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Agenda item 4.2

CAPACITY-BUILDING (ARTICLE 22, ARTICLE 28)

Capacity-building for the implementation of the Cartagena Protocol on Biosafety: submission by Germany

Note by the Executive Secretary

At the request of the delegation of Germany, the Executive Secretary is circulating herewith, for the information of participants in the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), a document entitled "Capacity Building for the Implementation of the Cartagena Protocol on Biosafety", published by the German Federal Ministry for Economic Cooperation and Development. The document is being circulated in the form and in the languages in which it was received by the Secretariat.

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Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

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Table of contents

1. Introduction

The effective implementation of the Cartagena Protocol on Biosafety (CPB) requires a whole range of institutional and technical preconditions to be fulfilled, which developing countries (DCs) as a rule find difficult or even impossible to meet under their own steam. This means that those industrial countries (ICs) having negotiated and signed the treaty are under the obligation to support the DCs within the framework of their development co-operation. The support should not wait until the entry into force of the CPB but start immediately by identifying the needs of the DCs for further capacity building on biosafety and encouraging effective efforts to prepare for the entry into force of the CPB.

With its signature to the CPB governments express their will to create the basis for following rights and obligations:

- Take the necessary and appropriate legal, administrative and other measures to implement the Protocol (Art. 2.1);
- Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health (Art. 2.2);
- Obtain the general right to take measures that are more protective than those envisaged by the Protocol, provided such actions are consistent with the Protocol and other international obligations (Art. 2.4);
- 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 LMOs (Art. 16.1);
- Endeavor to ensure that any LMO, whether imported or nationally developed, has undergone an appropriate observation before it is put to its intended use (Art. 16.4);
- Create notification and institution of proper emergency measures for unintentional transboundary movements of LMOs (Art. 17);
- Fulfill obligations relating to the effective administration of the Protocol (Art. 19 and others);
- Promote and facilitate public awareness, education ad participation, including access to information on LMOs identified in accordance with the Protocol that may be imported (Art. 23);
- Prevent, and if appropriate penalize illegal transboundary movements of LMOs (Art. 25).

Development co-operation has the task of providing effective support to the DCs in establishing the necessary environment for implementing the CPB at the national level, thus enabling the DCs to guarantee their own national biological safety and avoid a negative impact of transnational transport and use of products of modern biotechnology on man and the environment, consistent with CBD, national priorities and sustainable development.

Inadequate institutional and manpower competence, accompanied by a lack of pertinent legislation and participation of the public in decision-making processes often hamper the development of a suitable general setting for biological safety in DCs. This is precisely the point where development co-operation comes in, especially technical co-operation with its instruments of capacity building which mainly consist of:

1. policy advice;
2. institution building;
3. basic and further training of decision makers, experts and multiplicators;
4. public awareness raising, education and promotion of public participation.

In the context of implementing the CPB any capacity building effort has to guarantee that it enables developing countries to deal with following legal and administrative aspects:

- the right to regulate the transport of LMOs through a Party's territory, and obligation to communicate such transport to the Biosafety Clearing House (Art. 6.1);
- the right to set out standards for all contained use within a Party's jurisdiction (Art.

6.2);

- the application of the advanced informed agreement (AIA) procedure for intentional transboundary movements of LMOs for introduction into the environment of the importing Party, including such elements as notification, acknowledgement of receipt and decision-taking within the required timeframes and review of decisions; (Art. 7-10, 12);

- the notification of any final decisions regarding domestic use, including placing on the market, of a LMO that may be subject to transboundary movements for direct use as food, feed or for processing (LMO-FFP) (Art. 11.1);

- the notification of decisions on domestic regulatory or administrative measures in relation to the domestic use or placing on the market of LMO-FFP, or notification of the use of the Protocol provisions for intentional tansboundary movements of LMO-FFPs, as appropriate (Art. 11.4 – 11.6);

- the assessment of risks pursuant to the Protocol in a scientifically sound manner in accordance with the provisions in the Protocol and its Annexes (Art. 15);

- the formulation of risk management decisions based on the risk assessments (Art. 16);

- the right to take a decision in the context of a lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account the risks to human health (Art. 10.6, 11.8);

