



# THE BCH III PROJECT

**The Cartagena Protocol in Brief**

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# Basic concepts

- What is the difference between Biosafety / Biosecurity?

- 2 Terms that are sometimes used interchangeably although are not the same.

**Biosecurity:** The protection, control, and accountability for biological agents and toxins within facilities in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release

**Biosafety:** Containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological material or their accidental release

“**Biosafety** is about protecting people from bad ‘bugs’; **biosecurity** is about protecting ‘bugs’ from bad people”.

# Basic concepts

- What is meant by Biosafety in the context of Cartagena Protocol?
- a term used to describe efforts to minimize and avoid the potential environmental and human health risks resulting from modern biotechnology and its products.

# History

- Rio “Earth Summit” 92

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

- **Principle 15 (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.”



# History

- Rio “Earth Summit” 92

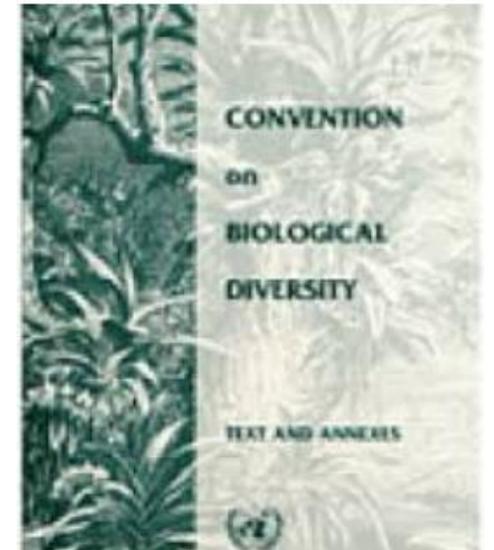
- The Convention on Biological Diversity (CBD) was opened for signature

- Global commitment to the:

- Conservation of biological diversity

- Sustainable use of its components

- Fair and equitable sharing of benefits arising from the use of its genetic resources.



- The CBD Formed the basis of international law on biosafety and entered into force on 1993.

# History

- The Convention on Biological Diversity (CBD)

- Article 8(g)

*Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;*

- Article 19(3)

*The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*

# History

- The Cartagena Protocol on Biosafety (CPB)

1996-1999

Ad Hoc Working Group to negotiation of a protocol text

2000

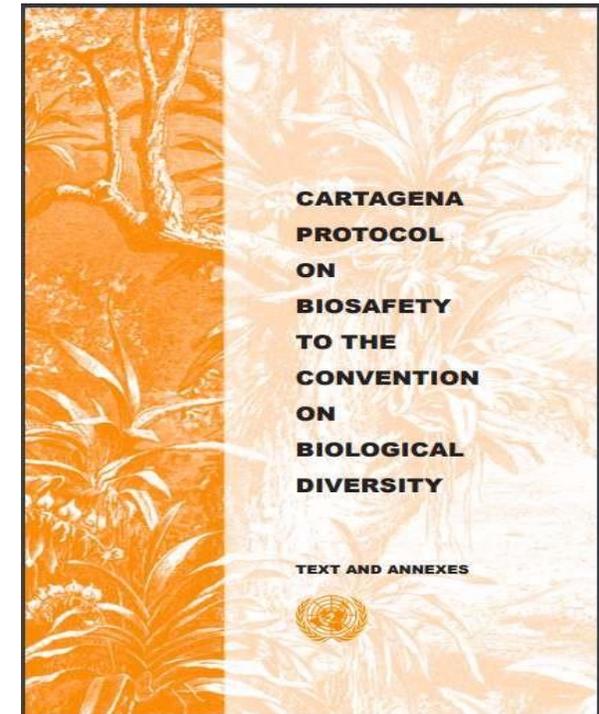
Adoption of the Cartagena Protocol

2003

Entry into force

2023

173 Parties



# The Cartagena Protocol on Biosafety (CPB)

Art. 3

- Use of terms

- Living Modified Organism (LMO)

Any living organism that possesses a novel combination of genetic material obtained through the use of *modern biotechnology*.

