UN environment programme

THE BCH III PROJECT

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# Environmental Risk Assessment

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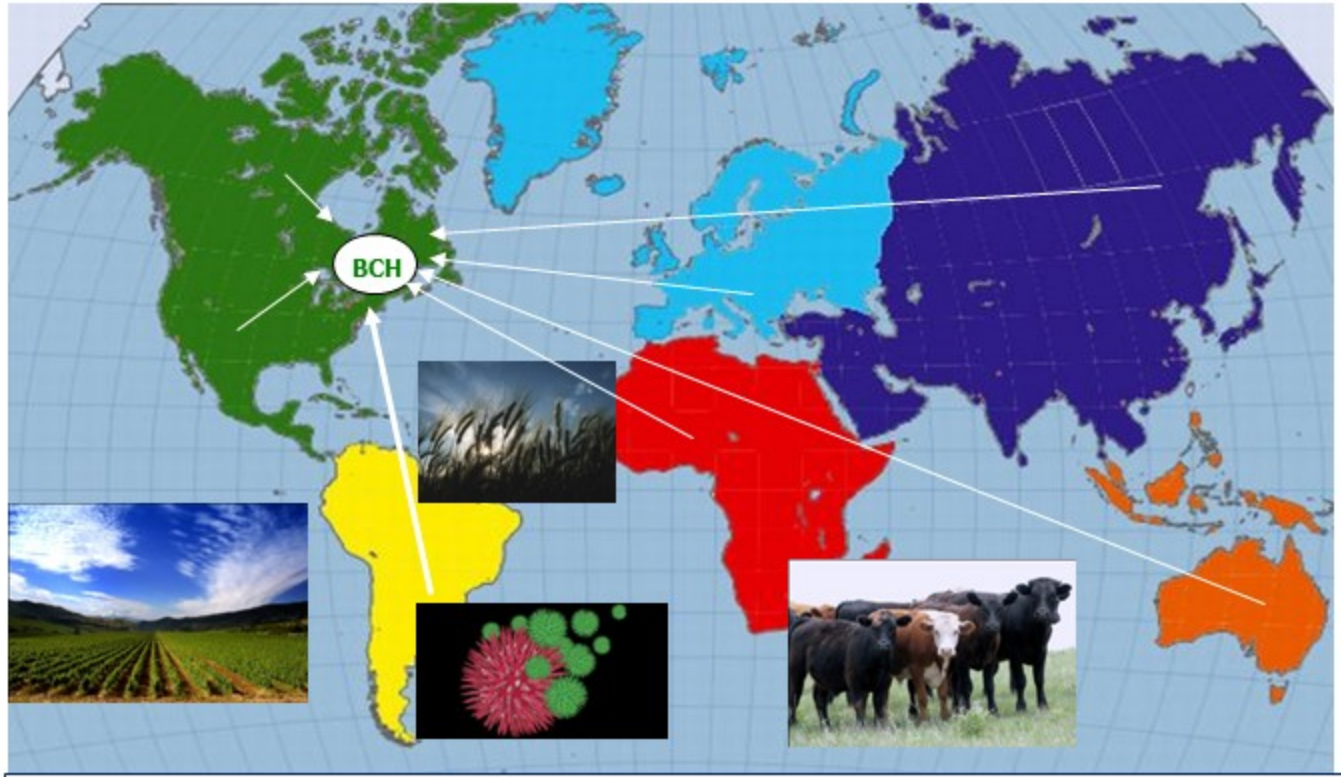
## CEE REGIONAL BCH TRAINING WORKSHOP

2024

# RISK ASSESSMENT




- The BCH is a very useful tool to assist evaluating and conducting risk assessment and support decision making on living modified organisms (LMO) and Products thereof

It constitutes a repository of scientific, technical, environmental and legal information on, and experience with LMOs.

# 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."

# RISK ASSESSMENT

- Synthesizing what is known about the LMO, its intended use and the likely potential receiving environment to establish the likelihood and consequences of potential adverse effects to biodiversity and human health resulting from the introduction of the LMO.

- Using and interpreting existing information, as well as identifying information gaps and understanding how to deal with scientific uncertainty, are crucial during the risk assessment.

