks; promoting regional and subregional information-sharing; and, promoting coordination among bilateral and multilateral organizations, including through partnerships;

(b) UNEP has prepared a project for GEF funding for the development of national biosafety frameworks, to extend its pilot study work.

(c) The United Nations Institute for Training and Research (UNITAR) is developing a training programme designed to assist developing countries to build capacity in the legal and policy requirements for implementation of the Cartagena Protocol. 8/

*(b) Bilateral cooperation*

68. A number of Parties have been active in providing capacity-building support for biotechnology, including biosafety, during the past decade, often in partnership with industry, research centres or international organizations. Technical and financial support has been provided both by development cooperation agencies using official development assistance funds, and national agencies and ministries responsible for biotechnology development and regulation in a number of sectors. Countries active in this

area have included Australia, Belgium, Canada, France, the Netherlands, Sweden, Switzerland, the United Kingdom and the United States.

69. Three major activities are indicative of such bilateral efforts:

(a) The Canadian International Development Agency has supported a number of projects with the International Development Research Centre (IDRC) and the Canadian biotechnology industry, particularly in Latin America through the Canada-Latin America Initiative on Biotechnology for Sustainable Development (CamBioTec). 9/ Capacity-building activities have included training on biosafety information systems, regulatory systems, including risk assessment, and public awareness;

(b) Switzerland has supported a number of capacity building activities for biosafety, including workshops in West and Central Africa, and the Indo-Swiss Cooperation Programme on Biotechnology; 10/

(c) The Swedish International Development Agency (SIDA) and a non-governmental organization — the Stockholm Environment Institute — have supported national field trials of living modified organism crops in Africa and South America. 5/

70. The International Workshop on Biosafety Regulatory Capacity Building, held in 1999 and known as "the Canada-Mexico Workshop" provided good summaries of lessons learned by countries with extensive biotechnology sectors, as well as those still in the process of establishing national biosafety regimes. Summary needs assessments were presented by a number of countries including Mexico, Malaysia, Cameroon, Brazil and Cuba. One recurrent theme was the importance of adequate capacity to assess the impact of living modified organism introductions in centers of origin and centers of plant diversity. Another was the lack of adequate human resources, particularly those with expertise in biotechnology and biosafety. In response to the latter point, it was suggested that an international biotechnology regulatory training institute be created.

71. Cross-cutting lessons for building biosafety regulatory capacities identified in the workshop included the following: 11/, 12/, 13/, 14/, 15/

(a) The value of extensive consultation with interest groups (from industry through to farmers and non-governmental organizations) and consumers and the public more broadly in the development of biotechnology policies regulations and implementation of procedures biosafety risk assessment and management;

(b) The importance of availability of, or access to, a sound scientific database and expert science input on which to base risk assessments;

(c) The importance of transparency in decision-making procedures, and supply of information to public and interests;

(d) The importance of coordination, cooperation and collaboration among agencies within a country and internationally in risk assessment;

(e) The need for clear standards which can be applied with flexibility to respond to new types of information and changing technology;

(f) The need to critically assess, and adapt to local needs where necessary, biosafety schemes from other countries.

72. Current bilateral initiatives which are directly relevant to building capacity for the Cartagena Protocol, and which are in a position to provide ongoing support, include:

(a) The German biosafety capacity-building initiative for implementation of the Cartegena Protocol, which is providing support for needs assessment, participatory approaches to policy

formulation, advice to Parties, and building scientific knowledge on risk assessment and decision-making. It is producing a "Biosafety Capacity Building Instrument" to be used in training initiatives; 16/

(b) The Netherlands project on implementation of national biosafety frameworks in pre-accession countries of Central and Eastern Europe; 17/ and

(c) Training projects related to implementation of the Cartagena Protocol by the Danish Cooperation for Environment and Development (Danced) in SouthEast Asia and related to European Union requirements on living modified organisms by the Danish Cooperation for Environment in Eastern Europe (Dancee) in the Baltic countries. 18/

*(c) Industry*

73. Biotechnology companies, both individually and through national industry and international biotechnology associations, have supported biosafety capacity-building as part of their broader efforts to promote and extend the commercialization and safe use of biotechnologies. These activities, often in collaboration with development and research agencies in the home countries of the industry, have helped develop scientific and technical capacities of researchers in risk assessment associated with specific biotechnology subsectors – e.g., seeds and other agricultural applications. They have also addressed awareness-building and training for government regulatory officials.

74. These activities have, in many cases, been undertaken in collaboration with national government agencies or international organizations and networks. Active organizations have included: BIOTECanada, Europabio – the association of European biotechnology industries, the Japan Bioindustry Association, and the Green Industry Biotechnology Forum. A substantial number of companies have also supported capacity building activities for biotechnology, including biosafety elements, among them AgrEvo GmbH, ANPROS (Chile), Cargill, Dupont, ELM/Seminis, ICI, Monsanto, Novartis, ProAgro (India) and Zeneca.

