Pending Regulatory Approvals.

EPA registration challenges for Dicamba use on DT crops.

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Final label directions for in-crop use of dicamba are pending EPA approval and are subject to change.
Always read and follow label directions. Final label directions for in-crop use of chemicals are pending EPA approval and are subject to change.

- Academics
  - Enables exploratory type research often done in collaboration with
  - GLP standards not required which enables greater flexibility for testing

- Commercial benefits and performance
  - Product development data is used to understand the system
  - Subject to criminal and civil penalties for deviation and falsification
  - GLP or GLP like standards required
  - EPA's registration decision

- Regulatory Data is used for risk assessments to support

Meet Specific Needs

Monsanto Generates Data Designed to
Always read and follow label directions.

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- All data and study file archived
- Comprehensive study report
- Reconstruct and reproduce
- Rigorous study documentation to enable ability to
  perform reexamination
- QA/QC review and audit/verification
- Test substance characterization
- Conducted under protocol with limited opportunity for
  change

What does GLP involve?
Always read and follow label directions.

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Regulatory data to address

- Can lead to more restrictive label language with subsequent need to develop additional data
- Previous incident allegations
- Product development data conducted with different end-point/FDA not relevant to EPA
- Use of information not generated with strict data quality standards
- EPA diverged from expected process for this DT use and moved away from risk-based approach to inform on label language

- Approval of appropriate label language to mitigate against potential risk
- Conducted under EPA guidelines and data quality standards
- Ensures relevant endpoints measured for assessment

Assessment using a risk-based approach

- Expected process would be to utilize regulatory datasets for risk extensively reviewed

Registration for DT use has been