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CAPACITY-BUILDING IN BIOSAFETY FOR DEVELOPING COUNTRIES

Note by the Secretariat

1. BACKGROUND

1. Article 25, paragraph 2(c), calls upon the SBSTTA to identify "innovative, efficient and stat -of-the-art technologies and kno -how relating to the conservation and sustainable us of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies".

2. At its first meeting, the SBSTTA proposed a mediu -term programme of work in recommendation I/2. Item 1.3.3 of this proposed mediu -term programme of work was:

> "Provision of advice on capacity-building in relation to the safe transfer, handling and use of living modified organisms resulting from biotechnology that may have advers effect on the conservation of biological diversity an d the sustainable use of its components. The Conference of the Parties should ensure that work of the SBSTT on this item should be consistent with its decision on Articl 19.3, in order to avoid duplication with any other work that the Conference of the Parties might set in train".

3. Decision II/1 of the COP requested the SBSTTA, in considering its programme of work for 1996, to ensure that the programme is based on the priorities set the programme of work for the COP for 1996 and 1997.

4. Decision II/5 of the COP established an Open-ended Ad Hoc Working Group on Biosafety, which held its first meeting from 22 to 26 July 1996, in Aarhus, Denmark. The report of this meeting is contained in UNEP/CBD/COP/3/24. The COP, at its third meeting, may consider this report under item 17 of its provisional agenda.

5. It is clear that until the COP has considered the report of the first meeting of the Open-ended Ad Hoc Working Group on Biosafety, it is premature for the SBSTTA to consider matters that may b addressed by the Open-ended Ad Hoc Working Group on Biosafety.

6. Capacity building may be considered by the Ad Hoc Working Group on Biosafety, and to th extent that it is, it would not be appropriate for the SBSTTA to consider this issue for the moment. Nevertheless, the issue of capacity building, especially at the national level, is not only a matter that th Open-ended Ad Hoc Working Group on Biosafety may not consider in its entirety, but it is also necessary for the successful conclusion of the work of the Working Group. This was recognised by th COP, which noted that interim measures, particularly with regard to capacity building, need to b developed. Consequently, the SBSTTA may wish to consider recommending to the COP that it consider ways and means by which capacity within developing countries can be developed during th course of deliberations of the Open-ended Ad Hoc Working Group on Biosafety.

7. To assist the SBSTTA in identifying such areas, the Secretariat has prepared this Note, which outlines the overall capacity needs of developing country Parties with regard to the issue of biosafety.

2. INTRODUCTION

8. In Agenda 21, as well as in the Convention on Biological Diversity, governments undertook to consider international co-operation on biotechnology and relevant safety aspects. That commitment includes: sharing experience, capacity building, and international agreement on principles for safety in biotechnology or biosafety. It is acknowledged that biotechnology will contribute substantively to th improvement of agriculture, fisheries, forestry, industry, health care and environmental management. Recent developments in modern biotechnological techniques present strong potential links between conservation and the optimum use of biological resources. Biotechnology also offers developing countries a means of tapping their genetic resources for economic development.

9. Major issues that will, however, affect the transfer and application of biotechnology are: th regulatory climate governing the safe development and application thereof; and the safe transfer and use of its products, particularly the release of living modified organisms (LMOs) into the environment. Questions arise regarding the capacity of existing regulatory approaches and institutions to address issues related to safety in biotechnology. A review of existing guidelines and legislation at both national and international levels, indicates that:

(a) a large number of countries have no national biosafety frameworks regulating living modified organisms (LMOs) resulting from biotechnology;

(b) existing national biosafety regulations address only activities relating to the domestic handling and use of LMOs;

(c) efforts at promoting international agreements on biosafety often address issues from a perspective different from that of the Convention on Biological Diversity and Agenda 21; and

relevant international agreements and/or guidelines currently under consideration are limited in scope.

(d) in essence, they lack the qualities that would charact rise effective biosafety frameworks, i.e., they should be credible, flexible, transparent, predictable, focused on clear objectives, adaptable to different socio-economic and cultural conditions, and cost-effective.