- the identification and analysis of options for employing risk management strategies to the extent necessary, to prevent adverse effects (Art. 16);

- the implementation of the risk management decisions (Art. 16.1);

- the application of appropriate measures to prevent unintentional transboundary movement of LMOs (Art. 16.3);

- the application of necessary measures to require that LMOs 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 (Art. 18.1);

- the sharing of information and ensuring the accuracy of information, including mandatory requirements in relation to the Biosafety Clearing-House (Art. 20 and others);

- the notification and protection of, confidential information (Art. 21);

- the inclusion of socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity in a risk assessment and decision-making process (Art. 26).

Capacity building is to be understood as a continuous and interdisciplinary process which will only succeed if the DCs do their very best to ensure sustainability of the measures implemented. All measures must take adequate account of the prevailing existing social, economic, ecological and political general environment in the DCs where measures are jointly carried out, with great importance being attached to transparency and the effective participation of civil society.

Development co-operation programs and projects on biosafety and biotechnology should be coordinated among the bilateral (especially EU Member States and the European Commission) and multilateral (especially GEF) governmental organizations also to explore possible partnerships between such organizations.

2. Policy Advice

In order to put the CPB into effect nationally, a process of ratification is required, as a rule, during which the CPB becomes national law through pertinent formal legislation adopted by parliament. Moreover, regulatory instructions must be issued which govern the administrative implementation of the CPB.

During the first phase of the implementation of the CPB in which capacity building can play a crucial role, the DCs will examine whether and to what extent existing national regulations (laws, decrees, guidelines) already fulfill the requirements set out in the CPB and where these must be supplemented in accordance with the CPB. Such efforts had been undertaken in several countries during the UNEP/GEF Pilot Program when a National Biosafety Framework was elaborated.

During the next steps of implementing the Protocol national capacities have to be build up that allow a Party to undertake risk assessments, to develop risk management strategies and to introduce an effective surveillance system. Being aware of the several innovative legal elements that the CPB introduces into international law, following priorities in capacity building in development co-operation have to be established to, in particular, enable DCs to:

- strengthen existing capacities in the field of environmental and health protection, and establish new capacities where needed, to assess the presented risk assessment documents and, if necessary, to perform or to commission independent risk assessment;
- establish decision mechanisms and structures responsible for the AIA-procedures concerning LMOs and LMO-FFPs that are independent from those public and private institutions which promote and apply modern biotechnology to avoid conflicts of interest and to lay the basis for public confidence in governmental decisions;
- base governmental decisions regarding the import of LMOs and LMO-FFPs on the precautionary approach as laid down in the Protocol, if necessary;
- facilitate public participation in the establishment of biosafety frameworks and regulations, in the AIA procedure and in the decision procedure;
- include socio-economic considerations into risk assessment.

In cases where no national regulations exist as yet for the handling of GMOs, the DCs can be supported in preparing bills in conformity with the CPB. The following instruments might be of use here:

- secondment of short-term experts (national or external) who give advice to the respective bodies of the legislative and executive branches in their work;
- political education measures on politically and legally relevant aspects of the CPB for decision makers in parliament, government and administration. Also, representatives from civil society should take part in further training measures so that they can participate at an early stage already in national policy formation.

3. Institution Building

3.1 Public Administration

According to Article 19 of the CPB each member state is obliged to nominate at least one authority which is responsible for the implementation of the functions required under the Protocol (e.g. evaluate and perform risk assessments, observe the precautionary principle, ensure public participation) and which takes on the necessary administrative work. Moreover, the states are also obliged to nominate a Focal Point for the CPB which is the official contact in international affairs for the implementation of the CPB and maintains a liaison to the Secretariat of the Convention on Biological Diversity (CBD). Both functions may be fulfilled by one governmental body.

The DCs can be supported when taking the measures required for the establishment and/or development of the administrative units needed for CPB implementation. Here, the focus should be on measures strengthening the provision of the necessary expert knowledge on risk assessment, risk management and monitoring along the lines of the CPB and on evaluating information received from the Clearing House Mechanism. In line with a holistic approach, competence must be developed in the areas of envi-

ronment, health, agriculture and life-sciences, with the aforementioned principles (precautionary principle, public participation and consideration of socio-economic aspects) again playing an eminent role.

