Understanding Cartagena Protocol on Biosafety: A Guide

Phase-II Capacity Building Project on Biosafety

Ministry of Environment, Forest and Climate Change
Government of India

In association with

BCIL
Biotech Consortium India Limited
New Delhi

2017

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Prepared by

Ministry of Environment, Forest and Climate Change (MoEF&CC)
andBiotech Consortium India Limited, New Delhi under UNEP/GEF supported Phase II Capacity Building Project on Biosafety

Resource persons:

Dr Amita Prasad
Additional Secretary, MoEF&CC
National Project Director, Phase II Capacity Building Project on Biosafety

Shri Gyanesh Bharti
Joint Secretary, MoEF&CC
National Project Coordinator, Phase II Capacity Building Project on Biosafety

Dr Vibha Ahuja
Chief General Manager
Biotech Consortium India Limited

Assisted by:

Dr Murali Krishna Chimata, Scientist-D, MoEF&CC and Ms Sonia Kaushik, Assistant Manager, Biotech Consortium India Limited, Project Coordination Unit, Phase II Capacity Building Project on Biosafety

Information sources including booklet, factsheet, FAQs etc available at http://bch.cbd.int/protocol/ are thankfully acknowledged

For further information, please contact

Ministry of Environment
Forest and Climate Change
Government of India
Indira Paryavaran Bhawan
Jor Bagh Road, Ali Ganj
New Delhi 110003
Email: biosafety-mef@nic.in

Biotech Consortium India Limited
Anuvrat Bhawan, 5th Floor
210, Deen Dayal Updhaya Marg
New Delhi - 110 002
Email: vibhaahuja.bcil@nic.in

अनिल माधव दवे
Anil Madhav Dave

सत्यमेव जयते

राज्य मंत्री (स्वतंत्र प्रभार)
MINISTER OF STATE (INDEPENDENT CHARGE)
पर्यावरण, वन एवं जलवायु परिवर्तन
ENVIRONMENT, FOREST & CLIMATE CHANGE
भारत सरकार / GOVERNMENT OF INDIA

MESSAGE

India is a signatory to the Cartagena Protocol on Biosafety, an international treaty governing the movement of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. The Ministry of Environment, Forest and Climate Change, being the nodal agency for implementation of the Cartagena Protocol on Biosafety in India, is committed to meet its obligations.

The Cartagena Protocol on Biosafety was signed in 2000 and came into force in 2003. There have been several developments through inter-governmental meetings held on regular basis. Biosafety Clearing House (BCH), is an information sharing mechanism set up under the Biosafety Protocol for sharing of relevant scientific, technical and legal information. BCH is an important repository of up-to-date information about the Protocol.

I am pleased that two booklets have been prepared to inform stakeholders about the salient features of the Cartagena Protocol on Biosafetyand Biosafety Clearing Houseas part of UNEP-GEF supported "Phase II Capacity Building Project on Biosafety", being implemented by MoEFCC.

I hope these booklets will help in enhancing awareness about these extremely important topics. I would like to congratulate all those who were involved in preparing this document and those involved in steering this initiative.

(Anil Madhav Dave)

Paryavaran Bhawan, Jor Bagh Road, New Delhi-110 003
Tel.: 011-24695136, 24695132, Fax : 011-24695329

अजय नारायण झा
AJAY NARAYAN JHA, IAS

सचिव
भारत सरकार
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
Secretary
Government of India
Ministry of Environment, Forest and Climate Change

FOREWORD

Capacity building is of strategic importance for effective implementation of any multilateral environment agreement (MEA) and the same is true for the Cartagena Protocol on Biosafety. Information sharing is one of the key components of capacity building projects and initiatives. The Ministry of Environment, Forest and Climate Change, being the nodal Ministry for implementation of the Cartagena Protocol on Biosafety and biosafety rules and regulations in the country, is committed to information sharing about key issues with the stakeholders.

MoEF & CC has brought out several publications from time to time for creating awareness about the salient features of Cartagena Protocol on Biosafety amongst stakeholders. Some of the publications have also been translated into other languages.

Continuing the practice, two booklets on Cartagena Protocol on Biosafety and Biosafety Clearing House have been prepared. These booklets provide an overview of India's compliance with the Protocol with an objective to serve as knowledge support for various stakeholders.

I hope these booklets will help in further strengthening our efforts for information sharing and creating awareness on this important protocol and biosafety issues.

Date: 10/03/2017
Place:New Delhi

9/3/17

(A. N. Jha)

इंदिरा पर्यावरण भवन, जोर बाग रोड़, नई दिल्ली-110 003 फोन : (011) 24695262, 24695265, फैक्स : (011) 24695270
INDIRA PARYAVARAN BHAWAN, JOR BAGH ROAD, NEW DELHI-110 003 Ph. : (011) 24695262, 2465265, Fax : (011) 24695270
E-mail : secy-moef@nic.in, ajay.jha@nic.in, Website : moef.gov.in

डा. अमिता प्रसाद
अपर सचिव
Dr. AMITA PRASAD, IAS
Additional Secretary

सत्यमेव जयते

भारत सरकार
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
नई दिल्ली - 110003
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST &
CLIMATE CHANGE
NEW DELHI-110003

PREFACE

Awareness about the procedures towards the regulation of transboundary movement of living modified organisms (LMOs)is important, particularly in view of the global increase in trade and commercialization of LMOs. As a Party to the Cartagena Protocol on Biosafety, India has been actively engaged in implementation of its obligations in the country. India has also actively participated in the meetings of the governing body viz., Conference of Parties serving as the Meetings of Parties to the Cartagena Protocol on Biosafety held every two years and followed various decisions taken during these meetings.

