Convention on Biological Diversity

Secretariat

Ref.: SCBD/BS/CS/WD/jh/36477

5 September 2003

NOTIFICATION

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

Madam/Sir,

I have the honour to refer to notification Ref.: SCBD/BS/CS/WD/jh/32159, dated 2 October 2002 which was conveying a note highlighting requirements that need to be fulfilled as at the date of entry into force of the Cartagena Protocol on Biosafety.

The Secretariat has prepared the attached revised version of this note, following inputs and comments received. The attached version replaces and supersedes the previous one.

I am, therefore, pleased to convey to you the revised note, 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 to facilitate the implementation of the Protocol following its entry into force.

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

Hamdallah Zedan
Executive Secretary

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

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HIGHLIGHTS OF SOME OF THE BASIC REQUIREMENTS OF THE CARTAGENA PROTOCOL ON BIOSAFETY

(Secretariat, Convention on Biological Diversity, September 2003)

I. Introduction

1. The fiftieth instrument of ratification of the Cartagena Protocol on Biosafety was deposited with the Secretary General of the United Nations, the Depository, on 13 June 2003 marking the entry into force of the Protocol ninety days thereafter i.e., 11 September 2003. The interim process that was put in place since the adoption of the Protocol on 29 January 2000 is going to come to an end, and implementation of the Protocol in a binding manner, is due to start.

2. The Protocol is entering into force at the time when more than 100 countries are still in the process of developing their national biosafety frameworks with the support of UNEP/GEF biosafety capacity building project. These countries are at different stages in the development of their national biosafety frameworks. While countries should expedite their domestic processes to put in place the necessary legal and administrative frameworks for biosafety, they should not necessarily await the formulation and adoption of these frameworks. The provisions of the Protocol themselves should offer the basis for implementing regulatory measures, as appropriate. But it should also be recognized that, ultimately, it would be difficult for any Party to the Protocol to implement the provisions of the Protocol effectively without a clear and comprehensive national biosafety policy and legal framework.

3. Being prompted by the high number of ratifications recorded in the wake of the World Summit on Sustainable Development, the Secretariat had issued a notification dated 2 October 2002 to all Governments conveying a note concerning requirements that need to be fulfilled as at the date of entry into force of the Biosafety Protocol. The note was intended to serve as a reminder to those Parties to the Convention that have ratified the Protocol on what was expected of them at the date of entry into force of the Protocol. The Secretariat received some feedback, including a request for a more comprehensive coverage of the requirements of the Protocol. In response to the request and taking into account the entry into force of the Protocol, the Secretariat submits the present revised version of the previous note on the requirements of the Protocol.

4. 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 or those that might ratify it soon, in identifying the basic requirements of the Protocol and what actions they might need to take in order to implement these requirements upon the entry into force of the Protocol to them.[1] Entry into force entails undertaking different measures necessary to comply with the Protocol without any delay. It is true that some countries have already started taking measures necessary for the implementation of the provisions of the Protocol while others are still in a planning stage.

5. In implementing the obligations under the Protocol, each Party needs to take various measures, including: **(i)** ***administrative measures:*** such as designating competent national authorities, a national focal point, and a point of contact; **(ii)** ***legal measures:*** such as ensuring the safe development, handling, transport, use, transfer and release of living modified organisms

[1] This note is not exhaustive as regards the requirements of the Protocol and is not intended to serve as a legal interpretation nor as a comprehensive guide for actions necessary for the implementation of the Protocol.

(LMOs); ensuring the accuracy of information provided during notifications for export; requiring identification of transboundary movements of LMOs in accompanying documentation; providing procedure for the protection of confidential information; promoting public awareness and participation; **(iii)** ***procedural measures***: for example, notifying the competent national authority of the Party of import of the first transboundary movement of LMOs intended to be introduced into the environment; providing written acknowledgment of receipt of notification and communicating decisions within the time limits specified in the Protocol.

6. The following sections of this note will look at some of these requirements and measures at length.

II. Requirements that need to be met as of the date of entry into force

7. There are two provisions in the Biosafety Protocol where each Party is required to take certain measures and notify those measures to the Secretariat or the Biosafety Clearing-House within a specific time frame. Both requirements relate to administrative arrangements that must be made at the national level by each Party and notified to the Secretariat as of the date of entry into force of the Protocol for that Party. These requirements are as follows:

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

8. 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.[2] 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.[3] 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.