- Modern biotechnology

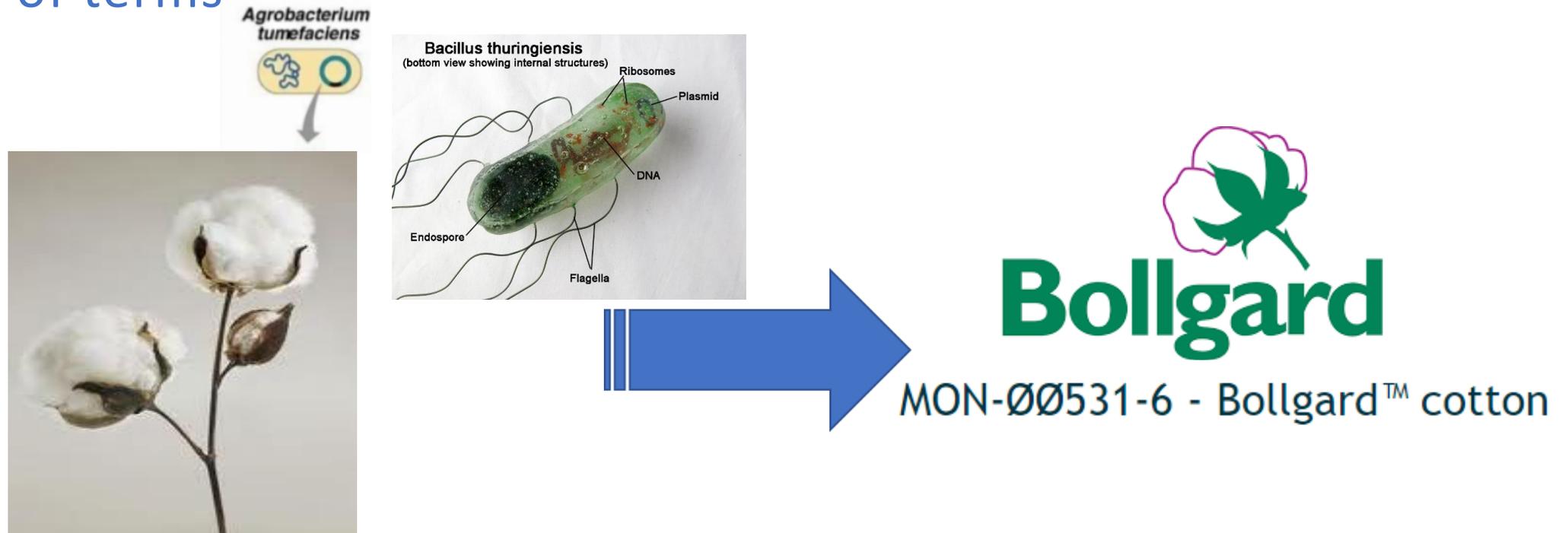
The application of:

- 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*.

# The Cartagena Protocol on Biosafety (CPB)

- Use of terms



The bollgard cotton line possesses a novel combination of genetic material (normal cotton genes + genes inserted from a soil bacteria) using modern biotechnology (Agrobacterium-mediated transformation) to overcome the natural physiological reproductive and recombination barriers

# The Cartagena Protocol on Biosafety (CPB)

- Objective

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.

# The Cartagena Protocol on Biosafety (CPB)

- Scope

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.*

# The Cartagena Protocol on Biosafety (CPB)

- Pharmaceuticals

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.*

- Art. 5 indicates that Pharmaceuticals that are LMOs for human **to be excluded** from the scope of the protocol they need to be addressed by other relevant international agreements or organizations. So far this did not happen and this exclusion remains as **an open door that has not been crossed**.

