Message

From: Larry Hodges [larryhodges@meycorp.com]
Sent: 5/9/2019 2:32:39 PM
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: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Mr. Miller,

Thanks for your response. I will contact Marion Johnson to see about scheduling a meeting to discuss data requirements and and how to provide the CCPR with the studies.

Regards,
Larry

From: Miller, David [mailto:Miller.DavidJ@epa.gov]
Sent: Thursday, May 9, 2019 10:22 AM
To: Larry Hodges <larryhodges@meycorp.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>
Subject: FW: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Dr. Hodges,

Thank you for your email below.

I have cc'd Marion Johnson in our Registration Division who I understand handles this chemical. You should likely be communicating with Marion on this issue as far as it relates to EPA matters or any meetings you might request with the Agency.

I took the liberty of also cc'ing Dr. Michael Doherty who is on JMPR and is knowledgeable in this area as well as Aaron Niman who interfaces with Dr. Reichstein on US chemicals scheduling with respect to CCPR.

We would be happy to meet with you regarding "what data are required and how this data will be submitted to the CCPR", but this should be arranged through Marion Johnson.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Larry Hodges <larryhodges@meycorp.com>
Sent: Wednesday, May 08, 2019 11:18 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Mr. Miller,

The email response from Mr. Ian Reichstein indicates that aldicarb is scheduled for CCPR review in 2020. It is my understanding that supporting residue and toxicology studies must be submitted by November 1, 2019. Would it be possible to schedule a meeting to discuss compliance with CCPR data submission? As a generic registrant, without access to the studies that support our US registration, we need to understand what data are required and how this data will be submitted to the CCPR.

Thanks for your help,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Reichstein, Ian [mailto:Ian.Reichstein@agriculture.gov.au]
Sent: Tuesday, May 7, 2019 8:40 PM
To: Larry Hodges <larryhodges@meycorp.com>
Cc: MADSEN, Soren <madsens@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Niman, Aaron <niman.aaron@epa.gov>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Brisco, Gracia (AGFC) <Gracia.Brisco@fao.org>; Codex Contact Point <Codex.Contact@agriculture.gov.au>; Black, Tom <Tom.Black@agriculture.gov.au>; Garwood, Jenna <Jenna.Garwood@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; wibke.meyer@croplife.org
Subject: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Larry

To be absolutely clear, as Chair of the CCPR eWG on Priorities, I have neither the power nor authority to change the status of a nomination in the CCPR Schedules and Priority Lists without first consulting with respective nominators. Accordingly my email of 6 May was circulated to vested interests in the 2020 Schedule of JMPR Evaluations.

I have received a response from Codex Secretariat which correctly refers to the Codex Procedural Manual and a 2020 JMPR Schedule of Evaluations confirmed at the 51st session of CCPR.
I believe the only way forward is to proceed with the 2020 Schedule as agreed at CCPR51 and note the addition of terbufos and carbaryl as carryovers from the 2019 Schedule.

At the September / October 2019 JMPR data call-in, nominators to the 2020 Schedule will be required to respond with respective data submissions.
JMPR will prioritise terbufos and carbaryl higher and do its best to attend to all of the compounds nominated in the 2020 Schedule. Given the available evaluator resources, it is unlikely all compounds will be evaluated in 2020.

Therefore it will be critically important for each nominator to respond to the JMPR data call-in promptly and correctly.

In regard to your concerns for the aldicarb data package, I suggest that between now and October 2019, you continue to engage with the USEPA and JMPR Secretariats to determine a way forward.

I hope this clarifies and assists.

Kind regards
Ian

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: Tuesday, 7 May 2019 11:21 PM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: MADSEN, Soren <madsens@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Niman, Aaron <niman.aaron@epa.gov>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Brisco, Gracia (AGFC) <Gracia.Brisco@fao.org>; Codex Contact Point <Codex.Contact@agriculture.gov.au>; Black, Tom <Tom.Black@agriculture.gov.au>; Garwood, Jenna <Jenna.Garwood@agriculture.gov.au>
Subject: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Mr. Reichstein,

I appreciate your email and information about aldicarb but I do not understand its current status. In your email of October 24, 2018 you said that aldicarb will be placed as a confirmed listing for the 2020 Schedule and in your email immediately below you indicate that aldicarb may be reclassified as RESERVE.