10. For biotechnology, as with any new technology, the rate of development and the level of success are dependent not only upon the scientific and technical capabilities of the country, but also on a supporting infrastructure and a conducive receiving environment in which to introduce and use it. As concerns about safety in biotechnology have been raised, a key component in the creation of a "biotechnology-accepting" environment is the establishment of a regulatory infrastructure to overs biosafety. The cornerstone of such an infrastructure is biosafety regulatory frameworks, including globally accepted international agreements and guidelines.

11. Equally important, however, is acquiring the capacity to implement regulations via scientifically sound environmental-impact assessment, including bo th risk assessment and risk management. Neither an international legally binding biosafety agreement nor biosafety guidelines will, in and of themselves, ensure the safe development and/or application of biotechnology. There must be a capacity for implementing them. Their implementation should be founded on sound scientific principles and applied with logical consistency, technical competence and judicious expedience. However, their implementation also depends on the availability of human resources (in ter s of quantity and quality), financial resources, information, and/or institutional and infrastructural capacities at the national, regional and international levels. Such resources and capacities, it should be noted, are currently either not available, or are not adequate in a number of countries at various stages of biotechnological development.

12. It is appropriate to provide a perspective on the breadth and depth of capacity -buildi requirements necessary for successfully achieving safety in biotechnol ogy research, development and application. In this regard, a succinct list that properly illustrates the important needs and constraints facing countries, particularly developing countries, would include:

- the lack of and need for formulated biotechnology and biosafety policies;
- an insufficient capacity for enforcing agreements, guidelines, directives and/or regulations;
- the need for training at all levels to address the shortage of human resources;
- an inadequate capacity for formulating and impleme nting agreements, guidelines, directives and/or regulations;
- the need for information gathering and information exchange (including access to databases and the knowledge of global developments);
- the need for risk-assessment research focusing on specific regional and/or sub -regional contexts;
- need for more facilities and equipment to carry out proper monitoring and risk - assessment research;

- the need for the establishment of biosafety advisory services and/or committees at th institutional, national and regional levels;

- need for planning and adapting methods to monitor the effects of field tests and to ensure compliance with regulations;

- the need to fund safety issues as integral parts of research and development projects;

- the need for national, sub-regional, regional and global collaboration; and

- need for the harmonisation, validation and mutual acceptance of data.

13. The issue of capacity building related to safety in biotechnology (or biosafety) has been highlighted during meetings held under the auspices of the Convention on Biological Diversity, namely the meeting of the Panel of Experts on Biosafety, held in Cairo from 1 to 5 May 1995, the meeting of the Open-ended Ad Hoc Group of Experts on Biosafety, held in Madrid from 24 to 28 July 1995, th first session of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), held in Paris from 4 to 8 September 1995, and the first meeting of the Open -ended Ad Hoc Working Group on Biosafety, held in Aarhus, from 22 to 26 July 1996. In all these fora, capacity building in th area of biosafety was recognised as a prime element that will facilitate the effective implementation of any biosafety regulations, guidelines, directives and/or any future international agreements on biosafety. It is identified as an area of high priority, requiring urgent global attention.

3. DEFINING CAPACITY BUILDING IN TERMS OF BIOSAFETY

14. It is also appropriate at this juncture to develop a common understanding and appreciation of what capacity building entails. In the context of biosafety, capacity building means the strengthening and/or development of both human resources and the institutional and infrastructural capacities that ensure that, in the wake of the emerging biotechnology revolution, countries (in particular developing countries) are able to cope with new developments in and applications of biotechnology as they arise, and to achieve safety in biotechnology, through the effective implementation of existing or planned biosafety guidelines, directives or regulations, and of any future international agreements on biosafety.

15. Capacity building should be undertaken in a way that also promotes the safe development and diffusion of biotechnology. Both the regulatory frameworks and the related capacity-building activities should, therefore, be such that they can facilitate the implementation of biosafety instruments as well as promote the safe research, development and application of biotechnological products. Understood and undertaken in this manner, capacity building should ensure and enhance the transfer of kno -how, the development or strengthening of appropriate facilities (and policies) and training in sciences related to biosafety and biotechnology, including training in risk-assessment and risk-management techniques and procedures.

