Cartagena Protocol on Biosafety

An overview

Phase-II Capacity Building Project on Biosafety

सत्यमेव जयते

UNEP

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Nature Protects if She is Protected

Ministry of Environment, Forest and Climate Change

Government of India

In association with

BCIL

Biotech Consortium India Limited

New Delhi

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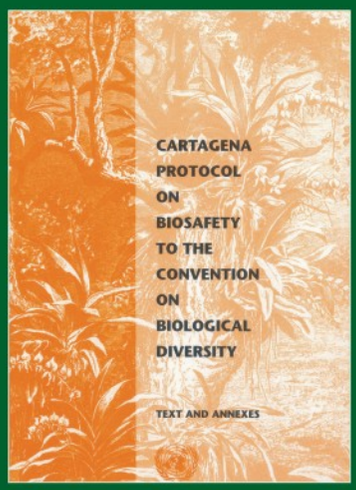
WHAT IS THE CARTAGENA PROTOCOL ON BIOSAFETY ?



The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January, 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September, 2003.

The Protocol has been developed in response to advancements in the area of modern biotechnology and associated concerns that LMOs resulting from modern biotechnology may have negative effects on biodiversity and human health.

The Protocol is called the Cartagena Protocol on Biosafety after the city in Colombia where it was originally scheduled to be concluded and adopted. The final text of the Protocol was agreed upon in January, 2000 in Montreal and it entered into force on 11 September, 2003.

WHAT IS THE PURPOSE OF THE CARTAGENA PROTOCOL ON BIOSAFETY ?

The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) 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 focusing, in particular, on transboundary movements. This objective is to be achieved in accordance with the precautionary approach.

About the Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD) is a multilateral treaty entered into force on **29 December, 1993**. The CBD has much broader aims regarding the conservation and sustainable use of biological diversity and the sharing of benefits arising from the use of genetic resources. The Cartagena Protocol on Biosafety was developed and adopted pursuant to the following articles of CBD:

- Article 8(g): require Parties to establish domestic regulatory and administrative measures
- Article 19(3): requires Parties to regulate, manage or control risks associated with LMOs
- Article 19(4): creates obligation for Parties to the CBD to provide information on any LMO transferred to another Party.

Key terms

- **Living Modified Organisms (LMOs)**: A Living Modified Organism (LMO) has been defined in the Protocol as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
- **Modern Biotechnology:** Modern biotechnology means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. (see Article 3).

SCOPE OF THE PROTOCOL

The protocol applies to transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

CATEGORIES OF LMOs COVERED UNDER THE PROTOCOL

- LMOs for intentional introduction into the environment (e.g. seeds, live fish).
- LMOs intended for direct use as food or feed, or for processing (e.g. agricultural commodities - corn, canola, cotton).
- LMOs for contained use (e.g. bacteria for laboratory scientific experiment).

Exemptions under the Protocol

- LMOs that are pharmaceutical for humans if they are covered by other international agreements or arrangements.
- Products derived from LMOs such as processed food (e.g. soybean oil, corn flour).

PARTIES TO THE PROTOCOL

States and regional economic integration organisations that join the Protocol and agree to be legally bound by its provisions are called "Parties" to the Protocol. Only Parties to the Convention on Biological Diversity can become Parties to the Cartagena Protocol on Biosafety.

As on June 2015, 170 countries have ratified or acceded to the Protocol. The list of Parties can be accessed at https://bch.cbd.int/protocol/parties/.

India is a Party to the Cartagena Protocol on Biosafety having ratified the Protocol on January 23, 2003.

INSTITUTIONAL ARRANGEMENT

Parties to the Protocol are required to designate one National Focal Point for liaisoning with the Protocol Secretariat and one or more Competent National Authority (CNA) to be responsible for performing the administrative functions required by the Protocol on behalf of the Party. More than one CNA can be designated for dealing with different types of LMOs.

Each Party is also required to designate National Focal Point for the Biosafety Clearing House and provide information about its point of contact for receiving notification from other Parties on unintentional transboundary movement of LMOs.

Ministry of Environment, Forest and Climate Change (MoEF & CC) is the Competent National Authority in India.

HOW DOES THE CARTAGENA PROTOCOL ON BIOSAFETY WORK?

