Regional Joint BCH and ABSCH Training of Trainers Workshop for Africa Region

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Environmental Risk Assessment

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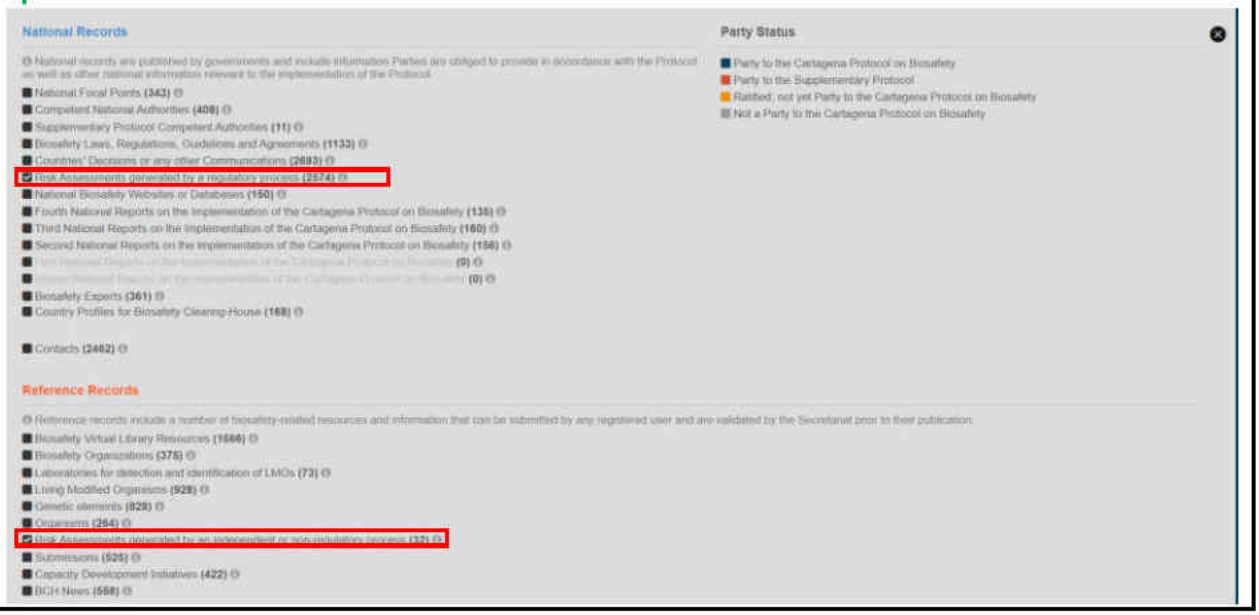
Environmental Risk Assessment