16. As stressed in the relevant Articles of the Convention on Biological Diversity, Agenda 21, Chapter 16 (Environmentally sound management of biotechnology), Chapter 34 (Transfer of environmentally sound tech nology, co -operation and capacity -building) and Chapter 37 (National mechanisms and international co-operation for capacity building in developing countries), the focus of capacity building should be addressed in a co-ordinated and concerted manner at the national, regional and international levels.

4. OBJECTIVES OF THE CAPACITY-BUILDING INITIATIVES FOR BIOSAFETY

17. The prime objective of any efforts or initiatives aimed towards capacity building for biosafety is to ensure the safe and judicious application of biotechnology, with a view to maximising its potential benefits while avoiding, to the maximum extent possible, adverse effects on human health and th environment. More specific objectives of the capacity-building initiatives would be:

(a) To strengthen the capacities of countries, developing countries in particular, to introduce and implement national mechanisms for safety in biotechnology consistent with th relevant provisions of the Convention on Biological Diversity and appropriate to their particular circumstances, while providing a harmonised approach to risk assessment and management in biotechnology within a global biosafety framework;

(b) To help harmonise national biosafety instruments and facilitate the implementation of any future international agreements on biosafety, as the initiatives will allow valuabl experience to be gained at the national, regional and international levels;

(c) To help build the technology-assessment capacity necessary at national and regional levels for the management of environmentally sound biotechnology, including environmental impact and risk assessment, with due regard to appropriate safeguards on the transfer of technologies;

(d) To create, among the public and key decision-makers, a greater awareness of th potential and relative benefits and risks of the environmentally sound application of biotechnology;

(e) To strengthen endogenous capacity building in the respective countries, so that they can assess, adopt, manage and apply environmentally sound techn ologies. This could be achieved through, *inter alia*:

(i) human resource development;

(ii) strengthening institutional capacities for the research, development and application of biotechnology;

(iii) integrated sector assessments of biosafety needs in national plans, objectives and priorities, as envisaged in Agenda 21 and the Convention on Biological Diversity at the national level;

(f) To initiate long-term technological partnerships between holders of environmentally sound biotechnologies and potential users;

(g) To contribute to the strengthening of international information networks that link relevant national, sub-regional, regional and other international systems;

(h) To facilitate and provide the regional and international consultations, harmonisation, advisory services and co -operation necessary to address biosafety issues beyond national borders, such as the transboundary movements of living modified organisms;

(i) To facilitate smooth and rapid progress of the work initiated by the Conference of th Parties to the Convention on Biological Diversity on the development of a biosafety protocol within the context of the Convention.

18. The options and attendant activities should be such that:

(a) They are compatible with and can be integrated into national, sub -regional and regional plans, policies and priorities in the formulation and implementation of the national biosafety mechanisms and framework.

(b) They provide effective interventions by all the relevant stakeholders and are targeted at all relevant ecosystems.

(c) They will synergise efforts to achieve regional and global benefits and ensure equitabl benefit sharing.

(d) They will contribute towards the development of a biodiversity conservation and sustainable use portfolio that encompasses all the representative ecosystems of regional and/or global biodiversity significance.

(e) The respective countries will, through the activities envisaged, achieve agreed-upon biodiversity, biotechnology and biosafety objectives in strategic and cost-effectiv ways.

19. The widest possible participation of the public sector, the scientific and the general community at large, as well as the private sector (in particular the biotechnology industry) is desirable. In developed countries, the private sector has played, and continues to play, an especially critical role in ensuring and enhancing safety in biotechnology. This could usefully be replicated in developing countries, most of which have serious resource constraints and cannot therefore mobilise adequate, if any, resources in the field of biosafety on a priority basis.

5. CAPACITY BUILDING REQUIREMENTS

20. Two types of approaches in support of biosafety activities are suggested to help achieve th above objectives:

(i) Support for governments for the development and implementation of national biosafety frameworks in a global context.

(ii) Support for sub-regional, regional and international collaboration and co -operation for, among others, experience sharing.