Enhancing public awareness is one of the key objectives of the Strategic Plan on CPB (2011-2020) and accordingly, it is one of the key components of the ongoing UNEP/GEF supported Phase II Capacity Building Project on Biosafety, being implemented by the Ministry of Environment, Forest and Climate Change. As part of the project, two booklets namely “Understanding Cartagena Protocol on Biosafety: A Guide” and “Handbook on Biosafety Clearing House” have been prepared to inform the stakeholders about these important topics. The booklets have been prepared in a simplified and easy to understand language for sensitizing range of stakeholders including regulators, scientists, researchers, enforcement officials (customs and plant quarantine) and general public.

I appreciate the efforts of officers of Biosafety Division in MoEFCC and Biotech Consortium India Limited (BCIL) for putting together these booklets.

Dr Amita Prasad
(Additional Secretary, MoEF&CC)

इंदिरा पर्यावरण भवन, जोर बाग रोड़, नई दिल्ली-110 003 फोन : 011-24695242, फैक्स : 011-24695260
INDIRA PARYAVARAN BHAWAN, JOR BAGH ROAD, NEW DELHI-110 003 Ph. : 011-24695242, Fax : 011-24695260
E-mail : asap.moefcc@gov.in

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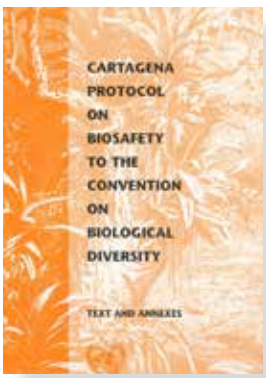
1. INTRODUCTION



The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) is an international treaty governing the movements of living modified organisms (LMOs)[1] resulting from modern biotechnology from one country to another. 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. It is an attempt to produce globally harmonized regime for biosafety to ensure the safe use of modern biotechnology. It was adopted on 29 January 2000 as a protocol[2] to the CBD and entered into force on 11 September 2003.

The Protocol is called the Cartagena Protocol on Biosafety after the city in Colombia where it was originally scheduled to be concluded and adopted. However, due to a number of outstanding issues, the final text of the Protocol was agreed upon in January 2000 in Montreal. It entered into force on 11 September 2003 after it was ratified by 50 parties.

2. ORIGIN

The Convention on Biological Diversity is a multilateral treaty that 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. When developing the Convention, the negotiators recognized that biotechnology can make a contribution towards achieving the objectives of the Convention, if developed and used with adequate safety measures for the environment and human health. The Contracting Parties agreed to consider the need to develop appropriate procedures to address the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. Accordingly, the Cartagena Protocol on Biosafety was developed and adopted pursuant to the following articles of CBD:

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[1]A Living Modified Organism (LMO) is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. In everyday usage LMOs are usually considered to be the same as GMOs (Genetically Modified Organisms), but definitions and interpretations of the term GMO vary widely. Common LMOs include agricultural crops that have been genetically modified for greater productivity or for resistance to pests or diseases. Examples of modified crops include tomatoes, cassava, corn, cotton and soybeans

[2]A "Protocol" is an agreement adopted within the framework of another international agreement.

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

The CPB is the result of above process. The text of the CPB is placed at Annexure.

3. STATUS

The Cartagena Protocol on Biosafety entered into force from September 11, 2003. States and regional economic integration organizations that joined the Protocol and agree to be legally bound by its provisions are called "Parties" to the Protocol. Only Parties to the Convention to the Biological Diversity can become Parties to the Cartagena Protocol on Biosafety. As of February 2017, 170 countries have ratified this Protocol. The list of Parties can be accessed at http:/bch.cbd.int/protocol/parties/.

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

4. OBJECTIVE

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 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. As stated in the Article 1, the objective of the Protocol is in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development[3].

5. SCOPE

The Cartagena Protocol on Biosafety applies to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of

[3]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."

biological diversity, taking also into account risks to human health.

The Protocol deals primarily with LMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified (GM) 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 LMOs[4], such as cooking oil from GM corn.

For the purpose of operationalization, LMOs covered under the CPB are categorized as under:

- 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)

6. KEY ELEMENTS

The Cartagena Protocol on Biosafety promotes biosafety by establishing practical rules and procedures for the 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

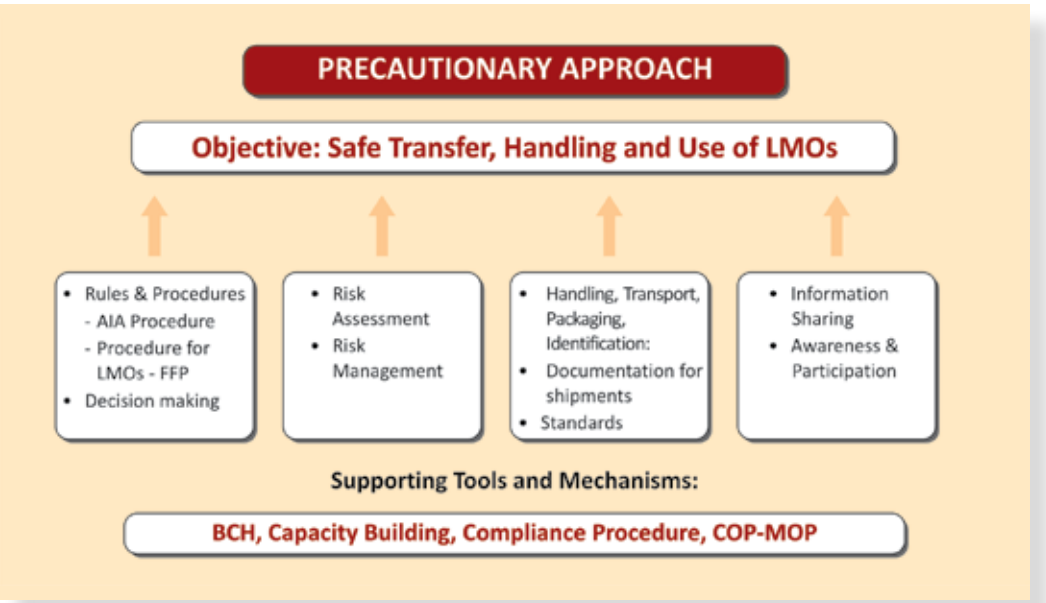
- Sets out general obligations and principles that are applicable to all LMOs
- Establishes specific rules and procedures that are applicable to the transboundary movement of specific categories of LMOs
- Establishes institutional arrangements for the administration, oversight and future evolution of the Protocol
- Sets out principles and methodology on risk assessment and risk management, while taking decisions.
- Provides for appropriate handling, packaging and transport of LMOs under condition of safety and guidance for appropriate documentation.
- Establishes a Biosafety Clearing House (BCH) for exchanging information.

