Message

From: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Sent: 9/14/2020 10:44:29 AM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

fyi

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Friday, September 11, 2020 1:39 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

HI Debra!

It's taken me some time to absorb these comments from Ann/Pyxis on behalf of the registrant. I believe that we will need to use the next six weeks, or so, to bring the additional items mentioned by Ann to the aldicarb workgroup, to confirm that they don't change anything from our current thoughts, considerations, and approaches. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

So, to sum it up, I don't think that there's any one direction to put forward, except to say that the group should continue to value input and discussion on what the registrant is attempting to suggest and/or offer. Perhaps, we can provide the team with the recent information and see where that lands us, in our contemplation. While you're away from the office, I'll see what Shanta thinks as well.

Best,

Marion J.

Marion J. Johnson, Jr.
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From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Friday, September 11, 2020 9:34 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

Hi Marion,

See her response below. I would really like your thoughts.....Perhaps in some areas I was not as clear as I needed to be on the call? Anyway, they are still pushing ACP as the pest and have confirmed 2-3 inches as the incorporation depth. (Which is different from what they said on the phone and what BEAD found before the briefing.)

They have agreed to a 3 month renegotiation. I will start the paperwork. But would like to know your thoughts before I respond to Ann.

Thanks.
Debra

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Friday, September 11, 2020 8:49 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

Dear Debra,

Thank you for taking time to explain the Agency's need for an extension to the PRIA date for the aldicarb pending actions for use on citrus. As a result, I wanted to send you some additional information and to request additional details on the on-going risk assessments. AgLogic also wanted to point out that the Agency has quite a bit of information that has been sent over the years and some of their critical points are mentioned below. Relevant attachments are included with this email since many of the Agency scientists or managers are no longer at the Agency or have moved to different positions and may not have seen this information.

Based on the call between you, Shanta, Amy Carter and myself, EPA will use a new, unvetted model to refine the estimated surface and ground water residues to be used in the aggregate risk assessment. We note that this assessment, which has changed since the last assessment (Aldicarb Interim Reg Rev Decision 2-17-18), indicates a concern for surface water residues while previous modeling showed that ground water residues were a concern. Is there any date by when that new model will be made available for use by industry? Can the Agency provide inputs being used in that model?

In addition, you mentioned that the food alone portion of the dietary risk is >99% of the aPAD for children 1-2. It would be most helpful for AgLogic to better understand the assumptions used in the revised Agency assessment (DEEM input and output files). AgLogic has submitted its own dietary risk assessments (food + water) as well as input on the % crop treated acres (see Feb. 11, 2020 attachment document) but the Agency has not provided any feedback other than verbal comments that the aPad is exceeded. If there is any additional information you can provide AgLogic in the meantime regarding the dietary risk cup assumptions and conclusions?

AgLogic filed its registration application on February 14, 2019 in response to citrus grower requests to reinstate the use of aldicarb. In a document dated March 6, 2020 (attached), AgLogic provided supplemental information indicating a reasonable basis for determination of treated orange and grapefruit acreage, and that EPA's estimate of percentage acreage treated was not supported by aldicarb historical use. In fact, EPA's estimate of treated acreage exceeded AgLogic's aldicarb production capacity by 400%. AgLogic also provided the attached March 6, 2020 document to show the Stewardship Requirements for aldicarb users, the undisputable tree health benefits provided by AgLogic aldicarb, and the rigorous Florida Rule and State local Application Permit requirements regulating all application of aldicarb to Florida citrus. As a reminder, AgLogic agreed to restrict the use of aldicarb on citrus to 100,000 acres (FL and TX combined).

AgLogic asked why imported commodities would contribute to the dietary risk since there are no registered uses of aldicarb in other countries. AgLogic has clearly refuted the assumption that any type of aldicarb is used

in Mexico (see attached Sept. 14, 2018 letter to R. Keigwin). Other than the U.S., no other commodities anywhere in the world are treated with aldicarb.

We discussed the label and incorporation of the granules into the soil. The label, as submitted, includes incorporation to depths of 2-3 inches and is accurate and realistic.

The timing for approval of these amendments is critical in order to meet the fast-approaching Florida-restricted application period for aldicarb (Nov 15, 2020 thru April 30, 2021). Florida citrus growers and University Professors, have unequivocally expressed the dire need for immediate use of aldicarb to mitigate the unprecedented crop and family citrus farm losses, caused by huanglongbing (HLB) citrus greening. The Citrus Research Defense Foundation indicates the growers desperately need to keep infected trees healthy. Unfortunately antibiotics have not produced the desired results.

AgLogic has patiently waited to be informed of any potential concerns or issues associated with the above actions so that they can be immediately addressed to avoid any additional delays. AgLogic profoundly respects EPA's responsibilities, and concerns and strongly desires to proactively work together with EPA to reach a favorable outcome for the iconic Florida and Texas citrus industries.

AgLogic agrees to a new PRIA date of Dec. 12, 2020 for the following actions:

Product:	Decision#
EPA Reg. No. 87895-2	549655
EPA Reg. No. 87895-4	549657

Please feel free to contact me with any follow-up questions or details regarding the on-going risk assessments.

Kind regards,

Ann

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, September 9, 2020 6:57 AM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

Hi Ann,

I will send you an invite for a MicroSoft Teams meeting. It will also have a call-in number that can be used to dial in separately. I don't believe that I have an email address for Amy. Please send me her email address and I will add her to the invite as well.

Thank you.
Debra

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Tuesday, September 08, 2020 7:37 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

Hi, Debra,

Janelle is out and not able to participate in the call tomorrow so she asked me to respond to your email. I've asked AgLogic's consultant, Amy Ritter, to participate in the call as well. The 3:00 time slot works best for us. Will you be able to set up a call-in number?

Ann

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, September 8, 2020 12:43 PM
To: Janelle Kay <Janelle@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

Hi Janelle,

Thank you for your patience with us as we have been working through your pending action for the proposed new citrus uses (oranges and grapefruit in TX and FL) for EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657).

The agency currently finds itself in a position of not being able to make an FQPA Safety Finding for these proposed and current uses. However, over the last couple of months the team and senior management have spent time brainstorming possible solutions. As a result, our senior management has asked the team to explore a new method for modeling and further refining the drinking water contributions to the risk cup.

Nonetheless, this line of investigation will require extended time and resources to work through. We expect an additional 3-4 months will be required and quite possibly additional time depending on the results of these new investigations and where they lead us.

While there are no guarantees that this new modeling/refinements will result in the agency being able to make a safety finding and moving forward, we are requesting an additional 4 months for the team to work through the process and make every attempt. This would extend the current PRIA due date from September 14, 2020 to January 12, 2021.

Please respond to this email with your "**agreement to the renegotiated PRIA Due Date of 01/12/2021 for Decisions 549655 and 549657.**"

If you would like to discuss further, Shanta and I have set aside the following times tomorrow to allow for a conference call:

Wed. 9/9/2020: 9:30 – 10:00 am (ET)
11:30 – 12:00 pm (ET)
3:00 – 3:30 pm (ET)

Please let us know if you would like to discuss at more length and at which time and I will set up the conference call-in information.

Regards,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist

Invertebrate & Vertebrate Branch 2
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