# The Cartagena Protocol on Biosafety (CPB)

- Questions on CPB Definitions and Scope

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

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

# The Cartagena Protocol on Biosafety (CPB)

- 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);

■ No specified Procedure / **just highlight some rights and obligations of a party**

4. LMOs in transit

3. Simplified Procedure. [Art. 13]

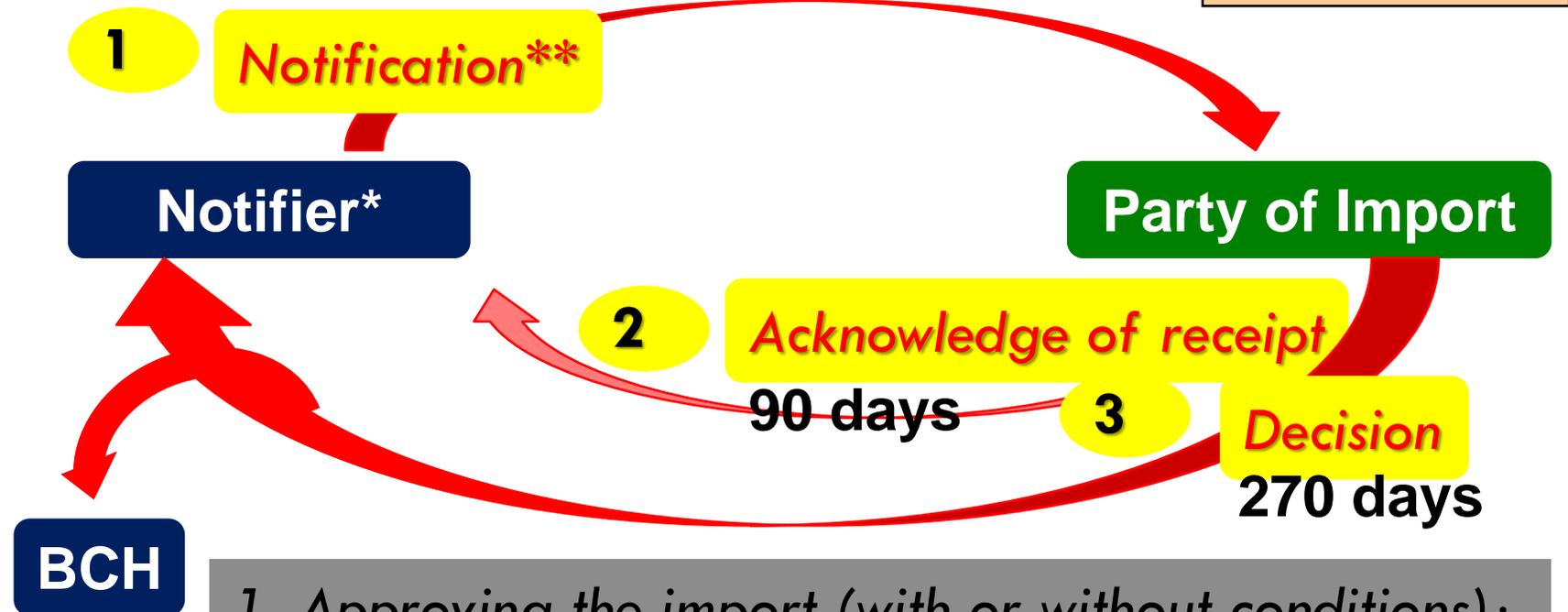
# The Cartagena Protocol on Biosafety (CPB)

- Advanced Informed Agreement procedure (AIA)

Art. 7 - 10



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

# The Cartagena Protocol on Biosafety (CPB)

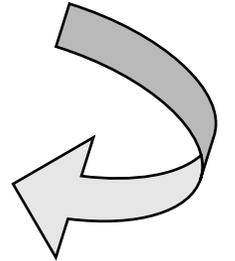
- Procedure for LMO for direct use for food or feed or processing (FFP)

## Art. 11

- A Party that makes 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.

Bulk grains  
export



# The Cartagena Protocol on Biosafety (CPB)

- Simplified procedure

Art. 13

Provided that **adequate measures are applied to ensure safe intentional transboundary movement of a specific LMO** in accordance with the Protocol's objectives. Parties can specify in advance to the BCH cases where:

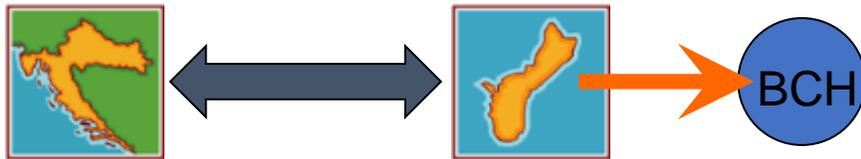
- the import of an LMO to it may take place at the same time as the transboundary movement is notified
- an LMO imports is exempted from AIA

