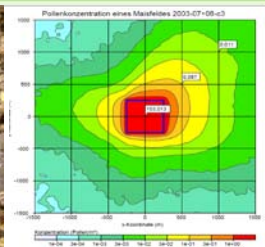


Selection of comparators for RA of single events

Division II 3.3, GMO-Regulation/Biosafety

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Comments are a joint effort of the division



Main Comments to the draft

- Legal references in the background need completion.
- Negative segregants useful as additional comparators only; impacts are not sufficiently discussed.
- Use of GM lines as only comparators not in line with 2001/18/EC.
- General approach to RA of stacked events has been modified.
- Comparative approach not suited in case (i) the conventional counterpart cannot be cultivated in the same environment (abiotic stress resistant) or (ii) there is no comparator because of major changes in metabolism and characteristics.
- Some issues are not covered by the terms of reference (appropriate treatments, e.g. herbicide or insect resistance).

Comments related to single events

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Background as provided by EFSA

- Stresses the central role of selection of appropriate comparators for RA of GMOs.
- Legal reference to Reg. (EC) 1829/2003 article 2 only.
- Annex II of Dir. 2001/18/EC and Decision 2002/623 (EC) should be referenced here as well,
- in order to balance legal references related to food/feed and to the environment.
- 1829/2003: “ ‘conventional counterpart’ means a similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use;”
- 2001/18: „identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations”

Use of GM lines as comparators

- Description of characteristics and use of negative segregants in chapter 3.1. is appreciated.
- Their use as *additional* comparators is welcome.
- However, a comprehensive discussion is missing about
 - the potential and actual contribution of backcrossings to eliminate unintended effects (u.e.) derived from genetic transformation
 - the approach to detect u.e. via comparative assessment only
 - the chance for u.e. to remain undetected through RA
- Use of negative segregants as only comparators is
 - therefore not/sufficiently scientifically justified
 - not in line with Annex II Dir. 2001/18/EC

Additional treatments/managements

- Refers to lines 61-63, 339-342 and 527-542
- Line 339-342
„Depending on the GMO and on the problem formulation, additional treatments/management regimes may need to be considered in the comparative analysis, e.g. conventional counterpart receiving no or minimal herbicide and/or pesticide treatment.“
- Issue is not covered by terms of reference and not related to *selection* of comparators.
- To avoid conflicting guidance the issue should be covered in main guidance documents.

Additional comments

Not related to selection of comparators, but to the draft on the whole and to comparison and assessment in general

- Comparative approach in the draft relates mainly to food aspects and reflects insufficiently on environmental aspects.
- Identity and purity of test and control material should be demonstrated (devoid of other transgenic traits; relevant for comparative and nutritional studies).