5.1 Support for governments for the development and implementation of national biosafety frameworks

21. A concerted global initiative is needed to provide financial and technical support to developing countries and countries with economies in transition that are Parties to the Convention on Biological Diversity to help initiate or strengthen their activities to formulate and implement national biosafety regulatory frameworks, including, as appropriate, a review of related legislation and policies. Th

activities to be undertaken (including the consideration of joint ventures) and the specific support required by the country will be determined by their respective governments. They should ideally includ common elements identified through sub-regional, regional and global consultative fora.

22. Accordingly, in considering the requirements for a biosafety framework at the national level, there is need, for example, for taking on board activities that encompass:

(a) The preparation of National Frameworks for Safety in Biotechnology within a global context, such a s that provided by the UNEP International Technical Guidelines for Safety in Biotechnology, incorporating: objectives; scope; scientific considerations for evaluating safety; implementation, monitoring and enforcement mechanisms; harmonisation of data and procedures; and regional and international co-operation, including the development of joint ventures.

(b) The development and establishment of mechanisms to oversee biosafety and th necessary infrastructure, covering such elements as:

(i) a National Authority and/or National Institutional Mechanism and its responsibilities, including the provision of advisory services and/or committees;

(ii) considerations by countries of what relevant legislative measures are in plac and what is required to fill identified gaps; and

(iii) a consideration of whether existing structures and measures suffice, or whether there will be need for additional ones, as appropriate, for the effectiv implementation of the mandates of the National Authority and/or National Institutional Mechanism. Are laws enforceable and easy enough to use for both applicants and regulators? Is legislation also risk-based and scientifically sound?

A flexible framework of legislation may be desirable.

(c) Human resources development and institutional capacity building. Activities in this regard should cater to the:

(i) sound assessment of the need for expertise, and the development of relevant training, research and education programmes, as appropriate;

(ii) training and/or research in biotechnology and related basic sciences, and in th use of risk-assessment and risk-management techniques and relevant scientific reviews;

(iii) provision of guidance and advice regarding scientific approaches to risk assessment and risk management (review bodies, directory of scientists), and effective discharge of responsibilities for reviewing risk assessment and proposed risk-management strategies (the use of different agencies, local, outside expertise should be considered);

(iv) formulation, streamlining and i plementation of review procedures, including approval of permits, acknowledgement notification, review period, etc.; establishment of appropriate knowledge bases and information-exchange mechanisms; and

(v) harmonisation of risk-assessment procedures and existing legislation.

5.2 Support for sub-regional, regional and international entities for collaboration and co-operatio

23. The activities adopted or initiated should aim to facilitate the holding of subregional, regional and global consultative fora and promote the sharing of experience, expertise and relevant information on biosafety issues. The intent is to provide fora for addressing biosafety issues with regional and global dimensions, such as: the transboundary movement of living modified organisms and/or organisms with novel traits resulting from biotechnology; information exchange; advance informed agreement mechanisms; appropriate training and research in risk assessment and risk management; and experience sharing, etc., at the sub-regional, regional and global levels.

24. There is a need to support activities that promote either the strengthening or establishment of both subregional and regional/global advisory services and information exchange networks, etc. An indicative list of requirements and /or activities needed at the sub-regional, regional and international levels for effective biosafety regulation, co-operation and co-ordination includes:

(a) advisory services at the sub-regional and regional, as well as global levels;

(b) information exchange mechanisms. Identification, strengthening and use of already existing mechanisms and/or organisations suitable for disseminating information relevant to th respective countries. Mechanisms for sharing information between countries of a region and/or subregion in order to facilitate Advance Informed Agreement (AIA) mechanisms;

(c) training, education and research programmes (for scientists, legislators, policy makers, administrators);

(d) joint research programmes in risk assessment and management. Establishment of south-south links to other regional research and development (R&D) centres and to centres in the north. Focus on research and development issues related to the region, with an appropriat combination of northern kno -how with developing countries' expertise;

(e) effective participation in biotechnology research and development activities and the us of relevant global scientific advances;

(f) access to and transfer of relevant techniques and technologies;

(g) harmonisation of risk-assessment procedures and guidelines, mutual acceptance of data, data validation, etc.; and

(h) the use of regional organisations to enhance regional and sub-regional co-operation in this area (OECD, IICA, ASEAN and the AMCEN/African Regional Focal Point for Biosafety).

