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GLOBAL ENVIRONMENT FACILITY
INVESTING IN OUR PLANET

PROJECT FOR SUSTAINABLE CAPACITY BUILDING FOR EFFECTIVE PARTICIPATION IN THE BIOSAFETY CLEARING HOUSE

OVERVIEW ON THE CARTAGENA PROTOCOL

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WHAT IS BIOSAFETY?

- Biosafety is a term used to describe efforts to minimise and avoid the potential risks resulting from modern biotechnology and its products.

THE PRECAUTIONARY APPROACH

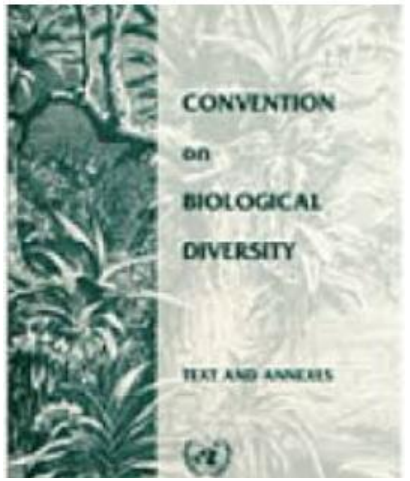
The United Nations Conference on Environment and Development in Rio de Janeiro, Brazil, 1992, adopted 27 principles to underpin sustainable development.

Principle 15 (also known as the precautionary principle) states that:

"*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.*"

THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

- Is an international treaty that has 3 objectives:
  - The conservation of biological diversity,
  - The sustainable use of its components and
  - The fair and equitable sharing of the benefits arising out of the utilization of genetic resources.



- It entered into force on 1993

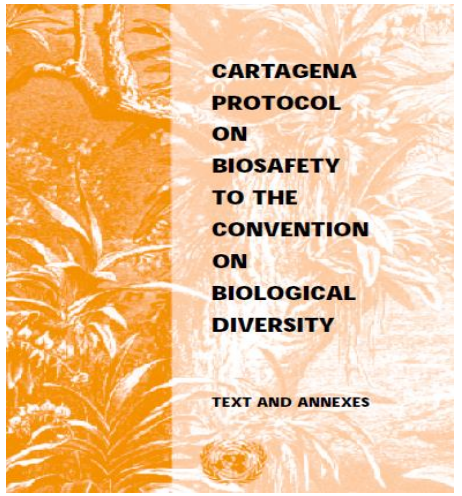
- The issue of safety in biotechnology is addressed in articles 8(g) and 19(3) of the CBD.

THE CARTAGENA PROTOCOL ON BIOSAFETY (CPB)

- The Conference of the Parties to the CBD adopted the Cartagena Protocol on Biosafety on 29 January 2000 in Montreal, Canada.

- The Cartagena Protocol on Biosafety is an international agreement (treaty), concluded and adopted in the framework of the Convention on Biological Diversity (CBD)

- It entered into force on September 11, 2003



AS OF DATE

171 Parties

- Governing body of the Protocol: COP-MOP
  - COP/MOP-1: 2004, KL, Malaysia
  - COP/MOP-2: 2005, Montreal, Canada
  - COP/MOP-3: 2006, Curitiba, Brazil
  - COP/MOP-4: 2008, Bonn, Germany
  - COP/MOP-5: 2010, Nagoya, Japan
  - COP/MOP-6: 2012, Hyderabad, India
  - COP/MOP-7: 2014, Pyeongchang, Republic of Korea
  - COP/MOP-8: 2016, Cancun, Mexico
  - COP/MOP-9: 2018, Sharm El-Sheikh, Egypt

