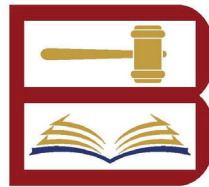


In The Matter Of:

*In re FIFRA Section 3(c)(2)(B) Notice of Intent to Suspend
Dimethyl Tetrachloroterephthalate (DCPA) Tech. Reg.*

*Vol. 2
January 25, 2023*



BURKE
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BEFORE THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

----- :
IN RE: :
FIFRA SECTION 3 (c) (2) (B) NOTICE : DOCKET NUMBER:
OF INTENT TO SUSPEND DIMETHYL : FIFRA-HQ-2022-0002
TETRACHLOROTEREPHTHALATE (DCPA) :
TECHNICAL REGISTRATION :
 :
AMVAC CHEMICAL CORPORATION; :
GROWER-SHIPPER ASSOCIATION OF :
CENTRAL CALIFORNIA; SUNHEAVEN :
FARMS, LLC, ; J&D PRODUCE; RATTO :
BROS, INC.; AND HUNTINGTON FARMS, :
Petitioners-Appellants. :
----- :

The above-entitled matter came on for virtual hearing pursuant to notice before the HONORABLE SUSAN BIRO, Administrative Law Judge, at the Environmental Protection Agency East Building, 1201 Constitution Avenue, NW, Room 1152, Washington, D.C., on Wednesday, January 25, 2023, at 9:00 a.m.

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Richard Freedlander	309	311	323	--
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P R O C E E D I N G S

(9:02 a.m.)

1
2
3 JUDGE BIRO: Good morning, everyone. Please be
4 seated. Mr. Reporter, are you ready? Okay. Are there
5 any preliminary matters before we continue today?

6 MR. ROSS: Yes, Your Honor. The parties have
7 prepared a joint filing that addresses a few procedural
8 issues concerning exhibits and expert stipulations. If
9 you would like, I can briefly run through the substance
10 of that filing. It addresses first the stipulations as
11 to expert testimony and the scope of expert testimony.
12 Second, it provides a stipulation as to a statement of a
13 particular AMVAC witness, who provided a verified witness
14 statement in June, but not an updated statement in
15 January.

16 JUDGE BIRO: Mr. Ross, could you put the
17 microphone a little bit closer to you, because I can't
18 hear you very well.

19 MR. ROSS: Second, it provides a stipulation
20 concerning the testimony from an AMVAC witness, who
21 provided a verified witness statement in June, but not a
22 revised witness statement in January. And based on that
23 stipulation, OPP has no further need to question that
24 witness and so we will not be calling that witness.
25 Third --

1 JUDGE BIRO: And who is that?

2 MR. ROSS: That is Julie Porter. Third and
3 finally, it jointly requests admission of several PAX and
4 RX exhibits. It notes a few objections, but does ask
5 that those be admitted into evidence. Finally, it
6 discusses Petitioner AMVAC's Exhibit 85, which is a copy
7 of the SETAC 1995 publication. We have uploaded only the
8 cover page, because we do not currently have copyright
9 clearance to put the entirety of that document on the
10 internet. But we will follow any direction we receive
11 from the Office of Administrative Law Judges concerning
12 that.

13 JUDGE BIRO: All right. You've filed that in
14 the docket, in this case?

15 MR. ROSS: We have not yet filed it. We will
16 file it this morning.

17 JUDGE BIRO: All right. So are there exhibits,
18 additional exhibits we need to admit now on that
19 document?

20 MR. ROSS: If you would like, I can -- I can
21 read in the stipulations as to those exhibits. And
22 then --

23 JUDGE BIRO: Just give me --

24 MR. ROSS: -- remove them from the filing.

25 JUDGE BIRO: Yeah, just give me the numbers

1 that we're agreeing to admit.

2 MR. ROSS: Certainly. The first, the parties
3 request that PAX-46, RX-13, RX-14, and RX-16 be entered
4 into evidence. These are internal agency documents that
5 were reviewed during the cross-examine -- cross-
6 examination testimony of Jill Bloom.

7 (Petitioner's PAX-46 identified.)

8 (Respondent's R-13, 14, and 16 identified.)

9 MR. ROSS: Second, the parties request that
10 PAX-48, 50, and 52 through 56 be entered into evidence.
11 These were also reviewed during the cross-examination
12 testimony of Jill Bloom. There were some additional
13 emails within that range that were previously entered
14 and, of course, remain in the record.

15 (Petitioner's PAX-48, 50, and 52 through 56 identified.)

16 MR. ROSS: And then finally the parties request
17 that Petitioner AMVAC's Exhibit 85, the SETAC
18 publication, be entered into evidence subject to OPP's
19 objection that PAX-85 is not relevant to the statutory
20 scope of the hearing.

21 (Petitioner's PAX-85 identified.)

22 JUDGE BIRO: I'm going to admit the SETAC
23 document over the Agency's objection. It would go to
24 weight, how much weight if anything we're going to give
25 it. You can admit the cover page and a select portion if

1 you think that's relevant. And that would be more than
2 sufficient.

3 MR. ROSS: Thank you, Your Honor.

4 JUDGE BIRO: What exhibit number did -- was
5 that given?

6 MR. ROSS: The SETAC book is Petitioner AMVAC's
7 Exhibit 85.

8 JUDGE BIRO: Okay. So PAX-85 is admitted over
9 the agency's objection.

10 (Petitioner's PAX-85 received.)

11 JUDGE BIRO: And then the ones that are
12 admitted by consent were PAX-46, RX-13, 14, 16, PAX-48,
13 50, and 52 to 56. Is that right?