The Cartagena Protocol

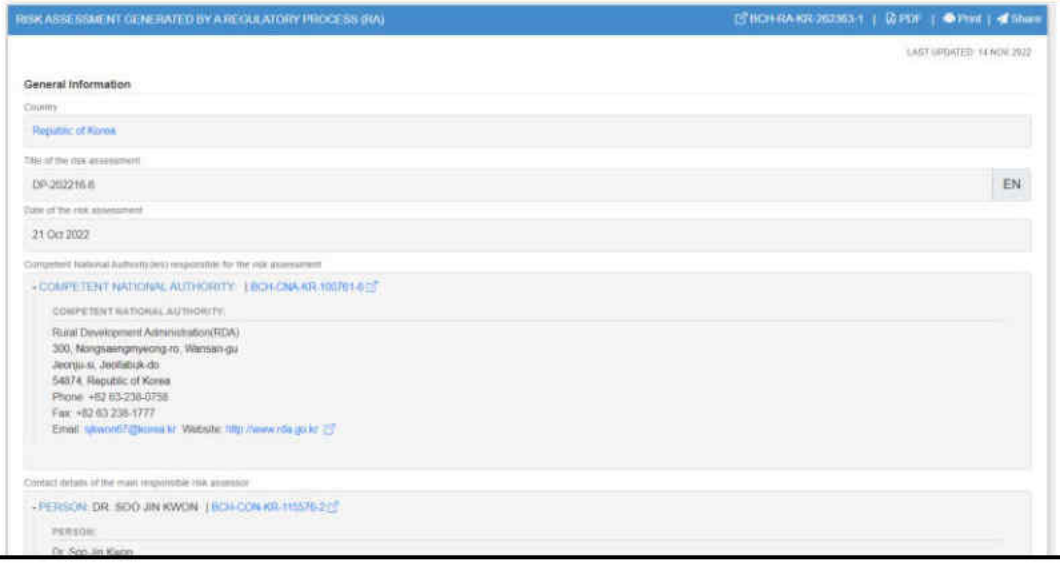
- The first international law to specifically regulate Modern Biotechnology.
- It recognizes that LMOs may have biodiversity, human health and socio-economic impacts, and that these impacts should be risk assessed or taken into account when making decisions on GMOs.
- It empowers governments to decide whether or not to accept imports of LMOs on the basis of risk assessments.
- Art.15 and Annex III of the CPB highlight the general principles, the methodology (steps of risk assessment) and points to consider.

Environmental Risk Assessment



Risk Assessment Records

- https://bch.cbd.int/en/database/RA/BCH-RA-KR-262363-1



Environmental Risk Assessment

LMOs Products thereof

Processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology

Environmental Risk Assessment

The Precautionary Approach

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."

Environmental Risk Assessment

General Principles

i. It must be carried out in a scientifically sound and transparent manner (reporting, verifiability, and reproducibility), and on a case-by-case basis.

ii. "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";

iii. "Risks associated with living modified organisms or products thereof, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment."

Individual Parties should use these general principles to guide the development and implementation of their own national risk assessment process.

Overview on ERA Process

1. Preparation phase

i. Establishing the elements of a case by case:

- The living modified organism: Characterization of the recipient organism and parental organisms, Description of the genetic modification, Identification of the LMO.
- The likely potential receiving environment(s):
  - Physical characteristics: geography, climate and soil and management status
  - Biological characteristics: living organisms and the interactions among them
- Intended use:
  - Context and exposure assessment
  - Consumers' habits, patterns, practices ?!!

Overview on ERA Process

1. Preparation phase

ii. Setting the context and scope:

- Protection goals:

- 'Ecosystems and Habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological process.'

- 'Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance for research into the conservation and sustainable use of biological diversity such as indicator species.'

Overview on ERA Process

1. Preparation phase

ii. Setting the context and scope:

- Selecting relevant assessment endpoints or representative species on which to assess potential adverse effects: to provide a measure to indicate whether or not the LMO may cause an adverse impact on a protection goal.
- Establishing baseline:
  - A snapshot of the environment prior to the introduction of the LMO.
- Establishing the appropriate comparator(s):
  - help in identifying the novel characteristics of the LMO.

Overview on ERA Process

2. Conducting Risk assessment

- Synthesizing what is known about the elements of the case to establish the likelihood and consequences of potential adverse effects to biodiversity and human health resulting from the introduction of the LMO.
- It has the following steps:
  - Hazard identification
  - Evaluation of the likelihood
  - Evaluation of the consequences
  - Estimation of the overall risk
  - Identification of risk management and monitoring strategies

Conducting risk assessment

Hazard evaluation

- Identification of novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects.
- Making well defined risk hypothesis or scenario and choosing representative species that can be affected by the LMO. This is why an exposure assessment should be considered when selecting assessment endpoints.
- E.g. 'Growing Bt corn may kill ladybird beetles due to ingestion of the Bt protein when preying on insects feeding on the GM corn, thereby reducing the abundance of coccinellids in the agroecosystem and increasing the incidence of pests'

