

Annex 9

Assessment:

Issues raised by CAs and MSs

1. New Guidance on ERA

- Detailed Protocols for ERA:
- Non-Target testing

2. New Approaches to ERA :

- > Risk – Benefit Assessment etc...
- > HT crops

3. Monitoring Methods :

Colloquium 8

Environmental Risk Assessment of Genetically Modified Plants: Future Challenges

20 -21 June 2007, Tabiano, Italy

1. Testing sensitivity of Non-Target organisms:
Approaches and Methods
2. Large scale/ long term Effects. Modelling in relation to scale
3. Broadening Scope of ERA : implications for agriculture, agricultural practices > environment
Risk - benefit analysis....

1. Testing sensitivity of Non-Target organisms: Approaches and Methods

- **GMO Panel Consider Working Group on methods for testing non-target organisms**
 - including statistical design and power, test species, environmental interactions,..
- **Use expertise from IOBC working groups and others**
- **Full consultation with all stakeholders**
- **Develop more detailed Guidance**

2. Large scale/ long term Effect Modelling in relation to scale

- ERA can only go so far
- GMO Panel propose that EFSA Statistics WG examine modelling issues
- Post Market Environmental Monitoring
EC and MS need to agree Strategies
 - Follow guidance from EFSA, ACRE and several other MSs

GMO Panel Proposed Procedure :

- ERA will indicate potential for adverse (and beneficial) effects of Herbicide Management on Biodiversity.
- ERA will recommend that Herbicides are managed so as to maintain or improve current levels of biodiversity in crops and fields.
- Risk managers (eg CAs and EC) put in place management and monitoring systems for use of the herbicides on

Broadening Scope of ERA

- **GMO Panel will consider establishing Working Group and Consultation**
- **Consider:- Risk : Benefit analysis**
 - Life Cycle Analysis**
 - Matrix Analysis**
 - Other RA methods**

Full consultation with Stakeholders

Environmental Risk Assessment

- Several MS/CAs now assessing cultivation dossiers
- Appreciate their work
- Encourage others to do ERAs
- Learn by experience.....