Message

From: Keigwin, Richard [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=151BAABB6A2246A3A312F12A706C0A05-RICHARD P KEIGWIN JR]
Sent: 6/30/2021 10:27:41 AM
To: Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]
CC: Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Lara, Rhina [Lara.Rhina@epa.gov]
Subject: Re: OCSPP IO review: The Intercept, Sharon Lerner re: malathion, DDL: 6/29

I'm fine with the response on the product reregistration numbers.

For malathion, the cancer peer review was over 20 years ago. There's nothing more recent?

Rick Keigwin
Acting Deputy Assistant Administrator for Management
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Phone: 202-564-2910
Sent from my iPhone (Please excuse typos!)

On Jun 29, 2021, at 11:30 PM, Siedschlag, Gregory <Siedschlag.Gregory@epa.gov> wrote:

Resending to include another inquiry from Ms. Lerner below. I'm not planning to get Michal's review of these – let me know if you think I should.

Greg Siedschlag
Chief, Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Phone: (703) 603-9044
Cell: Ex. 6 Personal Privacy (PP)
pronouns: he/him/his

From: Siedschlag, Gregory
Sent: Tuesday, June 29, 2021 11:28 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Lara, Rhina <Lara.Rhina@epa.gov>
Subject: OCSPP IO review: The Intercept, Sharon Lerner re: malathion, DDL: 6/29
Importance: High

Hi Rick,

See our response below regarding malathion to The Intercept. We're a little behind on this one – it was due COB today. Your quick review in the morning would be appreciated!

Inquiry: In February 2000, a working group at the EPA classified malathion as "likely to be carcinogenic to humans" based on evidence that mice and rats exposed to it developed liver tumors. The designation would have required the agency to do a risk assessment that could have limited exposure to the chemical. But after it learned of the agency's proposed classification , Cheminova, the one of the manufacturers, hired a company to reinterpret the evidence and convened another meeting to discuss the carcinogenicity of malathion. Brian Dementi, a senior EPA toxicologist who was an expert on malathion and led the committee that supported its classification as a likely human carcinogen, was not invited — or

even told about — this second meeting, at which the scientists paid to defend malathion suggested downgrading its status to "suggestive evidence of carcinogenicity," a classification that doesn't require a risk assessment.

Dementi wrote to Mike Leavitt and Stephen Johnson, then the EPA administrator and deputy administrator, laying out the evidence that malathion caused cancer and warning that if it was not classified as a likely human carcinogen, "public health will be endangered." Dementi suggested that the pesticide "should be re-assessed by pathologists not in the employ of the registrant." Later he wrote another letter to the EPA administrator, presenting the evidence that children were particularly susceptible to malathion.

Bill Hirzy, a scientist and an official in the union that represented DeMenti, remembers the pressure to give malathion a pass as intense. "When malathion was up for reregistration, when the heads of the various divisions who were looking at health effects were sitting around the table and planning to address the issue, the science advisor poked his head in the door and said 'this is a big-ticket pesticide and we don't want to have any problems,'" he said.

Despite the concerns that Dementi raised, malathion was given the less restrictive designation later that year.

Since then, mounting evidence has linked the pesticide to numerous cancers, including, including thyroid cancer, prostate cancer, and breast cancer. In 2015, the World Health Organization concluded that malathion is "probably carcinogenic to humans." And in 2017, the EPA itself found that 97 percent of federally protected species are likely harmed by it. Nevertheless, malathion remains classified as only having "suggestive evidence of carcinogenicity." Each year, about one million pounds of malathion are sprayed in the U.S.

Response: EPA is following the next steps in the registration review process for malathion in accordance with President Biden's commitment to protect human health and the environment. EPA expects to complete both the Proposed Interim Decision and Interim Decision for malathion in 2022. EPA is working on a revised human health risk assessment, incorporating physiologically based pharmacokinetic (PBPK) data received earlier this year.

Background:
The 2000 Final Cancer Assessment Document for Malathion is available online.

Incoming:
I'm finding a discrepancy between the number of cancelled pesticides and my academic source, spreadsheet attached below (which is from table S9 in the supplementary material for this 2019 article), which lists 37. (I've highlighted all the involuntary cancelations in yellow) Could you please provide me the list of the 40 pesticides EPA has canceled so I can sort it out? Or at the very least, please let me know which three canceled pesticides are not in the table and when they were canceled.

Response:
The list provided focused on *active ingredient* cancellations, not pesticide products that were suspended or canceled during reregistration. The original email inquiry focused on EPA's reregistration program, which has resulted in 40 product suspensions. A product suspension can occur, among other reasons, if the registrant has not submitted required product-specific studies within the time frame specified. The Agency may cancel a product's registration because the registrant did not pay the required registration maintenance fee. Alternatively, the registrant may request a voluntary cancellation of its end-use product registration.

