EFSA Consultative Workshop

Draft Guidance on selection of comparators for the Risk Assessment of GM plants

EuropaBio comments

Brussels

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General comments:

- **Clarity**
  - Example: "*Where applicants can **convincingly demonstrate** that a conventional counterpart for the stack cannot be made available, then applicants could use:…* "

➡ What would constitute convincing demonstration?

- **Choice of terminology**
  - Condition for using negative segregant(s) in comparative assessment of stacks should be the completed **risk assessment** of the corresponding GM events and not their **approval**

➡ The GM event approval does not provide more re-assurance with regards to safety than the scientific risk assessment itself, whilst there might be significant delay between the EFSA scientific opinion and the approval

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Additional comparisons

- *Comment:* The **scientific rationale** for having both the treated and untreated sample analysis for herbicide tolerant singles is **unclear**. This requirement is still a part of the draft Updated Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed.

- *Proposal:* In absence of scientific basis for this requirement, **further complexity** in the field trial designs **should be avoided** for stacks

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Assessment of sub-combinations of events present in the stack

- If behavior has been characterized and confirmed in single event as safe and absence of antagonistic/synergistic interactions is established, then combining transgenes into stack is not expected to produce any greater risk of unexpected novel genetic combinations than combining the tens of thousands endogenous genes in conventionally bred crops

- Further clarifications needed on the implications of the proposed stack approach
  - For the risk assessment
  - For approvals (e.g. commercial products vs segregating progeny)