SOME DEFINITIONS

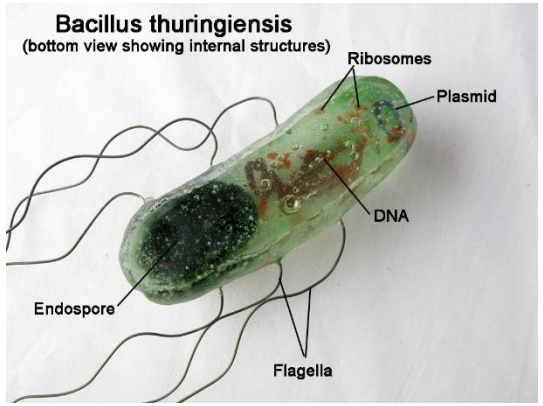
Living Modified Organism (LMO): Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology

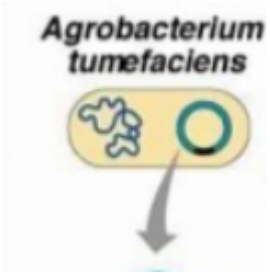
Modern biotechnology: means the application of:

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

EXAMPLE





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OBJECTIVE OF THE CARTAGENA PROTOCOL (ART.1)

Art. 1

- […] 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.*

- The phrase "may have adverse effects" indicates adherence to the precautionary approach: protection is called for not only if **the adverse effects are a certainty, and have been established as such by full scientific evidence,** but also if there is **a threat of adverse effects**.

SCOPE OF THE PROTOCOL

Art. 4

"This Protocol shall apply to ***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."*

Art. 5

[…] 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 organizations**

QUESTIONS ON CPB DEFINITIONS AND SCOPE

- For a shipment of cloned pigs arriving from abroad do we have to apply the requirements of the Biosafety Protocol?

- A pharmaceutical company wants to ship a genetically modified live vaccine for hepatitis B to its sister company in in another country. do we have to apply the requirements of the Biosafety Protocol?

