Message

From: Ann Tillman [Ann@PyxisRC.com]
Sent: 11/9/2020 4:24:58 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)
Attachments: 20201109 Specific questions for EPA.docx

Debra,

The questions AgLogic provided are attached. Sorry for the late response as I was on vacation last week.

Ann

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, November 4, 2020 4:03 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)

Hi Ann,

I will add your team to the calendar invite and send it out before I close down my computer tonight. The call in numbers won't change; however, they will be given a link to the Microsoft teams meeting.

The topics on the agenda that you provided in your last email are broad in some instances, do you have specific questions on the broader topics that I can provide to the team?

Again, sorry for the delay. I will send them out in the next hour or two.
Regards,
Debra

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Wednesday, November 04, 2020 3:57 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)

Debra,

Are you going to set up a Microsoft Meeting for this Nov. 10 call or should we use the information you sent below?

Ann

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, October 26, 2020 2:57 PM

To: Ann Tillman <Ann@PyxisRC.com>
Cc: Janelle Kay <Janelle@PyxisRC.com>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)

Hi Ann,

The call in information for the meeting will be the following:

Phone: 1 Ex. 6 Personal Privacy (PP)
Conferen

Regards,
Debra

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Monday, October 26, 2020 12:14 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Janelle Kay <Janelle@PyxisRC.com>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)

Debra,

Thanks for setting up this meeting. Tuesday Nov. 10 at 11-12 Easter works for all parties. Please send the call-in information so I can forward to AgLogic and their other consultants.

Thanks.

Ann

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, October 22, 2020 1:31 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Janelle Kay <Janelle@PyxisRC.com>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)

Hi Ann,

Thank you for your note and for providing your concerns over the agency's dietary analyses.

RD provided BEAD with your most recent email with your concerns and calculations for the dietary assessments. BEAD is reviewing that email in preparation for a conference call in which they will explain the methodology BEAD used in arriving at the most recent PCTn used by HED in the dietary analyses, as well as address the other concerns.

In our recent communications with BEAD, the team described a need for a little more time to prep for this conference call. As such, I have found a place on our calendars that will hopefully work for this call:

Tuesday, November 10, 2020 11-12 pm (Eastern Time)

Please let me know if this day/time will work for you and I will confirm the time slot with my EPA team. Currently I envision the agenda as being EPA explaining our PCTn methodology followed by responses to the concerns/calculations presented in your email (9/22/20).

Please let me know if this time will work for you and if the tentative agenda described above is what you are looking gain from this meeting.
Regards,
Debra

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Wednesday, October 21, 2020 8:16 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Janelle Kay <Janelle@PyxisRC.com>
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)

Hi, Debra,

AgLogic feels that EPA does not appear to be making any progress on the aldicarb dietary risk assessment issues and is requesting a conference call to discuss the percent crop treated data that BEAD provided. AgLogic believes that this call needs to take place soon so that this issue can be resolved well in advance of the second, renegotiated PRIA date. AgLogic provided the attached statement on the status of the pending petition for use on oranges and grapefruit

I have also attached a chronology of correspondence with EPA related to the use of aldicarb on citrus that was prepared by AgLogic. This exercise is somewhat revealing; since October 2017, AgLogic has submitted percent crop treated values for oranges and grapefruit at least 15 times, dietary exposure and risk assessments at least 7 times, and information and documentation that aldicarb is not used outside the US at least 10 times, but it appears that this information has not been considered by BEA.. AgLogic respectfully requests that you set up this call as soon as possible.

In the meantime, please let me know if you have any questions or if you need us to resubmit any of the information summarized in the attached.

Regards,

Ann

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, October 5, 2020 12:43 PM
To: Ann Tillman <Ann@PyxisRC.com>
Cc: Janelle Kay <Janelle@PyxisRC.com>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657): Response to Registrant - PCTn used in DEEM (domestic and import)

Hi Ann,

I am working with the BEAD team to see if they have any comments/answers to issues raised in your email below and whether another meeting would be beneficial at this time.

What I am able provide you with today is the break down of the numbers used in the dietary analysis with respect to the domestic and import PCTn used in the assessment.