In my emails to you of February 26, 2019 and April 15, 2019 I explained that AgLogic Chemical LLC is a generic registrant and we do not have access to the toxicology and residue studies that have been submitted to the US EPA in support of aldicarb. Although AgLogic Chemical has met the statutory requirements that allow the US EPA to rely all aldicarb data that have been submitted in support of registration we are not allowed to have copies of the actual studies. Therefore, we are not able to submit these studies to the CCPR and WHO for review.

In my emails I noted three possible alternatives for providing data for the 2020 aldicarb review:

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 if aldicarb will remain on the 2020 schedule or if it will be reclassified as RESERVE. If aldicarb remains on the 2020 schedule how should the data be provided? If aldicarb is reclassified as RESERVE please let me know what this means as I am not familiar with the term.

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

Phone: 919-932-5800

From: Reichstein, Ian [mailto:Ian.Reichstein@agriculture.gov.au]
Sent: Monday, May 6, 2019 7:18 PM
To: wibke.meyer@croplife.org; Dunlop Craig CHBS <craig.dunlop@syngenta.com>; Peter Chalmers <Peter.Chalmers@adama.com>; Larry Hodges <larryhodges@meycorp.com>; Michael Kaethner <michael.kaethner@bayer.com>; monika.a.richter@basf.com; Jane M Stewart <jane.stewart@basf.com>
Cc: MADSEN, Soren <madsens@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Niman, Aaron <niman.aaron@epa.gov>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Brisco, Gracia (AGFC) <Gracia.Brisco@fao.org>; Codex Contact Point <Codex.Contact@agriculture.gov.au>; Black, Tom <Tom.Black@agriculture.gov.au>; Garwood, Jenna <Jenna.Garwood@agriculture.gov.au>
Subject: FW: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear colleagues

Please note the email from our WHO representative Soren Madsen in regard to the JMPR periodic review of terbufos and carbaryl.
Both compounds are currently listed in the 2019 periodic review schedule.

For the reasons noted below, both compounds need to be moved to the 2020 JMPR Schedule of Periodic Reviews.
As the quota of periodic reviews is six compounds, two compounds in the current 2020 Schedule need to be reclassified as RESERVE.

For reference, the compounds in question are listed in the tables at the bottom of this message.

Two of the following compounds: aldicarb, metalaxyl / metalaxyl-M, diazinon, fipronil, prochloraz and methidathion need to be reclassified as RESERVE.
Please note that should evaluator resources become available, some of the reserves may be evaluated in 2020.

Noting the issues in regard Metalaxyl-M and proposed MRLs held at Step 7 for 15 years, I strongly recommend this compound and metalaxyl are not reclassified to RESERVE.

Please provide your thoughts / preferences within 5 working days?

Kind regards

Ian

ICReichstein

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: MADSEN, Soren [mailto:madsens@who.int]
Sent: Thursday, 2 May 2019 6:08 PM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Budd, Karina <Karina.Budd@agriculture.gov.au>
Cc: HO, Ngai Yin <hon@who.int>; LUNE, Nora <lunen@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>
Subject: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Ian and Karina,

It was a pleasure meeting you in Macau.
I wish to inform you that we have had to make some changes in the JMPR schedule for the evaluation of Terbufos and Carbaryl.
Despite several attempts, it has not been possible to find willing and able epidemiological expertise to commit to the evaluation of these two compounds for the September 2019 JMPR meeting.
As time is drawing near, I have had to choose between an evaluation without the epidemiological component or a postponement of the evaluation to September 2020. We now have a senior epidemiologist who have committed to undertake the 2020 epidemiological evaluation, and I have decided to go for a complete (but postponed) evaluation rather than a less complete evaluation in accordance with the initial schedule for the September 2019 JMPR meeting.
I suppose that you may want to reflect these changes in the CCPR spreadsheet.