9. ***Actions:***

- 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.

b. Identifying a point of contact for notifications on unintentional transboundary movements and emergency measures (Article 17)

10. 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.[4] 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

[2] Paragraph 1, Article 19 of the Cartagena Protocol on Biosafetty.
[3] Paragraph 2, Article 19.
[4] Paragraph 2, Article 17.

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.

11. ***Action:***

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

III. Requirements and possible actions following entry into force

12. 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 system or framework 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. These measures should aim at and result in ensuring that the development, handling, transport, use, transfer and release of living modified organisms (LMOs) are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.[5]

13. The following sections of this note highlight some of the basic requirements of the Protocol and the type of actions that countries that have ratified the Protocol should take with a view to meeting these requirements.

a. Making available information to the Biosafety Clearing-House (BCH)

14. The Biosafety Protocol relies heavily on the sharing of appropriate and timely information for its effective operation and implementation. In order to facilitate the exchange of information, the Protocol has established a Biosafety Clearing-House as part of the clearing-house mechanism of the Convention. The BCH is a system of information sharing and a tool for implementation. Each Party is required to make available to the Biosafety Clearing-House the information specified under paragraph 3 of Article 20 and other provisions of the Protocol. Under paragraph 3 of Article 20 each Party has to make available to the BCH:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required for the advance informed agreement procedure under the Protocol;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of risk assessments or environmental reviews of LMOs, including relevant information regarding processed products of LMO origin;

(d) Final decisions regarding the importation or release of LMOs (decisions such as under Article 10.3 and 11.4);

(e) Reports submitted by it pursuant to Article 33, including those on the implementation of the advance informed agreement procedure.

[5] Paragraph 2, Article 2.

15. In addition, the following information should also be made available to the BCH:

(f) Information on 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 or feed, or for processing (paragraph 1, Article 11);

(g) Copies of national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing (paragraph 5, Article 11);

(h) A declaration that a decision will be made prior to the first import of living modified organisms intended for direct use as food or feed, or for processing, by a developing country Party or a Party with an economy in transition that does not have a domestic regulatory framework in place (paragraph 6, Article 11);

(i) Information on review and change of a decision by a Party of import regarding intentional transboundary movement, as a result of new scientific information about the impacts of the living modified organism concerned (paragraph 1, Article 12);

(j) Information from a Party of import regarding simplified procedures (Article 13);

(k) A decision on whether that Party's domestic regulations shall apply with respect to specific imports to it (paragraph 4, Article 14);

(l) Notification of an occurrence under one's jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity (paragraph 1, Article 17);

(m) Relevant details setting out point of contact for the purpose of notifications of the occurrence of accidental releases of living modified organisms (paragraph 2, Article 17); and

(n) Information concerning cases of illegal transboundary movements (paragraph 3, Article 25).

16. ***Actions:***

- Put in place the necessary infrastructure and personnel at domestic level for the purpose of collecting, classifying, making available, use, access and disseminate relevant information to and from the BCH;
- Ensure, through the Biosafety Protocol national focal point or a BCH focal point, as appropriate, that information flow to and from the BCH is done in a timely manner.

b. Implementing the advance informed agreement procedure

17. Unless a Party of import opts for a simplified procedure as specified under Article 13[6], any first time intentional transboundary movement of living modified organisms destined for intentional introduction into the environment of the Party of import shall be subject to the advance informed agreement procedure (AIA) of the Protocol as described in Articles 8 to 10 and 12.

18. The AIA procedure is triggered by a notification from the Party of export or the exporter to the competent national authority of the Party of import. The notification shall contain information specified in Annex I of the Protocol as a minimum, and the accuracy of such

[6] A Party of import may allow transboundary movements of LMOs to take place at the same time as it is notified, or it may exempt imports from the advance informed agreement procedure, as long as adequate measures are applied to ensure safety. These simplified requirements and exemptions have to be declared in advance to the BCH.

information shall be ensured.[7] The Party of import has to acknowledge receipt of the notification in writing within 90 days of its receipt, and indicate whether it intends to apply its domestic regulatory framework (which needs to be consistent with the Protocol) or the procedure in the Protocol in handling the notification.[8] Where the decision procedure of the Protocol applies, the Party of import shall take a decision, in accordance with a risk assessment under Article 15, whether to approve the import with or without conditions, prohibit it, or seeks more information or extends the time to take the decision, and communicate such decision within 270 days of the date of receipt of the notification.[9]