[4]LMOs form the basis of a range of products and agricultural commodities. Processed products containing dead modified organisms or non-living GMO components include certain vaccines; drugs; food additives; and many processed, canned, and preserved foods. They can also include corn and soybean derivatives used in many foods and nonfoods, cornstarch used for cardboard and adhesives, fuel ethanol for gasoline, vitamins, vaccines and pharmaceuticals, and yeast-based foods such as beer and bread.

- Makes provision for capacity building and financial resources to assist developing countries and countries with economies in transition to implement the Protocol

The key elements of the Protocol are given in Figure 1.

Figure 1: Key Elements of the Protocol



7. COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

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 BCH 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), Government of India is the Competent National Authority for dealing with matters related to CPB in India.

8. PROCEDURES FOR TRANSBOUNDARY MOVEMENT OF LMOS

The Protocol feature a set of procedures including one for LMOs that are to be intentionally introduced into the environment (Advance Informed Agreement Procedure) and one for LMOs that are intended to be used directly as food or feed or for processing (LMO-FFP) as indicated in Box 1. There are also provisions for review of decisions, simplified procedures for specific LMOs, unintentional and illegal transboundary movements as explained below.

Box 1: Procedures applicable for three categories of LMOs

1. **LMOs for intentional introduction into the environment** (e.g. seeds, live fish) are subjected to Advanced Informed Agreement procedures which includes communication and decision making processes between the Parties.
2. **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 simplified procedure which includes communicating the decision through the BCH.
3. **LMOs for contained use** (e.g. bacteria for laboratory scientific experiment) and LMOs in transit are exempt from AIA procedures.

8.1 Advanced Informed Agreement

The Advance Informed Agreement (AIA) procedure applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. It includes four components: notification by the Party of export or the exporter, acknowledgment of receipt of notification by the Party of import, decision procedure and review of decisions. 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 Party of export or the exporter must notify the Party of import by providing a detailed, written description of the LMO in advance of the first shipment. The Party of import is to acknowledge receipt of this information within 90 days. Then, within 270 days of the date of receipt of notification, the Party of import must communicate its 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. Except in a case in which consent is unconditional, in other cases the Party of import must indicate the reasons on which its decisions are based as detailed under Article 7, Article 8, Article 9 and Article 10 of the CPB.

A Party of import may, at any time, in light of new scientific information, review and change

a decision. A Party of export or a notifier may also request the Party of import to review its decisions as detailed in Article 12 of the CPB.

However, the Protocol`s AIA procedure does not apply to certain categories of LMOs:

- LMOs in transit (Article 6);
- LMOs destined for contained use (Article 6);
- LMOs intended for direct use as food or feed or for processing (Article 7.3)

It should be noted that, while the Protocol`s AIA procedure does not apply to certain categories of LMOs, Parties have the right to regulate the importation on the basis of domestic legislation.

In addition, the Party of import may also specify in advance to the Biosafety Clearing-House that it will exempt certain imports of LMOs from the AIA procedure (Article 13). Also, the Conference of the Parties serving as the Meeting of the Parties (COP-MOP) to the Protocol may in future decide to exempt additional LMOs from application of the AIA procedure (Article 7.4).

8.2 Procedures for LMO intended as food or feed, or processing (LMOs-FFP)

LMOs intended for direct use as food or feed, or processing (LMOs-FFP) and not as seeds for growing new crops represent a large category of agricultural commodities. Instead of requiring the use of the AIA procedure, the Protocol establishes a simpler system for the transboundary movement of LMOs–FFP. Under this procedure, governments that approve these commodities for domestic use must communicate this decision to the world community *via* the BCH within 15 days of its decision. They must also provide detailed information about their decision.

Decisions by an importing country on whether or not to import these LMO-FFPs are taken under its domestic regulatory framework. In the absence of domestic regulatory framework a 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. In case of insufficient relevant scientific information and knowledge, the importing country may use precaution in making their decisions on the import of LMOs-FFP.

The key components and the timelines to be followed in the AIA procedure for LMOs for intentional release and procedure for LMOs-FFP are summarized in Box 2.

Box 2: Procedure for Transboundary Movement of LMOs: Key Components	
Advance Informed Agreement for LMOs for Intentional Release	**Procedures for LMOs for Food, Feed or Processing (FFP)**
Notification by the Party of export or the exporter	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
Acknowledgement of receipt of notification by the Party of import within 90 days	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
Party of import must communicate its decision on whether or not to import the LMO within 270 days of receipt of notification	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.
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	
While the AIA procedures is bilateral based on direct communication between Parties, the procedure for LMOs-FFP is essentially a multilateral information exchange mechanism centered on the BCH.	

8.3 Review of Decisions

Provision for review of decisions has been provided for in Article 12. The Party of import 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 decisions if there is a change in the circumstances of new information becomes available. The Party of import has to respond to any request for review of decision within 90 days.

