



CONVENTION ON BIOLOGICAL DIVERSITY

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THE CARTAGENA PROTOCOL ON BIOSAFETY: FREQUENTLY ASKED QUESTIONS IN PREPARATION FOR RATIFICATION

Note by the Executive Secretary

I. INTRODUCTION

1. Since the adoption of the Cartagena Protocol on Biosafety, several countries and organizations, as well as individuals, have been trying to study its provisions and their implications from two major perspectives, i.e. environment and trade. Many countries have signed the Protocol, and a few have ratified or acceded to it. Some countries are examining the nature and scope of the rights and obligations specified in the Protocol, with a view to initiating a process of ratification or accession. Others have been trying to know what procedural steps and related requirements are needed in order for them to proceed to sign, ratify and implement the Protocol. Still others have been interested in knowing whether they are required to make financial contributions and/or are entitled to some financial and other benefits, as a result of becoming a Party to the Protocol. The Secretariat has been receiving enquiries, from time to time, from national focal points and others, as regards these issues and, in response, has tried to provide explanations or share its views, as appropriate.

2. The present note is intended to provide further information in response to the questions frequently asked, particularly by developing countries, as regards some of the requirements of the Protocol, with particular emphasis on procedural issues such as signature,^{1/} ratification, acceptance, approval or accession of the Protocol; financial contributions and support for implementation; and capacity-building benefits.

3. The note provides some background to the Protocol, drawing mainly on the contents of the introduction to the text of the Protocol published by the Secretariat in 2000. The second part of the note describes the procedural steps that States and regional economic integration organizations would normally take in order to become a Party to the Protocol. The last part provides a highlight of some major requirements of the Protocol under three different categories, namely:

^{1/} As the Protocol has been closed for signature since 4 June 2001, the intention here is to describe the type of questions that used to be raised and to address the issue of signature to the extent that it helps clarify the procedure of ratification, acceptance, approval or accession.

- (a) The elements that Parties are required to have put in place upon entry into force of the Protocol for them;
- (b) The recurring requirements that are procedural and periodic in nature; and
- (c) Other substantive requirements that may need to be taken into account in considering the question of becoming party to the Protocol.

II. BACKGROUND TO THE PROTOCOL

4. Biosafety is one of the issues addressed by the Convention on Biological Diversity. The concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care. The Convention clearly recognizes these twin aspects of modern biotechnology. On the one hand, it provides for the access to and transfer of technologies, including biotechnology, that are relevant to the conservation and sustainable use of biological diversity (for example, in Article 16, para. 1, and Article 19, paras. 1 and 2). On the other hand, Articles 8(g) and paragraph 3 of Article 19 seek to ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity, taking also into account the risks to human health. Article 8(g) deals with measures that Parties should take at national level, while Article 19, paragraph 3, sets the stage for the development of an internationally binding instrument to address the issue of biosafety.

5. At its second meeting, held in November 1995, the Conference of the Parties to the Convention established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, focusing specifically on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. After five years of negotiations, the Protocol, known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was finalized and adopted on 29 January 2000 at the first extraordinary meeting of the Conference of the Parties to the Convention, in Montreal.

6. The conclusion of the Biosafety Protocol has been hailed as a significant step forward in that it provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry. The Protocol thus creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.

7. The Protocol was open for signature, in accordance with Article 36, at the United Nations Office at Nairobi from 15 to 26 May 2000, during the fifth meeting of the Conference of the Parties to the Convention, and it remained open at the United Nations Headquarters in New York from 5 June 2000 to 4 June 2001. The Protocol enters into force, in accordance with Article 37, on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

III. HOW TO BECOME A PARTY TO THE PROTOCOL

8. States and regional economic integration organizations are eligible to become party to the Cartagena Protocol on Biosafety. However, according to the Convention on Biological Diversity ^{2/} under which the Protocol was adopted, a state or a regional economic integration organization has to be a Contracting Party to the Convention before it becomes a Party to a protocol.

9. As indicated in section II above, the closing date for signing the Protocol was 4 June 2001. By that date, 103 signatures had been affixed. ^{3/} Signature is an expression of goodwill towards the adoption of an international agreement but does not imply any legal commitment to its specific provisions. The States or regional economic integration organizations that have signed the Protocol before the closing date for signature may then proceed to take steps that would enable them incorporate the provisions of the Protocol into their legal systems and deposit with the depositary, namely, the Secretary-General of the United Nations, instruments of ratification, acceptance or approval, depending on the relevant domestic arrangements.

