
□ THE CARTAGENA PROTOCOL ON BIOSAFETY

U.S. Department of State, July 2003

More than 130 countries adopted the Biosafety Protocol on January 29, 2000, in Montreal, Canada. It is called the Cartagena Protocol on Biosafety to honor Cartagena, Colombia, which hosted the extraordinary Conference of the Parties to the Convention on Biological Diversity (CBD) in 1999. The objective of this first Protocol to the CBD is to contribute to the safe transfer, handling and use of living modified organisms (LMOs) — such as genetically engineered plants, animals and microbes — that cross international borders. The Biosafety Protocol is also intended to avoid adverse effects on the conservation and sustainable use of biodiversity without unnecessarily disrupting world food trade.

The Protocol will enter into force on September 11, 2003. Although the United States is not a Party to the CBD and therefore cannot become a Party to the Biosafety Protocol, the U.S. participated in the negotiation of the text and the subsequent preparations for entry into force under the Intergovernmental Committee on the Cartagena Protocol. We will participate as an observer at the first Meeting of the Parties (MOP1), scheduled for February 2004 in Kuala Lumpur, Malaysia.

The Protocol provides countries the opportunity to obtain information before new biotech organisms are imported. It acknowledges each country's right to regulate bio-engineered organisms, subject to existing international obligations. It also creates a framework to help improve the capacity of developing countries to protect biodiversity.

WHAT IT DOES

The Protocol establishes an Internet-based "Biosafety Clearing-House" to help countries exchange scientific, technical, environmental and legal information about living modified organisms (LMOs).

It creates an advance informed agreement (AIA) procedure that in effect requires exporters to seek consent from an importing country before the first shipment of an LMO meant to be introduced into the environment, such as seeds for planting, fish for release or microorganisms for bioremediation.

It requires shipments of LMO commodities, such as maize or soybeans that are intended for direct use as food, feed or for processing, to be accompanied by documentation stating that such shipments "may contain" living modified organisms and are "not intended for intentional introduction into the environment." The Protocol establishes a process for considering more detailed identification and documentation of LMO commodities in international trade.

It also sets out information to be included on documentation accompanying LMOs destined for contained use, including any handling requirements and contact points for further information and for the consignee.

The Protocol includes a "savings clause," which states that the agreement shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement, including, for example, World Trade Organization (WTO) agreements.

The Protocol calls on Parties to cooperate with developing countries in building their capacity for managing modern biotechnology.

WHAT IT DOES NOT DO

The Protocol does not address food safety issues. Experts in other international fora, such as Codex Alimentarius, address food safety.

It does not pertain to non-living products derived from genetically engineered plants or animals, such as milled maize or other processed food products.

It does not require segregation of commodities that may contain living modified organisms.

It does not subject commodities to the Protocol's AIA procedure, which would significantly disrupt trade and jeopardize food access, without commensurate benefit to the environment.

The Protocol does not require consumer product labeling. The mandate of the Protocol is to address risks to

biodiversity that may be presented by living modified organisms. Issues related to consumer preference were not part of the negotiation. The Protocol's requirement for documentation identifying commodity shipments as "may contain living modified organisms" and "not intended for intentional introduction into the environment" can be accomplished through shipping documentation.

KEY PROVISIONS OF THE BIOSAFETY PROTOCOL

ADVANCE INFORMED AGREEMENT (AIA) PROCEDURE

The Protocol's AIA procedure, in effect, requires an exporter to seek consent from an importing country prior to the first shipment of a living modified organism (LMO) intended for introduction into the environment, e.g., seeds for planting, fish for release and microorganisms for bioremediation.

The AIA procedure does not apply to LMO commodities intended for food, feed or processing, e.g., maize, soy or cottonseed, to LMOs in transit, or to LMOs destined for contained use, e.g., organisms intended only for scientific research within a laboratory.

Importers are to make decisions on the import of LMOs intended for introduction into the environment based on a scientific risk assessment and within 270 days of notification of an intent to export.

COMMODITY REQUIREMENTS/ BIOSAFETY CLEARING-HOUSE

The agreement requires governments to provide the Biosafety Clearing-House with information concerning any final decisions on the domestic use of an LMO commodity within 15 days of making a decision.

DOCUMENTATION

The agreement sets forth different shipping documentation requirements for different types of LMOs. These requirements will be in effect after the Protocol comes into force.

Documentation accompanying shipments of LMOs intended for introduction into the environment, e.g., seeds for planting, must identify the shipment as

containing LMOs along with the identity and relevant traits and/or characteristics of the LMO, any requirements for safe handling, storage, transport and use, the contact point for further information, a declaration that the movement is in conformity with the Protocol and, as appropriate, the name and address of the importer and exporter.

Documentation accompanying shipments of LMO commodities intended for direct use as food or feed, or for processing, must indicate that the shipment "may contain" LMOs, that the shipment is not intended for intentional introduction into the environment, and specify a contact point for further information. The Protocol provides for a decision by the Parties on the need for detailed requirements for this purpose, including specification of the identity and any unique identification of the LMOs, no later than two years after the entry into force of the Protocol.

Documentation accompanying LMOs destined for contained use, e.g., for scientific or commercial research within contained facilities, must identify the shipment as containing LMOs and must specify any requirements for safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned.

EXISTING RIGHTS AND OBLIGATIONS UNAFFECTED

As evidenced by both the substantive content of the Protocol and its preambular "savings clause," Parties must implement rights and obligations under the Protocol consistent with their existing international rights and obligations, including with respect to non-Parties to the Protocol.

PRECAUTION

Precaution is reflected in the Protocol's preamble objective, with a reference to Principle 15 of the Rio Declaration on Environment and Development, and provisions on an importing Party's decision-making process regarding the import of an LMO:

“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 that living modified organism in order to avoid or minimize such potential adverse effects.”

Both the substantive content of the Protocol’s precaution provisions and the preambular “savings clause” make clear that a Party’s use of precaution in decision-making must be consistent with the Party’s trade and other international obligations.

TRADE WITH NON-PARTIES

The Protocol states that the “transboundary movement of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol.” Therefore, although the Protocol only requires trade between Parties and non-Parties in LMOs to be consistent with the “objective” of the Protocol, we anticipate that, as a practical matter, firms in non-Party countries wishing to export to Parties will need to abide by domestic regulations put in place in the importing Parties for compliance with the Protocol. □