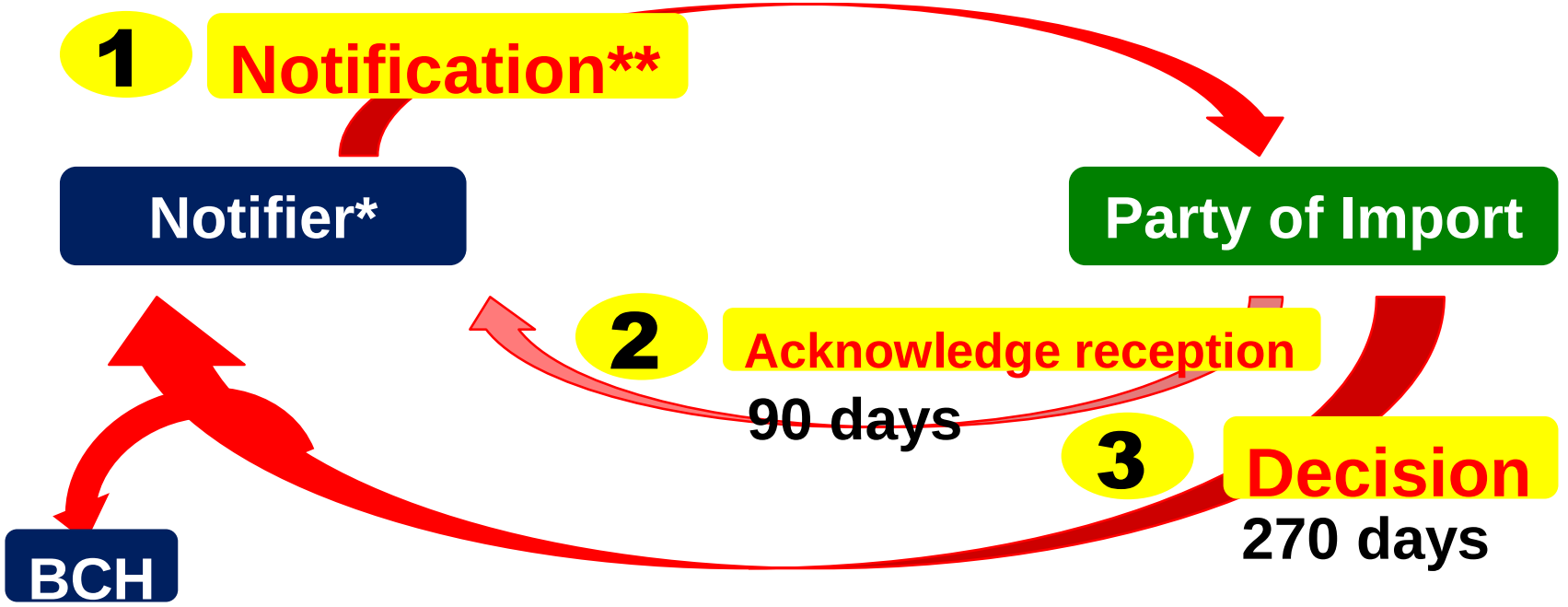
APPLICATION OF THE CPB

	Categories of LMOs	Procedures
[Art. 7-10]	1. LMOs for intentional introduction into the environment (eg. Seed for planting;	1. Advanced informed Agreement procedure.
[Art. 11]	2. LMOs for direct use as a food or feed, or processing (e.g. Corn for human consumption);	2. Procedure for LMOs Intended for Direct Use as Food or Feed, Or For Processing.
[Art. 6]	3. LMOs destined for contained use in the Party of import (GMO for laboratory use, R&D); 4. LMOs in transit	▪ No specified Procedure / just highlight some rights and obligations of a party

3. Simplified Procedure [Art. 13].

ADVANCED INFORMED AGREEMENT PROCEDURE

Introduction into the environment



1. *approving the import (with or without conditions)*
2. *prohibiting the import,*
3. *requesting additional relevant information*
4. *Informing the notifier that the period is extended*

*Notifier: Party of Export or Exporter

**Notification: shall contain at least the information detailed in Annex I to the CPB

PROCEDURE FOR LMO INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING (FFP)

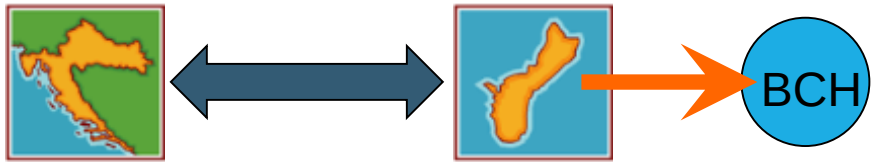
Art. 11

Bulk grains export

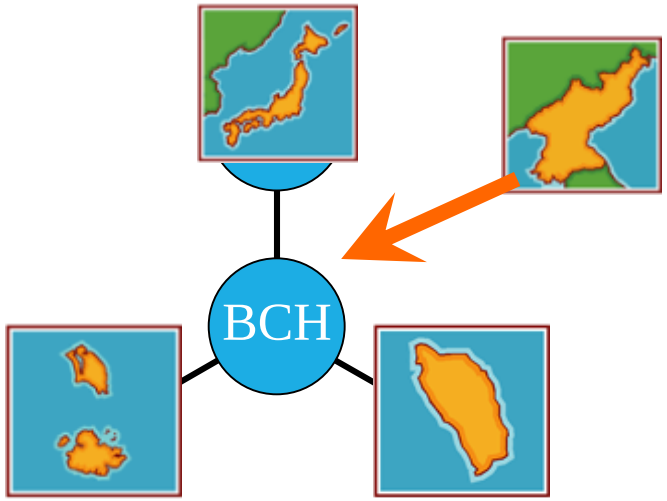
- *Final decision regarding domestic use, including placing on the market, of a LMO that may be subject to transboundary movement for direct use as FFP should, within 15 days of making that decision, inform the Parties through the BCH.* This information shall contain, at a minimum, the information specified in Annex II.
- **In the absence of the domestic regulatory framework** parties may declare through the BCH that its decision prior to the first import of a LMO for FFP, will be taken according to the following:
  - A risk assessment undertaken in accordance with Annex III; and
  - A decision made within a predictable timeframe, not exceeding **270 days**.