The following instruments might be of use here:

- secondment of long-term experts accompanying, and advising on, the establishment and further development of the administrative units needed for CPB implementation;
- support of the partner country in the development of effective instruments to include civil society;
- further training measures for the administrative unit entrusted with CPB implementation and representatives of civil society.

3.2 Biosafety-Clearing House Mechanism

The CPB requires the member states to set up the Biosafety-Clearing House Mechanism (Biosafety-CHM). National Focal Points of the worldwide information network are to be set up in each Protocol member state. Information along the lines of the prior informed consent principle are to be made available worldwide through the Biosafety-CHM.

National admission of LMOs for food, feed and processing in the Parties of the CPB will be made known via the Biosafety-CHM. Furthermore, information on national legislation and guidelines of member states on biosafety, pertinent authorities and national and international experts is to be rendered transparent (Article 20 of the Protocol). Moreover, the Biosafety-CHM is to be used especially to publish violations of the CPB regulations.

The following instruments might be of use here:

- secondment of short-term experts to accompany, and advise on, the setting up and further development of the Biosafety-CHM;
- technical and financial support in the establishment and equipment of the Biosafety-CHM;
- further training measures for the Biosafety-CHM Focal Point and representatives of civil society in the use of EDP tools, especially the internet;
- advisory support in fulfilling the national obligation to report to the CBD Secretariat.

3.3 Monitoring/Evaluation/inspection services

The member states must either establish national laboratory capacities or have secure access to regional laboratory facilities to ensure ongoing supervisory activities within the framework of a regular monitoring and inspection, and for the required evaluations. Member States must have access to the relevant technologies needed for establishing an inspection and monitoring system.

Development co-operation can support the dialogue between policy/administration and science/industry and can be of help in the development of the necessary monitoring and inspection infrastructure. In cases where for national considerations neither own monitoring nor inspection infrastructure is to be established development co-operation can also provide support in setting up the necessary contacts to trustworthy, regionally active scientific institutions.

The following instruments might be of use here:

- secondment of short-term experts to accompany, and advise on, the establishment and further development of the pertinent monitoring facilities;
- technical and financial support in the establishment and equipment of the required laboratories;
- further training measures for institutions entrusted with monitoring or inspection;
- support in the establishment and further development of regional network structures.

4. Basic and Further Training of Decision Makers, Experts and Multiplicators

The national authorities responsible for CPB implementation must be adequately and competently staffed. In addition to the head of the administrative unit responsible for the CPB -

and it would be expedient if this were also the Focal Point - another two or, better still, three staff members should be recruited. They must have undergone the comprehensive training needed for the technical assessment of an import request, i.e. for the assessment of potential risks of LMOs. Such training comprises first and foremost knowledge connected with the application of the AIA procedure:

- risk assessment;
- application of the precautionary principle;
- labeling responsibility;
- consideration of socio-economic aspects.

Under the last item, particular consideration must be given to aspects of maintaining and developing agro-biodiversity (e.g. protection of farm and land races as well as of regionally adapted varieties for sustainable food security). Of special importance is furthermore the aspect of supporting small scale farming and organic agriculture.

It must be ensured that incoming requests can be properly assessed and, if necessary, additional investigations are carried out by independent experts. This requires technical know-how in natural science disciplines (environmental impact, ecological risk management, identification of LMOs), in the socio-economic field (consideration of these aspects in legislation, admission procedures etc.), in public relations work and participatory approaches. Further training along these lines will combine these aspects in the form of an interdisciplinary concept. Enhancement of institutional competence is also required for the establishment of the Biosafety-CHM.

5. Public Awareness Raising, Education and Promotion of Public Participation

An essential element to ensure acceptance of modern biotechnology is an open discourse with civil society. The open dialogue with non-governmental organizations in the field of environment and consumer policy plays an eminent role in this connection. Only an honest dialogue with a society's critical voices and minority opinions will ensure the necessary acceptance in the long term. This dialogue should not be limited on national level but include the promotion of (sub-)regional cooperation and exchange of information and experience.