10. Accession is different from the other procedures, namely ratification, acceptance and approval, in that it enables States to become Parties to an international agreement without having previously signed it. However, ratification, acceptance, approval and accession have the same legal consequences. According to recognized international practice, instruments of ratification, acceptance, approval or accession are always a result of an act of a legislative organ or an executive decision of the head of State or Government to express their Governments consent to be bound by an international agreement. The relevant instruments are issued and signed either by a head of State or Government or by a minister for foreign affairs and represent an expression of explicit acceptance, at the international level, to be legally bound by the international agreement.

11. Like many other treaties, the entry into force of the Protocol depends on the submission of instruments of ratification, acceptance, approval or accession by a specific minimum number of States. As mentioned above, the Protocol requires the deposit of such instruments from 50 Parties to the Convention on Biological Diversity for it to enter into force. Once the Protocol has entered into force, Parties are required, among other things, to ensure that transboundary movements of living modified organisms that fall within the scope of the Protocol between them and non-Parties take place in a manner consistent with the objective of the Protocol. ^{4/} Whether the requirement to be consistent with the objective of the Protocol extends to complying with the specific standards and procedures of the Protocol appears an open question. However, a certain level of conformity with the rules of the Protocol that directly contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms is required.

IV. WHAT DOES BEING A PARTY TO THE PROTOCOL ENTAIL?

A. *What do new Parties have to have in place before entry into force?*

12. There are two requirements in the Protocol that those incoming Parties to the Protocol need to have fulfilled as of the entry into force of the Protocol for them. Both relate to the designation of focal or

^{2/} Article 32 of the Convention.

^{3/} Up-to-date information on signature and ratification of the Cartagena Protocol on Biosafety is provided on the web site of the Secretariat of the Convention on Biological Diversity, www.biodiv.org.

^{4/} Article 24 of the Protocol.

contact points. First, States have to designate one national focal point to be responsible for liaising with the Secretariat, and one or more competent national authorities, which shall be responsible for performing the administrative functions required by the Protocol, or a single entity entrusted with the task of fulfilling both functions. Each Party is required to notify the Secretariat, no later than the date of entry into force of the Protocol for it, of the names and addresses of its focal point and its national competent authority or authorities. ^{5/} In cases where a Party designates more than one national competent authority, it is required to include in its notification relevant information on the respective responsibilities of those authorities, and to indicate, as appropriate, which competent national authority, would be responsible for which type of living modified organism.

13. On the other hand, each Party is required ^{6/} to make available to the Biosafety Clearing-House, again no later than the date of entry into force of the Protocol for it, the relevant details setting out its point of contact for the purposes of receiving notifications as regards unintentional transboundary movements and emergency measures. This requirement is linked to a more substantive obligation, specified under Article 17, to notify cases of accidental releases of living modified organisms that are likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

14. Presumably, there is nothing that constrains Parties to merge the functions under Article 19 and Article 17 into the responsibilities of a single entity. Depending on the particular conditions and capabilities at the national level, Parties may designate a single entity to fulfil the functions of a focal point, a competent authority (Article 19), and a point of contact (Article 17) of the Protocol.

B. What sort of recurring requirements are Parties to the Protocol expected to fulfil?

15. One of the requirements of a recurring and procedural nature under the Protocol is reporting. Once a State or a regional economic integration organization becomes a Party to the Protocol, it is required, under Article 33, to monitor the extent of implementation of its obligations. Each Party also has an obligation to report to the Conference of the Parties serving as the meeting of the Parties to the Protocol, at intervals to be determined by the latter, on measures that it has taken to implement the Protocol. The monitoring and reporting requirements are intended to serve as one of the vehicles to measure, promote and facilitate compliance under the Protocol.

16. The other recurring requirement that is often associated with becoming a Party to an international agreement such as the Biosafety Protocol is the obligation to make financial contributions. Following the entry into force of the Protocol, Parties will be required to make annual contributions so as to cover the costs of the Secretariat relating to its services to the Protocol and the implementation of approved work plans.

17. In accordance with paragraph 5 of Article 29 of the Protocol, the financial rules of the Convention apply, as appropriate, to the Protocol. Under the financial rules of the Convention, every Party to the Convention is required to make an annual contribution to cover the costs of the administration of the Convention, including the functions of the Secretariat. The scale for assessing the levels of contributions that each Party is to pay is based on the United Nations scale of assessment for the apportionment of the expenses of the Organization. Contributions by developing country Parties, in particular the least developed countries, are relatively small and usually nominal. In fact, as far as the least developed country Parties

^{5/} Paragraph 2, Article 19 of the Protocol.

^{6/} Paragraph 2, Article 17.

are concerned, they are not, as a rule, required to pay more than 0.01 per cent of the total budget approved for any budget year. It should be emphasized that, since the Secretariat of the Convention serves also as the Secretariat to the Protocol, that part of the budget required to run the biosafety-related functions of the Secretariat, to the extent that the costs are distinct from the costs of secretariat services to the Convention, shall be met by the Parties to the Protocol. ^{7/} The Conference of the Parties serving as the meeting of the Parties to the Protocol is expected to decide, at its first meeting, on the necessary budgetary arrangements.