WHAT IS THE MAIN DIFFERENCE BETWEEN AIA AND FFP PROCEDURES ?

AIA procedure = bilateral procedure, which is based on direct communication between Parties



LMO-FFPs procedure = essentially a multilateral information exchange mechanism, centered on the BCH



SIMPLIFIED PROCEDURE

Art. 13

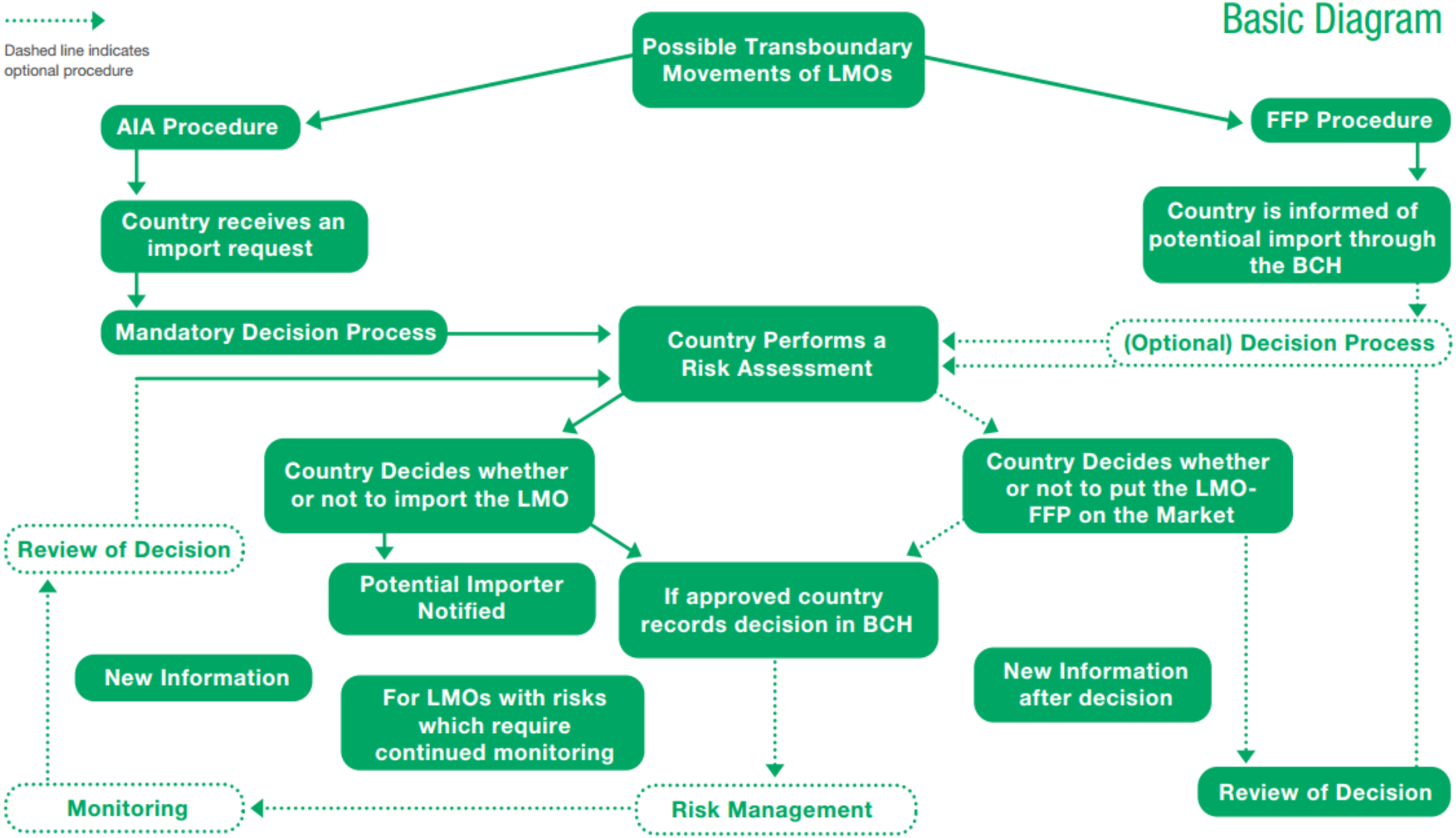
- Provided that adequate measures are applied to ensure safe intentional transboundary movement of LMOs in accordance with the Protocol's objectives.
- Parties specify in advance to the BCH cases in which import of an LMO :
  - Cases where TB movement occurs at same time as importing Party is notified
  - LMO imports exempted from AIA
- Information should contain, at a minimum, the information specified in Annex I