19. ***Actions:***

- Establish or maintain a procedure for the notification of exports, on the one hand, and for taking decision on imports on the other, of living modified organisms destined for intentional introduction into the environment of the Party of import.
- Ensure that any domestic regulatory framework used in place of the decision procedure of the Protocol's AIA is consistent with the Protocol.[10]
- Where adequate capacity to handle the transboundary movement of an LMO exists, a Party of import may wish to specify in advance to the BCH cases where transboundary movement could take place simultaneously with the notification, and imports exempted from the AIA procedure.[11]

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

20. 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 fifteen days of making that decision. In doing so, the Party has to make available, at a minimum, the information specified in Annex II of the Protocol.[12]

21. Parties to the Protocol that usually import agricultural commodities for food, feed or for processing may respond to such information regarding the commercialization of LMO-FFP by taking a decision under their domestic regulatory frameworks which have to be consistent with the objective of the Protocol. Each Party is required to make available to the Biosafety Clearing-House (BCH), copies of any laws, regulations and guidelines, if any, applicable to the import of LMOs-FFP.[13] 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[14]. 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.

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[7] Article 8.
[8] Article 9.
[9] Article 10.
[10] Paragraph 3, Article 9.
[11] Article 13.
[12] Paragraph 1, Article 11.
[13] Paragraph 5, Article 11.
[14] According to this paragraph the declaration has to specify that decision will be taken within a predictable timeframe, not exceeding 270 days according to a risk assessment undertaken in accordance with Annex III of the Protocol.

22. ***Actions:***

- Make sure to inform other 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 (see also 3.1 above);
- Declare (in the case of a developing country Party or Party with an economy in transition without a domestic regulatory framework that wishes to do so), trough the BCH, that decisions with regard to the first import of LMOs-FFP will be taken within a predictable timeframe, not exceeding 270 days, subject to a risk assessment undertaken in accordance with Annex III of the Protocol.

d. Carrying out risk assessments for decision taking

23. The Protocol requires that decisions taken by the Party of import as regards the first import of LMOs intended for intentional introduction into the environment of the Party of import be based on risk assessments.[15] The Protocol acknowledges the right of a Party to subject all LMOs, including LMOs that are pharmaceuticals[16], LMOs for contained use[17], as well as LMOs-FFP[18], to risk assessment prior to taking decisions on import.

24. Risk assessments shall be carried out in a scientifically sound manner in accordance with Annex III of the Protocol.[19] In the case of LMOs under the AIA, risk assessments must be based on information provided in accordance with Article 8, at a minimum, and other available scientific evidence.[20]

25. ***Actions:***

- Ensure that risk assessments are undertaken for decisions taken under the AIA procedure of the Protocol as regards the import of LMOs for intentional introduction into the environment;[21]
- Ensure that risk assessments are carried out in a scientifically sound manner and taking into account recognized risk assessment techniques;

e. Undertaking risk management measures (Article 16)

26. Parties have to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol.[22] They are also required to: (i) take appropriate measures to prevent unintentional

[15] Paragraph 1, Article 10.
[16] Article 5.
[17] Paragraph 2, Article 6.
[18] Paragraph 6, Article 11.
[19] Paragraph 1, Article 15.
[20] Paragraphs 1, Article 15.
[21] Please note that, according to paragraphs 2 and 3 of Article 15, the Party of import may seek the exporter to carry out the risk assessment or the notifier to bear the cost.
[22] Paragraph 1, Article 16.

transboundary movements of living modified organisms;[23] (ii) endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use;[24] (iii) cooperate in identifying LMOs or specific traits of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and in taking appropriate measures regarding the treatment of such LMOs or traits[25].

27. ***Action:***

- Ensure that appropriate mechanisms, measures, and strategies to regulate, manage and control risks associated with the use, handling and transboundary movement of LMOs as identified in the risk assessment, are established and maintained.

f. Identification of LMOs in accompanying documentation (Article 18)

28. 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. Every 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 provides a contact point for further information.[26] 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.[27] 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 need to be identified, in the accompanying documentation, as living modified organisms, and the identity and relevant traits and/or characteristics should be specified.[28] The documentation should also specify the contact point for further 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 shall also provide information on safe handling, storage, transport and use of the LMOs.

