Message

From: Niman, Aaron [niman.aaron@epa.gov]
Sent: 5/22/2019 3:37:54 PM
To: Doherty, Michael [Doherty.Michael@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]
Attachments: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Thanks Mike,

Here is the related email chain in which David recommended that Larry Hodges/AgLogic contact Marion to determine if there is a mechanism by which data can be submitted to CCPR/JMPR. It is also our understanding that AgLogic does not own the actual data that supported their U.S. registrations.

-Aaron

From: Doherty, Michael
Sent: Wednesday, May 22, 2019 11:27 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Sent to EPA only

All,

Ex. 5 Deliberative Process (DP)

Mike

From: Larry Hodges <larryhodges@meycorp.com>
Sent: Wednesday, May 22, 2019 10:39 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>
Subject: FW: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Mr. Miller,

Regarding the CCPR review of aldicarb, the email from Soren Madsen (WHO) suggests that it would be best if the EPA would provide the required studies to the CCPR and WHO for review by someone not from the EPA.

AgLogic is a generic registrant and our aldicarb registration is supported by studies that were conducted and submitted to the EPA by aldicarb's previous registrant. Although AgLogic Chemical has met the statutory requirements that allow EPA to rely upon all of the aldicarb studies in EPA's database we are not allowed to have copies of the actual studies that

support our registration. As we are not able to submit these studies the CCPR or WHO for review, the alternative suggested by Mr. Madsen is for EPA to submit the studies directly to the CCPR and WHO.

As you suggested I emailed Marion Johnson and asked him to arrange a meeting to discuss the aldicarb review but have not heard back from him. Hopefully, Mr. Johnson will be able arrange a meeting in the near future.

Thanks and Best Regards,
Larry

From: MADSEN, Soren [mailto:madsens@who.int]
Sent: Wednesday, May 22, 2019 5:05 AM
To: Larry Hodges <larryhodges@meycorp.com>
Cc: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>; VERGER, Philippe <vergerp@who.int>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry Hodges,

Of the 3 options for data submission regarding aldicarb to the JMPR, I think option 3 would be the most viable. JMPR will need original studies for the evaluation. In addition, it would be very useful to also have the US EPA registration document.

I order to avoid possible (or perceived) conflicts of interest, the JMPR secretariat seeks to assign monographers and reviewers that have not been directly involved in recent national evaluations of the assigned compound.

Regarding the possibilities for data submission, please refer to the previous calls for data available on the WHO website (https://www.who.int/foodsafety/call-data/en/).

Below is an extract from one of these calls:
"Governments, interested organizations, producers of these chemicals, and individuals are invited to submit data for the toxicological and the residues evaluations of the compounds listed."

The US National Authorities are of course welcome to submit data, should they wish to do so.

Best Regards,

Soren Madsen
Department of Food Safety and Zoonoses
World Health Organization
20, Avenue Appia, CH-1211 Geneva 27
Switzerland
Tel direct: + 41 22 791 36 97

From: VERGER, Philippe
Sent: Wednesday, April 17, 2019 7:46 AM
To: Larry Hodges <larryhodges@meycorp.com>; MADSEN, Soren <madsens@who.int>
Cc: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech

<antoinepuech@meycorp.com>
Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry

I forward your message to my colleague Soren Madsen who is the new WHO JMPR Secretary.

Best regards

Philippe
Dr. Philippe Verger
Advisor Food Safety
WHO/EMRO/CEHA

Le 15 avr. 2019 à 15:44, Larry Hodges <larryhodges@meycorp.com> a écrit :

Dear Dr. Verger and Mr. Reichstein,

I sent you the email immediately below requesting help in responding to the upcoming review of aldicarb. As AgLogic is a generic registrant we do not have access to the toxicology and residue studies that have been submitted to the US EPA in support of aldicarb. I made some suggestions on how we could possibly move forward and would like you thoughts on the best way to proceed.