Conducting risk assessment

Hazard evaluation

When establishing risk scenarios, several considerations may be taken into account. These include, for example:

- Gene flow followed by undesired introgression of the transgene into species of interest.
- Toxicity to non-target organisms.
- Allergenicity.
- Tri-trophic interactions and indirect effects.
- Resistance development.
- Will it perform as expected ?!!! (null hypothesis)

Conducting risk assessment

Evaluation of the likelihood

- Evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the LMO.
- The likelihood of an adverse effect may be dependent upon the probability of one or a series of circumstances actually occurring.
- E.g. Introgression of the transgene: outcrossing of the transgene with LMO with compatible non-modified organism and the likelihood of the establishment of the LMO progeny due to increased fitness resulting from the transgene.

Conducting risk assessment

Evaluation of the consequences

- Evaluation of consequences: They may be severe, minimal or anywhere in between. It may consider the effects on individuals (e.g. mortality, reduced or enhanced fitness, etc.) or on populations (e.g. increase or decrease in number, change in demographic, etc.) depending on the adverse effect being evaluated

- E.g. Consequences of the effects to non-target organisms: when the inserted trait causes the plant to produce potentially toxic compounds, or it flower characteristic are changed, i.e. color, flowering period, pollen production, etc. then effects on pollinators have to be measured. A test of effects on pollinators have to be measured. A test of effects on honeybees (Apis mellifera is always obligatory!!

Conducting risk assessment

Estimation of the overall risk (Risk Characterization)

- Integration of likelihood and consequence of each of the individual risks identified through the preceding steps, and takes into account any relevant uncertainty that emerged, thus far, during the process.

- The outcome of this step is the assessment of the overall risk of the LMO.

Conducting risk assessment

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Conducting risk assessment

Identification of risk management or monitoring strategies

- Risk Management: Measures to increase confidence when dealing with uncertainty or to the reduce likelihood or impact of the potential adverse effect to a level that is acceptable when the risk has been identified (Mitigation and preventive measures)
- Monitoring: Aims at detecting changes (e.g. in the receiving environment(s) or in the LMO) after the release of the LMO. It can designed on the basis of the protection goals identified by national legislation and regulation, if available,and those parameters relevant to the indication of any increasing risk to the assessment endpoints. The strategies include “general surveillance" and "case-specific monitoring".

