



THE CARTAGENA PROTOCOL ON BIOSAFETY

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TABLE OF CONTENTS

	Page
INTRODUCTION	1
LANGUAGE	2
KEY PROVISIONS.....	2
A. Biosafety Clearing-House.....	2
B. AIA – Advance Informed Agreement.....	2
C. Exclusions From the AIA.....	3
D. Documentation.....	4
E. The Precautionary Principle	4
F. Relationship With the World Trade Organization Agreement (Savings Clause).....	5
CANADA AND THE CARTAGENA PROTOCOL	6
CONCLUSION AND COMMENTARY	6



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THE CARTAGENA PROTOCOL ON BIOSAFETY

INTRODUCTION

The Cartagena Protocol on Biosafety (the Protocol) is the first protocol to the Convention on Biological Diversity that was agreed to at the United Nations Convention on the Environment and Development (UNCED, or the Earth Summit) held in Rio de Janeiro in 1992. It seeks to protect biological diversity from the potential risks posed by living modified organisms (LMOs – see “Language,” below) resulting from modern biotechnology.⁽¹⁾ Among other things, it establishes an advance informed agreement (AIA) procedure to provide information to countries in order to help them make informed decisions before agreeing to the importation of such organisms into their territory. It also creates a framework to help developing countries and countries with economies in transition to build human resources and institutional capacity in biosafety. Movements of LMOs between Parties and non-Parties are intended to be consistent with the objective of the Protocol, meaning that a potential exporter that is not a Party to the Protocol will be expected to abide by its rules, in general, if it wishes to export to a Party.

The initial negotiations of the Protocol took place in Cartagena, Colombia, in February 1999 but the Parties were unable to come to an agreement. The Protocol was finally adopted by the Conference of the Parties on 29 January 2000, in Montréal. With the ratification by Palau on 13 June 2003, the required number of nations have ratified the Protocol and it will come into force 90 days later, on 11 September 2003.

(1) Secretariat of the Convention on Biological Diversity, “Cartagena Protocol on Biosafety: About the Protocol,” <http://www.biodiv.org/biosafety/background.asp>.

LANGUAGE

In a number of cases, the Conference of the Parties avoided commonly used phrases in favour of terminology specific to the Protocol, in part to avoid potential negative connotations associated with common usage or other conventions. In particular, most people are familiar with the term GMO (genetically modified organism), but it can have different meanings and implications according to one's perspective. The Conference of the Parties therefore decided to use LMO instead of GMO, and it defined the term in the Protocol. In addition, "prior informed consent," which is used in conventions on hazardous waste, was replaced by "advance informed agreement."

KEY PROVISIONS

A. Biosafety Clearing-House

The Protocol established an Internet-based Biosafety Clearing-House (BCH) in order to help countries exchange scientific, technical, environmental and legal information about LMOs. The Clearing-House will also be a place to exchange experience about dealing with LMOs and to assist Parties in implementing the Protocol.⁽²⁾

B. AIA – Advance Informed Agreement

In large measure, the AIA procedure represents the core of the Protocol.⁽³⁾ The procedure applies to the first intentional export of LMOs from a Party for intentional introduction into the environment by a Party intending to import. The purpose of this procedure is to ensure that importing countries have both the opportunity and the capacity to assess risks that may be associated with the LMO before agreeing to its import.

Specifically, the exporting Party or the exporter must notify the importing Party by providing a detailed, written description of the LMO in advance of the first shipment. The importing Party is to acknowledge receipt of this information within 90 days. Then, within 270 days of the date of receipt of notification, the importing Party must communicate its

(2) Secretariat of the Convention on Biological Diversity, "Cartagena Protocol on Biosafety: Frequently Asked Questions," <http://www.biodiv.org/biosafety/faqs.asp>.

(3) S. Safrin, "Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements," *American Journal of International Law*, Vol. 96, July 2002, pp. 606-628.

decision: (i) approving the import, (ii) prohibiting the import, (iii) requesting additional relevant information, or (iv) extending the 270 days by a defined period of time. Unless consent is unconditional, the importing Party must indicate the reasons on which its decisions are based.⁽⁴⁾ Criteria to be met in a risk assessment to be used in making a decision are outlined in Annex III of the Protocol.

C. Exclusions From the AIA

A number of LMOs have been excluded from the AIA procedure, based on the specific activity or the intended use of the LMO involved. These are:

- LMOs in transit;
- LMOs destined for contained use; and
- LMOs intended for direct use as food or feed or for processing (LMOs-FFP).

Subsequent to the Protocol's coming into force, a Meeting of the Parties may also establish a list of excluded LMOs that it decides are not likely to have adverse effects on the conservation and sustainable use of biological diversity, while also taking into account risks to human health.

The Protocol establishes a simplified procedure for the movement of LMOs as agricultural commodities (LMOs-FFP) between Parties. Under this procedure, if a Party makes a regulatory decision regarding an LMO-FFP (particularly if it decides to put the LMO-FFP on the market, which could lead to its being exported), then it must inform other Parties within 15 days of this decision through the Biosafety Clearing-House.