Oranges (fresh): 15% domestic; 3% import (18%)
Orange (juice): 75% domestic; 15% import (90%)
Grapefruit (fresh)
Grapefruit (juice)

Regards,
Debra

From: Ann Tillman <Ann@PyxisRC.com>
Sent: Tuesday, September 22, 2020 3:05 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Janelle Kay <Janelle@PyxisRC.com>
Subject: RE: Request PRIA Renegotiation: Pending actions EPA Reg. No. 87895-2 (Decision# 549655) and EPA Reg. No. 87895-4 (Decision# 549657)

Hi, Debra,

After reviewing the revised % crop treated numbers BEAD is using in its refined dietary risk assessment, AgLogic believes that there may be a mistake in the BEAD calculations related to percent crop treated acres. In addition, no details were provided on imported crops (discussed below). These miscalculations may result in erroneous dietary risk cup assessments. After you have a chance to review this information, let me know if a meeting between AgLogic and BEAD can be arranged to discuss the inputs.

AgLogic is only applying for registration on oranges and grapefruit in the States of Florida and Texas. Given the reliable USDA statistics on the fresh fruit and juice fruit acreages in FL and TX, BEAD's crop treated percentages simply do not add up. Per 2019 USDA NASS data, the total number of US acres of citrus, including California and Arizona, are as follows (see the tables at the end of this email for detailed breakdowns; this information was provided to the Agency earlier this year):

Fresh fruit—orange + grapefruit = 168,457 + 24,896 = 193,353 Acres

Juice fruit—orange + grapefruit = 382,326 + 24,780 = 407,106 Acres

Based on BEAD's reassessment for crop treated acres (Orange: 18%, Orange juice: 90%, Grapefruit: 65%, Grapefruit juice: 90%), the following acres in FL and TX would be treated with aldicarb:

Fresh orange (168,457 x 0.18 = 30,322 A) + grapefruit (24,896 x 0.65 = 16,182 A) = 46,504 Acres

Juice orange (382,326 x 0.9 = 344,093 A) + grapefruit (24,780 x 0.9 = 22,302 A) = 366,395 Acres

Note that based on BEAD's % CT, the total acres of fresh oranges to be treated exceed the USDA NASS number of available acres to be treated in FL and TX (yellow highlight).

Fresh fruit—orange + grapefruit = 17,389 +16,796 = 34,185 **available** FL + TX Acres

Juice fruit—orange + grapefruit = 344,863 + 23,848 = 368,711 **available** FL + TX Acres

Furthermore, AgLogic provided information to EPA in March 2020 wherein AgLogic voluntarily offered to limit that the total number of orange and grapefruit acres that can be treated in FL and TX to 100,000 bearing acres of oranges and grapefruit combined. AgLogic did not provide a breakdown of acres treated of fresh vs. juice. **However, as a worst case scenario assuming all 100,000 of the FL+ TX acres are treated with AgLogic aldicarb and those fruit are destined for juice production, then those total acres account for**

24.6% of the total juice acres in the US (100,000 A in FL + TX divided by 407,106 A all acres planted for juice).

Juice fruit--orange + grapefruit = 382,326 + 24,780 = 407,106 total US Acres

Juice fruit--orange + grapefruit = 100,000 assumed total FL + TX Acres treated with aldicarb (24.6% of total US acres for juice production)

Since all application of aldicarb in Florida is made under Florida rule, the Florida Department of Agriculture and Consumer Services (FLDAC), specifically issues permits for all locations and acres that can be treated with aldicarb. Thus FLDACS *de facto* limits acres that can be treated by using permits required under the Florida rule. AgLogic itself has a rigorous industry leading Stewardship program which, among other restrictions, tracks all sales and aldicarb product movements from factory to dealer to end user. If AgLogic only produces enough product to treat 100,000 acres oranges and grapefruit per year, that will together with its other Stewardship programs and the Florida rule automatically cap the treated acreage.