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

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RELEVANT TABLES FROM THE CCPR PRIORITY LISTS AND SCHEDULES – CURRENT 23 APRIL 2019

YEAR	TOXICOLOGY	RESIDUE	COMMODITIES	PREVIOUS EVALUATION	ADI	ARfD	MEMBER / MANUFACTURER	Comments
2019	carbaryl (008)			2001T, 2002R	0.008 (2001)	0.2 (2001)	Bayer CropScience	toxicological review only

2019	terbufos (167)			2003T, 2005R	0.0006 (1989)	0.002 (2003)	AMVAC	toxicological review only

YEAR	TOXICOLOGY	RESIDUE	MEMBER / MANUFACTURER	COMMODITIES	COMMENTS
2020	Aldicarb (117)	Aldicarb (117)	AgLogic Chemical LLC		Awaiting further advice on commodities from sponsor
2020	Metalaxyl-M (212) Metalaxyl (138)	Metalaxyl-M (212) Metalaxyl (138)	Syngenta / Australia		Toxicology and animal metabolism data only
2020	Diazinon (22) Note: Diazinon was scheduled for toxicological and residue assessment by an interim JMPR to be held in Spring 2016, based on concerns raised by IARC on the possible carcinogenic properties of the substance (see Summary Report JMPR2015).	Diazinon (22)	Adama	Pineapple, apple, pears, cherries, wheat, barley, onion, tomato, cabbage, chili and potatoes.	Falls under the 15-year rule (listed in Table 2B), last evaluation in 1996. EU Concerns are as follows: The substance is not authorised in the EU. The EU-ADI of 0.0002 mg/kg bw/day) is much lower than the JMPR ADI (0.005 mg/kg bw/day). Using the existing CXLs and the EU ARfD/ADI in the EFSA PRIMo model, serious public health concerns are identified after long-term dietary exposure of diazinon. An acute dietary risk assessment was performed using CXLs. When using the JMPR IESTI model, the JMPR-ARfD is not exceeded. By using the EFSA PRIMo model and the CXLs, the EU-ARfD is exceeded (IESTI 1) in case of scarole (175%), plums (132%), carrots (127%), melons (121%), apples (118%), broccoli (117%), tomatoes (116%), pears (105%), head cabbage (105%), bovine meat (102%). Refinement (IESTI 2) of the variability factors would still lead to exceedances of the ARfD for scarole, melons, plums and bovine meat (102-175%). Use of the HR would lower the short term exposure by a factor of 2 which would not result in an exceedance of ARfD. Even without including the LOQs for the crops without MRLs, the highest calculated TMDI values in % (EU) ADI are 376-4990% in various populations (child, toddlers, general public) and countries, with meats, pome fruit, carrots and sugar beets contributing the most (all >>100 % of the ADI). It is acknowledged that the use of the STMRs would lower the long-term dietary exposure by approximately a factor of 4-5, but this would still lead to an exceedance of the ADI.
2020	Fipronil (202)	Fipronil (202)	BASF		006 Assorted tropical and sub-tropical fruits – inedible Peel; 006 Assorted tropical and sub-tropical fruits – inedible Peel; 006 Assorted tropical and sub-tropical fruits – inedible Peel; 006 Assorted tropical and sub-tropical fruits – inedible Peel; 015 Pulses; 016 Root and tuber vegetables; 020 Cereal grains; 021 Grasses for sugar or syrup production; 04 Nuts and seeds; 023 Oilseeds

