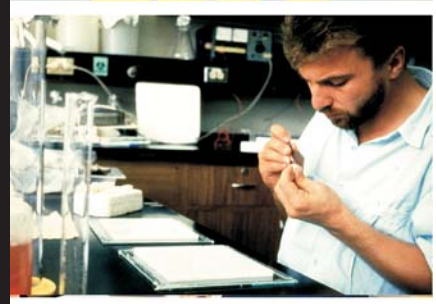
Biosafety

and the environment



An introduction to the Cartagena Protocol on Biosafety

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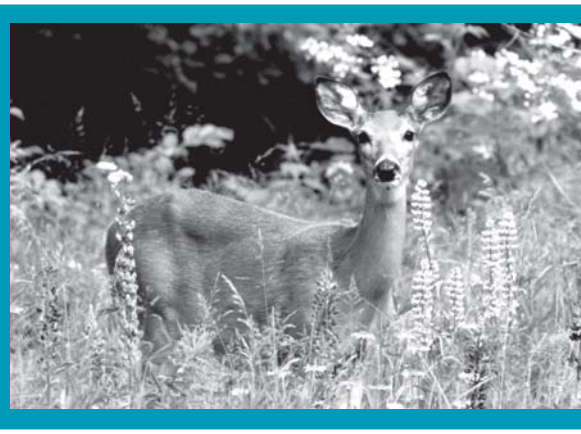

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THE BIOSAFETY PROTOCOL WILL ENABLE PEOPLE EVERYWHERE TO ENJOY THE BENEFITS OF BIOTECHNOLOGY WHILE AVOIDING UNNECESSARY RISKS.

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The Convention on Biological Diversity and its Cartagena Protocol on Biosafety

Governments and civil society are collaborating through the Convention on Biological Diversity to reverse the tide of devastation that humanity has inflicted upon the natural world. The stakes are high: although some 40% of the world economy is derived directly from biological diversity, humanity is pushing ecosystems, species and gene pools to extinction faster than at any time since the dinosaurs died out 65 million years ago.

At present, natural habitats and ecosystems are being destroyed at the rate of over 100 million hectares every year. More than 31,000 plant and animal species are threatened with extinction; according to the Food and Agriculture Organization of the UN, at least one breed of livestock dies out every week. Band-aids are not enough: only a fundamental and far-reaching solution can ensure a biologically rich world for future generations.

Adopted in 1992 under the auspices of the United Nations Environment Programme, the Convention is the first global treaty to provide a comprehensive framework that addresses all aspects of biodiversity – ecosystems, species, and genetic diversity. It also introduces a new strategy for the biodiversity crisis known as the "ecosystem approach", which aims to reconcile the need for environmental conservation with concern for economic development. By promoting "sustainable development", the Convention seeks to ensure that the earth's renewable resources are not consumed so intensively that they cannot replenish themselves.

Now boasting almost 190 member governments (known as "Parties"), the Convention has three goals: the conservation of biodiversity, the sustainable use of the components of biodiversity, and the fair and equitable sharing of the benefits arising from the use of genetic resources.

When crafting the Convention, governments recognized that modern biotechnology has the potential to contribute to achieving these three goals – as long as it is developed and used with adequate safety measures for the environment and human health. These governments put this conviction into action a few years later by establishing the Cartagena Protocol within the framework of the Convention.

1 Introduction: the biotech revolution

Genetic manipulation is not new. For millennia, farmers have relied on selective breeding and cross-fertilization to modify plants and animals and encourage desirable traits that improve food production and satisfy other human needs. Artisans have exploited traditional fermentation techniques to transform grains into bread and beer and milk into cheese. Such intentional modification of the natural world has contributed enormously to human well-being.

Over the past 30 years, however, our ability to alter life-forms has been revolutionized by modern biotechnology. Scientists have learned how to extract and transfer strands of DNA and entire genes – which contain the biochemical instructions governing how an organism will develop – from one species to another. Using sophisticated techniques, they can precisely manipulate the intricate genetic structure of individual living cells. For example, they can insert genes from a coldwater fish into a tomato to create a frost-resistant plant, or use bacterial genes to make herbicide-tolerant corn. The results are known as living modified organisms (LMOs) or, more popularly, genetically modified organisms (GMOs).

Since the first genetically modified tomato became available in shops in the United States in 1994, dozens of food crops and animals have been modified for greater commercial value, higher yield, improved nutrition, or resistance to pests and disease. Proponents argue that biotechnology will boost food security for the world's growing population by raising sustainable food production. It will benefit the environment by reducing the need for more farmland, irrigation and pesticides. It will also provide better medical treatments and vaccines, new industrial products and improved fibres and fuels.