C. *What other substantive requirements need to be taken into account in considering the question of becoming party to the Protocol?*

18. There are two obligations of a general nature under Article 2 of the Protocol. Paragraph 1 of Article 2 reiterates a general rule that usually appears in international treaties. Each Party has a responsibility to take necessary and appropriate legal, administrative and other measures to implement obligations under the Protocol. Paragraph 2, on the other hand, requires Parties to ensure that the development, handling, transport, use, transfer and release of any living modified organisms are carried out in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health. These provisions, particularly paragraph 2 of Article 2, tend to set the policy framework underlying the other substantive requirements of the Protocol.

19. The Protocol sets out a number of substantive obligations, the advance informed agreement (AIA) procedure being the central one. The AIA procedure is initiated by a notification from a Party of export or an exporter of living modified organisms. The Party of import is required to acknowledge notification and to take an appropriate decision within a specific period of time. The Protocol provides for differentiated approaches to living modified organisms for intentional introduction into the environment, and living modified organisms intended for direct use as food, feed or for processing. ^{8/}

20. The Biosafety Protocol relies heavily on the sharing of appropriate 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. In line with this arrangement, 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. The information required to be made available to the Biosafety Clearing-House, in addition to that specified under paragraph 3 of Article 20 of the Protocol, includes:

(a) 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);

(b) 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);

(c) 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);

^{7/} Paragraph 3, Article 31 of the Protocol.

^{8/} Article 7 of the Protocol.

(d) 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);

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

(f) 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);

(g) 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

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

21. In order to fulfil its substantive requirements, in particular those relating to the AIA procedure, the Protocol identifies the need for capacity-building as crucial. The Protocol envisages support for capacity-building for developing country Parties and for Parties with economies in transition, which includes scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management, and the enhancement of technological and institutional capacities in biosafety. The Protocol requires Parties to cooperate in the development and strengthening of human resources and institutional capacities in biosafety in developing country Parties, in particular the least developed and small island developing States among them and in Parties with economies in transition. For this purpose, paragraph 2 of Article 22 calls for account to be taken of the needs of developing countries, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how for building capacity in biosafety.

22. Under paragraph 2 of Article 28 of the Protocol, the mechanism for the provision of financial resources to developing country Parties under the Convention will also be the financial mechanism for the Protocol. In providing guidance to this financial mechanism, for the consideration of the Conference of the Parties to the Convention, the Conference of the Parties serving as the meeting of the Parties to the Protocol is required to take into account the need for financial resources by developing country Parties with regard to building their capacity, as referred to in Article 22 of the Protocol.

23. Immediately upon the adoption of the Protocol, the Global Environment Facility (GEF), the institutional structure operating the financial mechanism of the Convention, committed itself to implementing, in collaboration with UNEP, a capacity-building project intended to support the development of national biosafety frameworks. The overall objective of the project is to prepare countries for the entry into force of the Protocol. Initially, it aims at assisting up to 100 eligible countries to prepare their national biosafety frameworks. The project emerged as a response to the willingness of a number of countries that signed the Protocol in Nairobi in May 2000 to assume a number of obligations that further its objective. As a result, the criterion for eligibility to participate in this project was tied to whether or not the Party to the Convention signed the Protocol. However, the need for revising the criterion and adopting a flexible arrangement is under consideration by the GEF in view of allowing those countries that had not signed the Protocol when it was closed for signature, but are likely to join it and have expressed real capacity needs, to come on board and benefit from the project.

24. The objective of the project is also consistent with the general obligation established by paragraph 1 of Article 2 of the Protocol which requires each Party, as mentioned earlier above, to take the necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol. The development of national biosafety frameworks would eventually enable Parties to the Convention and to the Protocol to put in place appropriate legal and regulatory systems to assess any possible impact resulting from the release of living modified organisms into their environment and to take other necessary measures. It is believed that initiatives for capacity-building must primarily concentrate on procedures for risk assessment and risk management, including any scientific and organizational skills that might be required for taking the necessary and appropriate legal, administrative and other measures that help implement obligations under the Protocol.

25. In addition to what would be available through the financial mechanism, paragraph 6 of Article 28 of the Protocol states that developed country Parties may provide to the developing country Parties and Parties with economies in transition financial and technological resources for the implementation of the provisions of the Protocol through bilateral, regional and multilateral channels. For developing countries and countries with economies in transition to have access to these financial resources and other support for capacity-building in the context of the Protocol, they need to be Parties to the Protocol.
