The need for biosafety

While advances in biotechnology have great potential for improving human well-being, it is widely recognized that LMOs must be subject to adequate safety measures. Such measures, known collectively as biosafety, seek to ensure the safe transfer, handling, use and disposal of LMOs.

With the biotech industry growing by leaps and bounds, the international community agreed on the need to develop a legally binding biosafety protocol under the 1992 Convention on Biological Diversity. Governments recognized that, while many countries with biotechnology industries already had national biosafety legislation in place, there was no binding international agreement addressing the movement of LMOs across national borders.

In 1995, the Convention's member governments – who together constitute the Conference of the Parties (COP) – set up an open-ended ad hoc Working Group on Biosafety to draft a protocol. After several years of talks, the COP adopted the Cartagena Protocol on Biosafety in Montreal on 29 January 2000. The Protocol is named to honour the city of Cartagena, Colombia, which had hosted the COP's first extraordinary meeting on biosafety in 1999.

The Convention on Biological Diversity

The world's biological diversity is a vast and undervalued resource. Biodiversity encompasses every form of life, from the smallest microbe to the largest animal, plus the ecosystems that they form. It provides humanity with an abundance of goods and services, from food, energy and fibres to the genes that help us to control pests and diseases. It also underpins the natural processes that help control soil erosion, purify water and air and recycle carbon and nutrients.

The threat to biodiversity has never been so great as it is today. It has been understood for decades that human activities can affect the distribution and abundance of species, ecological systems and genetic variability and thus undermine the basis for life everywhere.

The 1970s and 1980s saw a large number of initiatives to stem the loss of species and the destruction of habitats and ecosystems. A consensus gradually emerged, however, that the Earth's priceless reservoir of biological diversity could be saved only through international cooperation and funding, based on the introduction of a suitable international legally binding instrument.

As a result, the Convention on Biological Diversity, negotiated under the auspices of the United Nations Environment Programme (UNEP), was adopted in 1992 and entered into force in 1993. Its aims are the conservation of biological diversity, the sustainable use of biological resources, and the fair and equitable sharing of benefits arising form the use of genetic resources.

For more information:

The Secretariat of the Convention on Biological Diversity also serves as the Secretariat of the Cartagena Protocol on Biosafety. Its mandate is to promote the ratification of the Protocol, make arrangements for meetings of the ICCP, and facilitate assistance to the Parties, particularly developing countries. Please contact us at:

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THE CARTAGENA PROTOCOL ON BIOSAFETY:

Reducing the environmental risks of modern biotechnology



Secretariat of the Convention CBD on Biological Diversity



The biotechnology revolution

For thousands of years, people have used various techniques to modify plants and animals to improve food production. Traditional fermentation techniques, for example, are still used to transform grains into bread and beer, and milk into cheese. Another traditional form of genetic manipulation is selective breeding, which makes it possible to promote preferred traits, such as certain colours in cut flowers or higher yields from milk cows. People even create hybrids of different species, as when crossing a horse and a donkey to create a mule.

Today, these low-tech methods of genetic modification are being supplemented and even replaced by the sophisticated tools of modern biotechnology. Researchers can now take a single gene from a plant or animal cell and insert it into another species to give that species a desired characteristic, such as resistance to a destructive pest or disease. The result is commonly referred to as a genetically modified organism (GMO), or as a living modified organism (LMO), resulting from modern biotechnology.

Proponents of this powerful new science argue that biotechnology has the potential, among others, to boost food security, reduce the need for clearing more land for farms, raise sustainable yields in marginal lands, and reduce the need for irrigation and agrochemicals. Others, however, are concerned over the possible risks that LMOs can pose for biological diversity – the ecosystems, species, and genetic resources whose interactions form the 'web of life' on Earth – and human health.



How the Protocol works

The Biosafety Protocol promises to provide an international regulatory framework for the growing biotechnology industry that will reconcile the interests of international trade and the need for environmental protection. The Protocol will thus promote the environmentally sound application of biotechnology, making it possible to benefit from biotechnology's potential while minimizing the risks to the environment and human health. It will also make it easier for governments, businesses, and civil society to collaborate with one another on strengthening biosafety.

The Protocol offers a number of tools for promoting biosafety:

 Advanced Informed Agreement **procedure (AIA)** – The Protocol sets out an advance informed agreement procedure that must be followed prior to the first shipment of an LMO intended for introduction into the environment (such as seeds or live fish). In these cases, the exporter must provide a detailed, written description of the organism to the importing country in advance of the shipment. The importer is to acknowledge receipt of this information within 90 days and then explicitly authorize the shipment within 270 days or state its reasons for rejecting the LMO. (The absence of a response, however, is not to be interpreted as implying consent.)

The purpose of the AIA procedure is to ensure that recipient countries have both the opportunity and the capacity to assess risks that may be associated with an LMO



before agreeing to its import. It should be stressed that the procedure applies only to the first intentional transboundary movement of an LMO intended for introduction into the environment. It does not apply to LMOs in transit through a country, LMOs destined for contained use (in a scientific laboratory for example), or LMOs to be directly used as food or animal feed or for processing (such as corn or tomatoes).

- Biosafety Clearing-House The Protocol establishes a Biosafety Clearing-House to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms. The Clearing-House will also include information on national laws and regulations applying to LMOs not covered by the AIA procedure – namely, agricultural commodities to be directly used as food, feed, or for processing, and LMOs in transit or contained use. This information will be vital for enabling governments to implement the Protocol.
- Risk assessment and risk management framework – Governments will decide whether or not to authorize the importation of LMOs after assessing the associated risks. These assessments are to be undertaken in a scientific manner based on recognized risk assessment techniques. However, in cases where the relevant scientific understanding is incomplete, a country may decide to apply the precautionary approach and refuse to permit imports.

In addition, the Protocol requires governments to establish and maintain mechanisms, measures and strategies for regulating, managing and controlling risks identified in the risk assessment procedures.

The Protocol also recognizes the right of importing countries, in reaching a decision on import, to take into account socioeconomic considerations such as the value of biological diversity to their indigenous and local communities, provided it is consistent with their international obligations.

- **Capacity building** The Protocol promotes international cooperation to help developing countries and countries with economies in transition build the needed human resources and institutional capacities. It also encourages governments to assist with scientific and technical training and to promote the transfer of technology, know-how, and financial resources. Because the Protocol is part of the Convention on Biological Diversity, biosafety activities will be eligible for support from the Convention's "financial mechanism". Governments are also expected to facilitate private-sector involvement in capacity building.
- Public awareness While the Protocol concentrates on international action, it recognizes that national measures are essential to making its procedures effective. Member governments therefore commit themselves to promoting public awareness, ensuring public access to information, and consulting the public in decisions about biosafety. They must also take national measures to prevent illegal shipments and accidental releases of LMOs, and they must notify affected or potentially affected states in the event that an unintentional transboundary movement occurs.

What happens next?

Only after 50 governments have signed and then ratified the Protocol will the agreement enter into force and become legally binding on its members. When this happens, perhaps as early as 2002, a decision-making body called the Meeting of the Parties to the Protocol (MOP) will manage the Protocol's development and implementation.

Until then, governments will continue to discuss biosafety and the Protocol within an Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP). The ICCP has been mandated by the COP to prepare for the first Meeting of the Parties to the Protocol, at which time the ICCP will cease to exist.

With biotechnology set to become more and more powerful as both a science and an industry, there can be little doubt that the Biosafety Protocol will remain high on the international environmental agenda for many years to come.