29. Each 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 meeting[29], 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.

[23] Paragraph 3, Article 16.
[24] Paragraph 4, Article 16.
[25] Paragraph 5, Article 16.
[26] Paragraph 2(a), Article 18.
[27] Paragraph 2(b), Article 18.
[28] Paragraph 2(c), Article 18.
[29] Recommendation 3/6 of the third meeting of the ICCP, (document UNEP/CBD/ICCP/3/10)

30. ***Actions:***

- Take measures to require the appropriate persons to clearly identify, in documentation accompanying LMO-FFPs, that they "may contain" LMOs and are not intended for intentional introduction into the environment, and also to specify a contact point;
- Take measures to require the appropriate persons to clearly identify, in documentation accompanying LMOs for contained use, as living modified organisms, and to specify any safety requirements, contact point for further information, including the name and address of the person to whom the LMOs are consigned; and
- Take measures to require the appropriate persons to clearly identify, in documentation accompanying LMOs for intentional introduction into the environment and any other LMOs within the scope of the Protocol, as living modified organisms; to specify the identity and relevant trait and/or characteristics; to specify any safety requirements, contact point for further information, the name and address of the importer and exporter, as appropriate; and to declare that the movement is in conformity with the requirements of the Protocol.

g. Protecting confidential information (Article 21)

31. Each Party is required to protect confidential information received under the Protocol and as identified by the notifier.[30] It has to put in place procedures to protect and treat such information in no less favourable manner than it treats confidential information in connection with domestically produced living modified organism.[31] The Party of import shall not use confidential information for commercial purposes without the written consent of the notifier.[32] Confidentiality shall also remain respected if the notifier withdraws or has withdrawn the notification. No information regarding (a) the name and address of the notifier; (b) general description of the living modified organism; (c) summary of risk assessment; and (d) methods and plans for emergency response, shall be considered confidential.[33]

32. ***Action:***

- Establish or maintain procedures to protect information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential information.

h. Promoting public awareness and participation (Article 23)

33. The Biosafety Protocol requires and encourages Parties to inform and involve their public in matters relating to living modified organisms. More specifically, Parties are required to promote and facilitate public awareness, education and participation[34], including access to information[35] concerning the safe transfer, handling and use of LMOs; consult the public in the decision-making process and make the results of such decisions available in accordance with domestic legislation and with a respect to confidential information as provided for in the Protocol[36]; and facilitate public access to the Biosafety Clearing-House[37].

[30] Paragraph 1 and 3, Article 21.
[31] Paragraph 3, Article 21.
[32] Paragraph 4, Article 21.
[33] Paragraph 6, Article 21.
[34] Paragraph 1(a), Article 23.
[35] Paragraph 1(b), Article 23.
[36] Paragraph 2, Article 23.

34. ***Action:***

- Take appropriate measure that would allow or demand all relevant bodies to inform the public as regards the safe transfer, handling and use of living modified organisms that are of interest to the Protocol, including a means of public access to the Biosafety Clearing-House.

i. Conducting transboundary movements of LMOs between Parties and non-Parties (Article 24)

35. The Protocol does not prohibit transboundary movements of LMOs between Parties and non-Parties. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of LMOs. They can enter into such agreements and arrangements among themselves or with non-Parties. In so doing, Parties to the Protocol are required to make sure that the agreements, arrangements or the actual transboundary movements of LMOs are consistent with the objective of the Protocol,[38]and do not result in a lower level of protection than that provided for by the Protocol[39].

36. A Party is also free to determine that its domestic regulatory framework or regulations apply to specific imports of LMOs to it[40], whether from a Party or a non-Party, provided the framework or the regulations are consistent with the Protocol,[41] or consistent with the objective of the Protocol[42]. Therefore, while transboundary movements of LMOs could take place between Parties and non-Parties, the Protocol imposes an obligation on the side of the Party to the Protocol to make sure that the transboundary movement is in conformity with, at least, the objective of the Protocol.[43]Parties are also required to encourage non-Parties to adhere to the Protocol and to contribute appropriate information to the Biosafety Clearing-House.[44]

37. ***Action:***

- Ensure that any transboundary movement of LMOs with non-Party, taking place either under domestic regulatory framework, or bilateral, regional and multilateral agreements and arrangements, is consistent with the objective of the Protocol.

