



**Update from GLP/GM
Crop Working Group**

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Purpose

- Common interpretation/application of test, control, and reference substance/item definitions as they pertain to studies conducted for transgenic crops
 - We are not redefining GLPS and this is not a policy document
- Publish document for industry use

Benefits

- Industry alignment and consistent use of terminology in protocols and reports
 - Quicker reviews during collaboration
 - Consistent terminology when studies are outsourced
 - Potential for fewer questions from auditors and inspectors
- Document will help Regulators understand industry interpretation

Test Substance Characterization - The Event

- Test substance characterization for a chemical follows identity, strength/concentration, purity, and composition, solubility if required, stability, or other characteristics...
- For a transgenic crops, test substance characterization needs more interpretation

Study Type	Sequence of the Insert and Flanking Junctions	Absence or Presence of Backbone DNA	Copy Number	Multi-generational Stability	Mendelian Inheritance
Purpose	Identity	Identity	Identity	Stability	Stability
Test System	Not applicable				
Test Substance	The Event				
Control Substance	Conventional counterpart				
Reference Substance	Molecular weight markers				

Study Type	Agronomic Assessment
Purpose	Agronomic equivalency between the Event and conventional counterpart
Test System	Crop
Test Substance	The Event
Control Substance	Conventional counterpart
Reference Substance	Commercial lines

Study Type	Compositional Analysis
Purpose	Compositional equivalency between the Event and conventional counterpart
Test System	Crop
Test Substance	The Event
Control Substance	Conventional counterpart
Reference Substance	Commercial lines (field component) & analytical standards (analytical component)

Study Type	Protein Expression Analysis
Purpose	Determine levels of expression of the protein(s) produced by the Event
Test System	Crop
Test Substance	The Event
Control Substance	Conventional counterpart as background control
Reference Substance	Protein as analytical standards

Study Type	Feeding Studies using Plant Material
Purpose	To confirm there are no adverse effects to the test system when exposed to the Event contained in the diet
Test System	Organism exposed to the test substance [genus, species, and strain (if applicable)]
Test Substance*	The Event <i>(Grain, processed commodity, or diet containing the Event)</i>
Control Substance*	Conventional counterpart <i>(Grain, processed commodity, or diet containing the conventional counterpart)</i>
Reference Substance*	Commercial lines <i>(Grain, processed commodity, or diet containing the commercial lines)</i>

Goals/Next Steps

- Finish writing 'white paper'
- Submit to NAICC Executive Board for review
- Present to Regulatory Authorities
- Publish 'white paper'