ENVIRONMENT AGENCY AUSTRIA umweltbundesamt

Environmental Risk Assessment Austrian Perspective

Andreas Heissenberger

Introduction

- General criticism
- ERA model and problem formulation
- Field trials
- Regional aspects
- Non-target organisms
- Monitoring
- Conclusions

General Criticism

- Data provided by the applicant not sufficient to perform a comprehensive ERA
- Basic requirements sometimes not met (low number of replicates, data incomplete, pooling of data, ...)
- extrapolation not sufficiently justified (different regions, different GMOs)

The ERA model and problem formulation – current problems

- GMO = plant + new compound
- Substantial equivalence
- Testing of the new compound only, e.g. Bt-toxin
- Secondary stressors (e.g. herbicides) excluded
- No investigation of possible unintended effects
- Secondary effects neglected

- Risk research hypothesis is missing
- Choice of comparators often not scientifically sound (influence on outcome)
- Effects are declared as „biologically irrelevant“

The ERA model and problem formulation – proposals

- Definition of hazard and scope
  - Focus on possible adverse effects that pose high risk
  - Define case (plant, novel trait + phenotypic characteristics, receiving environment)
- Exposure assessment
  - Research hypothesis and selection of test organisms based on relevant exposure pathways
- Determination of possible effects
  - Practical testing (testing vs. extrapolation)
- Risk characterisation
  - Data evaluation (outcome linked to hypothesis)

Field Trials – current problems

- varying and inconsistent design and methods
- data presentation often unclear
- insufficient characterisation of locations
  - representative?
  - comparable to the environment where the GMO will be used?
- duration (in many cases only one season)
- comparators (not always specified clearly)
- replication (no power analysis, lack of information, varying numbers, …)
- pooling of data across locations, from different field trials,…

Field Trials – proposals

- Clear guidance necessary
  - Definition of the aim of the field trial(s) or trial series
  - Experimental units (plot sizes, number of plants, sampling plan,...)
  - Number of locations and replicates necessary
  - Criteria for the selection of locations
  - Comparators
  - Statistical evaluation and interpretation of results

Regional Aspects – current problems

- Receiving environments (according to Directive 2001/18/EC) not considered sufficiently
- EU field trials very limited
- Different climatic conditions lead to different ecological situations
  - Physiology of the plant
  - Non target organisms
- Extrapolation of data not or not sufficiently justified

Regional Aspects - Proposals

- Choice of areas for field trials should cover different ecological situations
  - EEA model of bio-geographic areas
- Special consideration of ecological sensitive areas and/or protected areas
  - Council Conclusions December 2008

Non Target Organisms – current problems

- Lack of problem formulation, research hypothesis
- Insufficient description of test design and methodology
- Selection of test organism
  - Ecologically not always relevant
  - Not from receiving environment
  - Developmental stages not tested adequately
- Tiered approach
  - No criteria to evaluate if data are sufficient (stop testing or move to next tier)

Non Target Organisms – proposals

- Clear research hypothesis for laboratory tests and field trials (also for tiered approach)
- Selection of target organisms – stepwise approach
  - Functional groups (e.g. herbivores, pollinators, soil organisms) for relevant environment
  - Select most important species from each functional group (focus will reduce species to test)
- Test protocols need to be improved (whole plant studies vs. isolated protein)

Monitoring – current problems

- Lack of case specific monitoring
  - E.g. effects on non target organisms
- General surveillance
  - No or only few scientific studies
  - Mainly based on farmers questionnaires
  - Lack of scientifically sound long term data for renewal of applications

Monitoring – proposals

- Uncertainties and shortcomings in the ERA need to be considered for case specific monitoring
- General surveillance
  - Definition of parameters and aspects to be monitored
  - Use of existing networks and programs, check if routine data are adequate for GM monitoring
  - Scientific studies

Conclusions

Case-by-case principle is necessary and should be followed

but

for certain aspects (e.g. statistical approach, design of field trials, etc.) better standardisation is absolutely necessary to guarantee quality of data and a scientific sound approach to environmental risk assessment.