Message

From: ORR, THOMAS B [AG/1005] [thomas.orr@bayer.com]
Sent: 6/26/2019 6:26:26 PM
To: Meadows, Sarah [Meadows.Sarah@epa.gov]; ORR, THOMAS B [AG/1005] [thomas.orr@bayer.com]
CC: Baris, Reuben [Baris.Reuben@epa.gov]; Kenny, Daniel [Kenny.Dan@epa.gov]
Subject: RE: Dicamba Tolerant Corn

Sarah,

Thank you for following-up and proposing the new date. I will relay this proposed timing to my stakeholders and be in touch shortly.

Do you know if EPA has reviewed our data waiver request that was submitted in response to the February 6, 2019 deficiency letter?

Thanks,
Tom

From: Meadows, Sarah <Meadows.Sarah@epa.gov>
Sent: Tuesday, June 25, 2019 12:53 PM
To: ORR, THOMAS B [AG/1005] <thomas.orr@bayer.com>
Cc: Baris, Reuben <Baris.Reuben@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: Dicamba Tolerant Corn

Hi, Tom. We'll definitely need to renegotiate this date. More time is needed before we can develop an official position on this new use of dicamba. As you know, there are a litany of scientific and legal issues that we're dealing with which have been resource-intensive.

I suggest renegotiating for a year. If you are amenable to this, please send me an email requesting the new date of July 1, 2020 for EPA registration number 524-617, decision number 538753, and petition number 8F8659, decision number 538754.

Thanks,

Sarah
Sarah True Meadows, PhD
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division – Herbicide Branch
(703) 347-0505
meadows.sarah@epa.gov

From: Schmid, Emily
Sent: Monday, June 24, 2019 1:24 PM
To: ORR, THOMAS B [AG/1005] <thomas.orr@bayer.com>
Cc: Baris, Reuben <Baris.Reuben@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>; MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>; BHAKTA, TINA [AG/1005] <tina.bhakta@monsanto.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>
Subject: RE: Dicamba Tolerant Corn

Hi Tom,

Thanks for contacting me about this. The PRIA date will need to be renegotiated. This action is now assigned to Sarah Meadows. She is in the process of confirming how long will be needed to complete the review and is going to reach out to you soon to get this renegotiated.

Best regards,
Emily

From: ORR, THOMAS B [AG/1005] <thomas.orr@bayer.com>
Sent: Monday, June 24, 2019 12:55 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Baris, Reuben <Baris.Reuben@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>; MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>; BHAKTA, TINA [AG/1005] <tina.bhakta@monsanto.com>
Subject: RE: Dicamba Tolerant Corn

Hi Emily. I am transitioning to the dicamba tolerant corn project from Simone and wanted to follow-up with you regarding this action. My understanding is that the PRIA date for the new proposed dicamba use in corn is July 1, 2019.

Monsanto Company, as subsidiary of Bayer AG, previously received an application deficiency letter regarding this action from EPA on February 6, 2019 in which a field volatility study conducted using XtendiMax on dicamba-tolerant corn was requested. Monsanto responded to the February 6, 2019 letter with a data waiver request for additional volatility studies. In this response, Monsanto summarized the vast amount of field volatility data that were previously submitted to EPA and highlighted the direct relevance of those data to the proposed dicamba use on dicamba-tolerant corn to support the study waiver request.

Do you anticipate that EPA will be able to finish the review of the data waiver request and the new use application prior to the PRIA date of July 1, 2019 or does the Agency wish to renegotiate the PRIA date?

Best regards,

Tom Orr
Global Regulatory Affairs Manager

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From: Schmid, Emily
Sent: Tuesday, September 04, 2018 9:23 AM
To: SEIFERT-HIGGINS, SIMONE [AG/1005] <simone.seifert-higgins@bayer.com>; MARVIN, THOMAS [AG/1920]

<thomas.marvin@monsanto.com>; BHAKTA, TINA [AG/1005] <tina.bhakta@monsanto.com>
Cc: Baris, Reuben <Baris.Reuben@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: Dicamba Tolerant Corn

Simone,

I'm not sure about what happened with this action before it got to me but the PRIA date is definitely July 1, 2019. We will do everything we can to make the PRIA date but May 15, 2019 won't be possible.

Best regards,
Emily

From: SEIFERT-HIGGINS, SIMONE [AG/1005] [mailto:simone.seifert-higgins@bayer.com]
Sent: Tuesday, September 04, 2018 10:15 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>; SEIFERT-HIGGINS, SIMONE [AG/1005] <simone.seifert-higgins@bayer.com>; MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>; BHAKTA, TINA [AG/1005] <tina.bhakta@monsanto.com>
Cc: Baris, Reuben <Baris.Reuben@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: Dicamba Tolerant Corn

Emily,
Thank you for your follow-up!

Apologies for the back-and-forth but I am surprised to learn about a July 1, 2019 PRIA date for this new corn use. It is my understanding that this action was coded R170 during a manager's meeting on March 1 which was held prior to issuance/receipt of the milestone #2 note (attached).