Can BEAD provide more details to AgLogic regarding BEAD's assumptions regarding treated acreage on imported crops? In the past, BEAD has used erroneous assumptions regarding the long-expired Bayer Crop Science registration in Mexico. EPA has documentation on file confirming that in August 2010, Bayer canceled all its aldicarb registrations, exited the global aldicarb business, and terminated its global production and sales of aldicarb in all countries including the US and Mexico. AgLogic has provided the Agency with specific information and documentation that there are NO aldicarb uses on any crop in Mexico or any other country. There can be no imported commodities such as citrus, processing potatoes or sweet potatoes coming in from Mexico that could possibly contribute to the dietary risk assessment. If BEAD has valid information, documenting existing registration and sales of aldicarb in Mexico, then AgLogic should be provided those details for complete transparency in BEAD's assessment. AgLogic was not contacted by BEAD, but would be very pleased to provide BEAD with credible evidence confirming termination of aldicarb sales in Mexico.

Recently EPA Administrator Andrew Wheeler traveled to North Carolina on August 25, 2020, and on September 18, 2020 to Missouri. On each occasion farmers were lauded by the Administrator including in Missouri where he was directly quoted: "America's farmers—one of our strongest allies in our mission to protect public health and the environment".

Speaking of farmers, in July 2018 AgLogic sent EPA the written requests and sworn affidavits of the large and key Florida citrus growers strongly requesting reinstatement of aldicarb for use on citrus. It is clear in these letters that AgLogic aldicarb is a prized and unique crop production tool for citrus, eliminating use of some sprays, increasing fruit quality and yields, and crucially improving tree health.

University of Florida Professor, the late Dr. Phil Stansly, declared in the attached sworn affidavit that ""It may not be hyperbole to state that re-registration of aldicarb could make the difference between life and death of Florida's iconic citrus industry. Accordingly, I urged that no effort be spared in registering aldicarb again for citrus in Florida."

AgLogic profoundly respects the work of BEAD and the Agency, and is respectfully trying to work with the Agency through these comments and questions, so that some tangible progress can be made during the PRIA extension using relevant information pertaining to the proposed use of Aglogic aldicarb on citrus. Aldicarb was used for many decades on citrus. After its withdrawal, the bearing acres of Florida citrus were decimated by the greening disease. This application is critical to the Florida citrus industry.

Table 1. Fresh Orange Production[1]

Area	Acres	Percent of Total Acres
Florida	13,621	8.09%
Texas	3,768	2.24%
Florida and Texas only	17,389	10.32%

[1] USDA-NASS, 2019

Area	Acres	Percent of Total Acres
Total US	168,457	100.00%

Table 2. Orange Juice Production

Area	Acres	Percent of Total Acres
Florida	339,828	88.88%
Texas	5,035	1.32%
Florida and Texas only	344,863	90.20%
Total US	382,326[2]	100.00%

Table 3. Fresh Grapefruit Production

Area	Acres	Percent of Total Acres
Florida	10,497	42.16%
Texas	6,299	25.30%
Florida and Texas only	16,796	67.46%
Total US	24,896	100.00%

Table 4. Grapefruit Juice Production

Area	Acres	Percent of Total Acres
Florida	14,148	57.09%
Texas	9,700	39.14%
Florida and Texas only	23,848	96.24%
Total US	24,780	100.00%

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, September 16, 2020 7:00 AM
To: Ann Tillman <Ann@PyxisRC.com>; Janelle Kay <Janelle@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; 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,

As I explained on our call the last week, we do not have a finalized memo that can be shared. We will provide, as before, the current %CT, as refined by BEAD based on the limited amount of aldicarb available for the citrus uses. The % CT for these citrus commodities used in our DEEM analysis for Food Alone that resulted in aPAD of 100%, are the following:

Orange: 18%
Orange juice: 90%
Grapefruit: 65%
Grapefruit juice: 90%

[2] The total acres dedicated to orange juice is based on a calculation of number of boxes and yield per acre (by box) from California, Texas and Florida. As the value is estimated, based on averages of production, actual acreage may differ from calculated acreage.

I believe you have all of the other inputs used by HED in the DEEM analysis sent to you and Janelle (1/19/2020). At this time we are moving forward to explore the alternate water modeling to further refine those numbers. Let us know if you have any questions.

Regards,
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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U.S. Environmental Protection Agency

Phone: 703-306-0309