ENVIRONMENT AGENCY AUSTRIA umweltbundesamt

International Guidance on Risk Assessment of GMOs

The Cartagena Protocol on Biosafety

Introduction of the Speaker

- Dr. Helmut Gaugitsch
- Environment Agency Austria, Head of Unit Landuse & Biosafety
- Biotechnologist and molecular biologist by training, dealing with environmental effects of land use activities including risk assessment and monitoring of GMOs/LMOs
- Former chair of the OECD Working Group on Harmonization of regulatory oversight in biotechnology, as well as the UN ECE Aarhus Convention Working Group on GMOs
- Currently Chair of the Cartagena Protocol AHTEG on Risk assessment and risk management

Topics

- The Cartagena Protocol Draft Guidance on Risk Assessment of LMOs
  - AHTEG: the Process
  - Current stage of the Work
  - The way forward

Cartagena Protocol - Background

- Risk Assessment is a corner stone in decision making
- Transboundary movement and import
- Intentional release – field trial, commercialisation of an LMO product
- COPMOP Decisions on Risk Assessment and Risk Management
- Ad Hoc Technical Expert Groups

Cartagena Protocol – AHTEG on Risk Assessment and Risk Management

- COPMOP-4, Bonn, May 2008
- Establishment of an Ad Hoc Technical Expert Group on Risk Assessment – Mandate, 28 members
- Development of a „Road Map“ on Risk Assessment
- Further Guidance on Specific aspects of risk assessment
- Recommendation to COPMOP-5, Nagoya, October 2010
- Extend the current open-ended online forum and the AHTEG

AHTEG – Current Mandate

- Work primarily online to revise and test the version of the Guidance on the basis of a scientific review process
- Assess the overall utility of the Guidance to LMOs across different taxa and receiving environments

- Expected outcomes:
  - Revised version of the Guidance on Risk Assessment of LMOs
  - Mechanism for update of background materials
  - Further Guidance on new specific topics of risk assessment

Guidance on Risk Assessment of LMOs

- Part I: Roadmap for Risk Assessment of LMOs
- Part II: Specific Types of LMOs and Traits
  - LM plants with stacked genes or traits
  - LM plants with tolerance to abiotic stress
  - LM Mosquitoes

- Further Guidance (since AHTEG – 3):
  - LM Trees
  - Monitoring of LMOs released into the environment

The Roadmap

What is the roadmap for LMO Risk Assessment?

- Build on and complement Annex III
- Further guidance on how to undertake an LMO risk assessment
- All types of LMOs
- All types of applications (field trials, commercial products)

- Overarching issues such as consideration of uncertainty
- Planning Phase of the risk assessment
- Conducting the risk assessment (5 Steps)
- Flowchart (Visualisation of the Roadmap)

Planning Phase of the Risk Assessment

Setting the context and scope: may involve a process that includes risk assessors, decision makers and various stakeholders

- Existing policies and strategies (e.g. protection goals, assessment endpoints, risk thresholds and management strategies)
- Nature and level of detail of information
- Methodological and analytical requirements
- Experience and history of use of non-modified recipient
- The choice of comparators

Conducting the Risk assessment

- Step 1: Identification of potential adverse effects
- Step 2: Evaluation of the likelihood
- Step 3: Evaluation of the consequences
- Step 4: Estimation of the overall risk
- Step 5: Recommendation whether risks acceptable or manageable, any risk management strategies

Detailed contents of Roadmap

For each step:

- Rationale
- Points to consider
- Links to background material

Step 1

- Identification of any novel genotypic and phenotypic characteristics that may have adverse effects
- Rationale: identify biological changes resulting from the genetic modification – „hazard identification“, comparison with non-LMO
- Points to consider (*examples*):
  - Characteristics of the recipient
  - Molecular characteristics of the LMO
  - Genotypic or phenotypic changes
  - Receiving environment
  - Interaction LMO/environment (e.g. outcrossing, uncertainty)

Step 2

- Evaluation of the likelihood of adverse effects
- Rationale: whether the environment will be exposed, potential of the LMO to spread or establish, possibility of adverse effects to occur (tox, allergenicity, non-target effects)
- Points to consider:
  - Type and intended use of the LMO
  - Levels of expression
  - Receiving environment
  - Outcrossing
  - Expected exposure

Step 3

- Evaluation of the Consequences
- Rationale: magnitude of the consequences in the environment, test results, comparative evaluation (non-modified organism, existing practice)
- Points to consider:
  - Experience with consequences of existing practice
  - Combinatorial and cumulative effects in the environment
  - Results from the lab
  - Expression of the transgene in sexually compatible species

Step 4

- Estimation of the overall risk
- Rationale: based on steps 1, as well as 2 and 3.
- Points to consider:
  - Steps 1 to 3
  - Interaction between individual risks
  - Consideration of uncertainty arising in this and the previous steps

Step 5

- Recommendation whether risks are acceptable or manageable, strategies to manage risks?
- Rationale: interface risk assessment/risk management. Risks not acceptable or manageable – risk management? Iterative process with risk assessment.
- Points to consider:
  - Existing management practices (e.g. isolation distances)
  - Methods to detect and identify LMOs
  - Management options?
  - Criteria and thresholds for acceptable/unacceptable risk
  - Baseline for comparison

Additional Guidance

- Risk Assessment of LM Trees
- Monitoring of LMOs released into the environment (heavily discussed!) – Case specific monitoring, General Surveillance

Next steps

- Further development of the Guidance
- AHTEG -4 in June 2012: Finalization of tasks
- Report and Decision at COPMOP-6, India, October 2012

Further information on Cartagena Protocol and AHTEG

- http://bch.cbd.int/protocol/
- Biosafety Clearing House: http://bch.cbd.int/

GMOs in other international instruments

- WTO: SPS, TBT
- Codex Alimentarius (Food)
- Interntaional Plant Protection Convention (IPPC)
- OIE (animals)
- OECD
- Aarhus Convention

Contact & Information

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