8.4 Simplified Procedure

There are also provisions (Article 13) 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. The Parties are also required to specify in advance to the BCH cases in which intentional transboundary movement to it may take place at

the same time as the movement is notified to the Party of import and import of LMOs to it to be exempted from the AIA procedures.

8.5 Unintentional Transboundary Movements and Emergency Measures

While the process has been set up to seek permission for LMOs for different categories, the CPB contains relevant provision for unintentional transboundary movement of LMOs (Article 17). When a country knows of an unintentional transboundary movement of LMOs that is likely to have significant adverse effects on biodiversity and human health, it must notify affected or potentially affected States, the BCH and relevant international organizations regarding information on the unintentional release. To minimize any adverse effects and to determine appropriate response measures notifications should include:

a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the LMOs.

b) Information on the circumstances and estimated date of the release and on the use of the LMOs in the originating Party.

c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity including risks to human health, as well as available information about possible risk management measures.

d) Any other relevant information.

Countries must initiate immediate consultation with the affected or potentially affected States to enable them to determine response and emergency measures.

8.6 Illegal Transboundary Movements

As per Article 25, Parties are required to adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed 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 to the BCH information concerning cases of illegal transboundary movements pertaining to it.

Box 3: Definition of illegal transboundary movement and unintentional transboundary movement

Concerns expressed by Parties regarding lack of clarity in definitions of unintended and illegal transboundary movement have been considered at various COP-MOP meetings and by the Compliance Committee.

At the COP-MOP7 in the absence of clarity on what constitutes an "unintentional transboundary movement", some Parties were of the view that guidance is needed on how to (a) respond and implement emergency measures when an unintentional transboundary movement is detected; (b) develop a process for consultation and collaboration between possibly affected countries, including building regional and sub-regional collaborative systems and (c) respond to "adventitious presence", "low level presence of LMOs" and "unauthorized release" - which may or may not have overlapping meanings with the terms used in the Protocol.

Subsequent to detailed deliberations at the COP-MOP8, the following definitions were adopted:

"*Illegal transboundary movement*" is a transboundary movement of LMOs carried out in contravention of the domestic measures to implement the Protocol that have been adopted by the Party concerned.

"*Unintentional transboundary movement*" is a transboundary movement of a LMO that has inadvertently crossed the national borders of a Party where the LMO was released, and the requirements of Article 17 of the Protocol apply to such transboundary movements only if the LMO involved is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, in the affected or potentially affected States.

8.7 Transboundary Movement with Non-Parties

The Protocol addresses the obligations of Parties in relation to the transboundary movements of LMOs to and from non-Parties to the Protocol. The transboundary movements between Parties and non-Parties must be carried out in a manner that is 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. The first meeting of COP-MOP adopted a decision provding guidance on transboundary movement of LMOs between Parties and Non-Parties.

Regarding setting up of procedures for regulating LMOs, India was one of the early movers in development of a biosafety regulatory framework, way back in 1989 and has a systematic and structured science based regulatory system. In the Indian regulations, the terms Genetically Engineered Organism or Genetically Modified Organism are used, which are synonymous with LMOs. An overview of Indian regulatory framework is given in Box 4.

Box 4: Biosafety Regulatory Framework for GMOs in India

All genetically modified organisms (GMOs) and products thereof are regulated in India as per "Rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells, 1989" notified under the Environment (Protection) Act, 1986. These rules and regulations, commonly referred as Rules 1989 are very broad in scope, essentially covering entire spectrum of activities involving GMOs and products thereof including sale, storage, exportation, importation, production, manufacturing, packaging, etc. These rules cover areas of research as well as large scale applications of GMOs and its products and apply to:

- Manufacture, import and storage of microorganisms and gene technological products
- Genetically engineered organisms/ micro-organisms and cells and correspondingly to any substances and products and foodstuffs, etc., of which such cells, organisms or tissues hereof form part
- New gene technologies in addition to cell hybridization and genetic engineering

Series of biosafety guidelines have been issued under Rules, 1989 with a view to minimize any adverse impact that the GMOs and product thereof would have on the environment as well as human and animal health. There are separate guidelines for various stages of development and use of LMOs viz. contained use, confined field trials, food safety, environmental release etc. as indicated:

- Recombinant DNA Safety Guidelines, 1990
- Revised guidelines for research in transgenic plants, 1998
- Guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other biologicals, 1999
- Guidelines for Conduct of Confined Field Trials (CFTs) of Regulated, Genetically Engineered (GE) Plants, 2008
- Standard Operating Procedures (SOPs) for CFTs of Regulated, GE Plants, 2008
- Guidelines for Monitoring of CFTs of Regulated, GE Plants, 2008
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008 (Updated in 2012)
- Protocols for Food and Feed Safety Assessment of GE crops, 2008
- Guidelines and Handbook for Institutional Biosafety Committees, 2011
- Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization In India, 2012 (Updated in 2016)

The rules are implemented by Ministry of Environment and Forests, Department of Biotechnology and State Governments through six Competent i.e. Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC), State Biotechnology Coordination Committees (SBCCs) and District Level Committees (DLCs). Various sub-committees and Expert committees are set up by RCGM and GEAC on a case by case basis and comprise of experts from various disciplines drawn from public sector institutions to prepare and review various guidelines and biosafety data. Central Compliance Committees are also set up for monitoring of confined field trials on case by case basis.

In addition, there are other acts, rules and policies which are also applicable to these organisms. Some of these are Plant Quarantine Order, 2003; Food Safety and Standards Act, 2006; DGFT Notification Relating to Inclusion of GM Policy in Foreign Trade Policy, 2006-09 etc.

9. RISK ASSESSMENT AND RISK MANAGEMENT

The Protocol empowers governments to make its decisions in accordance with scientifically sound risk assessments. These assessments aim to identify and evaluate the potential adverse effects

that a LMO 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 LMO 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. 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. Article 15, 16 and Annex-III of the Protocol provide for guidance in this matter (Box 5).