25. All the foregoing activities will encompass various national, regional and global cross-cutti issues by nature of the interlinked components. Through support for carefully selected institutions, universities and centres of excellence under this initiative, developing countries will be enabled to:

(a) undertake many urgent follo -up actions and critical reviews to identify ways and means of strengthening endogenous capacities for the application of biosafety guidelines, regulations and/or directives;

(b) establish or adapt appropriate mechanisms for safety appraisal and risk assessment at the sub-regional, regional and international levels, as appropriate;

(c) further develop, as necessary, the existing safety procedures to promote scientific development and categorisation in the areas of risk assessment and risk management (information requirements; databases; procedures for assessing and managing risks, monitoring and inspection), taking account of ongoing sub -regional, regional and international initiatives and avoiding duplication wherever possible;

(d) organise workshops, symposia, seminars and other dialogues among the scientific community at the national, sub -regional, regional and global levels on specific priority biosafety themes, making full use of the existing scientific and technological expertise in each country for bringing about such dialogue;

(e) provide training at all levels (graduate, post-graduate and post-doctoral), as well as th training of administrators, policy makers, legislators, technicians and support staff, in various aspects of the application of biotechnology and biosafety, with an emphasis on training programmes for trainers to train scientists and technologists in advanced research institutions in the selected countries;

(f) assist in exchanging information about the procedures required for the safe, contained uses and releases into the environment of living modified organisms and/or organisms with novel traits, and establishing mechanisms for providing immediate assistance in case of emergencies that may arise in conjunction with the use of such products;

(g) collaborate and/or liaise with other relevant international institutions, organisations and agencies on on-going work in the field of biosafety.

6. CONCLUDING REMARKS

26. Biological diversity represents the very foundation on which biotechnology could thrive and flourish. Through biotechnology, important advances for the use of genetic and biological resources can be made for the economic development of nations and for human well -being, as well as for our understanding of the living world. Biotechnology may thus aid in assessing and monitoring th biological diversity upon which human life and existence depend.

27. Because of the potential for great benefits from biotechnology, its use is increasing rapidly and questions about its possible adverse impacts on human health and the environment have been raised. Of particular concern are the questions regarding the capacity of existing regulatory approaches and institutions to effectively address issues related to safety in biotechnological research, development and application, world-wide.

28. Capacity building for safety in biotechnology, particularly in developing countries, has thus been accorded high priority. It requires concerted and co-ordinated global efforts by all stakeholders at the national, subregional, regional and global levels. The objectives outlined in paragraph 17 and th capacity building requirements suggested in paragraph 18 and elaborated in paragraphs 21-25 above,

merit serious consideration in terms of both financial and technical support, particularly to aid developing countries in developing and implementing their own national biosafety frameworks and attendant capacity-building requirements.

29. In adopting the objectives and effecting the foregoing biosafety capacity-building initiatives, concerted international co-operation and co-ordination is needed to cement the strong partnerships that must be forged between countries, organisations, institutions, NGOs, industry, and the public at larg for undertaking the enormous work at hand (or ahead) in the area of capacity building to ensure and enhance the safe research, development and application of biotechnology products world-wide.

30. Decision II/5, which established the Open -ended Ad Hoc Working Group on Biosafety, also recognised a need for interim measures during the development of the protocol. In particular, the COP recognised the need to develop national capacities to assess and manage risks, establish adequat information systems and develop expert human resources in biotechnology. The COP also recognised the important role that the United Nations Environment Programme's International Technical Guidelines on Safety in Biotechnology could play in this respect and urged that they be finalised. No that these have been finalised, and in light of the overall capacity building needs of developing countries highlighted by this Note, the SBSTTA may wish to consider how these Guidelines might b developed and applied so as to support the work of the Open -ended Ad Hoc Working Group on Biosafety.