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2 October 2002

NOTIFICATION

**Requirements that need to be fulfilled as at the date of entry into force of
the Cartagena Protocol on Biosafety**

Madam/Sir,

This is to advise that the Cartagena Protocol on Biosafety has to date been ratified by 36 Parties, namely:

Africa:	Botswana, Djibouti, Kenya, Lesotho, Liberia, Mali, Mauritius, Uganda;
Asia/Pacific:	Bhutan, Fiji, Maldives, Nauru, Niue, Samoa;
Central and Eastern Europe:	Belarus, Bulgaria, Croatia, the Czech Republic;
Latin America/Caribbean:	Barbados, Bolivia, Cuba, Mexico, Nicaragua, Panama, Saint Kitts and Nevis, Trinidad and Tobago, Venezuela;
Western Europe and Others Group:	Austria, Denmark, the European Community, Luxembourg, Norway, Spain, Sweden, Switzerland, The Netherlands.

In addition, Cameroon, Colombia, India and Slovenia have informed us that they have finalized their internal procedures and are in the process of depositing their instruments of ratification with the Depositary.

This demonstrates that the process of ratification of the Cartagena Protocol on Biosafety has been expeditious over the past few months. As such, it may not take long to obtain the number of instruments of ratification required for entry into force of the Protocol. Given this scenario, the Secretariat of the Convention on Biological Diversity feels it is both appropriate and timely to remind Governments, in particular those that have ratified the Protocol, of the requirements which they have to meet at the entry into force of the Protocol.

To: ICCP National Focal Points
CBD National Focal Points (where ICCP focal points have not yet been designated)

.../



I am, therefore, pleased to convey to you the note attached herewith which highlights some of the important provisions of the Protocol as well as a few practical measures that Parties are required to fulfill or undertake as soon as the Protocol enters into force, for your consideration and action, as appropriate.

Accept, Madam/Sir, the assurances of my highest consideration.

Hamdallah Zedan
Executive Secretary

HIGHLIGHTS OF SOME BASIC REQUIREMENTS OF THE CARTAGENA PROTOCOL ON BIOSAFETY THAT NEED TO BE FULFILLED AS AT THE DATE OF ENTRY INTO FORCE

1. Background

1.1 The process of ratification of the Cartagena Protocol on Biosafety is proceeding quickly enough that entry into force may happen in the near future. The rate of ratification accelerated as the world was preparing for and conducting the World Summit on Sustainable Development (WSSD).

1.2 As Governments and all other stakeholders are digesting the outcomes of the WSSD, fulfillment of obligations under existing and new treaties has become one of the tangible means to better express commitments derived from the Summit. Those countries that have ratified the Protocol may have already initiated or are planning to initiate actions at the domestic level that would enable them comply with the requirements of the Protocol right from the date of entry into force of the Protocol to them. Those who have not ratified the Protocol yet may be contemplating to do so. Obviously, one of the advantages of becoming a party to the Protocol at this early stage is the right to participate in taking decisions that the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) is expected to make. Presumably, the first two or three meetings of the COP-MOP will take decisions that might fundamentally shape the future course of the process under the Protocol.

1.3 The main purpose of this note is to assist countries, in particular developing countries and countries with economies in transition that have already ratified the Protocol, to identify and take timely action with regard to those requirements of the Protocol that have to be fulfilled by the date of entry into force. Unless there are practical and justifiable limitations, such countries would have to undertake measures necessary to comply with the Protocol without any delay, and should not necessarily await the formulation and adoption of their domestic biosafety frameworks.

2. Requirements of the Biosafety Protocol that need to be fulfilled as at the date of entry into force and/or shortly thereafter

The first logical step in the process of implementing the obligations of the Protocol is putting the necessary and appropriate legal, administrative and other measures in place as required under paragraph 1, Article 2 of the Protocol. The importance of a domestic biosafety framework or system cannot be overstated. Such a system developed in the form of a biosafety policy, strategy, legislation and administrative set up provides the foundation for subsequent technical and regulatory implementation. Following is a list and description of some basic requirements of the Protocol that ought to be met as at the date of entry into force of the Protocol with a view to highlighting the type of actions that countries that have ratified the Protocol should undertake at that stage as part of the development and implementation of their domestic biosafety frameworks/systems.

2.1. Designation of competent national authorities and national focal points (Article 19)

The Protocol requires each Party to designate one national focal point and one or more competent national authorities, or one entity to act as both a focal point and a national competent authority.¹ The names and addresses of the focal point and the competent national authority or authorities have to be notified to the Secretariat, **no later than the date of entry into force of the Protocol** for that Party.² The notification should also include relevant information on the responsibilities of each authority in the case where more than one competent national authority has been designated; including at a minimum, the type of LMOs that each is responsible for.

Actions required:

- Designate and communicate to the Secretariat the name and addresses of one national focal point and one or more competent national authorities;
- In case more than one competent national authority is designated, notify the Secretariat about their respective responsibilities.

