Message

From: Schmid, Emily [Schmid.Emily@epa.gov]
Sent: 9/4/2018 2:22:53 PM
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,

Ex. 5 Deliberative Process (DP) 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.

Ex. 5 Deliberative Process (DP)

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. **Ex. 5 Deliberative Process (DP)** 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 Personal Phone / Ex. 6 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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