For many people, however, this rapidly advancing science raises a tangle of ethical, environmental, social and health issues. Because modern biotechnology is still so new, they say, much is unknown about how its products may behave and evolve, and how they may interact with other species. Could an ability to tolerate herbicides, for example, transfer from GM crops to related wild species? Might plants that have been genetically modified to repel pests also harm beneficial insects? Could the increased competitiveness of a GMO cause it to damage biologically-rich ecosystems?

While modern biotechnology may have great potential, it must be developed and used with adequate safety measures, particularly for the environment.

Such concerns have kept GMOs in the headlines. One new scientific study concludes that modified organisms pose little risk – and then another raises difficult new questions. Modified soya is found in export shipments that had been declared GMO free, or pollen from modified

corn is detected in a nearby non-modified field. Editors fret about potential trade conflicts, and commentators recite emotional arguments about the pros and cons of modern biotechnology.

Fortunately, this debate has led to a broad consensus that, while modern biotechnology may have great potential, it must be developed and used with adequate safety measures, particularly for the environment. Countries with strong biotechnology industries do have national legislation and risk-assessment systems in place. However, many developing countries interested in modern biotechnology and its products are still in the process of drafting regulations. And because biotechnology is a global industry, and GMOs are traded across borders, international rules are needed as well.

In 1995, the Parties to the Convention on Biological Diversity responded to this challenge by launching negotiations on a legally binding agreement that would address potential risks posed by GMOs. These discussions culminated in January 2000 with the adoption of the Cartagena Protocol on Biosafety. Named after the Colombian city where the final round of talks was launched, the Protocol for the first time sets out a comprehensive regulatory system for ensuring the safe transfer, handling and use of GMOs subject to transboundary movement. In this way, the Protocol seeks to meet the needs of consumers, industry and the environment for many decades to come. This booklet explains how this system works.

USING SOPHISTICATED TECHNIQUES, SCIENTISTS CAN PRECISELY MANIPULATE THE INTRICATE GENETIC STRUCTURE OF INDIVIDUAL LIVING CELLS.

To promote biosafety, the Protocol reflects a fundamental concept known as the precautionary approach.

2 Biosafety and precaution

Before turning to how the Protocol operates in practice, we must first examine two key underlying concepts, namely: biosafety and precaution.

The concept of biosafety encompasses a range of measures, policies and procedures for minimizing potential risks that biotechnology may pose to the environment and human health. Establishing credible and effective safeguards for GMOs is critical for maximizing the benefits of biotechnology while minimizing its risks. Such safeguards must be put in place now, while biotechnology is still relatively young.

Biosafety is currently being promoted in a variety of ways by industry, governments and civil society. The particular contribution of the Cartagena Protocol to global biosafety is helping to ensure:

> *"an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements".*

The Protocol deals primarily with GMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing). It does not cover pharmaceuticals for humans addressed by other international agreements and organizations or products derived from GMOs, such as cooking oil from genetically modified corn or paper from GM trees.

To promote biosafety, the Protocol reflects another fundamental concept known as the precautionary approach. It reaffirms Principle 15 of the 1992 Rio Declaration on Environment and Development, which states that, "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

Other international agreements also apply the precautionary approach to their particular concern. In the case of the Biosafety Protocol, this concept means that a government may decide on the basis of precaution not to permit a particular GMO to be imported across its borders. This is the case even if there is insufficient scientific evidence about the GMO's potential adverse effects.

The Protocol applies precaution not just to biodiversity, but to potential risks to human health as well. It also gives importing countries the right to take into account socio-economic concerns (provided their actions are "consistent with their international obligations"). Such concerns could include the risk that imports of genetically engineered foods may replace traditional crops, undermine local cultures and traditions or reduce the value of biodiversity to indigenous communities.

UNCERTAINTIES ABOUT THE EFFECTS OF GMOS ON WILD SPECIES, INCLUDING POLLINATORS SUCH AS BUTTERFLIES AND HONEYBEES, HAS LED TO INCREASED SUPPORT FOR THE PRECAUTIONARY APPROACH.

The Protocol aims to "contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms … "

3 The Biosafety Protocol in action

The Cartagena Protocol promotes biosafety by establishing practical rules and procedures for the safe transfer, handling and use of GMOs, with a specific focus on regulating movements of these organisms across borders, from one country to another.