2.2 Contact point for notifications on unintentional transboundary movements and emergency measures (Article 17)

Each Party is required to make available to the Biosafety-Clearing House, **no later than the date of entry into force of the Protocol for it**, the relevant details of its point of contact for the purpose of receiving notifications concerning any occurrence that leads or may lead to unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States.³ Incidents of this nature may happen any time, justifying the need to get prepared, from the date of entry into force of the Protocol, for emergency measures by, among other things, putting in place the necessary institutional infrastructure and making it known to other Governments. By so doing, notification among Parties and other Governments regarding accidental or unintentional releases of LMOs would be easier and faster.

Action required:

- Make available to the Biosafety Clearing-House (BCH) details of point of contact for the purpose of receiving notifications concerning any occurrence that leads or may lead to unintentional transboundary movement of a LMO.

2.3 Communicating decisions regarding LMOs intended for direct use as food or feed, or for processing (Article 11)

A Party making a final decision on the release (domestic use and placing on the market) of a LMO-FFP has to inform other Parties through the Biosafety Clearing-House, **within**

¹ Paragraph 1, Article 19 of the Cartagena Protocol on Biosafety.

² Paragraph 2, Article 19.

³ Paragraph 2, Article 17.

fifteen days of making that decision.⁴ Parties to the Protocol that usually import agricultural commodities for food, feed or for processing may avoid inconvenience or controversies that may arise eventually with regard to taking a decision on such imports by making available, immediately, to the Biosafety Clearing-House (BCH) copies of any laws, regulations and guidelines, if any, applicable to the import of LMOs-FFP.⁵ In the absence of a domestic regulatory framework, a developing country Party or a Party with an economy in transition **may declare, again through the BCH**, that it will take a decision with regard to a first import of a LMO-FFP following the procedures specified under paragraph 6 of Article 11. Thus, it would be to the advantage of the Party that may import agricultural commodities to either make known its domestic regulatory framework with regard to the import of LMOs-FFP, if it exists, or its intent to make a decision at every first shipment of LMO-FFP.

Actions required:

- Inform the Parties through the BCH of any final decision regarding domestic use, including placing on the market of a LMO that may be subject to transboundary movement for direct use as food or feed, or for processing (LMO-FFP) within fifteen days of making that decision;
- Make available to the BCH copies of any national laws, regulations and guidelines applicable to the import of LMOs-FFP;
- For a developing country Party or Party with an economy in transition without a domestic regulatory framework, declare through the BCH that decisions with regard to the first import of LMOs-FFP will be taken following the procedure specified under paragraph 6 of Article 11.

2.4 Identification of LMOs in accompanying documentation (Article 18)

Transboundary movements of LMOs must be accompanied by documentation that contains information on identification and other facts relevant to safe handling, storage, transport and use, as appropriate. Each transboundary movement of LMOs-FFP should be accompanied by documentation that clearly identifies as it “may contain” living modified organisms that are not intended for intentional introduction into the environment, and a contact point for further information.⁶ In the case of LMOs that are destined for contained use, the accompanying documentation should identify them as living modified organisms, and specify the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned.⁷ The transboundary movement of LMOs that are intended for intentional introduction into the environment of the Party of import and any other LMOs within the scope of the Protocol needs to be identified, in the accompanying documentation, as living modified organisms, and the identity and relevant traits and/or characteristics should be specified.⁸ The documentation should also specify the contact point for further

⁴ Paragraph 1, Article 11.

⁵ Paragraph 5, Article 11.

⁶ Paragraph 2(a), Article 18.

⁷ Paragraph 2(b), Article 18.

⁸ Paragraph 2(c), Article 18.

information, and contain a declaration confirming that the movement is in conformity with the requirements of the Protocol. In the case of the last two categories of LMOs, i.e. LMOs for contained use and LMOs for intentional introduction into the environment, the accompanying documentation should also provide information on safe handling, storage, transport and use of the LMOs.

Each concerned Party is expected to meet these requirements as the Protocol comes into force to it. In fact, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), taking into account the difficulties involved in the elaboration of these requirements and reaching a consensus, noted, at its third meeting⁹, that the lack of consensus does not set aside the obligations to implement paragraphs 2(a), 2(b) and 2(c) of Article 18 of the Protocol.

Actions required:

- Clearly identify transboundary movements of LMOs in accompanying documentation, that they “may contain” LMOs-FFP and specify contact point;
- Clearly identify transboundary movements of LMOs for contained use and LMOs for intentional introduction into the environment, in accompanying documentation, as living modified organisms, and specify contact points and safety requirements, as appropriate.

2.5 Making available information to and using the BCH (Article 20)

The BCH is a system of information sharing and a tool for implementation. The implementation of several provisions of the Protocol requires countries to use the BCH, including those **provisions described in this note that have to be fulfilled at the time of entry into force of the Protocol**. Clearly, there is a consequential need to put in place some level of capacity by each Party, at the date of entry into force, that would allow it to access the BCH. The Protocol, for example, requires Parties to make available, through the BCH, the following information: a final decision regarding domestic use, including placing on the market of a LMO-FFP¹⁰; a declaration by a developing country Party or a Party with an economy in transition that doesn't have a domestic regulatory framework regarding its desire to make a decision before the first import of LMOs-FFP¹¹; relevant details of point of contact for the purpose of notifications of the occurrence of accidental releases¹²; and also cases of illegal transboundary movement¹³. These are some of the requirements that illustrate the need for making readily available some level of capacity or preparedness to retrieve and provide information to the BCH by the time the Protocol enters into force.

