

Message

From: BHAKTA, TINA [AG/1000] [/O=Monsanto/OU=NA-1000-01/cn=Recipients/cn=TTBHAK]
on behalf of BHAKTA, TINA [AG/1000] [/o=monsanto/ou=na-1000-01/cn=recipients/cn=ttbhak]
Sent: 2/9/2015 7:51:32 PM
To: MARTINO-CATT, SUSAN J [AG/1000] [susan.j.martino-catt@monsanto.com]
Subject: RE: Discuss Dicamba drift stats re-analysis



From: MARTINO-CATT, SUSAN J [AG/1000]
Sent: Monday, February 09, 2015 6:04 PM
To: STORK, LEANNA G [AG/1000]
Cc: BHAKTA, TINA [AG/1000]
Subject: RE: Discuss Dicamba drift stats re-analysis
Importance: High

Hi LeAnna-

I've been following this chain and feel like I need to say something to help calibrate this effort. The Dicamba project is complex from all angles. The pace at which this project twists and turns can be unnerving on a good day. A key to all of this is we must be incredibly agile and flexible so we can stay ahead. Sometimes (ok, most of the time), this means we do things quickly without immediately complying to standard processes, as again, there is nothing that is standard for this. We have gotten a clear message from the ET, reiterated through Phil and I, that we must do everything we can to facilitate getting this registration....and sometimes that means not having all the paperwork in place. It just is what it is, and we all are working to make the outcome favorable-truly an all-hands-on deck.

As for this particular "ask", a couple of things I'd like to stress. We do not have the luxury of time to try and convince EPA our methods, approaches, techniques, etc... are reasonable (or even superior) to theirs...we have lost a lot of time on this project trying to convince them. Even though our scientific arguments are sound, they really don't care and have told us this in many ways/forms with the bottom line being for us to do it their way with no deviations. We know from past discussions they do not like the hockey stick method of analysis of our field data, and therefore we need to not rely on this method. As best we can, we have to do the analysis based on what we know they have done in the past including using their methods/tests and the parameters they have decided (i.e. confidence intervals).

The request that is being discussed in this chain hits on a lot of angles. Namely, EPA is aware we have done collaborative work, they are talking directly with the collaborators and are coming away with an incomplete story that is causing them to jump to wrong conclusions, putting our entire registration at very high risk. We have made no decision as to what, if any, of these data will be submitted formally to EPA. To help inform this decision, I would like to see the analysis done per EPA methodology to assess any correlation that might exist between distance:plant height, distance:visual symptomology (by %, for example to 5%, to 10%, to 15%, etc...), distance:yield. Then perhaps we can see if there can be any conclusion made to correlate difference plant height:visual symptomology or plant height:yield, etc... At this point, I am more focused on soybean as the most sensitive species....would entertain looking at cotton if we have time. Again, we need to see what the analysis says in case we do submit to EPA and they do their own analysis, we won't be surprised by the outcome.

I know your team is already strapped for resources. If this type of analysis is not possible to get done ASAP (this week would be great), please let me know and we will explore other sources of stats support (Biotech, Breeding, Chem Tech, BASF, outsource). I'm less concerned about who does it as long as we are following EPA guidelines to the best of our knowledge and this gets turned quickly.

I realize this type of work doesn't really fit into our processes....we will make it fit as best we can as long as we don't compromise speed, and sometimes the fit has to be a retroactive one. Yes, it is a bit unsettling...welcome to the world of Dicamba☺ Please let me know if I can provide any more context or help...appreciate your efforts to dig in with us.

Talk with you later, Susan

From: STORK, LEANNA G [AG/1000]
Sent: Monday, February 09, 2015 3:10 PM
To: BHAKTA, TINA [AG/1000]; WRIGHT, JOHN P [AG/1000]
Cc: SCHAPPAUGH, ADAM [AG/1000]; HONEGGER, JOY L [AG/1000]; BRADDOCK, PHILIP K [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]
Subject: RE: Discuss Dicamba drift stats re-analysis

Tina,

As requested and captured in the meeting notes below (3 and 4), please go ahead and submit the PSSR request. This is an essential part of our process to formally request and track this work for QA and stats, and also to loop in QA so that they can begin to review the data in the event we do submit it to the EPA.

Also, based on our meeting and agreement on Friday, Adam is working on analyzing the data in the way in which we think the EPA is requesting (i.e., the hockey stick model). The discussions which occurred over the weekend would be an additional analysis. If there is a need for additional analyses on the correlation aspect I think it would be best if you could schedule a discussion with this group to align on the specific request as it's not clear to us at this point.