The subject of active ingredient cancellations goes beyond the scope of product reregistration. EPA can confirm that 40 *pesticide products* have been sent for suspension since the beginning of the reregistration process.

Greg Siedschlag
Chief, Communications Branch
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From: Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Sent: Tuesday, June 29, 2021 5:12 PM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Lara, Rhina <Lara.Rhina@epa.gov>
Subject: FW: OPP IO review: The Intercept (4th follow-up) re: malathion, DDL: 6/29

Hi Cheryl – For your review below is the follow-up regarding malathion. The other follow-up will be shared shortly.

Response:

EPA is following the next steps in the registration review process for malathion in accordance with President Biden's commitment to protect human health and the environment. Both the Proposed Interim Decision and Interim Decision for malathion are expected to be completed in 2022. EPA is currently working on a revised human health risk assessment, incorporating physiologically based pharmacokinetic (PBPK) data received earlier this year.

Background:
The 2000 Final Cancer Assessment Document for Malathion is available online.

On Jun 21, 2021, at 3:37 PM, Sharon Lerner <sharon.lerner@theintercept.com> wrote:

Hi Robert, Ken and Nancy-
Sorry there's one - hopefully last - thing I should run by you. After speaking with several people involved and reviewing the documents attached below, I noted the following about malathion. I welcome EPA's perspective on this:

In February 2000, a working group at the EPA classified malathion as "likely to be carcinogenic to humans" based on evidence that mice and rats exposed to it developed liver tumors. The designation would have required the agency to do a risk assessment that could have limited exposure to the chemical. But after it learned of the agency's proposed classification , Cheminova, the one of the manufacturers, hired a company to reinterpret the evidence and convened another meeting to discuss the carcinogenicity of malathion. Brian Dementi, a senior EPA toxicologist who was an expert on malathion and led the committee that supported its classification as a likely human carcinogen, was not invited — or even told about — this second meeting, at which the scientists paid to defend malathion suggested downgrading its status to "suggestive evidence of carcinogenicity," a classification that doesn't require a risk assessment.

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warning that if it was not classified as a likely human carcinogen, "public health will be endangered." Dementi suggested that the pesticide "should be re-assessed by pathologists not in the employ of the registrant." Later he wrote another letter to the EPA administrator, presenting the evidence that children were particularly susceptible to malathion.

Bill Hirzy, a scientist and an official in the union that represented DeMenti, remembers the pressure to give malathion a pass as intense. "When malathion was up for reregistration, when the heads of the various divisions who were looking at health effects were sitting around the table and planning to address the issue, the science advisor poked his head in the door and said 'this is a big-ticket pesticide and we don't want to have any problems,'" he said.

Despite the concerns that Dementi raised, malathion was given the less restrictive designation later that year.

Since then, mounting evidence has linked the pesticide to numerous cancers, including, including thyroid cancer, prostate cancer, and breast cancer. In 2015, the World Health Organization concluded that malathion is "probably carcinogenic to humans." And in 2017, the EPA itself found that 97 percent of federally protected species are likely harmed by it. Nevertheless, malathion remains classified as only having "suggestive evidence of carcinogenicity." Each year, about one million pounds of malathion are sprayed in the U.S.

<Dementi Critique of malathion PWG.pdf>
<BAD SLJ 06.20.05 EPA-HQ-OPP-2006-0618-0028.2[1].pdf>
<BAD SLJ 09.28.06 EPA-HQ-OPP-2006-0618-0028.1[1].pdf>
<PSI Grievance Post hearing brief.pdf>

Please get me all of the outstanding responses by Thursday.

Thank you,
Sharon

Sharon Lerner
Investigative Reporter
The Intercept
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PGP:
CB29 D9FF 9285 3205 087E 83A1 0C30 2F39 4F30 8BFE

On Jun 21, 2021, at 1:21 PM, Sharon Lerner <sharon.lerner@theintercept.com> wrote:

Hi Ken and Robert-
I'd like to add one more question to my follow-ups:
You mentioned in your response that 8,846 pesticide products (i.e., registrations) have been reviewed and

accepted to meet the requirements of the REDs for the active ingredients in each product.

My question is: how many are still awaiting review? i.e. 8,846 have been completed out of how many overall?

Thanks,

Sharon

Sharon Lerner
Investigative Reporter
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PGP:
CB29 D9FF 9285 3205 087E 83A1 0C30 2F39 4F30 8BFE

On Jun 18, 2021, at 2:40 PM, Daguillard, Robert <Daguillard.Robert@epa.gov> wrote:

Thanks Sharon. Ken will get back to you when we return to the office on Monday.

Enjoy the weekend – hopefully sunny where you are.

