

Environmental monitoring and risk assessment

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Outline

- Consider what is required in regulations
- How interpreted in guidelines
- How undertaken in practice
- Ask two questions:
 - are the regulations being followed?
 - is the approach being used scientifically justified?
- What could be done

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Environmental risk assessment - what is adequate?

- How long and in which environments?
- Which species to be tested?
- How can food web impacts be understood?
- How is conflicting evidence weighed up?
- What about uncertainties?
- Look at monitoring as highlights the significance of these questions

Monitoring requirements 2001/18 and 1829/2003

Annex VII - objective

- confirm that **any assumption** regarding the occurrence and impact of potential adverse effects of the GMO or its use in the e.r.a. are correct, and
- identify the occurrence of adverse effects of the GMO or its use on human health or the environment **which were not anticipated** in the e.r.a.

Environmental monitoring and EFSA guidelines

- Focus to be on:
 - the **possible effects** of the GM plant, **identified** in the formal risk assessment procedure, and
 - to identify the occurrence of adverse unforeseen effects of the GMO or its use which were **not anticipated** in the environmental risk assessment
- EFSA Guidelines do require reference to assumptions (11.2)

Definition of “assumption”

- Something taken for granted or accepted as true without proof; a supposition

What assumptions do applicants refer to in monitoring plans?

- Bt11 - none
- GT73 - none
- all the rest - none

- Applicant argue that is RA says hazard 'remote', 'unlikely' etc then no need to monitor!

How does GMO panel consider assumptions?

- GMO panel reports have not mentioned the word 'assumption' except in context of the rules and in other isolated cases:
 - identically (and wrongly) in Bt 11 and 1507 when referring to a potential hazard
 - in 1507 in relation to insert details
- Not plausible scientifically that these are the only assumptions in risk assessments

What assumptions exist in GMO panel opinions?

- Few (non-exhaustive) examples:
- Bt :
 - data on species specificity to Cry1Ab relevant to all EC species (Bt11/1507)
 - monarch butterfly data relevant to EC species (1507)
 - field trials and US data accurately reflect commercial growing EC

More assumption examples

Oilseed rape:

- Crawley et al (2001) adequate to conclude no enhanced weediness/fitness except + herbicide:
 - tested on undisturbed habitats - highly unlikely to detect effects
 - year on year recruitment not examined (3 yrs for OSR)
- restriction of spillages and management as claimed - cf Japan

What needs to be done

- Currently a bias in system - assumptions that harmful tested; that safe ignored (Bt insect resistance cf impact on soil fauna)
- Assumptions should be described and monitoring determined based on best ways of determining whether correct - or justified why not
- Applicants should be required to do this and GMO panel should evaluate