REVIEW OF DECISIONS

Art. 12

- **A Party of import** may, at any time, in light of new scientific information, **review and change a decision**… but should inform the notifier and the BCH within 30 days of the decision and its reasons.
- **A Party of export or a notifier** may also request the Party of import to **review its decisions** if there is a change in circumstances influencing the outcome of risk assessment or new technical information becomes available.

Basic Diagram



GENERAL PROVISIONS

Art. 2

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

- […] 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.

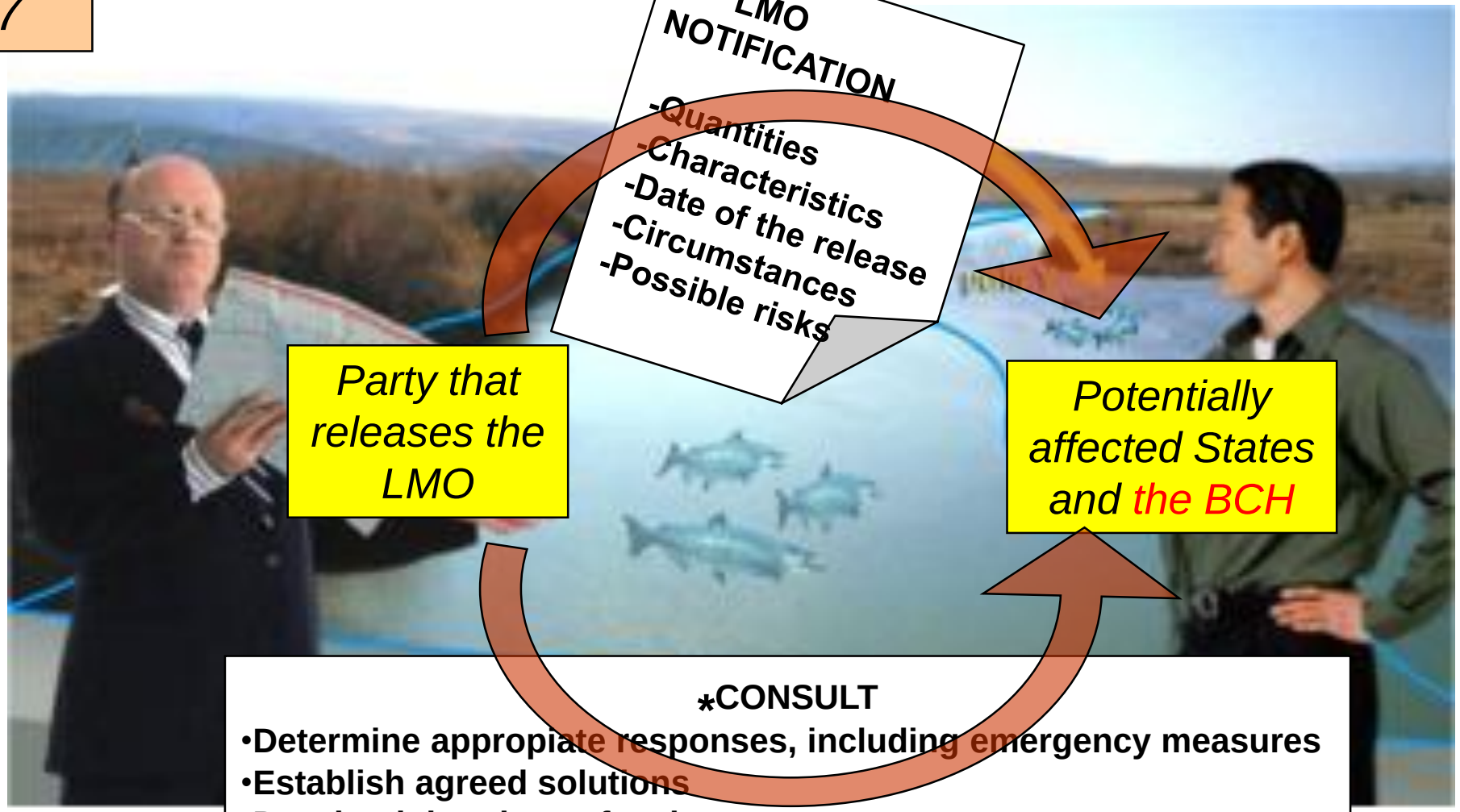
RISK ASSESSMENT (RA)