Thanks and Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Larry Hodges
Sent: Tuesday, February 26, 2019 11:35 AM
To: VERGER, Philippe <vergerp@who.int>; Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Dr. Verger and Mr. Reichstein,

It is my understanding that the toxicology and residue dossiers for aldicarb must be submitted by December 2019. AgLogic Chemical LLC can certainly meet this deadline and submit the data that we have developed on aldicarb. However, AgLogic is a generic registrant and, as allowed by US law, our aldicarb registration is supported by toxicology and residue data that were developed and submitted to the US Environmental Protection Agency (US EPA) by aldicarb's previous registrant, Bayer CropScience.

Although AgLogic Chemical has met the statutory requirements that allow EPA to rely upon Bayer's aldicarb data, including payment of compensation to Bayer, we are not allowed to have copies of the

actual studies that support registration. Therefore, we are not able to submit these studies the CCPR or WHO for review.

Since it is not possible for AgLogic to submit the toxicology and residue studies that support aldicarb, I would like to propose three possible alternatives:

1. The US EPA recently completed and published its registration review for aldicarb. This document reviews and discusses all data required to support aldicarb registration in the USA. We could submit this document in place of the studies.
2. Since the US EPA already has all of the supporting studies, the aldicarb reviews could be written by the US EPA's residue and toxicology experts that participate in the CCPR and WHO.
3. The US EPA could provide the required studies to the CCPR and WHO for review by someone not from the US EPA.

Please let me know how best to proceed.

Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: VERGER, Philippe [mailto:vergerp@who.int]
Sent: Friday, October 26, 2018 10:21 AM
To: Larry Hodges <larryhodges@meycorp.com>; Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry,

I am responding as I guess Australia is sleeping now... The date mentioned by Ian is to apply to the prioritization. My date 1 year later is to submit the full tox dossier.

Hope it helps

Philippe

Dr Philippe Verger MD, PhD
Department of Food Safety and Zoonoses
World Health Organization
20, Avenue Appia, CH-1211 Geneva 27
Switzerland
Tel direct: + 41 22 791 30 53
Mobile: + Ex. 6 Personal Privacy (PP)
Website: http://www.who.int/foodsafety/chem/en/

From: Larry Hodges [mailto:larryhodges@meycorp.com]
Sent: 26 October 2018 15:25
To: Reichstein, Ian; VERGER, Philippe
Cc: Miller, David; Niman, Aaron; Doherty, Michael; YongZhen.Yang@fao.org; Antoine Puech
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Mr. Reichstein,

Dr. Verger said the deadline for submission was December 2019. It was my understanding that Dr. Verger was referring to all data. Is the date for the residue data December 2018 and the date for the toxicology data December 2019?

Thanks for the clarification,
Larry

From: Reichstein, Ian [mailto:Ian.Reichstein@agriculture.gov.au]
Sent: Thursday, October 25, 2018 8:08 PM
To: Larry Hodges <larryhodges@meycorp.com>; VERGER, Philippe <vergerp@who.int>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry

Receipt of information to include against aldicarb should be lodged by 1 December 2018 for inclusion in the draft CCPR agenda paper.

I have moved the compound to the 2020 list.

Kind regards
Ian

IC Reichstein

Ian Reichstein
Director - National Residue Survey
Residues & Food | Exports Division
Department of Agriculture and Water Resources

Position number: 13107
Phone +61 (0) 2 6272 5668
Mobile Ex. 6 Personal Privacy (PP)
Location: M9.185 Marcus Clarke Building
18 Marcus Clarke Street CANBERRA ACT 2601 Australia
PO Box 858 CANBERRA ACT 2601 Australia

From: Larry Hodges [mailto:larryhodges@meycorp.com]
Sent: Friday, 26 October 2018 1:48 AM
To: VERGER, Philippe <vergerp@who.int>; Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>

Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Dr. Verger and Mr. Reichstein,

Thank you for moving aldicarb from the 2019 agenda to the 2020 agenda.

Dr. Verger, please clarify if this is to be a follow up evaluation or a full toxicology evaluation. It is my understanding that only data not previously submitted to the JMPR need to be submitted and that the submission should focus on data relevant to determine the potential for public health concerns.

Also, can you tell me the deadline for submission of the studies that will be reviewed in 2020.