Box 5: Relevant Articles on Risk Assessment and Risk Management

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

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.

Several decisions have been taken in various meetings of COPMOP emphasizing on need for capacity building in risk assessment and risk management. A number of measures have been taken by the CBD Secretariat and other agencies to improve the technical and scientific knowledge in the area of risk assessment and risk management. Regional workshops and online discussion forums on capacity-building and exchange of experiences on risk assessment and risk management of LMOs have been organized by the Secretariat. The compilation of available guidance documents on risk assessment and risk management have been expanded in the Biosafety Information Resource Centre (BIRC) of the BCH. More than 1500 summaries of risk assessments earned out to evaluate the potential adverse effects of LMOs on biodiversity and human health have been posted in the BCH. An expert group on RARM was 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. Guidance documents and training tools have been developed through the technical groups, which are presently under discussion and testing.

In India, series of guidelines are available for risk assessment and risk management of GMOs. In continuation to these efforts, MoEF&CC in association with the Department of Biotechnology (DBT) have prepared a set of three documents to strengthen the environmental risk assessment of genetically engineered (GE) plants in India. These include Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016; Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders and Risk Analysis Framework, 2016 (Box 6).

Box 6: Environmental Risk Assessment Guidance for GE plants in India

Guidelines on Environmental Risk Assessment of GE Plants provide a comprehensive and science-based framework for identification of potential harms, collection of relevant scientific data pertaining to the nature and severity of any harm, and characterize the level of risk posed by GE plants. The accompanying Guide for Stakeholders has been prepared to provide additional explanatory material, illustrative examples, and references to scientific literature to provide a better understanding. The Risk Analysis Framework (RAF) describes the principles of risk analysis to be used by the Regulatory Agencies to protect human health and safety, and the environment. RAF also includes concepts related to risk management, and risk communication in addition to risk assessment. The three documents put together provides a practical elaboration of risk assessment framework included in the Indian regulations in conjunction with Annex-III of the CPB, to which India is a Party.

10. HANDLING, TRANSPORT PACKAGING AND IDENTIFICATION (HTPI)

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 and identification (HTPI) 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 subject to intentional transboundary movement.
- **Para 2 of Article 18** specifies different requirements 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. Out of the above, the documentation requirements for LMOs for FFP have been extremely controversial as countries had different views regarding specific identification requirements to be included in the documentation. It was agreed that documentation may mention "may contain" LMOs. Further details have been elaborated in "Curitiba Rules" agreed in COP-MOP 3 after intense negotiations (Box 7).
- **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 the Protocol.

Box 7: Curitiba Rules: Documentation requirements for LMOs-FFP

At COP-MOP3 held at Curitiba, Brazil in 2006, an important breakthrough was made regarding the contentious issue of detailed requirements for documentation accompanying shipments of LMOs-FFP, which had eluded Governments during the last segment of the negotiations of the Protocol and since its adoption.

Documentation accompanying LMOs-FFP, in commercial production and authorized in accordance with domestic regulatory frameworks, is to be in compliance with the requirements of the country of import, and clearly state:

a) In cases where the identity of the LMOs is known through means such as identity preservation systems, that the shipment contains LMOs - FFPs.

b) In cases where the identity of the LMOs is not known through means such as identity preservation systems, that the shipment may contain one or more LMOs - FFPs.

c) That the LMOs are not intended for intentional introduction into the environment;

d) The common, scientific and, where available, commercial names of the LMOs;

e) The transformation event code of the LMOs or, where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code;

f) The Internet address of the BCH for further information;

It was further stated that in accordance with Article 24 of the Protocol, transboundary movements of LMOs between Parties and non-Parties shall be consistent with the objective of the Protocol, and that the specific requirements set out above do not apply to such movements. However, Parties shall encourage non-Parties to adhere to the Protocol;

It was agreed that the expression "may contain" does not require a listing of LMOs of species other than those that constitute the shipment.

10.1 Documentation Requirements

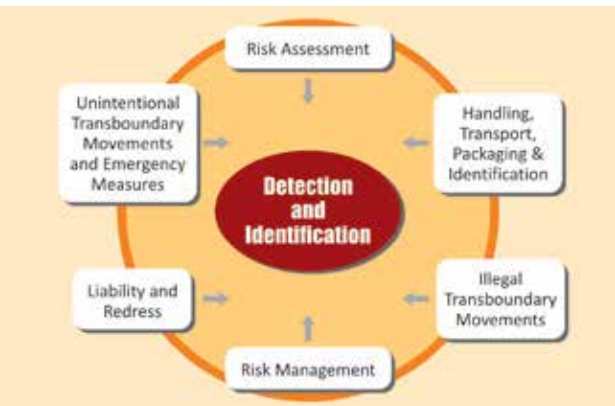
In line with the above decisions, the documentation requirements for transboundary movement of various categories of LMOs are elaborated in Table 1.

Table 1: Documentation Requirement for Transboundary Movement of LMOs

LMOs-FFP Article 18, para2 (a)	LMOs for contained use Article 18, para2 (b)	LMOs for intentional introduction into environment Article 18, para2 (c)
• Where identity of the LMOs is known, that the shipment contains LMOs-FFP	• Clearly identifies content as LMOs including common scientific names of organisms and as "destined for contained use"	• 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 system of unique identification
• Where identity of the LMOs is not known, that the shipment may contain one or more LMOs-FFP	• 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	• 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
• That the LMOs are not intended for intentional introduction into the environment	• 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	• Contains the name and address of exporter and importer
• Common, scientific where available, commercial names of the LMOs	• 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	• Provides a contact point for further information, including an individual or organization in possession of relevant information in case of emergency

• Transformation event code or, where available, the LMOs' unique identifier		• Includes a declaration that movement of the LMOs is in conformity with the Protocol's requirements
• The website of the BCH for further information		• Provides further information, where appropriate, e.g. commercial name, risk class import approval for first transboundary movement of the LMO

10.2 Detection and Identification of LMOs



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. The detection and identification of LMOs is important not only for Article 18, but also Article 17, Article 25 and provisions related to risk assessment and risk management.