IV. Other requirements and actions of a practical nature

38. 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.

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[37] Paragraph 3, Article 23.
[38] Paragraph 1, Article 14 and paragraph 1, Article 24.
[39] Paragraph 1, article 14.
[40] Paragraph 2(c), Article 9; paragraph 4, Article 11; and paragraph 4, Article 14.
[41] Paragraph 3, Article 9.
[42] Paragraph 4, Article 11.
[43] Paragraph 1, Article 24.
[44] Article 24.

a. Assessing capacity building needs

39. 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. It would be necessary as an urgent first strategic step for those 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.

40. ***Action:***

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

b. Building or maintaining capacity to use the BCH

41. 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. As highlighted under paragraphs 14 and 15 above various types of information are required to be made available to the BCH. These requirements 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.

42. ***Action:***

- Put in place some level of capacity at the national level that would allow access to and use of the BCH.

c. Preparing for the first meeting of the COP-MOP

43. 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.

44. 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 to participate in taking decisions.[45] 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, await consideration and appropriate decisions by the first meeting of the COP-MOP. In that regard,

[45] Paragraph 2, Article 29.

preparation in advance by Parties to the Protocol will have an enormous contribution towards achieving efficiency in the decision –taking process and quality in the decisions themselves.

45. ***Action:***

- Undertake the necessary preparation, both at national and regional level, as appropriate, to participate and take decisions during the first meeting of COP-MOP.

V. Conclusion

46. The Biosafety Protocol is entering into force. Those that have ratified or acceded to the Protocol will become Parties to it in time for the first meeting of the COP-MOP. While several other countries are continuing and would continue to join the Protocol over time, implementation of the requirements of the Protocol by those that are already Parties to it would start right away upon entry into force. Looking at the nature of the various provisions of the Protocol, implementation takes place at different levels. There are obligations that have to be met at the national level by each Party, individually, or at international level by COP-MOP, collectively.

47. The focus of the present note has, however, been on requirements that need to be fulfilled by each Party. As we have seen in this note, there are requirements that need to be met by each Party on the date of entry into force of the Protocol or immediately thereafter. For example, the requirements relating to the provision of information on point of contact for unintentional transboundary movement (Article 17.2), and designation of a focal point and national competent authority/authorities (Article 19), constitute clear obligations that have to be fulfilled no later than the date of entry into force of the Protocol for each Party.

48. Like many other international agreements, implementation of the requirements of the Biosafety Protocol will remain to be a continuous process. There are requirements of which fulfillment would be recurring. The practical implementation of some of the requirements may in fact be relevant only when and where the situation which gives rise to the requirements exists. However, as highlighted at the beginning of this note the translation of the requirements of the Protocol into a specific and comprehensive domestic law should be the primary step in such a continuous process of implementation of the provisions of the Protocol. For instance, as the Protocol provides the option to take decisions on import of LMOs in accordance with a domestic regulatory framework that needs to be consistent with the objective of the Protocol, much may be desired from the Party of import's side to spell out its positions and requirements well in advance so that transboudary movements of LMOs could be conducted in a much more predictable way.

49. Finally the Secretariat would like to emphasize once again that the present note should not be considered as exhaustive or some kind of a guide to the Protocol. It provides the highlights of only some of the requirements of the Protocol to help Parties focus on actions that may be necessary to fulfill these requirements. A summary of the requirements and actions highlighted in this note is attached herewith as Appendix I. For an almost complete checklist of the obligations of the Protocol, it might be useful to consult the implementation toolkit adopted by ICCP in Annex III of its recommendation 3/5. The toolkit provides a compilation of the requirements specified in the Biosafety Protocol by creating different categories based on the nature of such requirements. The toolkit is also attached herewith as Appendix II for ease of reference.[46]

[46] Please note that the requirement of notification under Article 8.1 of the Protocol is inadvertently omitted from the third set of requirements (III. legal requirements and/or undertakings) in the toolkit, which should be corrected when using the toolkit.