This system features two separate sets of procedures, one for GMOs that are to be intentionally introduced into the environment, and one for GMOs that are to be used directly as food or feed or for processing. Both sets of procedures are designed to ensure that recipient countries are provided with the information they need for making informed decisions about whether or not to accept GMO imports. Governments exchange this information through a Biosafety Clearing-House and base their decisions on scientifically sound risk assessments and on the precautionary approach.

When a country decides to allow the import of a GMO, the exporter must ensure that all shipments are accompanied by appropriate documentation. Governments must also adopt measures for managing any risks identified by risk assessments, and they must continue to monitor and control any risks that may emerge in the future. This applies to traded as well as domestically produced GMOs.

To ensure its own long-term effectiveness, the Protocol also contains a number of "enabling" provisions, including capacity-building, public awareness and participation and a financial mechanism.

These various elements all merit a closer look:

An Advance Informed Agreement procedure. The most rigorous procedures are reserved for GMOs that are to be introduced intentionally into the environment. These include seeds, live fish and other organisms that are destined to grow and that have the potential to pass their modified genes on to succeeding generations.

The exporter starts by giving the government of the importing country detailed written information, including a description of the organism, in advance of the shipment. A Competent National Authority in the importing country acknowledges receipt of this information within 90 days and then explicitly authorizes the shipment within 270 days or states its reasons for rejecting it – although the absence of a response is not to be interpreted as implying consent.

In this way, the Advance Informed Agreement procedure ensures that recipient countries have the opportunity to assess any risks that may be associated with a GMO before agreeing to its import.

The AIA procedure applies only to the *first* intentional transboundary movement of any particular GMO intended for introduction into the environment. It does *not* apply to GMOs in transit through a country, GMOs destined for contained use (in a scientific laboratory for example) or GMOs to be directly used as food or animal feed or for processing (such as corn or tomatoes). However, a country may, under its domestic regulatory framework, and consistent with the objective of the Protocol, decide to subject such GMOs

THE MOST RIGOROUS BIOSAFETY RULES AND PROCEDURES ARE RESERVED FOR GMOS THAT ARE TO BE INTRODUCED INTENTIONALLY INTO THE ENVIRONMENT.

to risk assessment and other requirements.

In the future, the Parties to the Protocol may also decide to exempt additional GMOs from the AIA procedure.

A simplified system for agricultural commodities. The largest category of GMOs in international trade is bulk shipments containing genetically modified corn, soybeans and other agricultural commodities intended for direct use as food or feed or for processing and not as seeds for growing new crops.

Instead of requiring the use of the Advance Informed Agreement procedure for such commodities, the Protocol establishes a simpler system. Under this system, governments that approve these commodities for domestic use have to communicate this decision to the world community via the Biosafety Clearing-House. They must also provide detailed information about their decision. In addition, countries may take decisions on whether or not to import these commodities on the basis of their domestic law and must then declare these decisions through the Clearing-House.

In this way, the Protocol seeks to limit the extra costs involved for commodity producers and traders

while ensuring that the international trading system is transparent.

Risk assessments. The Protocol empowers governments to decide whether or not to accept imports of GMOs on the basis of risk assessments. These assessments aim to identify and evaluate the potential adverse effects that a GMO may have on the conservation and sustainable use of biodiversity in the receiving environments. They are to be undertaken in a scientific manner using recognized risk-assessment techniques.

While the country considering permitting the import of a GMO is responsible for ensuring that a risk assessment is carried out, it has the right to require the exporter to do the work or to bear the cost. This is particularly important for many developing countries.

Risk management and emergency procedures. No technology or human activity is completely risk-free. People accept new technologies because they believe the potential benefits outweigh the potential risks. The Protocol requires each country to manage and control any risks that may be identified by a risk assessment. Key elements of effective risk management include monitoring systems, research programmes, technical training and improved domestic coordination amongst government agencies and services.

The Protocol also requires each government to notify and consult other affected or potentially affected governments when it becomes aware that GMOs under its jurisdiction may cross international borders due to illegal trade or release into the environment. This will enable them to pursue emergency measures or other appropriate action. Governments must establish official contact points for emergencies as a way of improving international coordination.

The Biosafety Clearing-House facilitates transparency and the sharing of information, which are vital to a dynamic and effective global biosafety system.

Export documentation. For GMOs intended for direct introduction into the environment, the accompanying documentation must clearly state that the shipment contains GMOs. It must specify the identity and relevant traits and characteristics of the GMO; any requirements for its safe handling, storage, transport and use; a contact point for further information; and the names and addresses of the importer and exporter. The documentation must also declare that the shipment conforms to the Cartagena Protocol.