Mr. Reichstein, please let me know when you need for us to provide you with the spreadsheet with commodities supported.

Thank You,
Larry

From: VERGER, Philippe [mailto:vergerp@who.int]
Sent: Thursday, October 25, 2018 6:14 AM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: Larry Hodges <larryhodges@meycorp.com>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: Re: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Larry

The solution proposed by Ian is fine for me in particular if you are planning to submit a full tox (and not tax !) dossier. In practice I can remove the compound from the 2019 agenda.
Be aware that the compound was placed on the agenda for public health concern so you may consider also proposing residue data.

Best regards

Philippe Verger
WHO - OMS

Le 24 oct. 2018 à 23:05, Reichstein, Ian <Ian.Reichstein@agriculture.gov.au> a écrit :

> Dear Larry
>
> Thank you for clarifying the ongoing support for aldicarb.
> I do recall our earlier conversation in regard to this compound. Unfortunately I had heard nothing on aldicarb until now and several reservations had been received in the interim.

In any case, the matter can be resolved immediately with aldicarb reinstated as a supported compound awaiting periodic review.
Noting the 2019 Schedule of periodic reviews has reached its quota, aldicarb will be placed as a confirmed listing for the 2020 Schedule.

For the CCPR Schedules and Priorities spreadsheet to which you refer, could you provide a data line (following the spreadsheet format) which I can cut and paste into the file. This should include the commodities supported and the expected number of field trials to be submitted for each?

In regard to the tax data package, Dr Verger is best placed to advise.

I apologise for any confusion in this matter.

Fortunately in almost all cases, these matters are easily rectified.

Kind regards
Ian

Ian Reichstein
Director - National Residue Survey
Residues & Food | Exports Division
Department of Agriculture and Water Resources

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PO Box 858 CANBERRA ACT 2601 Australia

From: Larry Hodges [mailto:larryhodges@meycorp.com]
Sent: Thursday, 25 October 2018 5:39 AM
To: vergerp@who.int; Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; YongZhen.Yang@fao.org; Antoine Puech <antoinepuech@meycorp.com>
Subject: Toxicological Evaluation Aldicarb (177) [SEC=UNCLASSIFIED]

Dear Dr. Verger and Mr. Reichstein,

Aldicarb (177*) is listed as an unsupported compound in Annex 1 of the list of substances scheduled for follow up evaluation at the 2019 Extraordinary Joint FAO/WHO Meeting on Pesticide Residues (see attachment). This document indicates that the deadline for submission of the toxicology data is November 1, 2018.

Additionally, the 50th report of the CCPR, dated April 2018 (see attachment) stated on page 13 that Aldicarb (177*) was unsupported and would be reviewed by the WHO in 2019, presumably at the Extraordinary Meeting in Ottawa.

Would you please clarify/confirm:

- Is aldicarb on the agenda for the Extraordinary JMPR Meeting scheduled in Ottawa on May 7-17, 2019?
- If so, do we need to submit toxicology data by November 1, 2018? (Paragraph 145 from CCPR50 indicated that members/observers needed to commit to provide support/data prior to CCPR51. If so, can the follow up evaluation of aldicarb be rescheduled?)
- Is aldicarb on the 2019 CCPR (51st) meeting to be held in China on April 20-19?

In February 2016 we contacted Mr. Ian Reichstein (Chair of the CCPR Electronic Working Group on Priorities) and recently contacted Mr. David Miller (USA EPA) clarifying our support of aldicarb. AgLogic Chemical LLC is the only USA registrant of aldicarb and fully supports all registered uses and all USA tolerances and corresponding Codex MRLs. Specifically, the supported crops are cotton, dry bean, peanut, soybean, sweet potato, orange, grapefruit, lemon, lime, potato, and coffee.

As we are approaching the November 1, 2018 submission deadline, please let us know if aldicarb is scheduled for review in 2019 or if it can be rescheduled.

*Please note that both of the attached documents list aldicarb as compound 177 whereas previous CCPR and JMPR documents list aldicarb as compound 117.

Thank You,

Larry Hodges
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

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