

Challenges in Data Generation for Risk Assessment of GM crops

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On behalf of ABLE-AG

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Agenda

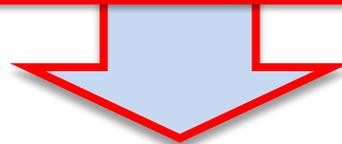
- Guidelines and protocols
- Food/ Feed safety
- Environmental safety
- Summary

Guidelines for Safety Assessment

ICMR Guidelines/ protocols for safety assessment of foods derived from GE plants 

Standard Operating Procedures (SOPs) for confined field trials of regulated, GE plants 

Guidance document for data generation for safety assessment of regulated, GE plants – *DRAFT since 2009*

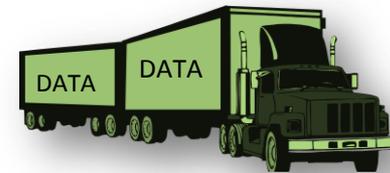


Need to revise and finalize the DRAFT guidance document



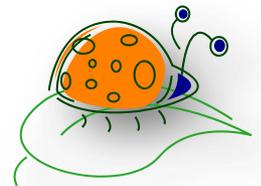
Challenges in Food/ Feed safety data generation

- Animal feeding studies - background
- Do we need animal feeding studies?
 - History of safe use
 - Protein familiarity/ safety
 - Compositionally equivalent
- Data transportability to be explored
 - Subchronic rodent study
 - Livestock feeding study
- If needed, feeding studies on case-by-case basis and hypothesis driven



Challenges in Environmental Risk Assessment

- Reproductive isolation for GE field trials
 - Guidelines: Spatial isolation or alternative methods recommended
 - Spatial isolation is allowed – implementation is very challenging
 - Alternate isolation options (eg. Temporal) to be suggested
- Rationalization of studies on non-targets
 - Tiered approach in risk assessment
 - Lab>> Extended lab/ semi-field >> Field
 - Lab studies better predict effect of GE crops on non-target organisms (NTOs) and soil microflora than field studies



Summary

- Finalize the “Draft” Guidance Document and to be published by Govt. of India
- Animal feeding studies need not be a routine requirement
- Data transportability of animal feeding studies
- Hypothesis-driven approach for study requirements
- Need Protocol/ Data harmonization
- ‘Regulatory Science Working Group’ to suggest RCGM/ GEAC on technical matters