# THE CARTAGENA PROTOCOL

- The first international law to specifically regulate Modern Biotechnology.
- It recognizes that GMOs 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.
- The Protocol 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

- **LMOs and 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,

# GENERAL PRINCIPLES FOR RISK ASSESSMENT

- Scientific soundness (Reporting, verifiability and reproducibility);
- The Concept of a case by case base (LMO, Receiving Environment and the intended use);
- 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;
- "Risks associated with living modified organisms or should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment. (comparator)

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

# ESTABLISHING THE ELEMENTS OF A CASE-BY-CASE RA

- Living modified organism
  - Characterization of the recipient organism or parental organisms
  - Description of the genetic modification
  - Identification of the LMO
- Likely potential receiving environment(s)
  - Physical characteristics
  - Biological characteristics
- Intended use
  - Consumers' habits, patterns, and practices?!!

# SETTING THE CONTEXT AND SCOPE

(i) Selecting relevant assessment endpoints or representative species on which to assess potential adverse effects;

(ii) Establishing baseline information; and

(iii) Establishing the appropriate comparator(s).

# 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: 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…"

# CONDUCTING RISK ASSESSMENT

1. Hazard identification;
2. Evaluation of the likelihood;
3. Evaluation of the consequences;
4. Estimation of the overall risk;
5. Identification of risk management and monitoring strategies.

# STEP 1

- Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects
- Making risk hypothesis or scenario
- E.g. "The possibility that 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."

# STEP 1

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; and
- Will it perform as expected ?!!! (null hypothesis)

# STEP 2

- 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 is dependent upon the probability of one or a series of circumstances actually occurring
- E.g. Introgression of the transgene: Outcrossing of the transgene with a non-modified organism and the likelihood of the establishment of the LMO progeny due to increased fitness resulting from the transgene for example

# STEP 3

- 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 demographics, etc.) depending on the adverse effect being evaluated.

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

# STEP 4

- 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, this far, during the process.
- The outcome of this step is the assessment of the overall risk of the LMO.

# STEP 5.

- 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".

# MONITORING

- Three categories of effects should be monitored: :
  - Anticipated effects which fall mainly but not exclusively under case specific monitoring (CSM),
  - Interactive or cumulative effects These include "e. g. effects That might arise as a result of an Increase in the scale of cultivation and potential effects arising as a result of interactions between the GM crop and future varieties." and
  - Unanticipated effects ["i. e. potential effects not identified in the ERA (environmental risk assessment), which can only be addressed by general surveillance."

| | Case specific monitoring | General surveillance |
|---|---|---|
| Used for investigating | potential adverse effects identified during the RA are investigated e.g. Effects that rarely occur, but may have large environmental implications. (effects on soil functions due to horizontal gene transfer). | (i) Effects identified in RA but are difficult to predict or assess with regards to either the likelihood of exposure (e.g. cumulative effects by releasing different types of GMOs with the same transgenic traits, like herbicide tolerance genes or Cry-toxins) or with regards to the consequences (e.g. effects resulting from increasing the cultivation scale in a wide area and for a long time period).<br>(ii) Effects which are difficult to assess because of their complexity (e.g. impacts on ecological functions, food-chain effects); and<br>(iii) unanticipated effects |
| Based on | Identified scenarios that are case specific, for instance to take mitigation or preventive measures | Overseeing of the geographical regions where GM plants are grown without having any specific hypothesis on adverse effects on human health or the environment. As General Surveillance is not hypothesis-driven, it is not conducted using directed experimental approaches However, robust scientific methodology should be applied wherever possible in order to produce statistically valid data for determining causes and effects |
| Relevant articles | Article 8j annex III of the CPB | Articles 7 and 8 of the CBD emphasize the need to identify and monitor important components of biological diversity for the purpose of managing or controlling the risks associated with the use and release of LMOs that are likely to have significant adverse effects |