The Cartagena Protocol on Biosafety promotes biosafety by establishing practical rules and procedures for the safe transfer, handling and use of LMOs, with specific focus on regulating transboundary movements of LMOs (i.e. movements of LMOs across borders, from one country to another). The Protocol

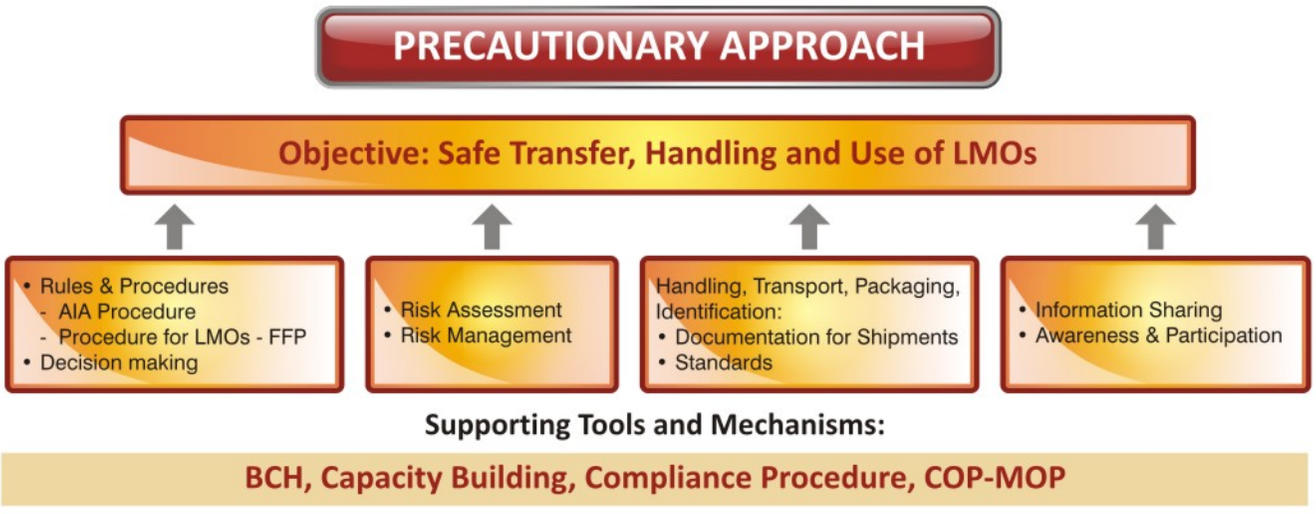
- Sets out general obligations and principles that are applicable to all LMOs
- Establishes specific rules and procedures that are applicable to the transboundary movement of specific categories of LMOs
- Establishes institutional arrangements for the administration, oversight and future evolution of the Protocol
- Makes provision for capacity building and financial resources to assist developing countries and countries with economies in transition to implement the Protocol

Specific procedures have been defined for:

- LMOs for intentional introduction into the environment (e.g. seeds, live fish) are subjected to **Advanced informed Agreement (AIA)** procedures which includes communication and decision making processes between the Parties.
- LMOs for direct use as a food or feed, or for processing (e.g. agricultural commodities such as corn, soybean etc. but are not intended for use as seeds may be subjected to **separate procedure** which includes communicating the decision through the Biosafety Clearing House.

All parties are expected to take decisions in accordance with the provisions and timelines specified in the Protocol.

KEY ELEMENTS OF THE PROTOCOL



ADVANCE INFORMED AGREEMENT FOR LMOs FOR INTENTIONAL RELEASE

The AIA procedure applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. The AIA procedure is designed to ensure that before an LMO is imported into a country for the first time for intentional introduction into the environment, the Party of import is notified about the proposed import, receives full information about the LMO and its intended use and has an opportunity to assess the risks associated with that LMO and to decide whether or not to allow the import.

Specifically, the AIA procedure includes four components:

- Notification by the Party of export or the exporter.
- Acknowledgement of receipt of notification by the Party of import within 90 days.
- Party of import must communicate its decision on whether or not to import the LMO within 270 days of receipt of notification.
- Parties are required to ensure that their decisions are based on a risk assessment of the LMO, which must be carried out in a scientifically sound and transparent manner

The AIA procedure does not apply to:

- **LMOs in transit**
- **LMOs destined for contained use**
- **LMOs for FFP**

PROCEDURES FOR LMOs FOR FOOD, FEED OR PROCESSING (FFP)

LMOs intended for direct use as FFP represent large category of agricultural commodities. A separate procedure has been established by the Protocol for the transboundary movement of LMOs-FFP.

Under this procedure:

- A Party must inform other Parties through the BCH, within 15 days, of its decision regarding domestic use of LMOs that maybe subject to transboundary movement.
- Decisions by an importing country on whether or not to import these LMOs-FFP are taken under its domestic regulatory framework that is consistent with the objective of the Protocol.
- In absence of domestic regulatory framework, importing Country may declare through the BCH that its decisions on the first import of LMOs-FFP will be taken in accordance with risk assessment as set out in the Protocol and timeframe for decision making.

