



# Selection of Comparators for Single Events

## Comments from Consultation

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# Effect of management systems

- Any new technique may induce indirect effects;
- Direct effects of GM and/or differences should be put into the context of receiving environments and management systems which themselves are evolving;
  - Large-scale and long-term effects
- ERA GD
  - « In Europe current agricultural management and production systems are diverse (intensive, integrated, organic, etc) and already cover a wide range of management practices and cultivation techniques,... »
  - “The ERA should aim at comparing the range of different systems likely to occur in the practical management of GM crops, with the continuously evolving management in non-GM systems, using scenario analysis »
  - « The ERA shall consider under what circumstances the specific GM management and production systems adopted may lead to greater, similar or lower adverse environmental effects than the current systems they are likely to replace »

- **Background**
  - Current principles unchanged: the risk assessment of single events includes a conventional counterpart;
  - Diversity of field trials:
    - Plant-oriented: semi-field trials, compositional analysis field trials;
    - System-oriented: ecological field trials, agronomic field trials;
  - Possible use of additional comparators and of management treatments;
- **Comments received (16)**
  - RA strategy → cross-refer to guidance documents
  - Major comments on clarification and guidance

- Use of GM commercial varieties as reference
  - Not considered by EFSA for the time being
- Use of negative segregants → not a non-GM comparator
  - Potential effects of the genetic modification process cannot be discounted;
  - RA of single events should cover unintended effects;
- Conventional counterpart and backcrossing
- Criteria for selecting alternative comparators in ERA
  - Only for specific agronomic traits and field trials;