75. Lessons learned from these activities include: 19/, 20/, 21/

(a) Differing cultural perspectives – both between individuals from different countries, and between individuals from the commercial, research and governmental sectors – need to be addressed and confidence built for successful capacity-building to take place;

(b) Regional approaches, including establishment of regional centers of excellence, offer an important means for strengthening technical expertise needed to mitigate possible environmental risks and to support regulatory processes;

(c) Industry has an active interest in voluntarily playing a role in assisting developing countries to develop their biosafety regulatory capacity, focusing on development of risk assessment expertise, but also extending to benefit sharing activities;

(d) Industry will use criteria such as adequate existing base of information technology, laboratory and science infrastructure, intellectual property protection and political commitment, to determine in which projects to engage;

(e) Capacity-building efforts are expensive and human-resource requirements are intensive;

(f) There is a need to sustain the capacity once build, and, to do so, a strong commitment is required from all stakeholders, particularly the Government.

76. The Global Industry Coalition, which represents companies in 130 countries working in sectors relevant to biotechnology, has conducted a review of capacity-building projects for biotechnology and biosafety undertaken in whole or in part by industry. An earlier survey of such efforts identified over 50 capacity-building- projects with the primary objective of information-sharing, benefit-sharing or risk assessment and management. 22/

77. The Coalition has recently indicated its interest to support capacity-building initiatives to assist in the implementation of the Biosafety Clearing-House.

*(d) Non-governmental organizations*

78. International non-governmental organizations, such as the Third World Network, Genetic Resources Action International (GRAIN), Greenpeace have been active in raising awareness and disseminated information on biosafety. 23/ For example, the Third World Network, together with The Edmonds Institute, has held briefing sessions where scientists and lawyers addressed key scientific and regulatory issues relating to genetic engineering. The Edmonds Institute itself has produced a risk assessment manual for living modified organisms, 24/ and has presented workshops on biosafety and impacts of modern biotechnology in a number of countries. Other international non-governmental organizations, such as IUCN–The World Conservation Union, and the Centre for International Environmental Law (CIEL) prepare analyses and provide advice on legal requirements related to the Protocol.

79. At the regional and national levels, a number of non-governmental organizations support the creation of capacities for local involvement, including farmers, in decisions on the use of modern biotechnology, and for ensuring that biosafety information is made available widely. 25/, 26/

80. The experience of non-governmental organizations with biosafety capacity–building has identified the need for cost-benefit analysis in the risk assessment of living modified organisms, the need for monitoring and enforcement capacity, and the importance of strong, local scientific capacity with expertise in government, universities, research institutions and civil society organizations. 27/

*(e) Foundations*

81. A small number of private foundations have been active in biotechnology capacity development, most prominent among them the Rockefeller Foundation (U.S.), the M.S. Swaminathan Foundation (India), the Biofocus Foundation (Sweden) and the Crawford Foundation (Australia).

82. The Rockefeller Foundation has supported research into increasing crop yields of poor, smallholder farmers in developing countries profitably and without degrading natural resources, including using modern biotechnology. It has funded substantial efforts in plant biotechnology research and has trained over four hundred scientists from Asia, Africa and Latin America, with several locations in Asia now having a critical mass of talent applying the new tools of biotechnology to rice improvement. 28/

83. The Swaminathan Foundation is active in research and training for the conservation of biodiversity, with an emphasis on its role in human food and livelihood security. It has experience with biotechnology and conducted an Asia-Pacific Workshop on Biosafety: Environmental Impact Analysis of Transgenic Plants in 1997. 29/

## *C. Regional efforts*

84. A number of regional cooperation organizations have capacity-building activities, with the intent of raising awareness and knowledge to a common level among regulators, in particular, across countries; and, in some cases, with the objective of promoting harmonization of national risk assessment and management approaches within a region. For example, the African Agency of Biotechnology — a grouping of member States and scientists from 16 countries — has a programme on biodiversity, biosafety and bioethics. It supports the development of appropriate legislation and regulatory bodies, compatible with international law, to monitor the import of living modified organisms so as to ensure Biosafety. 30/ The Asia Pacific Economic Cooperation Forum's Agricultural Technical Cooperation Experts' Group has held workshops to build common knowledge on biosafety regulation among member

states. The United Nations Economic Commission for Europe is maintaining an inventory of safety guidelines for biotechnology. 5/

85. These bodies provide a useful vehicle for capacity-building but their level of activity to date has not been high. However, a substantial number of capacity-building projects supported by international and bilateral cooperation organizations have focused on building capacities at the regional and subregional levels, as is noted in the sections above.

## VI. POSSIBLE ISSUES FOR DISCUSSION

86. The ICCP is invited to consider the following issues at its first meeting:

(a) Areas for further elaboration or analysis in the Indicative Framework, including the table on pages 5 and 6 above and the potential approaches and options, to assist Parties and other entities in current and future cooperation on capacity-building for biosafety;

(b) Key elements of capacity-building, and modalities and strategies needing further elaboration to assist ICCP at its second meeting to develop proposals for consideration by the first meeting of the Parties.

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