Canada-Norway Expert workshop on risk assessment for future applications of modern biotechnology

CEE Regional Workshop on Capacity Building in LMO Risk Asessment

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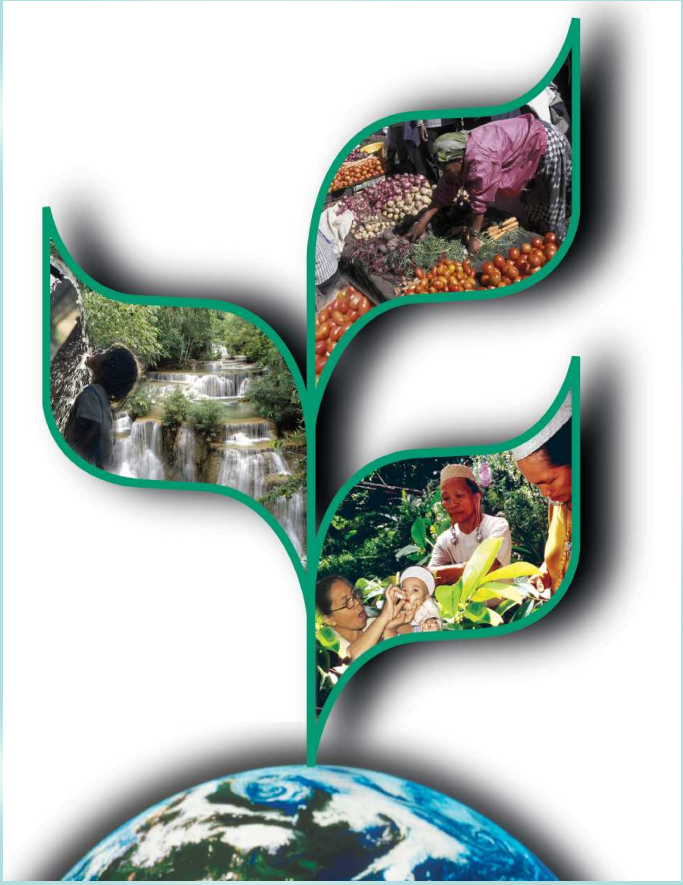
Overview

- **Background**
- **Purpose of the workshop**
- **Recommendations from the four working groups and the summary recommendations of the Workshop**
- **Way forward?**

Background

- The Cartagena Protocol states the importance of scientifically based RA
- The RA priciples in Annex III of the CP are very general
- RA discussed since first meeting of Parties



Ad Hoc expert Group on Risk Asessment

- Establishment of an *ad hoc* group to consider: existing guidelines for RA, identify gaps and consider need for capacity building (Rome meeting, November 2005)
- Some conclusions:
  - Sufficient ”general” guidelines
  - Lack of specific guidelines for several GM plants, animals and microorganisms
  - Certain lack of empirical data which are necessary for RA

Next steps after the AHTEG

- Conclusions from the Rome meeting were the basis for discussions at **COPMOP/3 (BS-III/11)**
  - Consider the need and way forward for specific guidance for particular LMOs → will be discussed at **COPMOP/4**

- **Norway & Canada** suggested co-hosting a workshop to consider environmental risk assessment of certain categories of LMOs

Purpose of Can/Nor WS

- Look at current state of art/available science useful for RA
- Available guidance
- Identify gaps of knowledge/guidance

- **4 chosen topics**: LMO fish, trees, pharmaplants and viruses
- Plenary and WG discussions

Working group - fish

Model species (and ornamental)

Growth hormone

Production of pharmaceuticals

Disease resistance

GM-fish: Some conclusions

- **Issues concerning ERA unique to fish**:
  - Fish are not domesticated, wild animals that move easily to different, possibly large geographical areas
  - Fish have potential for rapid population expansion
  - Fish are ectothermic by nature → sensitive to changes in abiotic conditions

Specific issues fish- continued

- Introduction of fish into new areas is highly uncontrolled
- Fish will interact with many different species in broad areas
- Field trials often cannot be carried out, thus it is important to have lab experiments with conditions close to nature, use of surrogate models

Recommendations - specific data needs

- Method development needs
- Develop different worldwide scenarios on the introduction of GM-fish into the environment by an expert group (ecology, fish physiology & genetics)
- Sensitivity analysis in models to identify critical life stages/fitness components etc.
- Identify more model fish study environmental risk assessments
- Develop case-by-case protocols for GM-fish assessment

WG-trees

- Forest tree field trials: *Populus*, *Pinus*, *Eucalyptus*
- Fruit trees: *Carica* Papaya (commercial), *Malus*, *Prunus* etc