Art. 15

- RA should be carried out in a scientifically sound manner and in accordance with Annex III of the protocol
- The right of a party to subject all living modified organisms to risk assessment prior to the making of decisions on import
- The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

Article 17



ILLEGAL TRANSBOUNDARY MOVEMENTS

Art. 25

- Parties need to adopt appropriate domestic measure aiming at preventing and penalizing transboundary movements of LMOs carried out in contravention to domestic measures;
- Affected party may request the party of Origin to dispose at its own expense the LMO in question;
- Parties need to make available to the BCH information concerning illegal transboundary movements pertaining to it.

CONFIDENTIAL INFORMATION (1/2)

Art. 21

1. Notifier identifies submitted information that is to be treated as confidential;

2. Prior to any disclosure, The Party of import inform the notifier of its decision if the information qualify for such treatment;

3. If the notifier diagree and withdraw the notification, the Party of import respect the confidentiality of commercial and industrial information, including research and development information as well as information on which their confidentiality diasgreement.

4. Confidential information are to be disclosed (not to be published on the BCH) or used for commercial purpose

CONFIDENTIAL INFORMATION (2/2)

Art. 25 (6)

The following information can not be considered as 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.

OTHER ISSUES

Handling, Transport, Packaging and Identification	*Art. 18*
Liability and Redress	*Art. 27*

WHAT IS A UNIQUE IDENTIFIER?

- It is a digital alpha numeric code each living modified plant that is approved for commercial use, including for use as food or feed.
- Identifiers are generated by the developers of a new transgenic plant, and included in the dossiers that they forward to national authorities during the safety assessment process.
- Once approved, national authorities can then forward the unique identifier to the OECD Secretariat for inclusion in the OECD's product database, from which the information is automatically shared with the Biosafety Clearing-House.

UNDERSTANDING THE CODE

2 or 3 alphanumeric digits to designate the applicant

5 or 6 alphanumeric digits to designate the transformation event

One numerical digit for verification (to reduce errors by ensuring the integrity of the alphanumeric code)

MON-15985-7

SYN-EV176-9

DAS-Ø15Ø7-1

MON = Monsanto
SYN = Syngenta
DAS = Dow Agro-Science

UNIQUE IDENTIFIER AND THE CARTAGENA PROTOCOL

- In accordance with the Protocol, it is expected that the Unique identifier for LMOs intended for direct use as food, feed or for processing (decisions taken under Article 11) to be available, since most of these organisms are expected to be approved for use in trade.
- The Third Meeting of the Parties to the Protocol also requested Governments to provide information on the unique identifier, where it exists, when decisions taken under the Advanced informed agreement are registered.

For more information, please email

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Thank you !