In cases where a government agrees to import a genetically modified commodity intended for direct use as food or feed or for processing, the shipment must clearly indicate that it "may contain" living modified organisms and that these organisms are not intended for introduction into the environment.

The Biosafety Clearing-House (BCH). The Biosafety Clearing-House is one of the cornerstones of the Protocol's biosafety regime. It facilitates transparency and the sharing of information, which are vital to a dynamic and effective global biosafety system. In addition to enabling governments to inform others about their final decisions regarding the import of GMOs, the Biosafety Clearing-House contains information on

national laws, regulations, and guidelines for implementing the Protocol.

The Biosafety Clearing-House also includes information required under the AIA procedure, summaries of risk assessments and environmental reviews, bilateral and multilateral agreements, reports on efforts to implement the Protocol, plus other scientific, legal, environmental and technical information. Common formats are used to ensure that the information collected from different countries is comparable.

The Biosafety Clearing-House has been developed largely as an Internet-based system and can be found at *http://bch.biodiv.org.*

THE PROTOCOL CALLS FOR THE SAFE TRANSFER, HANDLING AND USE OF GMOS AND SPECIFICALLY HIGHLIGHTS THE NEED FOR PUBLIC AWARENESS AND EDUCATION.

Capacity-building and finance. Countries that trade in GMOs need to have the capacity to implement the Protocol. They need skills, equipment, regulatory frameworks and procedures to enable them to assess the risks, make informed decisions, and manage or avoid any potential adverse effects of GMOs on their natural relatives. Those governments that do not already have a domestic regulatory system for biosafety need to develop one – the sooner the better.

The Protocol therefore actively promotes international cooperation to help developing countries and countries with economies in transition build the human resources and institutions needed for biosafety. It also encourages governments to assist others with scientific and technical training, to promote the transfer of technology and know-how and to provide financial resources to those countries.

Biosafety activities under the Cartagena Protocol are eligible for support from the Global Environment Facility – an international fund that was established to help developing countries protect the global environment. Governments are also expected to promote private-sector involvement in building capacity.

Public awareness and participation. It is clearly important that individual citizens understand and are involved in national decisions on GMOs. The Protocol therefore calls for cooperation on promoting public awareness of the safe transfer, handling and use of GMOs. It specifically highlights the need for education, which will increasingly have to address GMOs as biotechnology becomes more and more a part of our lives.

The Protocol also calls for the public to be actively consulted on GMOs and biosafety. Individuals, communities and non-governmental organizations should remain fully engaged in this complex issue. This will enable people to contribute to the final decisions taken by governments, thus promoting transparency and informed decision-making.

4 The Cartagena Protocol and other international agreements

Although the Cartagena Protocol on Biosafety is the only international instrument that deals exclusively with GMOs, it does not exist in a vacuum. The Convention on Biological Diversity, the "parent" of the Protocol, itself requires governments to take measures to regulate, manage or control the risks associated with the use and release of GMOs. There are also a number of separate international instruments and standard-setting processes that address various aspects of biosafety.

These include:

The International Plant Protection Convention (IPPC), which protects plant health by assessing and managing the risks of plant pests. The IPPC is in the process of setting standards to address the plant pest risks associated with GMOs and invasive species. Any GMO that could be considered a plant pest falls within the scope of this treaty. The IPPC allows governments to take action to prevent the introduction and spread of such pests. It also establishes procedures for analysing pest risks, including impacts on natural vegetation.

The Codex Alimentarius Commission, which addresses food safety and consumer health. The Commission has established an *ad hoc Intergovernmental Task Force on Foods Derived from Biotechnologies* that is responsible for developing standards and guidelines for genetically modified foods. The Commission is also considering the issue of labeling biotech foods to allow the consumer to make an informed choice.

The World Organization for Animal Health (OIE), which develops standards and guidelines designed to prevent the introduction of infectious agents and diseases into the importing country during international trade in animals, animal genetic material and animal products. The OIE Standards Commission published, in 2000, the Manual of Standards for Diagnostic Tests and Vaccines. Some of the tests and vaccines described are genetically engineered. Likewise, the OIE working group on biotechnology has produced several technical publications relating to animal production and risk analysis. However, it has not as yet approved international standards on biotechnology.

Biosafety considerations are also covered in codes of practice on the use of introduced species and GMOs adopted by some Regional Fisheries bodies of the Food and Agricultural Organization of the United Nations.

A number of **World Trade Organization (WTO)** agreements, such as the Agreement on the Application of Sanitary and Phytosanitary Measures and the Technical Barriers to Trade Agreement, contain provisions that are relevant to biosafety.

