



Introduction to Monitoring

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- Monitoring according to Directive 2001/18
- Case-specific monitoring
- Requirements for General Surveillance
- Existing environmental networks
- Recommendations

Monitoring

- Investigation of effects on the environment and human health
- Case specific monitoring
- General surveillance

- 2001/18/EC lays down requirements for
 - Field releases in Annex III (information requirements)
 - Placing on the market in Annex VII plus Guidance notes
- No formalized procedure
- Notifier has to develop programme
- Evaluation by CA (may ask for additional parameters)
- Case-by-case decision
- multidisciplinary

Company

- Development of monitoring plan
- Performance of monitoring concerning field releases

Authorities

- Evaluation of monitoring plan (additional requests)
- On-site inspections
- Probably perform monitoring in co-operation with company and research institutions at field releases
- Monitoring and inspection concerning placing on the market

- Interdisciplinary approach covering effects on the environment and human health
- Environment
- Botany (Ecology, population ecology, ...)
- Zoology (Entomology, Ornithology, ...)
- Microbiology (classification, bio-geo-chemistry, ...)
- Molecular biology (detection, stability, ...)
- Phenotypic methods (herbicide spraying, ...)

Federal Environment Agency

- Monograph "Ecological Monitoring of GMOs"
- Monitoring Concepts for Oilseed Rape and maize
- Case studies: GMO contamination in conventional maize

Scientific Disciplines (in collaboration with University Institute)

- Vegetation ecology
- Entomology
- Soil microbiology
- Molecular biology (plant - green tissue, cob; soil)
- Final report end of 2004
- On behalf of main CA

Further considerations

- Baseline for comparison
 - Non-GMO plots
 - isogenic lines
 - comparable ecological conditions
- Clear distribution of competencies and tasks
 - Notifier
 - CA
 - Science

Further considerations

- Concepts for case - specific Monitoring and General Surveillance
- Storage and Interpretation of Data (Registers)
- Financing of the development and implementation of concepts
 - Public
 - Private

Requirements for General Surveillance

- Legal requirement: Based on Annex VII and the Guidance Notes
- What are the questions to be answered? (hypothesis, checklist)
- Scientifically valid design:
 - Parameters and methods
 - Time frame
 - Sampling and statistics
 - Baseline
 - Reference areas
- Is the programme able to answer the questions in a scientific way?

- There is no Monitoring without hypothesis
- What is a hypothesis?
- Indicators for testing
- Distinction between CS-monitoring and GS?
- More important:
 - Which kind of monitoring is necessary?
 - Arguments for not performing certain tasks
 - Interpretation of results
 - Compilation of results (regional, national and EU-wide)
 - Responsibilities of notifiers?

Possible useful example

- Austrian study „Biodiversity hotspots in agro-ecosystems as a basis for risk assessment and monitoring of GMOs“, available end of 2005
- Plant ecology and entomology (butterflies)
- Result: Data Base, GIS map
- Baseline knowledge, Monitoring parameters
- Reference areas

Recommendations for General Surveillance

- Specific development and implementation of General Surveillance
- Use experience from Biodiversity and FFH Monitoring
- Develop concept (list of questions) for GS
- General Surveillance is the answer, but what is the question?
- Grey area between CS-Monitoring and GS:
 - Further work on baseline, indicators, reference areas
 - Regional basis, EU wide compilation