# The Cartagena Protocol on Biosafety (CPB)

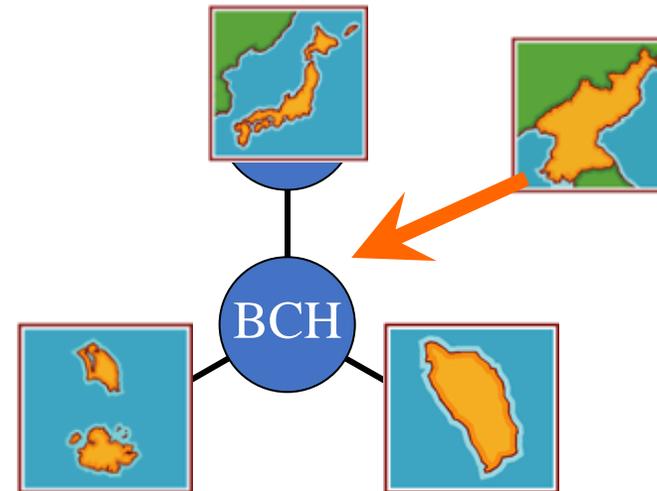
- Questions on procedures

- 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



# The Cartagena Protocol on Biosafety (CPB)

- Questions on procedures

- Is there any legal requirement by the Cartagena Protocol for the party of export to directly inform the party of import about any shipments containing LMOs intended for direct use for food or feed or for processing pertaining to it ?

- *No, this requirement can be laid in the domestic regulatory framework of the party of import.*

- *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 Art. 22 (Capacity building) and Art. 28 (Financial mechanism) of the CPB.*

# The Cartagena Protocol on Biosafety (CPB)

- 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.*

# The Cartagena Protocol on Biosafety (CPB)

## • 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



# The Cartagena Protocol on Biosafety (CPB)

## • Risk Assessment

*- Risk assessments should be carried out in a scientifically sound manner and in accordance with Annex III.*

*- The Party of import should ensure that risk assessments are carried out for decisions taken under Article 10.*

*- 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.*

Art. 15



# The Cartagena Protocol on Biosafety (CPB)

- 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.