Decisions by an importing Party on whether or not to accept an LMO-FFP are to be taken under its domestic regulatory framework, as long as it is consistent with the objective of the Protocol. A developing country Party or a Party with an economy in transition may, in the absence of a domestic regulatory framework, declare through the Biosafety Clearing-House that its decisions will be taken in accordance with risk assessment as set out in the Protocol.⁽⁵⁾

(4) Secretariat of the Convention on Biological Diversity, "Cartagena Protocol on Biosafety: Frequently Asked Questions."

(5) *Ibid.*

D. Documentation

The Protocol sets out different requirements for shipping documentation for different types of LMOs. Documentation accompanying shipments of LMOs meant for intentional release into the environment, such as seeds for planting, must specify the identity and relevant traits of the LMO, handling requirements, and contact information for the exporter and importer. Documentation must clearly identify LMOs as such.

Bulk shipments of LMO-FFP commodities such as corn or soybeans are to be accompanied by documentation stating that such shipments “may contain” living modified organisms and that they are not intended for intentional introduction into the environment. The Protocol has established a negotiation process for considering more detailed documentation requirements for LMO-FFP, which are to be completed no later than two years after the Protocol has taken effect.

E. The Precautionary Principle

For the first time in an environmental agreement, the Protocol includes the precautionary principle in the operational sections of the text (as opposed to in the preamble, for instance). Articles 10.6 (governing the import of LMOs) and 11.8 (governing the import of LMOs-FFP) of the text read:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism..., in order to avoid or minimize such potential adverse effects.

While Article 15 of the Protocol states that decisions must be based on recognized scientific risk assessment, the introduction of the power to use the precautionary principle (“as appropriate”) was a significant event for global environmental governance.⁽⁶⁾ It has also sparked concern that it could be used as an inappropriate mechanism to block trade. This is of particular concern given the explicit absence of the precautionary principle in the World Trade

(6) A. Gupta, “Governing Trade in Genetically Modified Organisms,” *Environment*, Vol. 42, May 2000, pp. 23-33.

Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

F. Relationship With the World Trade Organization Agreement (Savings Clause)

The SPS Agreement under the WTO states, in Article 2, that:

Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

Paragraph 7 of Article 5 gives WTO members some leeway to introduce measures when scientific information is insufficient. The powers given to Parties to the Biosafety Protocol by its precautionary principle, however, are potentially broader than those that would be allowed under the SPS Agreement, creating the possibility of conflict between the two. In recognition of this possibility, the Biosafety Protocol includes a "savings clause" in the preamble that:

- recognizes that trade and environment agreements should be mutually supportive with a view to achieving sustainable development;
- emphasizes that the Protocol does not change rights and obligations under existing international agreements; and
- understands that the Protocol is not subordinate to other international agreements.

The savings clause basically states that neither agreement will be subordinate to the other. Clarification of the operation of the two agreements will likely occur only after the Protocol has been implemented. Some commentators have said that the potential for conflict between the SPS Agreement and the Protocol has been exaggerated.⁽⁷⁾

(7) Safrin (2002).

CANADA AND THE CARTAGENA PROTOCOL

Canada signed the Protocol on 19 April 2001 but has yet to ratify it. The Canadian government is currently undertaking analysis and consultation regarding the regulatory and administrative changes that would be required in order to implement the Protocol. Draft regulations required for the potential implementation of the Protocol under the *Canadian Environmental Protection Act, 1999* were placed in the *Canada Gazette*, Part I, for comment in July 2002. The Canadian Food Inspection Agency (CFIA) has also published (not as yet in the Gazette) draft regulations mainly governing the documentation aspects of the Protocol, which would enable exporters to deal with the more familiar CFIA, rather than Environment Canada.

Currently, Canadian exports of biotechnology products are worth over CAN\$2 billion per year. The biotechnology sector employs thousands of Canadians and is projected to continue growing at a rate of 10% per year.⁽⁸⁾ The Protocol provisions are not the only ones that would have to be met by Canadian exporters. The new European Union labelling requirements, should they come into force, would require tracing food products to their origin, regardless of whether the final product contained modified material such as protein or DNA (deoxyribonucleic acid).

CONCLUSION AND COMMENTARY

With the Protocol coming into force in September 2003, Canada must decide whether or not to ratify it. One possible deadline for the decision could be set by the first Meeting of the Parties, scheduled for 23 February 2004 (MOP 1). Should Canada want to be fully involved in determining how the Protocol will operate (particularly, for instance, in discussions around liability, redress and compliance, which were left to the MOPs), it may want to participate in this meeting as a Party, meaning that ratification would have to take place at least 90 days before. Should Canada remain outside the Protocol, it would still have to abide by it when exporting to a Party to the Protocol, with disputes likely being settled at the WTO. In such cases, the ability of the WTO SPS Agreement to resolve Protocol issues will be a significant factor in determining how the Protocol will operate.

(8) Environment Canada, News Release, "Canada Signs the Cartagena Protocol to the United Nations Convention on Biological Diversity," 19 April 2001, http://www.ec.gc.ca/press/2001/010419_n_e.htm.