While the AIA procedures is bilateral based on direct communication between Parties, the procedure for LMOs-FFP is essentially a multilateral information exchange mechanism centred on the BCH.

REVIEW OF DECISIONS

The Party of import may at any time, in the light of the new scientific information relevant to the scope of the Protocol, review and change a decision regarding an intentional transboundary movement. The Parties of export can also request for review of decision if there is a change in the circumstances or new information becomes available.

SIMPLIFIED PROCEDURES

There are also provisions to notify simplified procedures for specific LMOs provided that adequate measures are applied to ensure safe intentional transboundary movement of LMOs in accordance with the Protocol's objectives. In all such cases, the Parties are required to specify the same in advance to the BCH.

Parties do have the right to regulate their importation on the basis of domestic legislation.

RISK ASSESSMENT AND RISK MANAGEMENT (RARM)

The Biosafety Protocol requires Parties to make decisions on import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments. These assessments aim at identifying and evaluating the potential adverse effects of LMOs. The Protocol sets out principles and methodologies on how to conduct a risk assessment. The Protocol also requires Parties to adopt measures and strategies for preventing adverse effects and for managing and controlling risks identified by risk assessments. The obligation implies the establishment and implementation of a regulatory system with the capacity to manage and control such risks.

Risk Assessment

Article 15 on Risk Assessment establishes the basic requirements for risk assessment under the Protocol and refers to Annex III for further guidance.

Annex III sets forth the objectives of the risk assessment, what the risk assessment will be used for, general principles that the risk assessment must follow, the methodology of the risk assessment and particular points to consider when assessing the potential risks of LMO.

The general principles include:

- Risk assessment should be carried out in a scientifically sound and transparent manner
- Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk
- Risk associated with LMOs or products thereof, should be considered in the context of risks posed by the non-modified recipient or parental organisms in the likely potential receiving environment.
- Risk assessment should be carried out on a case by case basis

The methodology of the risk assessment follows the conventional risk assessment paradigm, beginning with identification of a potential hazard, such as characteristics of an LMO, which may have an adverse effect on biodiversity. Risks are then characterized based on combined evaluation of the likelihood of adverse effects, and the consequences should those effects be realized.

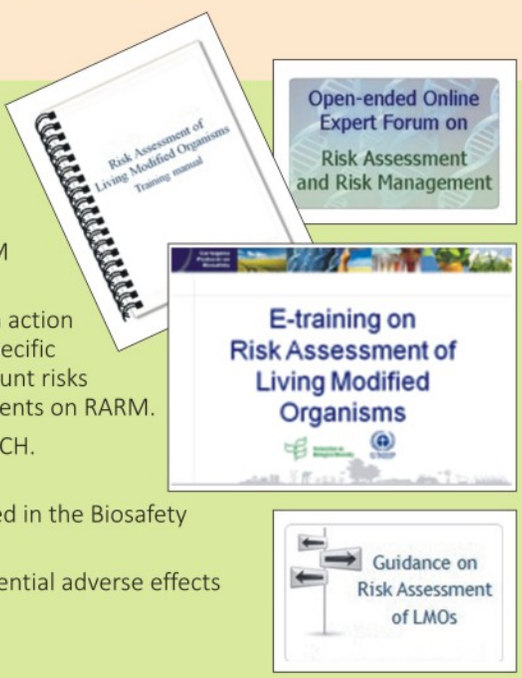
Risk Management

Article 16 on Risk Management deals with the management of risks of those organisms that fall within the scope of the Protocol. The Protocol requires each Party to manage and control any risks that may be identified by a risk assessment. Parties are required to do the following:

- adopt measures and strategies for preventing adverse effects and for managing and controlling the risks identified by risk assessments
- take measures to prevent unintentional transboundary movements
- ensure that LMOs undergo appropriate periods of observation prior to use
- cooperate in identifying LMOs or traits that may pose risks to biodiversity and take appropriate management measures.

Activities on RARM

- A number of measures have been taken to improve the technical and scientific knowledge in the area of RARM.
- Regional workshops on capacity-building and exchange of experiences on RARM of LMOs have been organized by the Secretariat.
- An expert group on RARM has been established to prepare a "roadmap" and an action plan and consider possible modalities for cooperation in identifying LMOs or specific traits that may have adverse effects on biological diversity, taking also into account risks to human health. Discussions are still underway to finalize the guidance documents on RARM.
- Regional Real-time Online Conferences on RARM have been held through the BCH. To date, eight such conferences have been organized.
- The compilation of available guidance documents on RARM have been expanded in the Biosafety Information Resource Centre (BIRC) of the BCH.
- More than 1500 summaries of risk assessments carried out to evaluate the potential adverse effects of LMOs on biodiversity and human health have been posted in the BCH.