# RISK ASSESSMENT

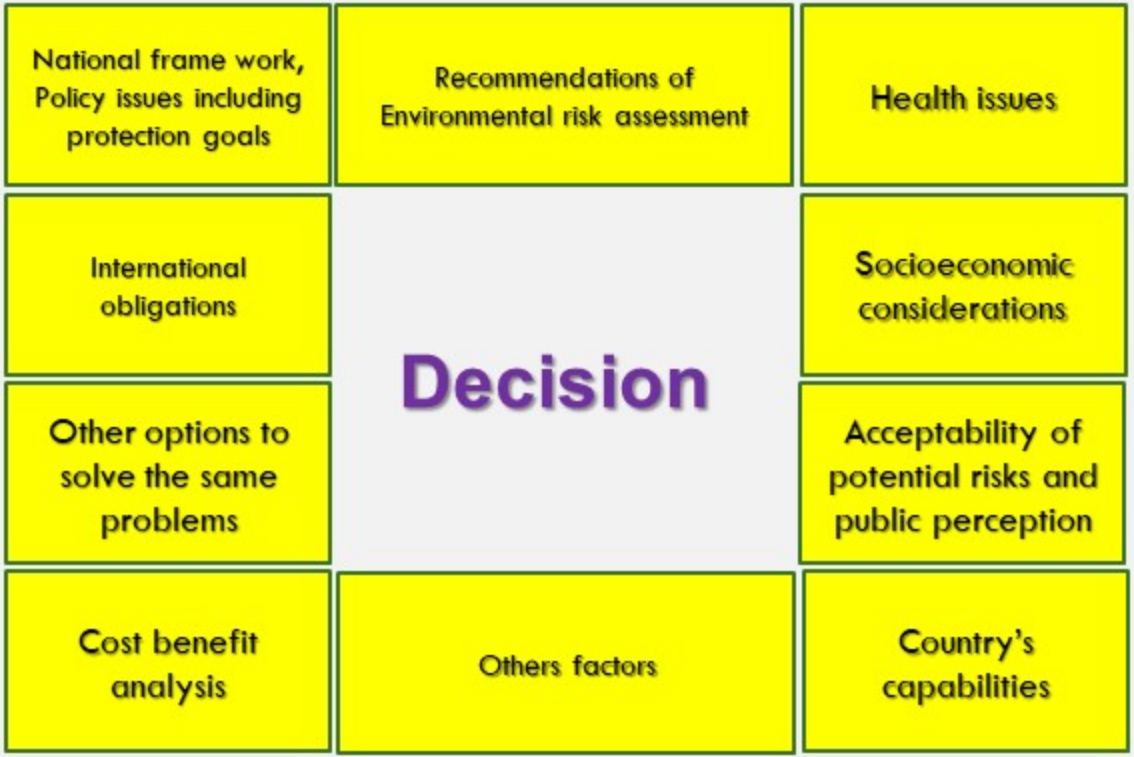
## CONDUCTING RISK ASSESSMENT

- The risk assessment process may also need to be conducted in an iterative manner, where certain steps may be repeated or re-examined to increase or re-evaluate the reliability of the risk assessment.