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 initiatives in India are elaborated in Box 8.

Box 8: Strengthening of LMO Detection Laboratories in India

MoEFCC in association with DBT and other concerned agencies has been actively engaged in strengthening the capacities for detection and identification of LMOs in the country. As part of the GEF- World Bank Capacity Building Project, few laboratories were strengthened in the area of detection and identification of LMOs.

In the UNEP/GEF supported Phase II Capacity Building Project on Biosafety, the institutional capacities with respect to the infrastructure and equipments for four national laboratories viz., DNA Fingerprinting and Transgenic Crop Monitoring Lab (DFTCML), Hyderabad; Export Inspection Agency-Kochi; National Bureau of Plant Genetic Resources, New Delhi and Punjab Biotechnology Incubator, Mohali have been strengthened.

The human resource capacities from these four institutions have also been strengthened for detection and identification of LMOs through trainings of the laboratory staff and scientists in a phased manner at national and international level. Capacity building of enforcement personnel in the area of identification and sampling of LMOs, which is critical in implementing the requirements under CPB, have also been strengthened through a series of trainings convened specifically for the Plant Quarantine and Customs officials.

11. BIOSAFETY CLEARING HOUSE

A Biosafety Clearing House has been established as per provisions of Article 20 of CPB, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs; and assist Parties to implement the Protocol. It has been developed as an Internet-based system and is accessible at; http://bch.cbd.int/. The BCH not only provides access to information made available by the Parties relevant to the implementation of the Protocol, but also other international biosafety information exchange mechanisms.

Each Party has to make available the following information to the Biosafety Clearing- House:

- Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
- Any bilateral, regional and multilateral agreements and arrangements;
- Summaries of its risk assessments or environmental reviews of living modified organisms

generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

- Its final decisions regarding the importation or release of LMOs; and
- National Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

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.

12. CONFIDENTIAL INFORMATION

In accordance with the AIA or other procedures specified by the Protocol, the information is required to be submitted to the Party of import so as to allow for taking decision on the import of LMO in question. In return, the Party of import has an obligation to permit the notifier or applicant to identify information that needs to be treated confidential. The Party of import may ask for justification of why certain information should be kept confidential and in the event of difference, it should consult the notifier prior to any disclosure.

Accordingly, as per Article 21 of the CPB, 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.

13. CAPACITY BUILDING

Recognizing the need for capacity building for effective implementation of the CPB, there is a provision for Parties to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety. Countries that trade in LMOs in particular, 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 LMOs on their natural relatives. The Protocol promotes international cooperation to help developing countries and countries with economies in transition to build human resources and institutional capacity 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. Some of actions suggested are elaborated in Box 9.

Box 9: Action Plan for strengthening the Capacity Building initiatives: Key Components

- Develop capacity building materials and guidelines on mainstreaming biosafety into National Biodiversity Strategies and Action Plans (NBSAPs) and national development plans
- Organize sub regional trainings on mainstreaming biosafety into NBSAP and development plans, making use of the above e-learning module and toolkit (Activity 97), in collaboration with partners
- Support selected developing countries to implement pilot projects to develop and apply practical measures and approaches for integrated implementation of the Cartagena Protocol and the CBD at the national level and share emerging good practices and lessons learned
- Organize training courses in risk assessment of LMOs
- Develop e-learning modules on risk assessment of LMOs
- Organize regional and sub-regional training courses to enable Parties to implement the LMO identification requirements of paragraph 2 (a) of Article 18 and related decisions
- Organize workshops on sampling, detection and identification of LMOs
- Organize online discussions and knowledge-sharing sessions through the Network of Laboratories on the detection and identification of LMOs
- Organize sub regional workshops on public awareness and education concerning LMOs
- Develop, in collaboration with relevant organizations, training materials on sampling, detection and identification of LMOs
- Develop learning materials on public awareness and education concerning LMOs
- Organize workshops to raise awareness of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

Parties are encouraged to assist with scientific and technical training and to promote the transfer of technology, know-how, and financial resources. Biosafety activities under the CPB are eligible for support from the Global Environment Facility (GEF) an international fund that was established to help developing countries protect the global environment. Extensive international financial assistance has been provided for biosafety capacity development in developing countries, the large proportion coming through the GEF. Several capacity-building projects have been completed/are underway in different countries/regions. India has also implemented two projects supported by GEF (Box 10).

Box 10: GEF supported projects implemented in India

In view of continuous developments in biotechnology as also emerging challenges in its regulation, several capacity building activities have been regularly undertaken in the country by MoEF&CC, the nodal Ministry for implementation of CPB. In addition to national initiatives, MoEF&CC had also accessed funding from the GEF through the World Bank in 2004 for a biosafety capacity building project, under which a series of activities were undertaken for a period of four years upto 2007.

Building on the foundations of the above project, the "Phase II Capacity Building Project on Biosafety" has been implemented by MoEF&CC, since 2012 for a period of four years with an objective to strengthen the biosafety management capacity in the country. The Project including the project design and thrust areas were prepared through a consultative process by seeking inputs from various stakeholder viz. government, scientists, public-sector institutions, NGOs and potential project partners. The Phase II project has been implemented to supplement the ongoing biosafety capacity building initiatives in India, integrate international experience and promote regional cooperation. The key thrust areas are Risk Assessment and Risk Management, Handling, Transport, Packaging and Identification, Socio-economic Considerations and Public Awareness.