Action required:

⁹ Recommendation 3/6 of the third meeting of the ICCP, (document UNEP/CBD/ICCP/3/10)

¹⁰ Paragraph 1, Article 11 of the Protocol.

¹¹ Paragraph 6, Article 11.

¹² Paragraph 2, Article 17.

¹³ Paragraph 3, Article 25.

- Put in place some level of capacity (human and technical) at the national level that would allow access to and use of the BCH at the date of entry into force.

2.6 Other practical requirements

There are some measures that are not directly required by the Protocol but are necessary for its effective implementation right from the date of entry into force. These measures may sometimes be prerequisites to achieve full compliance with the Protocol. The following are some of these practical requirements that are not directly provided for or authorized by the Protocol but their fulfillment is so essential that effective implementation of some of the specific obligations of the Protocol may depend on the level of performance in those respects.

2.6.1 Assessment of capacity building needs

Most developing countries lack the necessary capacity (institutional infrastructure as well as skills and competence in a variety of fields, such as risk assessment, risk management, information management) to be able to implement the Protocol effectively. Although not specifically required to be done at entry into force of the Protocol, it would be necessary as an urgent first strategic step for countries to assess and communicate through the BCH their capacity-building needs in order to facilitate needs-driven international cooperation in capacity-building-capacities as provided for in article 22 of the Protocol.

Action required:

- Assess and communicate through the BCH broader capacity-building needs.

2.6.2 Preparation for the first meeting of the COP-MOP

ICCP has requested, at its third meeting, Parties, Governments and relevant international organizations, as appropriate, to submit to the Executive secretary their views and/or information as regards several items so that the Executive Secretary can prepare synthesis reports of the views and information and submit them to the first meeting of the COP-MOP. These include information on liability and redress¹⁴, views on the transition between the pilot phase and the fully operational BCH; views and comments on the preliminary set of indicators for monitoring implementation of the Capacity- Building Action Plan; comments on the draft reporting format; views on unique identification systems such as the one being developed by the OECD and their applicability to the requirements of identification of LMOs under the Protocol and their linkage to the BCH; views on operational experience regarding a need for criteria for categorization of LMOs; and views on items to be included in a medium-term programme of work for COP-MOP. The submission of these views, comments and information in time would enable the

¹⁴ Information on national, regional and international agreements in the field of liability and redress for damage resulting from transboundary movements of LMOs; information or initial understandings on the basis of the questionnaire circulated and views on terms of reference for an ad hoc group of legal and technical experts (Recommendation 3/3 of the third meeting of the ICCP)

Executive Secretary to prepare the documentation necessary for the first meeting of COP-MOP for its consideration and appropriate action.

Last but not least, as entry into force of the Protocol will be followed by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), a State or a regional economic integration organization that has ratified the Protocol is required to get prepared for this important meeting. Although not a direct requirement from the Protocol, the responsibility to make the meetings of COP-MOP, including the first meeting successful, must be taken as a primary and standing requirement from each Party. COP-MOP is the supreme body of the Protocol and the principal vehicle to promote and monitor its implementation by making appropriate decisions. Only Parties to the Protocol have the right as well as the obligation to take decisions.¹⁵ In that regard, a number of recommendations and draft proposals by the ICCP on several items that it has been addressing during the past few years, including (i) procedures and mechanisms to facilitate decision-making by Parties of import; (ii) a process for the elaboration of liability and redress rules and procedures; (iii) budgetary arrangements with regard to the costs of the secretariat services for the Protocol; (iv) procedures and institutional mechanisms for compliance; (v) capacity building; and (vi) medium-term programme of work of the COP-MOP, will be considered by this first meeting and decisions are expected to be made.

Action required:

- Provide to the Executive Secretary the views and information that the third meeting of the ICCP requested for under different items of its recommendations;
- Undertake the necessary preparation, both at national and regional level, as appropriate, to participate and take decisions during the first meeting of COP-MOP.

3. Concluding remarks

3.1 This note is prepared to serve only as a reminder to States or regional economic integration organizations that have already ratified or acceded to the Protocol on what is expected of them at the date of entry into force of the Protocol or shortly thereafter by way of complying with the requirements of the Protocol. The Protocol will be as good as the timely and effective implementation of its provisions. This document has tried to outline those provisions of the Protocol that need to be met as soon as the Protocol becomes legally effective, without any claim to be exhaustive or prescriptive.

3.2 As pointed out in the background section above, by identifying the requirements that need to be fulfilled as at the date of entry into force, it is not intended to mean that actions with regard to the other provisions of the Protocol have to be deferred for some time. In fact, it is commonly known that entry into force entails compliance with all the requirements of the Protocol promptly and adequately.

¹⁵ Paragraph 2, Article 29.