DRAFT FOR REVIEW: Dicamba Research Protocol Review

Minutes: 12/18/16 Meeting

Boyd Carey - Greg Elmore

Participants |

- Greg Elmore
- **Boyd Carey**
- Tina Bhakta
- Jerry Cubbage

Meeting Objectives

- 1. Review specific research project proposal from University of Missouri for potential impacts to dicamba registration strategy
- 2. Determine process for review and approval of all 2016 Technology Development protocols that include dicamba

NOTES

- A. University of Missouri protocol proposal by Reid Smeda:
 - Protocol is a controlled greenhouse experiment evaluating soil activity of dicamba. Field experiments could be a logical follow-up request
 - Suggest to add a Rowel + dicamba treatment
 - OK to use XtendiMax formulation or old MON # (formulation without dye) if inventory of this product
 - The protocol objectives as submitted pose minimal risk to dicamba registration: APPROVAL TO PROCEED WITH THIS PROTOCOL
- B. Proposed process for Review and Approval of all 2016 Technology Development protocols that include dicamba:
 - Process proposal:
 - a. All field work must be conducted with a protocol
 - b. Regulatory (Bhakta and Cubbage) will enable TDMs and TDM Managers to review all TD protocols with guidance to key objectives or elements with potential to compromise regulatory strategy.
 - i. Protocols determined to have no potential to compromise regulatory strategy: TD may proceed with implementation.
 - ii. Protocols determined to have potential to compromise regulatory strategy: TD to take one of the following two actions:
 - 1. Terminate the protocol
 - 2. Recommend the protocol for review and approval by Regulatory
 - c. Regulatory (Cubbage and Bhakta) reviews protocols recommended by TD. Escalate if necessary to next level of management (Vaughn, Chambers).
 - Key protocol objectives or elements requiring additional review include:
 - Volatility
 - Herbicide impacts to sensitive areas
 - Synergy (protocols objectives should focus on products with different sites of action and complementary or overlapping weed control spectrums for effective weed control systems and weed resistance management)
 - New performance claims beyond those already established
 - Competitor formulations
 - Additional guidance
 - Planting buffers around trials reduces risks
 - Bare ground trials without nearby crops pose less risk
 - Smaller trials/demonstrations pose less risk

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Message

From: CAREY, BOYD J [AG/1000] [/O=MONSANTO/OU=EA-5040-01/CN=RECIPIENTS/CN=91297]

Sent:

1/20/2016 12:07:21 PM

To:

KRUGER, HENDRIK [AG/1000] [hendrik.kruger@monsanto.com]

Subject:

FW: PLEASE REVIEW: Notes from Dec 18 Meeting: Review of TD Protocols with Dicamba

Attachments: Dicamba TD Protocol Review Mtg 12-18-15 011816.docx

Importance:

High

Hendrik

Attached are notes from a 12/18/15 meeting Greg Elmore and I held with Tina Bhakta and Jerry Cubbage specifically to determine how we would get regulatory approval for our dicamba protocols. We held this meeting before having seen the process document from Jean Golev.

After seeing the document from Jean, we held a subsequent meeting bringing Jean together with Tina and Jerry with goal of getting to a single process. Out of that meeting we agreed to hold the Jan 29 meeting (you are invited) to review and approve (hopefully) as a team in a single meeting ALL 2016 chem protocols to facilitate moving ahead for 2016. Going forward we would plan ahead but follow a similar model to review the bulk of protocols as a group in a team meeting setting, and use the hard copy process document for any one-off protocols that don't hit the normal protocol development cycle

Sorry for all the background but it may help to understand context of what we have done so far and hope to do on Jan

Thanks

boyd

From: CAREY, BOYD J [AG/1000]

Sent: Monday, January 18, 2016 12:57 PM

To: GOLEY, JEAN C [AG/1005] < jean.c.goley@monsanto.com>; CUBBAGE, JERRY W [AG/1000]

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Importance: High

Team

Per the agreed actions from our meeting last Friday (1/15/16).

Attached are the DRAFT notes from the meeting held 12/18/15 between Jerry, Tina, Greg and I. Please review and edit these for accuracy and representation of our agreed upon approach.

Thanks bovd

J. Boyd Carey, Ph.D.

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