14. PUBLIC AWARENESS AND PARTICIPATION

The Cartagena Protocol on Biosafety calls for cooperation on promoting public awareness of the safe transfer, handling and use of LMOs. It specifically highlights the need for education, which will increasingly have to address LMOs as biotechnology becomes more and more a part of our society. The Protocol also calls for the public to be actively consulted on LMOs 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.

In view of the above the Parties are required to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties are encouraged cooperate, as appropriate, with other States and international bodies.

The Parties are also required to consult the public in the decision making process regarding LMOs and make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21 in accordance with their respective laws and regulations.

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

15. SOCIO-ECONOMIC CONSIDERATIONS

Article 26 of the CPB provides an enabling provision to Parties to take into account socio-economic considerations into account in making decisions on imports of LMOs, or under its domestic measures implementing the Protocol. It has been indicated that any decision on the inclusion of socio-economic considerations, however, must be consistent with that country & other international obligations.

The Protocol further 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 (AHTEG) on Socio-economic Considerations 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.

As per COP-MOP decisions, Parties are also encouraged to conduct research on socio-economic impact of LMOs through involvement of local institutes of higher education with a view to build domestic capacity in socio-economic impact analysis.

Accordingly, resource tools are being developed under Phase II Capacity Building Project on Biosafety in India to work on guidelines and methodologies for socio- economic assessment and cost benefit analysis. These activities are expected to be helpful in understanding relevance of socio-economic considerations in domestic scenario as well as develop India's position for future meetings of the COP-MOP.

16. LIABILITY AND REDRESS

As consensus could not be reached on the issue of liability and redress during negotiations on CPB, Article 27 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. Accordingly, a Working Group comprising of legal and technical experts was established in 2004 to work on issues related to liability and redress.

After six years of hectic negotiations, Parties finalized the negotiation of a new treaty known as the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress. 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 CPB by providing international rules and procedures on liability and redress for damage to biodiversity resulting from LMOs. The Supplementary Protocol fulfills the commitment set forth in Article 27 of the CPB and has been agreed after several years of negotiations

The objective of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress is to contribute to the conservation and sustainable use of biological diversity, also taking into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to LMOs.

As of February, 2017, 37 Parties have ratified the Supplementary Protocol. The Protocol will come into force after ratification by 40 Parties.

The key features of the Supplementary Protocol are:

- It focuses, mainly, on administrative procedures and requirements with respect to response measures that need to be taken in the event of damage by LMOs that adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health.
- It provides flexibility in regulatory approaches by allowing Parties to apply existing or new domestic laws that may be general or specific as regards 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.
- It creates an enabling environment and builds further confidence in the safe development and application of modern biotechnology

- It contributes to the prevention or mitigation of damage by creating incentives for operators to ensure safety in the development or handling of LMOs India has ratified the Supplementary Protocol in December, 2014. The obligations of a Party to the Supplementary Protocol are given in Box 12.

Box 12: Obligations of a Party to the Supplementary Protocol

The core obligations that a Party to tile Supplementary Protocol must fulfil are two fold. Parties must provide some essential elements (damage, response measures and definition of operator) in the rules and procedures on liability and redresses 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.

17. CONFERENCE OF PARTIES SERVING AS MEETING OF PARTIES

The Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the CPB (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. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the COP-MOP, however, decisions under this Protocol are taken only by those that are Parties to it.

The COP-MOP performs the following functions assigned to it by this Protocol:

- Make recommendations on any matters necessary for the implementation of this Protocol;
- Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

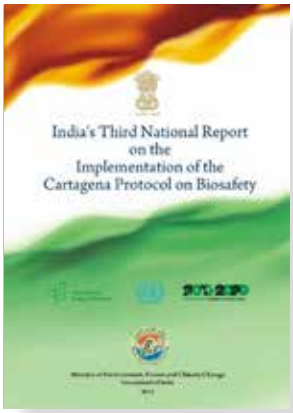
- Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;
- Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;
- Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and
- Exercise such other functions as may be required for the implementation of this Protocol.

The COP-MOP currently meets every two years in conjunction with the regular meetings of the Conference of the Parties (COP) to the CBD. Till date, the COP-MOP has convened eight meetings as indicated in Table 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
COP-MOP 8*	December 2 - 17, 2016	Cancun, Mexico	Mainstreaming Biodiversity for Well-being
* For the first time COP13, COP-MOP8 to the CPB and COP-MOP2 to the Nagoya Protocol on Access and Benefit Sharing were held concurrently			

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.

18. MONITORING AND REPORTING



Each Party is expected to monitor the implementation of its obligations under this Protocol at regular intervals. Among other things, preparation of national reports is an important obligation of all Parties to the CPB. 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. India has submitted all its reports and the same are available at BCH.

19. STRATEGIC PLAN

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

19.1 Vision

Making biodiversity adequately protected from any adverse effects of LMOs.

19.2 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.

19.3 Strategic objectives

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

- Facilitating the establishment and further development of systems for the implementation of the Protocol;
- Capacity-building;
- Compliance and review;
- Information sharing; and
- 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 was carried out in conjunction with the third assessment and review of the effectiveness of the Protocol through the work of a subsidiary body on implementation. The recommendations were considered at the COP- MOP8, wherein the Parties have been advised to undertake targeted capacity building activities on biosafety, and Parties that have not already done so to put in place national biosafety frameworks, to use the BCH to share national experiences and to enhance capacity for public awareness, education and participation. A final evaluation of the Strategic Plan will take place at the tenth meeting of the Parties to the Protocol in 2020.