Reference to Precautionary Approach in the Cartagena Protocol

Elements of the precautionary approach find reflection in a number of the provisions of the Cartagena Protocol, such as:

- The preamble, reaffirming "the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development";
- Article 1, indicating that the objective of the Protocol is "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development";
- Article 10.6 and 11.8, stating "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on biodiversity, taking into account risks to human health, shall not prevent a Party of import from taking a decision, as appropriate, with regard to the import of the LMO in question, in order to avoid or minimize such potential adverse effects."
- Annex III on risk assessment, stating "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."

Principle 15 of the Rio Declaration on Environment and Development states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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."

Confidential Information

As per Article 21 of the Biosafety Protocol, each Party is required to protect confidential information received under the Protocol. It has to put in place procedures to protect and treat such information received from a Party of export or in connection with domestically produced LMOs.

It has been specified that such information cannot be used for commercial purpose, without the written consent of the notifier (applicant). In case, the notification is withdrawn, the Party is expected to respect the confidentiality of commercial and industrial information, including research and development information.

The Protocol specifies that the following information may never be treated as confidential;

- The name and address of the notifier;
- A general description of the living modified organism or organisms;
- A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
- Any methods and plans for emergency response.

Once information is made available to the BCH in accordance with Article 20 and other provisions of the Protocol, it will not be treated as confidential.

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LMOs

The Protocol requires Parties to take measures to ensure that LMOs being moved from one country to another are safely transported, handled and packaged. Accordingly, the requirements for the handling, transport, packaging & identification of LMOs set out in the Article 18 of the Protocol include:

- Para 1 of Article 18 specifies a general obligation on each Party to the Protocol to take necessary measures for safe handling, transport, packaging & identification of LMOs subjected to intentional transboundary movement.
- Para 2 of Article 18 specifies three different set of requirements for documentation according to the intended use of the LMOs divided into three categories viz. LMOs for FFP, LMOs for intentional release and LMOs for contained use.
- Para 3 of Article 18 provides for possible future development of standards for handling, transport, packaging and identification of LMOs by the meetings of the Parties to this Protocol.
- The documentation requirements for LMOs for FFP has been extremely controversial as countries had different views regarding specific identification requirements to be included in the documentation. It was agreed that documentation can mention "may contain" LMOs where identity of LMOs is not known. Further details have been elaborated in "Curitiba Rules" agreed in COP-MOP 3 after intense negotiations in Curitiba, Brazil in 2006.
- Shipments of LMOs must be accompanied by documents that clearly identify these organisms. The identification information may be incorporated into a commercial invoice or other documents used by existing systems or required by domestic law.

Documentation Requirement for Transboundary Movement of LMOs

LMOs-FFP Article 18 (2a)	LMOs for contained use Article 18 (2b)	LMOs for intentional introduction into environment Article 18 (2c)
• Where identity of the LMOs is known, that the shipment contains LMOs-FFP. • Where identity of the LMOs is not known, that the shipment "may contain" one or more LMOs-FFP. • That the LMOs are not intended for intentional introduction into the environment. • Common, scientific &, where available, commercial names of the LMOs. • Transformation event code or, where available, the LMOs' unique identifier. • The website of the Biosafety Clearing-House (BCH) for further information.	• Clearly identifies content as LMOs including common & scientific names of organisms and as "destined for contained use". • Provides the name & address of the consignee, and exporter or importer, including contact details necessary to reach them as fast as possible in case of emergency. • Specifies any requirements for the safe handling, storage, transport and use of the LMOs. In the event that there is no requirement, indicate that there is no specific requirement. • Provides further information, where appropriate, such as the commercial name of the LMOs, new or modified traits, transformation events, risk class, specification of use, and any unique identification as a key to accessing information in the BCH.	• Clearly identifies content as LMOs and briefly describes the organisms, including: ❖ Common & scientific names ❖ Relevant traits and genetic modification, including transgenic traits and characteristics such as transformation event(s) or reference to a system of unique identification • Gives any requirements for safe handling, storage, transport and use. In the event that there is no requirement, indicates that there is no specific requirement. • Contains the name & address of exporter & importer. • Provides a contact point for further information, including an individual or organization in possession of relevant information in case of emergency. • Includes a declaration that movement of the LMOs is in conformity with the Protocol's requirements. • Provides further information, where appropriate, e.g. commercial name, risk class & import approval for first transboundary movement of the LMO.

