



Pending Regulatory Approvals

EPA Registration Challenges for Dicamba Use on DT crops

Tina Bhakta



Final label directions for in-crop use of dicamba are pending EPA approval and are subject to change.
ALWAYS READ AND FOLLOW LABEL DIRECTIONS.

Pending Regulatory Approvals. This information is for educational purposes only and is not an offer to sell Roundup Xtend[®] with VaporGrip[™] Technology, Xendimax[™] with VaporGrip[™] Technology or M1691. These products are not yet approved for sale or use anywhere in the United States.

MONSANTO



Monsanto Generates Data Designed to Meet Specific Needs

- **Regulatory Data is used for risk assessments to support EPA's registration decision**
 - GLP or GLP like standards required
 - Subject to criminal and civil penalties for deviation and falsification
- **Product development data is used to understand the system, commercial benefits and performance**
 - GLP standards not required which enables greater flexibility for testing
 - Enables exploratory type research often done in collaboration with academics

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

ALWAYS READ AND FOLLOW LABEL DIRECTIONS.

Pending Regulatory Approvals. This information is for educational purposes only and is not an offer to sell Roundup Xtend™ with VaporGrip™ Technology, XtendMax™ with VaporGrip™ Technology or M1691. These products are not yet approved for sale or use anywhere in the United States.

MONSANTO



What does GLP involve?

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

Final label directions for in-crop use of dicamba are pending EPA approval and are subject to change.
ALWAYS READ AND FOLLOW LABEL DIRECTIONS.

3

Pending Regulatory Approvals. This information is for educational purposes only and is not an offer to sell Roundup Xtend™ with VaporGrip™ Technology, XtendMax™ with VaporGrip™ Technology or M1591. These products are not yet approved for sale or use anywhere in the United States.

MONSANTO

Registration for DT use has been extensively reviewed

- **Expected process would be to utilize regulatory datasets for risk assessment using a risk-based approach**
 - Ensures relevant end-points measured for assessment
 - Conducted under EPA guidelines and Data quality standards
 - Approval of appropriate label language to mitigate against potential risk
- **EPA diverged from expected process for this DT use and moved away from risk-based approach to inform on label language**
 - Use of information not generated with strict data quality standards
 - Product development data conducted with different end-points not relevant to EPA assessment
 - Previous Incident allegations
 - Patent Data
 - Can lead to more restrictive label language with subsequent need to develop Regulatory Data to address

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

ALWAYS READ AND FOLLOW LABEL DIRECTIONS.