Robert Daguillard
Public Affairs Officer
U.S. Environmental Protection Agency
Washington, DC
+1 (202) 564-6618 (O)
Ex. 6 Personal Privacy (PP) (M)

From: Sharon Lerner <sharon.lerner@theintercept.com>
Sent: Friday, June 18, 2021 2:25 PM
To: Labbe, Ken <Labbe.Ken@epa.gov>
Cc: Press <Press@epa.gov>
Subject: Re: Questions about pesticide regulation

Hi Ken-

I have three follow-up questions:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thanks,
Sharon

Sharon Lerner
Investigative Reporter
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PGP:
CB29 D9FF 9285 3205 087E 83A1 0C30 2F39 4F30 8BFE

On Jun 17, 2021, at 4:16 PM, Labbe, Ken <Labbe.Ken@epa.gov> wrote:

Hi Sharon, Please see our responses below:

1. I spoke to more than two dozen people for this story about pesticide regulation, including 12 who used to work at OPP. One of the subjects they consistently brought up was the influence of pesticide companies over the office. One person who worked at OPP for 40 years told me: "When you come into the lobby, many times there's a chemical or ag lobbyist there. They just bop in. They want to be your friend. They always

complement you. But if you don't do what they want, they'll go to your boss or above your boss and say we can't work with you anymore. And you'll be taken of the project and put on something that's meaningless. I've seen it happen a number of times.

2. Regarding post-EPA employment of former OPP directors: I found that, since 1974,all seven former OPP directors who continued to work after leaving the agency (Dan Barolo, Marcia Mulkey, Steve Schatzow, Jim Jones, Steve Bradbury, Edwin Johnson, and Debra Edwards) went on to make money from the pesticide industry, either as direct employees, attorneys, or consultants. (The two other former directors who left the agency went directly into retirement.)

   One PhD level former EPA scientist told me he thought that the "revolving door" influenced the culture within OPP, saying "management officials are loathe to take any action that is likely to limit their post-EPA employment opportunities"

3. One former OPP staffer told me that she felt the scientists in the office are overwhelmed by the amount of science they receive from registrants. "There aren't enough resources to go through all the studies. And there isn't enough time. What

happens then is that people at EPA look at what the contractors said and decide whether to accept it or not. For the most part they just accept it."

RESPONSE:

Ex. 5 Deliberative Process (DP)

4.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

RESPONSE:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

5. Are OPP staff members allowed to count crop/farm tours as/toward work time? If so, is there a limit to the number of hours that can be spent this way? And is there a limit to the amount of money sponsoring groups can spend per person on these tours?

   RESPONSE:
   Crop tours are typically held during the work week. EPA abides by all ethics statutes and maintains a culture of the highest ethical conduct with the amount of money sponsoring groups can spend on activities that EPA staff attend.

   Staff participation in crop tours have provided an increase in awareness and more educated discussions on the subject at hand such as farmworker issues.

6. QUESTION:
   Are bonuses for OPP staff sometimes based or partially based on the number of pesticides registered or reregistered?

RESPONSE:
EPA does not award bonuses to staff based on the number of pesticide registrations issued.

7. Ex. 5 Deliberative Process (DP)

RESPONSE:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

8. Ex. 5 Deliberative Process (DP)

RESPONSE:

9. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

RESPONSE:
In May 2020, EPA issued the interim decision (ID) for pelargonic acid, which includes a thorough review of the best available science, as required under FIFRA. EPA has concluded that there is no new information that would require pelargonic acid to

be reassessed by the Cancer Assessment Review Committee (CARC).

10. I spoke to biostatistician Lianne Shepperd about this paper, in which she described a "flawed analysis" of a 1972 paper commissioned by Dow and used by EPA to set risk tolerances for chlorpyrifos from 1984 and through the 1990s. Shepperd told me that Dow statisticians "conveniently left out one of the two baseline measurement days," in their analysis. "The outrageous thing was that the group they declared as NOEL was only that because they left out data from their analysis." Shepperd said that the paper continues to be influential, even though the EPA officially withdrew it from consideration in 2009 for ethical reasons. I asked her why she thought the EPA didn't detect what she described as "data falsification" and she told me: "EPA didn't scrutinize it at the level I did. The science is hard. And once a study has been around, who goes back and looks after it's been accepted for 10, 15, or 20 years?"

RESPONSE:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

11.

Ex. 5 Deliberative Process (DP)

RESPONSE:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

12. In 2013, GAO and NRDC put out reports on conditional approval of pesticides. NRDC found that thousands had been approved through this loophole. Do you dispute that number? Do you have updated numbers on conditional approvals?

RESPONSE:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

To view all pesticide active ingredients that were initially registered under the conditional registration authority in FIFRA sec. 3(c)(7)(C) from FY 2000 through August 2020, visit our website.

13. Ex. 5 Deliberative Process (DP)

Nguyen's memo remained stapled into the larger file on
acetamiprid. QUESTION: Why did the NOEL for acetamiprid go back up to 10 mg/kg day in 2017?

RESPONSE:

Ex. 5 Deliberative Process (DP)

Kenneth T. Labbe
U.S. Environmental Protection Agency
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