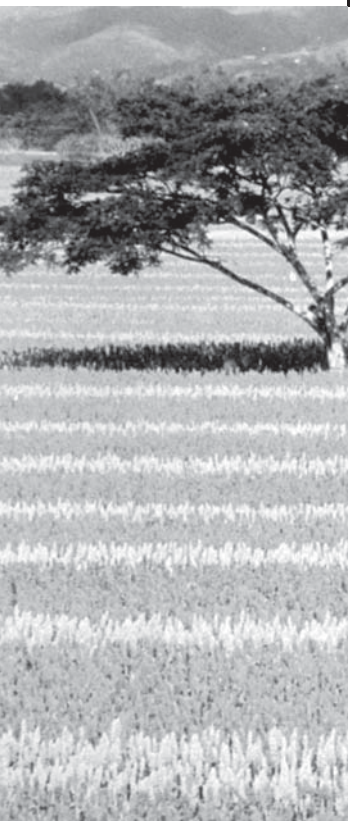
The drafters of the Cartagena Protocol made every effort to ensure that its provisions and the trade agreements are mutually supportive. The Protocol states that its provisions are intended neither to override nor to be subordinate to existing international agreements.

THE CARTAGENA PROTOCOL IS COMPLEMENTED BY SEVERAL OTHER INTERNATIONAL INSTRUMENTS AND STANDARD-SETTING PROCESSES THAT ADDRESS ASPECTS OF BIOSAFETY SUCH AS FOOD SAFETY AND CONSUMER HEALTH.

These various agreements on biosafety, trade, agriculture, and related topics are all intended to function together and to be mutually complementary. However, avoiding potential conflicts often requires good will and careful management. Improving the coordination among the various international regimes can greatly strengthen biosafety while avoiding potential conflicts and reconciling the legitimate interests of trade, biosafety and other sectors.

Improving the coordination among the various international regimes can greatly strengthen biosafety while reconciling the legitimate interests of trade, biosafety and other sectors.

5 Conclusion: a role for everybody



The Cartagena Protocol can only ensure that the global use of biotechnology is safe if each and every country actively promotes biosafety at the national level.

National policymakers and legislators have a vital role to play in establishing and strengthening laws and standards for reducing the potential risks of GMOs. Under the Protocol, it is governments that are ultimately responsible for preventing illegal shipments and accidental releases, managing any risks or emergencies and regulating national biotech industries.

But governments cannot achieve biosafety on their own: they need the active involvement and cooperation of other stakeholders, in particular agricultural and health-care research institutes and the biotechnology industry. Biotech researchers and companies have the expertise, the resources and the incentive for keeping biotechnology and its products safe and beneficial. As for civil society, individual citizens and non-governmental organizations need to understand the issues and make their views clear to both policymakers and industry. The media have a vital watchdog role to play.

Governments cannot achieve biosafety on their own: they need the active involvement and cooperation of the other stakeholders.

Because biotechnology is such a revolutionary science, and has spawned such a powerful industry, it has great potential to reshape the world around us. It is already changing agriculture and what many of us eat. Any major mistakes could lead to tragic and perhaps permanent changes in the natural world. For these reasons, future generations are likely to look back to our time and either thank us or curse us for what we do – or don't do – about GMOs and biosafety.

Doing the right thing is not simple. Our efforts today are complicated by the wide array of stakeholders and countries engaged in the issue. The people involved in biosafety often have widely differing values and expectations. Only a continuing debate that is transparent, respectful and vigorous can ensure that all points of view are reflected in the final outcome.

Given the complexities and the high stakes, it is reassuring that the global community has already agreed on a regulatory safeguard at this early stage in the development of modern biotechnology. Of course, the science continues to advance rapidly. To ensure that the biosafety regime keeps pace, governments will formally review the effectiveness of the Protocol and its procedures every five years – with an eye to revising and improving the agreement if required.

There can be no doubt that biosafety will remain at the top of the international environmental agenda for many years to come.

BIOTECHNOLOGY HAS GREAT POTENTIAL TO RESHAPE THE WORLD AROUND US AND IS ALREADY CHANGING AGRICULTURE AND WHAT MANY OF US EAT.

Biotechnology could contribute significantly to the achievement of the objectives of the Convention on Biological Diversity and the attainment of the Millennium Development Goals. However, it must be developed judiciously, and used with adequate and transparent safety measures.

– United Nations Secretary-General Kofi Annan

Additional publications on the Convention on Biological Diversity and the Cartagena Protocol on Biosafety may be obtained from:

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