Thanks,
LeAnna

From: BHAKTA, TINA [AG/1000]
Sent: Saturday, February 07, 2015 8:01 AM
To: WRIGHT, JOHN P [AG/1000]
Cc: STORK, LEANNA G [AG/1000]; SCHAPPAUGH, ADAM [AG/1000]; REMUND, KIRK M [AG/1005]; HONEGGER, JOY L [AG/1000]; SANDBRINK, JOSEPH J [AG/1000]; TRAVERS, JEFF N [AG/1005]; BRADDOCK, PHILIP K [AG/1000]; MARTINO-CATT, SUSAN J [AG/1000]; COLE, RICHARD M [AG/1000]
Subject: Re: Discuss Dicamba drift stats re-analysis

John

I think that's exactly what we will want to show. Did we ever analyze for this correlation? Or lack of?

Tina

Sent from my iPad

On Feb 7, 2015, at 6:09 AM, WRIGHT, JOHN P [AG/1000] <john.p.wright@monsanto.com> wrote:

Visual assessment of effects includes affects on plant height, morphology, and any other visible effects. What we should be able to show is that at 20% visible effect, there is no discernible effect on height after exposure to Dicamba. For example, a 50% visual effect should also have a

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50% reduction in plant height. For Dicamba, at very low effects levels, the morphological effects begin at rates lower than those where plant height is affected.
John

Sent from my iPhone

On Feb 6, 2015, at 3:26 PM, BHAKTA, TINA [AG/1000] <tina.bhakta@monsanto.com> wrote:

Thanks for the write up.

As I mentioned this morning the EPA is linking visual injury to plant height and we need to steer them away from that. Can the data for soybean be analyzed to make the statement that there is no correlation. Is this possible? If this data can show no correlation then perhaps it is something that we can use in our response back.

Susan, Rick any further comments from any of you?

Thanks

Tina

From: STORK, LEANNA G [AG/1000]
Sent: Friday, February 06, 2015 10:01 AM
To: STORK, LEANNA G [AG/1000]; SCHAPAUGH, ADAM [AG/1000]; REMUND, KIRK M [AG/1005]; BHAKTA, TINA [AG/1000]; HONEGGER, JOY L [AG/1000]; WRIGHT, JOHN P [AG/1000]; SANDBRINK, JOSEPH J [AG/1000]; TRAVERS, JEFF N [AG/1005]; BRADDOCK, PHILIP K [AG/1000]
Cc: MARTINO-CATT, SUSAN J [AG/1000]
Subject: RE: Discuss Dicamba drift stats re-analysis

All,

Here are my notes from the meeting. Please feel free to correct anything I may have missed. Please also note several action items below.

Thanks,
LeAnna

1. We need the raw data to submit to QA so they can begin the audit of raw data
 - a. Action: Kirk will contact Teri Matthews for the raw data and protocol for 2012 and 2013
 - b. QA will review the protocols and data to be submitted, also rejected data
2. Kirk will provide all 2012 and 2013 data to Adam; Adam will subset the data as discussed

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3. Adam will run the statistical model as closely as possible based on our interpretation of EPAs comments
4. Action: **Tina** to submit PSSR (i.e., unplanned work request) to formally track and document the request including:
 - c. QA to inform them that the raw data will be coming to them for audit
 - d. STC (LeAnna) to formally request and track the stats re-analysis
5. Adam will summarize the results in an informal presentation to be shared with the group late next week

-----Original Appointment-----

From: STORK, LEANNA G [AG/1000]

Sent: Thursday, February 05, 2015 11:57 AM

To: STORK, LEANNA G [AG/1000]; SCHAPAUGH, ADAM [AG/1000]; REMUND, KIRK M [AG/1005]; BHAKTA, TINA [AG/1000]; HONEGGER, JOY L [AG/1000]; WRIGHT, JOHN P [AG/1000]; SANDBRINK, JOSEPH J [AG/1000]; TRAVERS, JEFF N [AG/1005]; BRADDOCK, PHILIP K [AG/1000]

Cc: MARTINO-CATT, SUSAN J [AG/1000]

Subject: Discuss Dicamba drift stats re-analysis

When: Friday, February 06, 2015 8:00 AM-9:00 AM (UTC-06:00) Central Time (US & Canada).

Where: O-368 and WebEx

WebEx added.

All,

The purpose of this meeting is to propose a path forward for the statistical re-analysis of the Dicamba drift study, based on feedback and comments from the EPA (see attached Word file as prepared by Joy). Also attached is the original analysis (ppt file).

Thanks,
LeAnna

<< File:

2014_SWSS_Cobb_Presentation_Dicamba_Drift_in_Soybean_Under_Field_Condition_01-10.pptx >> << File: LeAnna_info.docx >>

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