GM poplar in China


Papaya

GM-trees: Some conclusions

- **Specific characteristics of trees**:
  - Perennial, Release may be long term
  - Often many years before flowering
  - Complex ecological background
  - Huge range of domestication from non-domesticated to highly managed
  - Often dominant species in the environment

Gaps of knowledge

- How to properly measure fitness as a basis for risk assessment?
- Field trials – strategy and duration?
- Baseline knowledge to understand state of environment before introduction of GM-trees (specifically in semidomesticated, unmanaged systems)
- Pleiotropic effects
- Study of myccorhizae & interacting microflora

Recommendations

- Consider trees in the managed and wild habitats differently
- Study effective way of risk assessment for trees, taking into account the life cycle of trees
- Identify effective measurement of fitness suitable for trees

GM-viruses for management of wild animal populations

- Case study: GM-virus release and case of *conservation versus control* of rabbits (Angulo and Cooke, 2002)
- Challange: transboundary movement and different aims in different countries, specific characteristics of viruses

WG- Viruses for management of animals: case Australia

Problem:

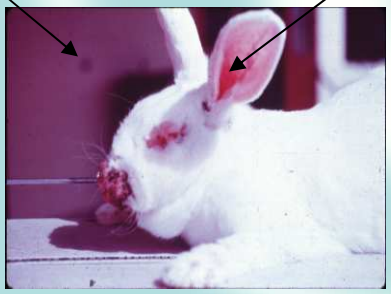
Solution: Use of GM-virus with gene
coding for Rabbit zona pellucida glyco-
protein B to produce immunocontraception

GM-Viruses: Case Spain

Iberian lynx

Imperial eagle

Myxoma virus (a poxvirus)



Rabbit with symptoms of myxoma virus

GM-Viruses: some conclusions

- Very little data or information exists on environmental effects of GM-viruses as previous focus has been on human or animal health
- Guidance on environmental effects is limited or non-existent (partial guidance may be found e.g. viral shedding to the environment)

Knowledge gaps & recommendations

- There is insufficient knowledge of biology of viruses concerning ecological interactions and therefore a need to:
  - develop consensus documents summarizing existing body of knowledge e.g. On Vaccinia, Adenovirus
  - Identify groups of viruses according to their use
  - Develop or use existing international databases

Knowledge gaps - ctd

- There is insufficient knowledge of:
  - Indigenous viruses (in area of intended release) → these are sources of possible recombination
  - Virus/host interactions (e.g. host range, co-evolution, cytopathogenicity). Tiered, case-by-case approach with both wild type and modified virus
  - Need for co-ordination and collaboration between existing organisations!

WG-Pharmaplants

Edible vaccines

Pharmaplants for extraction of compounds

Pharmaplants – issues of RA

- The line between RA and RM is not always clear in the case of pharmaplants (PP)
- No special restrictions to date concerning which plants to use for pharmaplants (exception: Mexico → no use of maize)
  - Crop plants: risk of entry into food-chain
  - Non-crop plants: biological properties less known (weediness, persistance etc)

Select criteria for choice of plant species?

Issues of RA - ctd

- Toxicity to non-targets may even be more relevant to consider than in other GM plant cases (level of protein expression is very relevant)
- Environmental degradation of pharma protein vs. persistance in environment
- Non-target effects after release of PP: important to consider biological activity of protein produced

Recommendations

- A number of general RA elements apply equally to PP and non-PP, but certain special characteristics of PP may require a unique approach to prevent or reduce the risks to biodiversity / human health

- **Knowledge gaps** were found, amongst others, in the following areas:

Knowledge gaps

- Processes by which the PP (products) may enter the food/feed chain & potential effects on humans, animals and non-target organisms
- Phenotypic effect of high levels of newly expressed proteins, pleiotropic effects
- Potential for occupational hazards
- Handling of PP for direct consumption
- Effect of disposal in environment

Overall Summery and Conclusions of the Workshop

- General Principles and methodologies for risk assessment (Annex III of the Protocol) apply
- Insufficient guidance for GM fish and viruses
- Need for specific methodologies and protocols for data generating
- Need for additional data, further research to fill knowledge gaps
- Feild trials and alternative models for generating data
- Highly managed and wildlife ecosystems
- Use of BCH to exchange information

Way forward?

- Report has been distributed to national governments and the CBD Secretariate
- will be formally submitted in due time as an input to COPMOP/4
- Discussion at COPMOP/4
  - Further meeting of an AHTEG?
- Other Possibilities?