Unique Identifiers

- Documentation requirements for all categories of LMOs require reference to a unique identifier code.
- To date, only one unique identification system exists: OECD Unique Identifiers for Transgenic Plants.
- OECD Unique Identifier is a simple alphanumeric code that is given to each living modified plant that is approved for commercial use.
- Developers of transgenic plants are the ones to assign the unique identifier.
- 9-digit code composed of 3 elements separated by dashes
  - ❖ 2 or 3 alphanumeric digits to designate the applicant;
  - ❖ 5 or 6 alphanumeric digits to designate the transformation event; and
  - ❖ 1 numerical digit for verification Example: MON-00810-6 Monsanto's YieldGard Maize
- Unique identifier codes can be used to search BCH for information about specific LMOs.

In addition to intentional transboundary movement of LMOs, the Cartagena Protocol on Biosafety also contains provisions on Unintentional Transboundary Movements (Article 17), Transboundary Movement with Non-Parties (Article 24) and Illegal Transboundary Movements (Article 25).

UNINTENTIONAL TRANSBOUNDARY MOVEMENT

- In the event of a release which leads to, or may lead to, an unintentional transboundary movement of an LMO that is likely to have adverse effects on biodiversity, Parties are required to notify the BCH, and potentially affected States.
- Each Party is required to specify a contact point for the purpose of receiving such notifications.
- Parties under whose jurisdiction such releases occur are also required to consult potentially affected States to determine appropriate responses, including emergency measures.

ILLEGAL TRANSBOUNDARY MOVEMENT

- Parties are required to adopt domestic measures to prevent and if appropriate, penalize transboundary movement of LMOs that occur in contravention of its domestic measures to implement the Protocol. Such movements are deemed as illegal transboundary movements.
- In the case of such illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the LMO in question by repatriation or destruction, as appropriate.
- Each Party is required to make available information concerning cases of illegal transboundary movement to BCH.

TRANSBOUNDARY MOVEMENT WITH NON-PARTIES

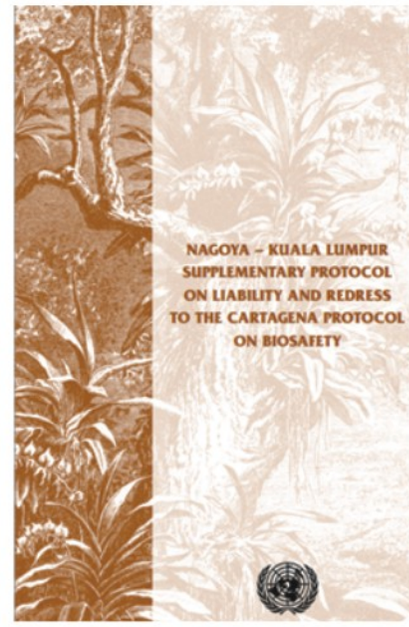
- The transboundary movements between Parties and non-Parties must be carried out in a manner i.e. consistent with the objective of the Protocol.
- The Parties can enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding transboundary movements of LMOs.
- Parties are required to encourage non-Parties to adhere to the Protocol and to contribute information to the BCH.

DETECTION AND IDENTIFICATION OF LMOS

- In the context of Article 17, 18 and 25, the detection and identification of LMOs is important for national authorities to distinguish whether or not there are LMOs in a shipment.
- This is accomplished both through proper packaging and labeling of shipments and through the analytical, laboratory based analysis of the contents of a shipment to detect unauthorized and unintended LMOs.
- To facilitate the above, a "Portal on detection and identification of LMOs" has been established on the BCH.
- This Portal is home to ongoing discussions and work on the HTPI of LMOs and includes links to activities such as
  - Network of Laboratories for the Detection and Identification of LMOs;
  - Training of Trainers' Workshops for customs officials on the identification and documentation of LMOs
  - Online Forum on Standards for LMO Shipments

- The network of laboratories also provides compilation of methods for the detection of LMOs, in particular those unauthorized or unintentionally released into the environment
- Capacity building in this area is an ongoing activity at both national and international level