APPENDIX 1

SUMMARY OF SOME OF THE BASIC REQUIREMENTS OF THE BIOSAFETY PROTOCOL AND THOSE RELATED ACTIONS HIGHLIGHTED IN THE PRESENT NOTE

Requirements	Article	Actions
Designating competent national authorities and national focal point	Article 19	1.Designate and communicate to the Secretariat, no later than the date of entry into force of the Protocol, the name and addresses of one national focal point and one or more competent national authorities; 2. In case more than one competent national authority have been designated, notify the Secretariat about their respective responsibilities.
Identifying a point of contact for notifications on unintentional transboundary movements and emergency measures	Article 17	Make available to the Biosafety Clearing-House (BCH), no later than the date of entry into force of the Protocol, details of a point of contact for the purpose of receiving notifications concerning any occurrence that leads or may lead to unintentional transboundary movement of a LMO.
Making available information to the Biosafety Clearing-House (BCH)	Articles 20(3), 11(1), 11(5), 11(6), 12(1), 13, 14(4), 17(1), 17(2), 25(3)	1.Put in place the necessary infrastructure and personnel at domestic level for the purpose of collecting, classifying, making available, use, access and disseminate relevant information to and from the BCH; 2.Ensure, through the Biosafety Protocol national focal point or a BCH focal point, as appropriate, that information flow to and from the BCH is done in a timely manner.
Implementing the advance informed agreement procedure	Articles 7, 8 to 10 and 12	1.Establish or maintain a procedure for the notification of exports, on the one hand, and for taking decision on imports on the other, of living modified organisms destined for intentional introduction into the environment of the Party of import; 2.Ensure that any domestic regulatory framework used in place of the decision procedure of the Protocol's AIA is consistent with the Protocol; 3.Where adequate capacity to handle the transboundary movement of an LMO exists, a Party of import may wish to specify in advance to the BCH cases where transboundary movement could take place simultaneously with the notification, and imports exempted from the AIA procedure.
Communicating decisions regarding LMOs intended for direct use as food or feed, or for processing (LMOs-FFP)	Article 11	1.Make sure to inform other 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 within fifteen days of making that decision; 2.Make available to the BCH copies of any national laws, regulations and guidelines applicable to the import of LMOs-FFP; 3.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 within a predictable timeframe, not exceeding 270 days, in accordance with a risk assessment undertaken in accordance with Annex III of the Protocol.

Requirements	Article	Actions
Carrying out risk assessments for decision taking	Articles 15 and Articles 5, 6(2) and 11.6, as appropriate	1.Ensure that risk assessments are carried out in a scientifically sound manner and taking into account recognized risk assessment techniques; 2.Ensure that risk assessments are undertaken for decisions taken under the AIA procedure of the Protocol as regards the import of LMOs for intentional introduction into the environment
Undertaking risk management measures	Article 16	1.Ensure that appropriate mechanisms, measures, and strategies to regulate, manage and control risks associated with the use, handling and transboundary movement of LMOs as identified in the risk assessment, are established and maintained
Identification of LMOs in accompanying documentation	Article 18	1.Take measures to require the appropriate persons to clearly identify transboundary movements of LMOs-FFP in accompanying documentation, that they "may contain" LMOs and are not intended for intentional introduction into the environment and also to specify a contact point; 2.Take measures to require the appropriate persons to clearly identify, in accompanying documentation, transboundary movements of LMOs for contained use as living modified organisms, and to specify any safety requirements, contact point for further information, including the name and address of the person to whom the LMOs are consigned; and 3.Take measures to require the appropriate persons to clearly identify, in accompanying documentation, LMOs for intentional introduction into the environment and any other LMOs within the scope of the Protocol, as living modified organisms; to specify the identity and relevant trait and/or characteristics; to specify any safety requirements, contact point for further information, the name and address of the importer and exporter, as appropriate; and to declare that the movement is in conformity with the requirements of the Protocol.
Protecting confidential information	Article 21	Establish or maintain procedures to protect information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential information.
Promoting public awareness and participation	Article 23	Take appropriate measure that would allow or demand all relevant bodies to inform the public as regards the safe transfer, handling and use of living modified organisms that are of interest to the Protocol, including a means of public access to the Biosafety Clearing-House.
How transboundary movements of LMOs between Parties and non-Parties must be conducted	Articles 24, and 14	Ensure that any transboundary movement of LMOs with non-Party, taking place either under domestic regulatory framework or bilateral, regional and multilateral agreements and arrangements, is consistent with the objective of the Protocol;
Assessment of capacity building needs		Assess and communicate through the BCH broader capacity-building needs.
Developing or maintaining capacity to use the BCH		Put in place some level of capacity at the national level that would allow access to and use of the BCH.
Preparing for the first meeting of the COP-MOP		Undertake the necessary preparation, both at national and regional level, as appropriate, to participate and take decisions during the first meeting of COP-MOP.

