

EFSA NGO Consultation: 22 February 2006

**Guidance document for the risk assessment of
genetically modified plants and derived food and
feed**

Environmental Risk Assessment

**Chapter III D, Sections 8-10 ,
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- **Detlef Bartsch - MONITORING**

Environmental Risk Assessment: Guidance - update of previous Annexes & Guidance Notes :-

- **More Emphasis on :**
 - **Direct Impacts - consequences of gene flow/introgression**
 - **Indirect impacts**
 - *non-target effects at different trophic levels*
 - *impacts of changes in management & cultivation*
 - *impacts from scale - - Monitoring*
 - *delayed impacts - - Monitoring*

8. Mechanism of interaction between the GM plant and target organisms (if applicable)

Understanding these mechanisms is Key part of ERA for pesticidal plants

9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

.. potential changes in the interactions between the GM plant and the biotic environment (e.g. non-target organisms) .. on **a case-by-case basis** taking into account the biology of the transformed plant and, where gene transfer might occur, of any other recipient organisms, the characteristics and expression of the introduced genetic material, the properties and consequences of the genetic modification, the **scale of release** and gene transfer and .. any risk to the receiving environment ...

ERA

- Tolerable levels of impact ? - - **Harm ? EU Definition**
- Species and ecosystem types studied
- interactions with receiving environments and their biota > consequences
- **BASE LINES.....All ecosystems dynamic and in flux**
 - **No balance in nature**
 - **Consequences of GMP ??**

9.1 *Persistence and invasiveness*

Persistence of volunteers

Weediness of GM crops (cf base line)

**Persistence in wild relatives is also
considered under consequences of gene flow**

9.2 *Selective advantage or disadvantage*

Ecological fitness –

**increased fecundity
invasiveness.....**

>> *Impact on ecosystems ??*

9.3 *Potential for gene transfer*

.. the potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GM plant and **any selective advantage or disadvantage conferred to those plant species.**

The potential consequences arising from out-crossing to other plant cultivars should be considered and assessed for environmental risk.

- **Also consider combinations with other (novel) genotypes that might occur and their possible advantages**
 - **Gene Stacking.....**
- **Gene flow studies >> impact/consequence studies**

9.4 Interactions between the GM plant and target organisms

Emphasis on Bt *interactions* > *Resistance in target*

Conclusion that case specific monitoring for Bt resistance is needed

- ***9.5 Interactions of the GM plant with non-target organisms***
- **Tiered approaches to determining impacts and to separate out knock on effects from direct effects**

Tiered Approach to Risk Assessment

- **Tier 1. Laboratory Experiments** > **Hazard**, Impacts at first trophic level, > **dose** > direct > non-targets.
- **Tier 2. Growth Room/Glasshouse** > Interactions, 2nd trophic level, indirect > non targets (eg paras)
- **Tier 3. Field Experiments** > **Exposure** at range of trophic levels, indirect/agronomic effects
- **H X E >> RISK > > > ASSESSMENT**
- **Tier 4. Monitoring** > long term/large scale impacts
 - **Confirm ERA**

■ **9.8 *Effects on bio-geochemical processes***

.. effects on biogeochemical processes resulting from potential direct and indirect interactions of the GM plant and target and non-target organisms.....

- **relate to nutrient cycles, soil functions of microbial communities etc..**
- **difficult to assess, location dependant,**
- **affected by management**
- **>> *Functional systems***

9.9 Impacts of the specific cultivation, management and harvesting techniques

> eg: Herbicides used on HT crops

- Minimum tillage**
- Difficult to predict regional and future usage -
subject of PMEM?**
- Discussions with PPD Panel on AgChems....**

- **New Arrangements : ERA conducted by a Member state**
- **Future:**
 - > ERA of hybrids, stacked genes...
 - > ERA Of GM Microbes
- **The Guidance Document is a living document which is constantly evolving**
- **We welcome comments on the ERA Guidance..**