THE NAGOYA-KUALA LUMPUR SUPPLEMENTARY PROTOCOL ON LIABILITY AND REDRESS



- Article 27 on Liability and Redress of the Cartagena Protocol on Biosafety contained an enabling provision by which a process was to be adopted with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movement of LMOs within a period of four years, as consensus could not be reached during the negotiation process.
- In fulfillment to Article 27, a Working Group comprising of legal and technical experts was established to work on issues related to liability and redress in 2004 at Kuala Lumpur, Malaysia.
- Parties finalized the negotiation of a new treaty known as the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress after six years of hectic negotiations. It was adopted on 15 October 2010 at Nagoya, Japan.
- The Supplementary Protocol takes its name from the city of Nagoya, where negotiations were concluded and from the city of Kuala Lumpur, in recognition of the contribution made by Malaysia in hosting several meetings pertaining to the negotiations on liability and redress.
- The Supplementary Protocol is intended to supplement the Cartagena Protocol on Biosafety by providing international rules and procedures on liability and redress for damage to biodiversity resulting from LMOs. It provides for administrative procedures and requirements regarding response measures that need to be taken in the event of damage by LMOs that adversely affect the conservation and sustainable use of biodiversity, taking into account risks to human health.
- It also provides flexibility in regulatory approaches by allowing Parties to apply existing or new domestic laws that may be general or specific as regards to response measures to damage.
- The Supplementary Protocol defines "damage" as an adverse effect on the conservation and sustainable use of biological diversity that is measurable and significant. It also provides for an indicative list of factors that should be used to determine the significance of an adverse effect. Once the threshold of significant damage has been met, the need for response measures arises.
- It also defines "response measures" as reasonable actions to (i) prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate; and (ii) restore biological diversity.

Obligations of a Party to the Supplementary Protocol

The core obligations that a Party to the Supplementary Protocol must fulfil are twofold. Parties must provide some essential elements (damage, response measures and definition of operator) in the rules and procedures on liability and redress in its existing domestic law or enact a new law that address damage arising from LMOs. In that regard, response measures in the event of a damage from LMOs must include the following:

a. Require the appropriate operator, in the event of damage, to (i) immediately inform the competent authority; (ii) evaluate the damage; and (iii) take appropriate response measures.
b. Make sure that the competent authority (i) identifies the operator which has caused the damage; (ii) evaluates the damage; and (iii) determines which response measures should be taken by the operator and provides reasons for such determination.
c. Require the operator to take appropriate response measures where there is sufficient likelihood that damage will result if timely response measures are not taken.
d. Put in place a requirement whereby the competent authority itself may implement appropriate response measures, in particular situations where the operator has failed to do so, subject to a right of recourse by the competent authority to recover, from the operator, costs and expenses incurred in relation to the implementation of the response measures.

As on June, 2015, 41 Countries have ratified the Supplementary Protocol. Nine more ratifications are required for the Supplementary Protocol to come into force. India has ratified the Supplementary Protocol in December, 2014.

OTHER KEY PROVISIONS

Socio Economic Considerations

- In Article 26, the Protocol has provided that Parties may take socio-economic considerations into account in making decisions on imports of LMOs, or under its domestic measures implementing the Protocol.
- Any decision on the inclusion of socio-economic considerations, however, must be consistent with that country's other international obligations.
- The Protocol encourages Parties to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially on indigenous and local communities.
- An Ad Hoc Technical Expert Group on Socio-economic Considerations (AHTEG) is working to develop conceptual clarity on socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity and developing an outline for the guidance. An online portal on socio-economic considerations has been set up in addition to online regional conferences and discussions.

Public Awareness and Participation

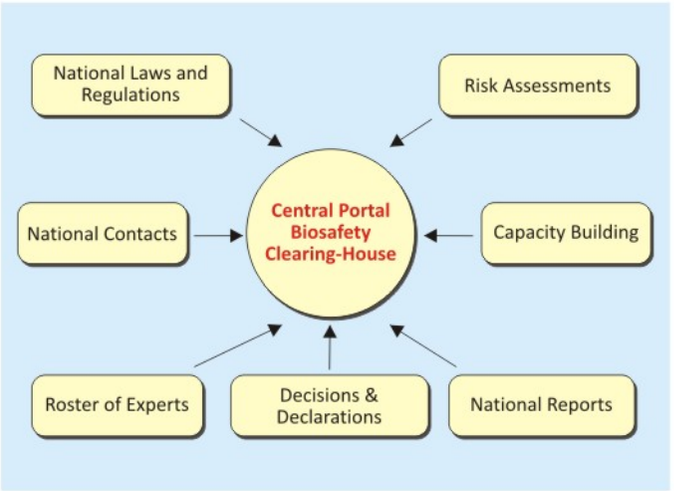
- Parties are required to cooperate with other States and international bodies to promote and facilitate public awareness and education including access to information regarding the safe transfer, handling and use of LMOs.
- Parties are also required to consult and inform the public in the decision making process.
- A programme of work on public awareness, education and participation has been formulated and is under implementation by Parties. The programme has four elements viz. capacity building, public awareness and education, public access to information and public participation.