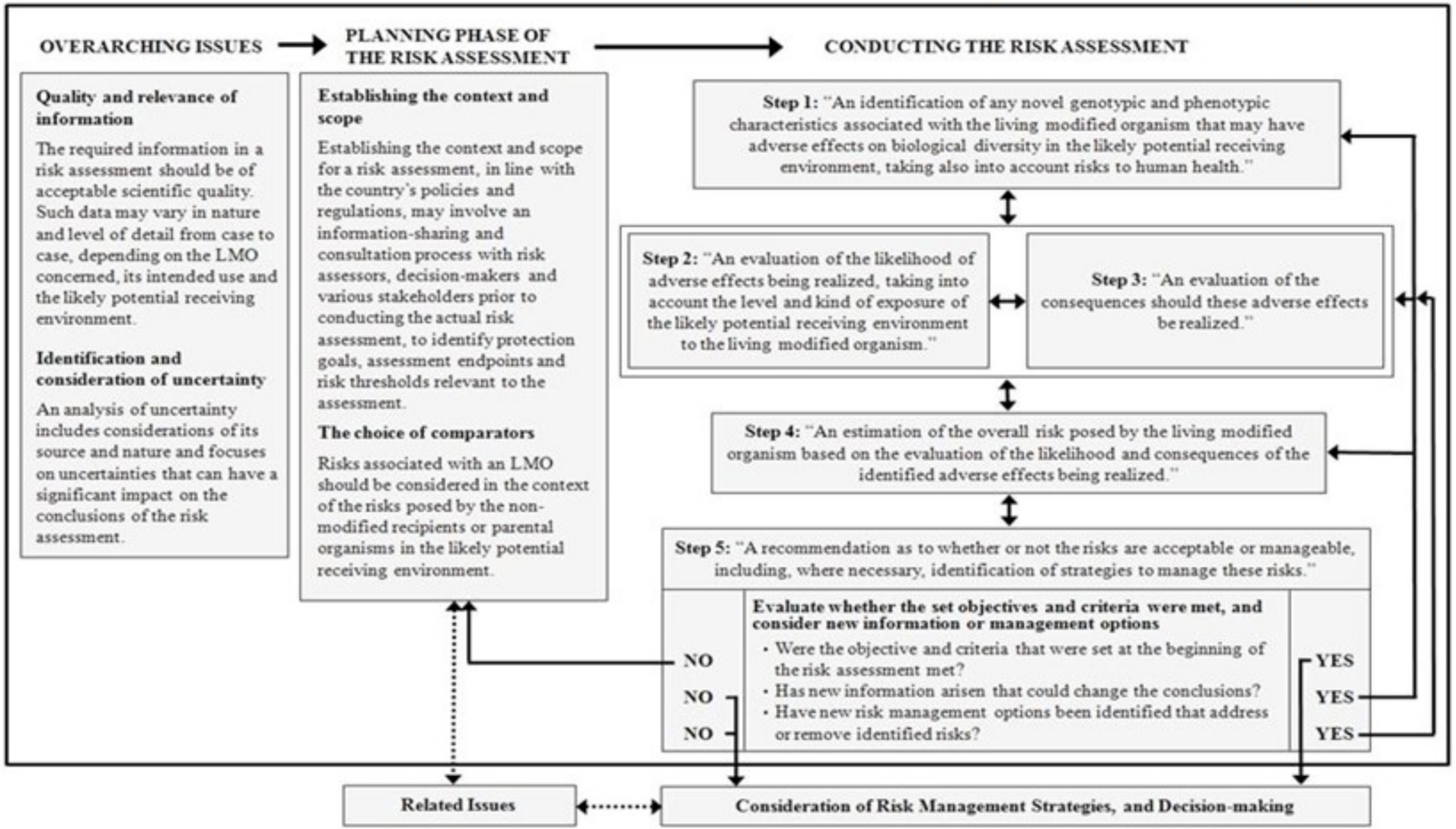
- As uncertainty is inherent in the concept of risk, it is important to consider and analyze, in a systematic manner, the various forms of uncertainty that can arise at each step of the risk assessment process. Ultimately, it is the responsibility of the decision-makers to decide how to take into account the precautionary approach when making a decision on an LMO. Precaution is the basis for the Protocol itself, and is operationalized in risk assessment and decision-making..