APPENDIX II

Annex III, Recommendation 3/5, third meeting of the ICCP

IMPLEMENTATION TOOL KIT

This implementation tool kit provides a compilation, as a checklist, of obligations found in the Cartagena Protocol on Biosafety. These obligations are organized in the following categories:

- **Administrative tasks (initial and future)**
- **Legal requirements and/or undertakings**
- **Procedural requirements (AIA and Article 11)**

I. ADMINISTRATIVE TASKS

	Tasks	***Article***	*Ö*
	Initial actions		
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)	
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)	
3.	Provide to the Biosafety Clearing-House: - any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMO-FFPs; and - any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)-(b), 11(5), 14(2)	
4.	Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	
5.	Specify to the Biosafety Clearing-House imports of LMOs exempted from the AIA procedures.	13(1)(b)	
6.	Notify the Biosafety Clearing-House if domestic regulations shall apply with respect to specific imports.	14(4)	
7.	Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	
8.	Notify the Secretariat if there is a lack of access to the Biosafety Clearing-House and hard copies of notifications to the Clearing House should be provided.	(e.g., 11(1))	
	Follow-up actions		
9.	Provide to the Biosafety Clearing-House: - Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15; - Final decisions concerning the import or release of LMOs; and - Article 33 reports.	20(3)(c)-(e)	
10.	Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25(3)	
11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	
12.	Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.		

II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

	Tasks	*Article*	*Ö*
1.	Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	
2.	Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.	8(2) 11(2)	
3.	Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	
5.	Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)	
6.	Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)	
7.	Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	
8.	Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	
9.	Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	
10.	Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)	
11.	Take measures to require that documentation accompanying LMO-FFPs - clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment; and - provides a contact point for further information.	18(2)(a)	
12.	Take measures to require that documentation accompanying LMOs destined for contained use: - Clearly identifies them as LMOs; - Specifies any requirements for their safe handling, storage, transport and use; - Provides a contact point for further information; and - Provides the name and address of individuals or institutions to which they are consigned.	18(2)(b)	
13.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: - Clearly identifies them as LMOs - Specifies the identify and relevant traits and/or characteristics; - Provides any requirements for the safe handling, storage, transport and use; - Provides a contact point for further information; - Provides, as appropriate, the name and address of the importer and exporter; and - Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18(2)(c)	
14.	Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21(1),(6)	
15.	Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)	

	Tasks	*Article*	*Ö*
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	
19.	Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	
21.	Endeavor to inform the public about the means of public access to the Biosafety Clearing-House.	23(3)	
22.	Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	
23.	Dispose, at its expense, LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	

III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

	Tasks	*Article*	*Ö*
1.	Provide written acknowledgement of receipt of notification to notifier within 90 days, including:		
	- Date of receipt of notification;	9(2)(a)	
	- Whether notification meets requirements of Annex I;	9(2)(b)	
	- That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; **OR** - Whether the import may proceed after 90 days without further written consent.	10(2)(a), 9(2)(c) 10(2)(b)	
2.	Communicate in writing to the notifier, within 270 days of receipt of notification: - Approval of the import, with or without conditions; - Prohibition of the import; - A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or - Extension of the 270 day period by a defined period of time; **AND**	10(3)(a)-(d)	
	Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10(4)	
3.	Provide in writing to the Biosafety Clearing-House the decision communicated to the notifier.	10(3)	
4.	Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2),(3)	

IV. PROCEDURAL REQUIREMENTS: LIVING MODIFIED ORGANISMS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

	Tasks	***Article***	*Ö*
1.	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II.	11(1)	
2.	Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing-House.	11(1)	
3.	Provide additional information contained in paragraph (b) of Annex II about the decision to any Party that requests it.	11(3)	
4.	In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMO-FFPs: - either as approved under the domestic regulatory framework consistent with the Protocol; **OR** - in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11(4),(6)	