Capacity Building

- Recognizing the need for capacity building for effective implementation of the Cartagena Protocol on Biosafety, there is a provision for Parties to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety.
- A number of decisions and initiatives have been taken to facilitate the strengthening of the capacities of Parties to implement the Protocol. This includes establishing a coordination mechanism, a roster of experts and regional capacity building workshops.
- An action plan has been adopted to guide the capacity building efforts by identifying priority areas requiring urgent action and outlining a series of strategies/activities to be undertaken.
- Extensive international financial assistance has been provided for biosafety capacity development in developing countries, the large proportion coming through the Global Environment Facility (GEF). Several capacity-building projects have been completed/are underway in different countries/regions. India is also implementing Phase II Capacity Building Project on Biosafety supported by GEF and UNEP.

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE (BCH)

- The Biosafety Clearing-House (BCH) is a mechanism established under the Protocol to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs and assist the Parties to better comply with their obligations under the Protocol.
- It has been developed as an Internet-based system and is accessible at: http://bch.cbd.int/.
- Each Party is required to designate one National Focal Point for BCH, who is responsible for managing national records register in the BCH through the management centre.
- BCH has two categories of records i.e. national records and reference records.
- National records contain information that Parties are required to provide under Article 20. All other category of information in the BCH are characterized as reference records.
- The Central Portal of the BCH is available in all the 6 official languages of the United Nations: Arabic, Chinese, English, French, Russian and Spanish.



NATIONAL REPORTING ON IMPLEMENTATION OF CPB

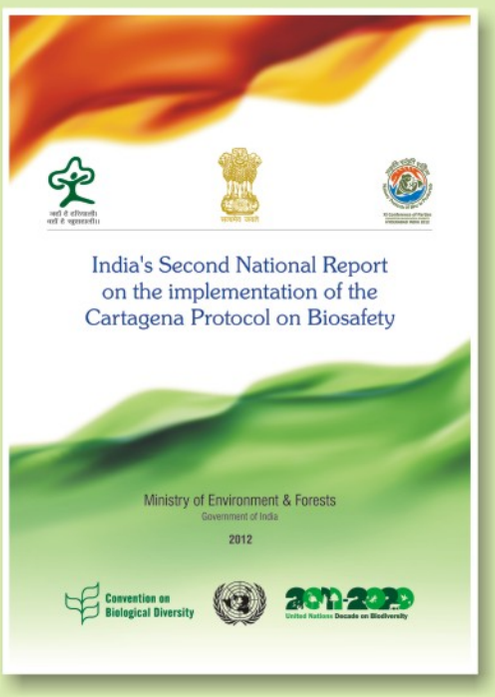
Preparation of national reports is an important obligation of all Parties to the Cartagena Protocol on Biosafety. National reporting is a mandatory requirement under Article 33 of the Protocol and these reports are submitted by Parties on a four yearly basis in accordance with decision taken by COP-MOP 1 in 2004.

These reports help Parties to monitor implementation of their obligations under the Protocol and to report to the COP-MOP on the measures taken to implement the Protocol.

To ensure that information submitted by Parties are comparable, the content and format is decided in meetings of COP-MOP.

So far, three reports have been submitted by Parties i.e. interim report (2005), first national report (2007) and second national report (2011). India has submitted all the three reports. Copies of these reports and their analysis are available on the BCH. The third national report is due for submission in November, 2015. The reports are submitted 12 months prior to the COP-MOP.

These reports also serve as a baseline information to the Assessment and Review process under Article 35 of the CPB.



WHAT IS COP-MOP ?

The Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) is the governing body of the Cartagena Protocol. The main function of this body is to review the implementation of the Protocol and make decisions necessary to promote its effective operation, including the operation of the BCH. These decisions give further guidance to Parties on how they should implement the Protocol.