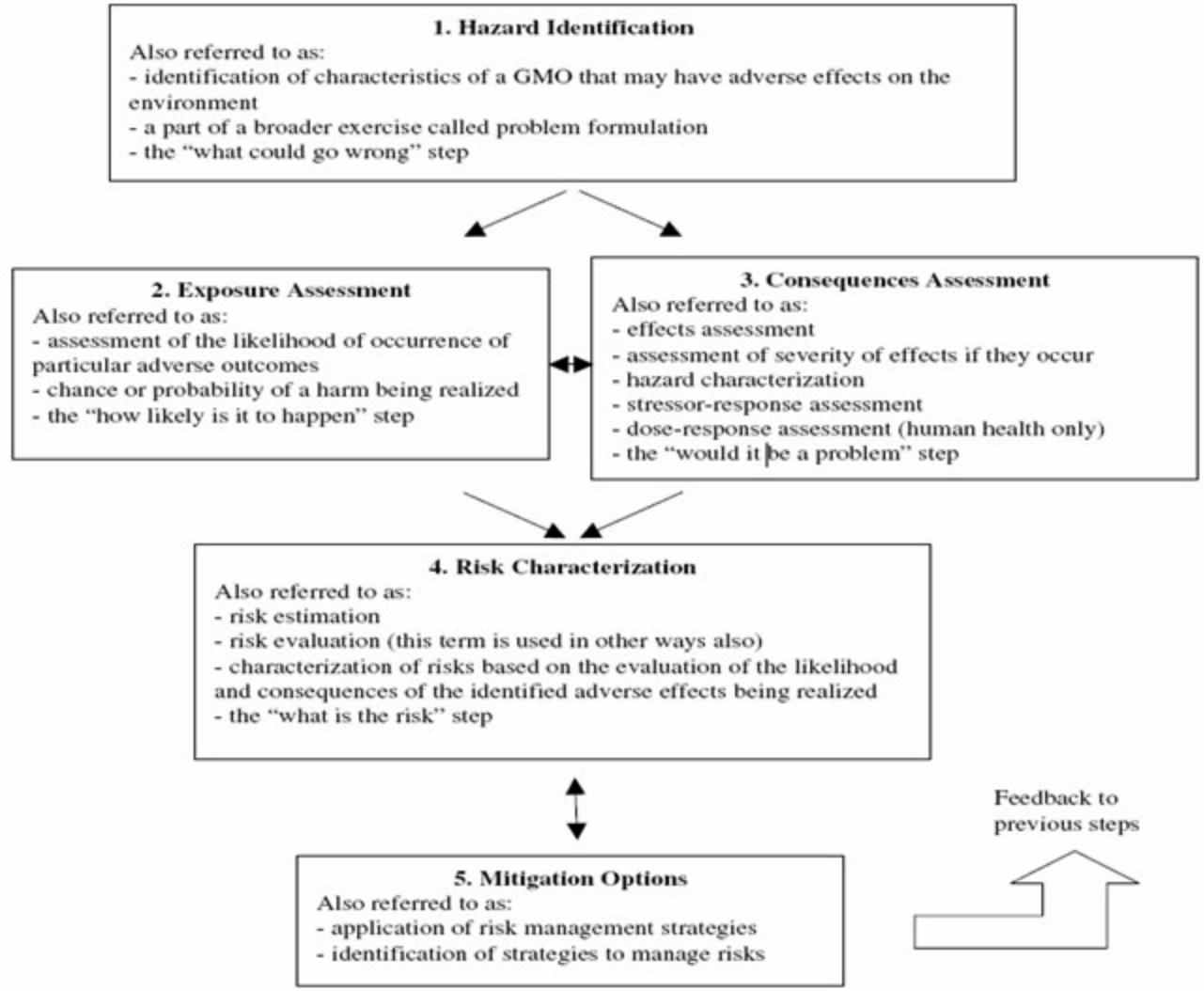
# RISK ASSESSMENT

## DECISION MAKING



# OVERVIEW OF RISK ASSESSMENT PROCESS (FLOW CHART)




1. Hazard Identification
Also referred to as:
- identification of characteristics of a GMO that may have adverse effects on the environment
- a part of a broader exercise called problem formulation
- the "what could go wrong" step
2. Exposure Assessment
Also referred to as:
- assessment of the likelihood of occurrence of particular adverse outcomes
- chance or probability of a harm being realized
- the "how likely is it to happen" step
3. Consequences Assessment
Also referred to as:
- effects assessment
- assessment of severity of effects if they occur
- hazard characterization
- stressor-response assessment
- dose-response assessment (human health only)
- the "would it be a problem" step
4. Risk Characterization
Also referred to as:
- risk estimation
- risk evaluation (this term is used in other ways also)
- characterization of risks based on the evaluation of the likelihood and consequences of the identified adverse effects being realized
- the "what is the risk" step
5. Mitigation Options
Also referred to as:
- application of risk management strategies
- identification of strategies to manage risks
Feedback to previous steps

# EXERCISES


SUBJECT
RESEARCH
METHOD
KNOWLEDGE
CASE STUDY
CONCLUSION
CRITERIA
EVIDENCE
DATA


Case Study
research
subject
case
studies
knowledge
cases
may
theoretical
single
study
local
thus
focus
whether
retrospective
Outlier
evidence
criteria
information
object
based
quantitative
in-depth
circumstances
researchers
multiple


case studies

# 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.

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?

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- The Cartagena Protocol in its annex III, sets out points to consider in Environmental risk assessment.

-These points are relevant to the elements of a case-by-case approach.

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;