Are you indicating that it is expected to be difficult to meet the May 15, 2019 deadline? Could you please confirm the PRIA due date for this action.

Regards,
Simone

From: Schmid, Emily [mailto:Schmid.Emily@epa.gov]
Sent: Tuesday, September 04, 2018 7:01 AM
To: SEIFERT-HIGGINS, SIMONE [AG/1005] <simone.seifert-higgins@bayer.com>
Cc: Baris, Reuben <Baris.Reuben@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: Dicamba Tolerant Corn

Simone,

Thank you for making me aware of the meeting. However, the PRIA date for the corn use is 7/1/19. With our current resource constraints it has been difficult to complete new uses within the PRIA timeframe so I don't see how it would be possible to complete our review 1-2 months early. I assume the milestone that gave you the date in May was before it was recoded since the decision time for an R298 is 13 months and for R170 it is 15 months.

Let me know if you have any other questions.

Best regards,
Emily

From: SEIFERT-HIGGINS, SIMONE [AG/1005] [mailto:simone.seifert-higgins@bayer.com]
Sent: Monday, August 27, 2018 9:46 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>; SEIFERT-HIGGINS, SIMONE [AG/1005] <simone.seifert-higgins@bayer.com>
Subject: RE: Dicamba Tolerant Corn

Emily,
Thank you for your explanation! As indicated I did not intend to reassign PRIA but wanted to better understand timelines for review and decision-making. Based on the systems-generated milestone #2, PRIA timeline for the proposed dicamba use in dicamba-tolerant (DT) corn is set to be due on May 15, 2019.

I do want to share with you that Monsanto, now Bayer, submitted dicamba data for evaluation at the 2019 Extraordinary Joint FAO/WHO Meeting on Pesticide Residues (JMPR). The Extra JMPR session will be held May 7-17, 2019. Bayer is requesting to amend the existing Codex definition of residue for dicamba to include DCSA (dichlorosalicylic acid), which is the major metabolite in DT crops. Dicamba use over-the-top in/on DT cotton and soy is approved; however, the new use pattern (GAP) for DT corn is pending. While we have obtained permission from the Secretariat to include corn data in our submission, it is desirable to have the corn GAP approved at the time of the JMPR meeting. I do recognize the extremely tight timeline and am aware of the current resource constrains at the EPA; therefore, please don't hesitate to reach out to me if there is any assistance I can provide to facilitate your review.

Looking forward to working with you!

Best regards,

Simone Seifert-Higgins, Ph.D.
Regulatory Affairs Manager

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From: Schmid, Emily [mailto:Schmid.Emily@epa.gov]
Sent: Thursday, August 23, 2018 10:26 AM
To: SEIFERT-HIGGINS, SIMONE [AG/1005] <simone.seifert-higgins@bayer.com>
Subject: RE: Dicamba Tolerant Corn

Hi Simone,

I think all new GMO uses are given PRIA codes as new food uses since all of the work that goes into reviewing a new use must also be done for a GMO so it is basically a new use. I think if PRIA 4 is ever passed, there will be a more clear code. In the CFR, the tolerance is not specified as genetically modified, it is just listed as corn, soybean, etc. So the new tolerance will be set for a crop that already has a tolerance, therefore it will be amended. I hope this answers your question. If not, you might want to contact Reuben since he works with coding much more than I do.

Best regards,
Emily

From: SEIFERT-HIGGINS, SIMONE [AG/1005] [mailto:simone.seifert-higgins@bayer.com]
Sent: Wednesday, August 22, 2018 4:04 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: Dicamba Tolerant Corn

Hi Emily,

I would like to offer some additional explanations to my voice mail related to the HT3 corn submission and your review. While I certainly agree with your assessment to refer to this action as an amendment of an existing tolerance I would like to understand your thoughts that led to your conclusion. Reason for my question it that I originally submitted this petition under PRIA R298 (amendment); however, after some back-and-forth with the PRIA team this action was re-coded as R170 (new use/establishing new tolerance). I have attached respective email correspondence with Mick Yanchulis for your reference.

I would appreciate if you could give me a ring at your convenience at (636) 737-9571 to further discuss.

Regards,
Simone

From: Schmid, Emily [mailto:Schmid.Emily@epa.gov]
Sent: Wednesday, July 11, 2018 3:25 PM
To: SEIFERT-HIGGINS, SIMONE [AG/1005] <simone.seifert-higgins@monsanto.com>
Cc: MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>
Subject: Dicamba Tolerant Corn

Good afternoon,

I am the reviewer assigned to the dicamba tolerant corn use you submitted. Could you revise the notice of filing to reflect that this is amending a tolerance instead of establishing a tolerance? Also, please specify the corn... I assume it is field corn? I have attached a cleaned up version that I wanted to let you look at before I sent it in to be published anyway so if you could make those changes to the attached version and make sure you are okay with my edits, that would be great.

Let me know if you have any questions.

Best regards,

Emily Schmid
Biologist
U.S. Environmental Protection Agency
Registration Division
Herbicide Branch

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