Meetings of the COP-MOP

- The (COP-MOP) currently meets every two years in conjunction with the regular meetings of the Conference of the Parties (COP) to the Convention on Biological Diversity.
- Till date, the COP-MOP has convened seven meetings as indicated below:

Meeting No.	Date	Venue	Themes
COP-MOP 1	February 23-27, 2004	Kuala Lumpur, Malaysia	Global Biosafety FROM CONCEPTS TO ACTION
COP-MOP 2	May 30 - June 3, 2005	Montreal, Canada	FACING THE BIOSAFETY CHALLENGE Towards Effective Implementation of the Protocol
COP-MOP 3	March 13-17, 2006	Curitiba, Brazil	BIOSAFETY Building Further Consensus for Action
COP-MOP 4	May 12 – 16, 2008	Bonn, Germany	Biosafety TAKING FURTHER STEPS TOWARDS EFFECTIVE IMPLEMENTATION OF THE PROTOCOL
COP-MOP 5	October 11 – 15, 2010	Nagoya, Japan	Biosafety SETTING A NEW AGENDA
COP-MOP 6	October 1-5, 2012	Hyderabad, India	Biosafety TOOLS TO ADVANCE IMPLEMENTATION
COP-MOP 7	September 29 - October 3, 2014	Pyeongchang, Republic of Korea	Biodiversity for Sustainable Development

- Participants representing Parties to the Protocol and other governments, UN agencies, intergovernmental and non-governmental organizations, academia and industry attend the meetings of the COP-MOP.
- Report of each COP-MOP is available at http://bch.cbd.int/protocol/cpb_mopmeetings.shtml.

STRATEGIC PLAN FOR THE CARTAGENA PROTOCOL ON BIOSAFETY 2011–2020

The Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020 was adopted by the Parties to the Protocol in October 2010 in Nagoya, Japan. It comprises a vision, a mission, five strategic objectives and twenty-three operational objectives.

Vision

Making biodiversity adequately protected from any adverse effects of LMOs.

Mission

Strengthen global, regional & national action and capacity in ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity.

Strategic objectives

The focal areas underlying the five strategic objectives are as follows:

1. Facilitating the establishment and further development of systems for the implementation of the Protocol;
2. Capacity-building;
3. Compliance and review;
4. Information sharing; and
5. Outreach and cooperation.

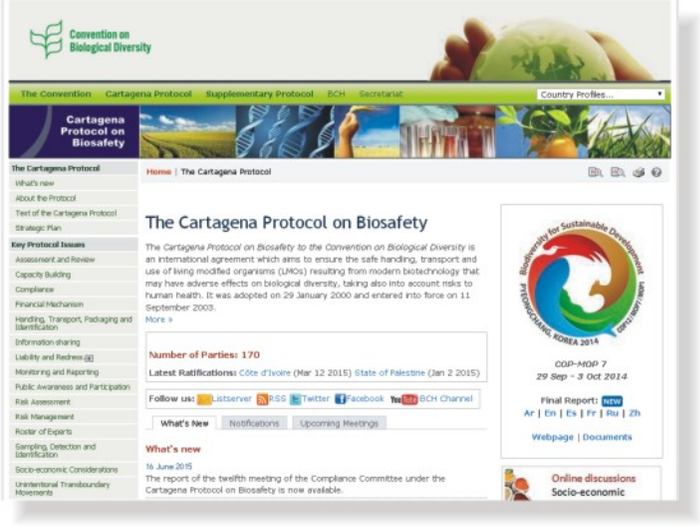
For each strategic objective a number of operational objectives, expected outcomes and indicators are outlined.

- All Parties are required to allocate adequate human and financial resources to expedite the implementation of the Strategic Plan.
- A mid-term evaluation of the Strategic Plan will be carried out in conjunction with the third assessment and review of the effectiveness of the Protocol at the eighth meeting of the Parties to the Protocol in 2016.
- A final evaluation of the Strategic Plan will take place at the tenth meeting of the Parties to the Protocol in 2020.

LEARN MORE

The information about various activities, documents, publications etc. regarding the Cartagena Protocol on Biosafety can be accessed at **http://bch.cbd.int/protocol/**. The Biosafety Clearing House (BCH) can be accessed at **http://bch.cbd.int/**.

This brochure has been compiled using the information available on the above websites and documents published by the Secretariat. Readers are encouraged to visit these websites for more information.



The Cartagena Protocol on Biosafety, a legally binding environmental treaty, to the Convention on Biological Diversity entered into force on 11 September 2003. The Protocol establishes rules and procedures to ensure the safe handling, transfer and use of living modified organisms resulting from modern biotechnology.

Over the years, Parties have taken measures to establish legal, administrative and other biosafety management systems, yet significant challenges still remain in making them fully functional to support effective implementation of the Protocol.

This brochure aims to provide a comprehensive overview of the Protocol to facilitate easier understanding of its key provisions and obligations among biosafety stakeholders.

This brochure is a part of the **Biosafety Resource Kit** prepared under the Phase-II Capacity Building Project on Biosafety being implemented by Ministry of Environment, Forest and Climate Change.

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