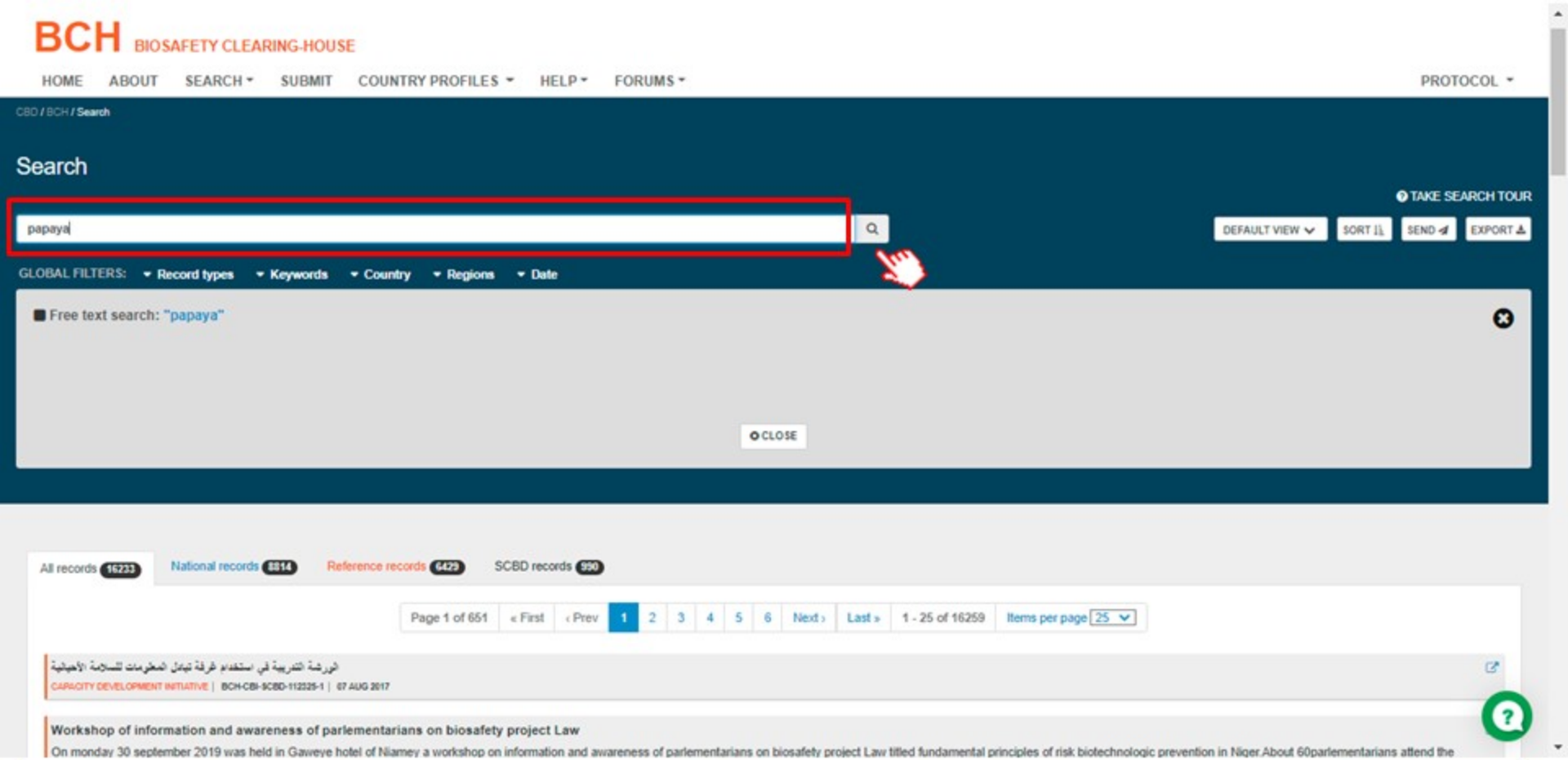
(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

# SEARCHING FOR INFORMATION

## CASE STUDY (CSFI11): (BRAIN STORMING)

-**In addition to the information relevant to the case-by-case elements, you could also benefit from**

- Contact details for relevant experts
- Biosafety Regulatory system of the country (e.g. biosafety policy where the protection goals are identified, the presence of national risk assessment framework)
- Risk assessment summaries performed in other countries (may be useful although most probably not sufficient for decision)
- Decisions taken in other countries (for different uses, for example) and contact details for those countries' focal points
- Relevant scientific background information
- The Monitoring plan and emergency measures plan




*Go to the search page of the BCH, then type 'papaya' in the 'Free text search' and click 'enter' or on the 'magnifier' icon.*

# SEARCHING FOR INFORMATION

## CASE STUDY (CSFI11): (BRAIN STORMING)

*Then classify the records into the following categories:*

1. *Records relevant to the points to consider*
2. *Records for relevant experts*
3. *Ghana Biosafety Regulatory system*
4. *Relevant risk assessment summaries*
5. *Relevant decisions*

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# 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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