Conducting risk assessment

Identification of risk management or monitoring strategies

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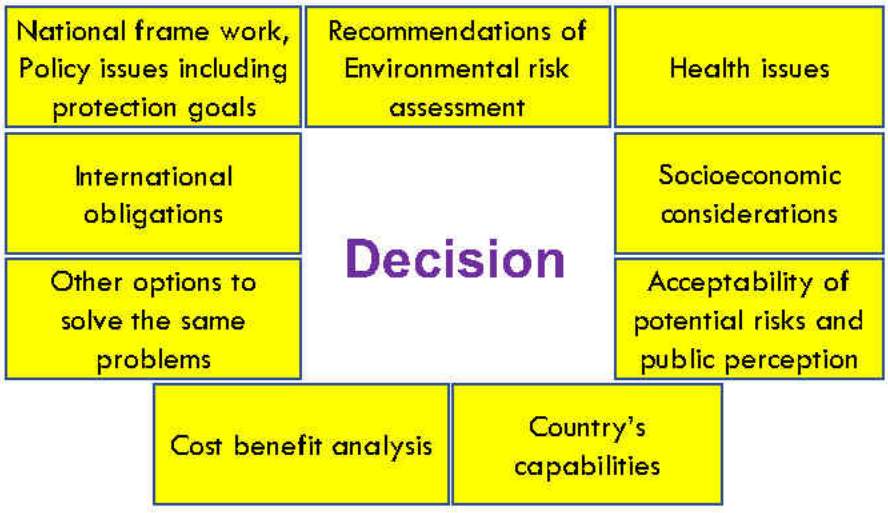
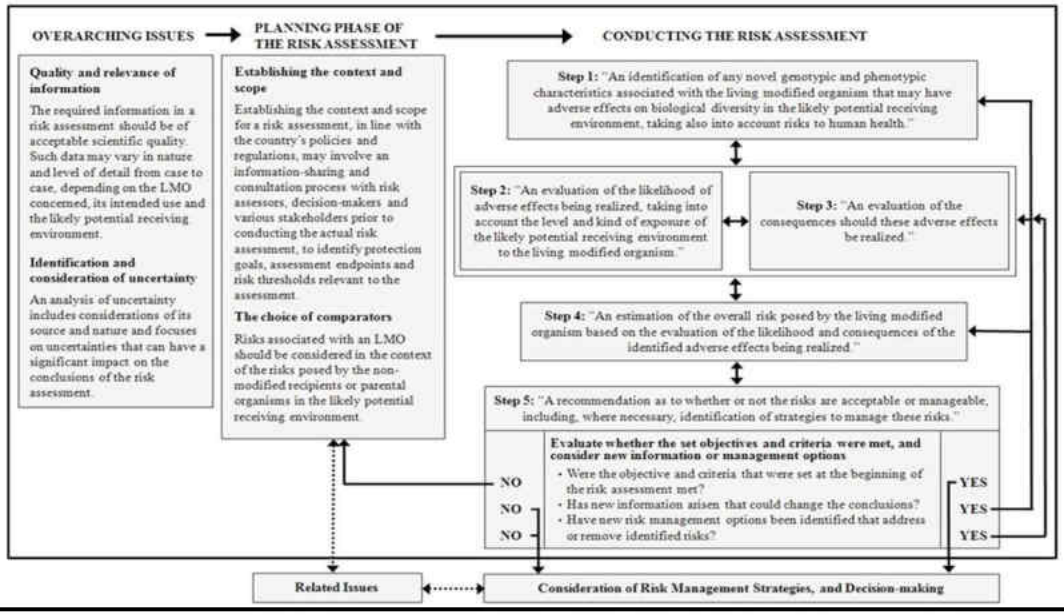
Monitoring:

- Aims at detecting changes (e.g. in the receiving environment(s) or in the LMO) after the release of the LMO.
- It can designed on the basis of the protection goals identified by national legislation and regulation, if available, and those parameters relevant to the indication of any increasing risk to the assessment endpoints.
- The strategies include "general surveillance" and "case-specific monitoring" to check for anticipated, cumulative, and unanticipated effects

Decision making



Overview of the RA Process



Exercises

Searching for information

CASE STUDY (CSFI11):

You work for the Competent National Authority in Ghana. You received your first application to import genetically modified papaya for field trials. The modified papaya contains a coat protein gene from the papaya ringspot virus (PRSV), making it resistant to the virus.

Q. Carry out a quick survey of relevant information on the BCH that may assist you in undertaking a risk assessment.

Searching for information

CASE STUDY (CSFI17):

You are a journalist based in Nigeria. You found the following unique identifier 'DAS-Ø15Ø7-1' on the documentation of a maize shipment. Use the BCH to answer the following questions:

Q1. What is the trade name for DAS-Ø15Ø7-1?

Q2. For what specific use is it imported?

Q3. What is the name of the importer?

Q4. What is the name of the competent national authority responsible for the decision regarding the import?

Q5. When were the decisions on the variety taken, and when were they published?

Q6. Is the import with or without conditions? Can it be used for human food?

Searching for information

CASE STUDY (CSFI07):

A Competent National Authority is contacted by a National Development Agency that wants to support efforts to strengthen environmental risk assessment training of regulators in the Caribbean. The agency wants to know if there are any opportunities for them to tie into existing capacity building programs that are already underway. Please answer the following questions:

Q1. What ongoing capacity-building programs are available for the Caribbean and/or other regions?

Thank you !

For more information, please email

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