20. BENEFITS OF BEING A PARTY TO THE PROTOCOL

Becoming a Party to the Protocol presents a number of benefits, such as the following:

- Influence on the implementation of the Protocol and shaping of its further development through participation in the decisionmaking processes of the Conference of the Parties serving as the meeting of the Parties to the Protocol
- For developing country Parties and Parties with economies in transition, eligibility for financial support from the GEF (the financial mechanism for the Protocol) for capacity-building, as well as other support for implementation of the Protocol and participation in its processes;
- Enhanced visibility and credibility of national systems for regulating biosafety within the global community,
- Contribution to harmonized rules, procedures and practices in managing the transboundary movement of LMOs,

- Facilitation of mechanisms and opportunities for governments to collaborate with other governments, the private sector and civil society on strengthening biosafety,
- Improved access to relevant technologies and data, and benefiting from a regular exchange of information and expertise and
- Demonstration of commitment to conservation and sustainable use of biological diversity through the implementation of biosafety measures.

FULL TEXT OF THE CARTAGENA PROTOCOL ON BIOSAFETY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

ARTICLE 1. OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this 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 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.

ARTICLE 2. GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.
3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.
4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.
5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

ARTICLE 3. USE OF TERMS

For the purposes of this Protocol:

a) "Conference of the Parties" means the Conference of the Parties to the Convention;

b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

c) "Export" means intentional transboundary movement from one Party to another Party;

d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

e) "Import" means intentional transboundary movement into one Party from another Party;

f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

i) "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;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

ARTICLE 4. SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

ARTICLE 5. PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

ARTICLE 6. TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

ARTICLE 7.APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. “Intentional introduction into the environment” in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

ARTICLE 8. NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

ARTICLE 9. ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.
2. The acknowledgement shall state:
   a) The date of receipt of the notification;
   b) Whether the notification, prima facie, contains the information referred to in Article 8;
   c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.
3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.
4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

ARTICLE 10. DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.
2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:
   a) Only after the Party of import has given its written consent; or
   b) After no less than ninety days without a subsequent written consent.
3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:
   a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;
   b) Prohibiting the import;
   c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or
   d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.
4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.
5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.
6. 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 question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

ARTICLE 11. PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.
2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.
3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.
4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.
5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.
6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:
   a) A risk assessment undertaken in accordance with Annex III; and
   b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.
7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.
8. 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 intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.
9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

ARTICLE 12. REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human

health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:
   a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
   b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

ARTICLE 13. SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:
   a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and
   b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

ARTICLE 14. BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

ARTICLE 15. RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound

manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

ARTICLE 16. RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:
   a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
   b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

ARTICLE 17. UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:
   a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

d) Any other relevant information; and

e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

ARTICLE 18. HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

   a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

   b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the 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 living modified organisms are consigned; and

   c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

ARTICLE 19. COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be

responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

ARTICLE 20. INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:
   a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
   b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:
   a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
   b) Any bilateral, regional and multilateral agreements and arrangements;
   c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;
   d) Its final decisions regarding the importation or release of living modified organisms; and
   e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall

be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

ARTICLE 21. CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.
2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.
3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.
4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.
5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.
6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:
   a) The name and address of the notifier;
   b) A general description of the living modified organism or organisms;
   c) 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
   d) Any methods and plans for emergency response.

ARTICLE 22. CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.
2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

ARTICLE 23. PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:
   a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
   b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

ARTICLE 24. NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.
2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

ARTICLE 25. ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.
2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.
3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

ARTICLE 26. SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2. The Parties are encouraged to cooperate on research and information exchange on any socio economic impacts of living modified organisms, especially on indigenous and local communities.

ARTICLE 27. LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting,

adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

ARTICLE 28. FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

ARTICLE 29. CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

   a) Make recommendations on any matters necessary for the implementation of this Protocol;

   b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 30. SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

ARTICLE 31. SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

ARTICLE 32. RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

ARTICLE 33. MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

ARTICLE 34. COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

ARTICLE 35. ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

ARTICLE 36. SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

ARTICLE 37. ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration

organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

ARTICLE 38. RESERVATIONS

No reservations may be made to this Protocol.

ARTICLE 39. WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 40. AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

ANNEX–I TO CARTAGENA PROTOCOL ON BIOSAFETY

Information required in notifications under Articles 8, 10 and 13

a) Name, address and contact details of the exporter.

b) Name, address and contact details of the importer.

c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

d) Intended date or dates of the transboundary movement, if known.

e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

j) Quantity or volume of the living modified organism to be transferred.

k) A previous and existing risk assessment report consistent with Annex III.

l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

o) A declaration that the above-mentioned information is factually correct.

ANNEX–II TO CARTAGENA PROTOCOL ON BIOSAFETY

Information required concerning living modified organisms intended for direct use as food or feed, or for processing under Article 11

a) The name and contact details of the applicant for a decision for domestic use.

b) The name and contact details of the authority responsible for the decision.

c) Name and identity of the living modified organism.

d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

e) Any unique identification of the living modified organism.

f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

i) Approved uses of the living modified organism.

j) A risk assessment report consistent with Annex III.

k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

ANNEX–III TO CARTAGENA PROTOCOL ON BIOSAFETY

Risk assessment

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
4. 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.
5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.
8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:
    a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
    b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
    c) An evaluation of the consequences should these adverse effects be realized;
    d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
    e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
    f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:
    a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;
    b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
    c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

NOTES

Important Contacts:

NATIONAL PROJECT DIRECTOR
Dr Amita Prasad, Additional Secretary

NATIONAL PROJECT COORDINATOR
Shri Gyanesh Bharti, Joint Secretary

Ministry of Environment, Forest and Climate Change
Government of India
Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj, New Delhi 110003

Project Coordination Unit

BCIL

Biotech Consortium India Limited
Anuvrat Bhawan, 5th Floor, 210 Deen Dayal Upadhyaya Marg, New Delhi- 110002

For further information, please contact at biosafety-mef@nic.in