# The Cartagena Protocol on Biosafety (CPB)

- Unintentional transboundary movements

Art. 17

Party that  
releases the  
LMO

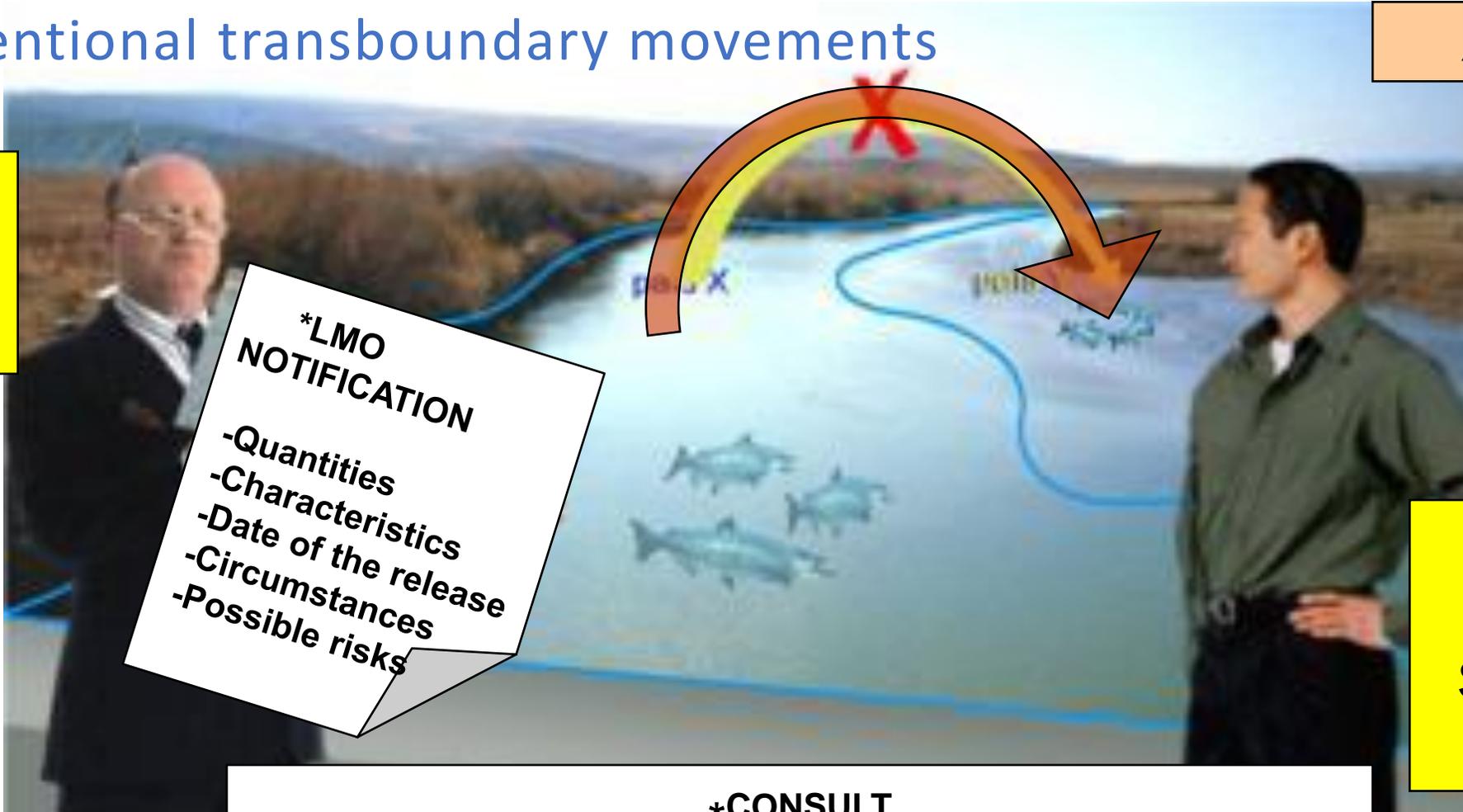
**\*LMO  
NOTIFICATION**

- Quantities
- Characteristics
- Date of the release
- Circumstances
- Possible risks

**\*CONSULT**

- Determine appropriate responses, including emergency measures
- Establish agreed solutions
- Develop joint plans of action

Potentially  
affected  
States and  
the **BCH**



# The Cartagena Protocol on Biosafety (CPB)

- Confidential information

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 disagree 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 disagreement.*

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

# The Cartagena Protocol on Biosafety (CPB)

- Confidential information

Art. 21

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.

# The Cartagena Protocol on Biosafety (CPB)

- Issues not fully finalized in the negotiation of the text of the CPB

## Handling, Transport, Packaging and Identification:

*Art. 18*

- Mandated Parties to take necessary measures requiring that living modified organisms that are subject to intentional transboundary movement are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.
- The need for and modalities of developing standards with regard to identification, handling, packaging and transport practices were left for the conference of the parties to decide on later as clearly stated in Article 18.3

# The Cartagena Protocol on Biosafety (CPB)

- Issues not fully finalized in the negotiation of the text of the CPB

## The Liability and Redress:

*Art. 27*

- Mandated the Conference of the Parties serving as the meeting of the Parties to the Protocol to adopt , at its first meeting, 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.
- later, the process led to the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

# The Cartagena Protocol on Biosafety (CPB)

- Conference of the Parties serving as the meeting of the Parties to CPB

COP-MOP:

*Art. 29*

- Keeps under regular review the implementation of the Protocol and make decisions necessary to promote its effective implementation. This may include establishing necessary subsidiary bodies or Considering and adopting, as required, amendments to the Protocol and its annexes, as well as any additional annexes that are deemed necessary

- So far 10 conferences of the parties were conducted.

# Questions and discussions

Thank you !

For more information, please email

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