2020	Prochloraz (142)	Prochloraz (142)	BASF / FMC / ADAMA		Last reviewed by JMPR in 2001. In 2011, Prochloraz was re-evaluated in the EU and a lower acute toxicological endpoint of 0.025 mg/kg/bw/d was established compared to a value of 0.1 set by JMPR in 2001. From the JMPR report (2004) the IESTI was calculated to be greater than 25% of the ARfD at 0.1 for several commodities. With a lowering of the ARfD by a factor of 4, the CXLs for banana, edible offal (mammalian), grapefruit, mandarin, orange, papaya, pineapple, shaddocks/pomelos are expected to be of concern. The EU values were derived from 2 studies that do not appear to have featured in the JMPR evaluation. The multi-generation rat study "Reader 1993" submitted as part of a dossier by a notifier and a 90 day dog study " Lancaster 1979" submitted by another notifier. In addition a change in the interpretation the significance of extended gestation in both the "Cozen 1980 study" and the "Reader 1993" study also impacted. It should also be noted the many papers reviewed as part of the literature search around prochloraz were also considered when the list of endpoints and critical values were set.
2020	Methidathion (51)	Methidathion (51)		Peach, mango, apple, pear, cherry, mandarin, tea	Manufacturer support from Zenno Chem for mango and peach scheduled for 2020¶If no support for existing CXLs, then revocation of CXLs at CCPR49. - The active substance has been re-evaluated for residues (after its first inclusion in 1972) in 1992. An ARfD was derived in the toxicological re-evaluation in 1997.¶As a consequence of this ARfD a couple of MRLs are not safe for consumers. Due to the fact that no periodic re-evaluation of residues took place in 42 years it is proposed to carry out a new evaluation. The JMPR has established an ADI of 0.001 mg/kg bw/d and an ARfD of 0.01 mg/kg bw/d in 1997. A risk assessment was performed using the EFSA PRIMo including all MRLs that were considered relevant for international trade. The ADI was exceeded for 25 European diets with the highest exposure representing 2392% of the ADI. Citrus fruits, olives for oil production and milk were shown to be the main contributors. Citrus fruits also exceeded the ARfD (up to 6631%). A second exposure calculation delete the existing MRLs for citrus fruits, pome fruits and sunflower seeds still showed an that the ADI for 5 European diets was exceeded (up to 301%). For further details see EFSA evaluation on the internet at http://www.efsa.europa.eu/en/efsajournal/doc/1639.pdf

RESERVE	Quintozene (64)	Quintozene (64)	Crompton–AMVAC		Falls under the 15-year rule (listed in Table 2B), last evaluation in 1995. The EU proposes submit a concern form on the basis of public health concerns. Quintozene containing more than 0.1% hexachlorobenzene is banned in the EU. For quintozene (containing less than 0.1% hexachlorobenzene), the necessity for deriving an ARfD has not been assessed (EU or JMPR). Using the CXLs, the JMPR IESTI model and the ADI as surrogate ARfD, an exceedance of the ARfD is found for ginger root (240%); no exceedance is found for the EFSA PRIMo model. Using the (temporary) ADI of 0.01 mg/kg bw/day, the TMDI in the long-term dietary risk assessment does not exceed the ADI using the Codex MRLs and the EFSA PRIMo model However, there are many uncertainties regarding the metabolites that can be formed, depending on application of the active substance at growth stage and on type of plant. There is a lack of sufficient data to exclude consumer risks.
RESERVE	Ethoxyquin (35)	Ethoxyquin (35)			ONE CXL - PEAR The substance is not authorised in the EU and no import tolerances exist. EFSA concluded that the metabolism data used by JMPR for establishing the residue definition for enforcement and risk assessment could not be confirmed as the metabolism data showed deficiencies using the JMPR residue definition. EFSA concluded that the CXL for pears exceeded the ARfD (109%) and proposed to lower the EU MRL to the LOD. The last periodic review of residues was performed by JMPR in 1999 and of toxicology in 1998. This is approximately 15 years ago. It seems that Japan has recently performed a toxicological evaluation of the substance. / COMMENT: a toxicological review occurred in 2005 – reviewed ADI and set ARfD

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