14 MR. ROSS: Correct.

15 JUDGE BIRO: I see everybody nodding. And
16 that's right, Ms. Rose?

17 MS. ROSE: Yes, Your Honor.

18 JUDGE BIRO: Okay. So all those exhibits are
19 admitted into the record.

20 (Petitioner's PAX-46, 48, 50, and 52 to 56 received.)

21 (Respondent's RX-13, 14, and 16 received.)

22 JUDGE BIRO: Is there any other preliminary
23 matters?

24 MR. ROSE: Yes, Your Honor. I have one.

25 JUDGE BIRO: Okay.

1 MS. ROSE: Your Honor, the Growers have three
2 witnesses as you know who are also in the Pacific Time
3 zone. And I've discussed with counsel for AMVAC and OPP
4 trying to find a window of time it makes sense to have
5 them appear so that they can continue uninterrupted and
6 scheduling purposes. And we have agreed, the parties
7 have agreed 11:00 a.m. tomorrow, Thursday, Eastern Time,
8 which would be starting at 8:00 a.m. Pacific.

9 The OPP has indicated that they object to the
10 relevance of their testimony, but do not intend to
11 cross-examine them at this time. So subject to the
12 Court's questions and me laying foundation for a couple
13 of documents, the testimony of these three witnesses
14 might be relatively brief.

15 JUDGE BIRO: Couldn't we just admit their
16 written statements in lieu of them actually coming to the
17 hearing, by consent, and their exhibits?

18 MR. PITTMAN: If, Your Honor, that would be
19 both the exhibits and testimony would be subject to the
20 same relevance objection, but if you were to admit them
21 over objection we have no further.

22 JUDGE BIRO: Is there any objection to that?

23 MR. ROSS: No objection, Your Honor.

24 JUDGE BIRO: Ms. Rose, would that be acceptable
25 to you?

1 MS. ROSE: I believe so. Let me go back to my
2 notes. There are a couple of issues that they intended
3 to add by way of update, would clearly take 2 or 3
4 minutes. Perhaps we could also do a short supplement to
5 their written testimony submissions and see if OPP has
6 any objection or AMVAC has any objection. And if not, we
7 can proceed in that manner.

8 JUDGE BIRO: Okay. Well, why don't you get
9 back to me this afternoon on that.

10 MS. ROSE: Okay, okay. Thank you.

11 JUDGE BIRO: Thank you, Ms. Rose.

12 MS. ROSE: Thank you.

13 JUDGE BIRO: I think we were going to -- I
14 think did the Agency rest?

15 MR. PITTMAN: Yes, Your Honor.

16 JUDGE BIRO: Okay. Thank you, Mr. Pittman. So
17 I think that we're onto the Petitioner in this case.
18 Would you like to call your first witness?

19 MR. ROSS: Yes, Your Honor. We will call Dr.
20 Niamh McMahon.

21 JUDGE BIRO: Mr. Ross, are we admitting -- go
22 ahead Dr. McMahon. Are we admitting Ms. Porter's
23 statement into the record or we're not having her
24 testimony at all?

25 MR. ROSS: Ms. Porter's --

1 JUDGE BIRO: Yes.

2 MR. ROSS: -- statement will not be moved into
3 evidence.

4 JUDGE BIRO: All right. Dr. McMahon, could you
5 stand and raise your right hand, and let the reporter
6 swear you in.

7 DR. McMAHON: Yes.

8 (Whereupon,

9 CATHERINE NIAMH McMAHON,
10 having been first duly sworn, was called as a witness
11 herein and testified as follows:)

12 JUDGE BIRO: Thank you, Ms. McMahon -- Dr.
13 McMahon. Please be seated. Okay, please proceed.

14 DIRECT EXAMINATION

15 BY MR. ROSS:

16 Q. Good morning, Dr. McMahon.

17 A. Good morning.

18 Q. Can you please state your full name for the
19 record?

20 A. Yep, Catherine Niamh McMahon.

21 Q. Do you have a copy of your written or witness
22 statement in front of you?

23 A. I do.

24 MR. ROSS: Can you -- Mr. Sayres, could you
25 please bring up Dr. McMahon's January 9th statement,

1 please?

2 THE WITNESS: Yes, I see it.

3 BY MR. ROSS:

4 Q. Dr. McMahon, do you recognize the document --

5 A. I do.

6 Q. -- in front of you?

7 A. Yes.

8 Q. Is this a true and accurate copy of your
9 written witness statement in this matter?

10 A. It is.

11 Q. Can you just briefly state your, your current
12 position with AMVAC?

13 A. Yes. I'm a regulatory manager at AMVAC.

14 Q. Can you briefly summarize your history as it
15 relates to the registration review of dacthal and the
16 notice of intent to suspend?

17 A. Yep, sure. So I took on the responsibility for
18 dacthal or DCPA at the end of April 2022. So it was due
19 to the retirement of the previous regulatory manager, who
20 had the same role as I did at that time. And the first
21 action I did on the DCI for dacthal was working on the
22 NOITS and receiving the NOITS. Yeah.

23 Q. In connection with working on both the
24 registration review of dacthal and the NOITS, have you
25 reviewed AMVAC's records as it relates to both

1 registration review and the NOITS?

2 A. Yes.

3 MR. ROSS: I tender the witness.

4 JUDGE BIRO: Okay. Is there any cross, Mr.
5 Pittman?

6 MR. PITTMAN: Yes, Your Honor.

7 CROSS-EXAMINATION

8 BY MR. PITTMAN:

9 Q. Good morning, Dr. McMahon. Nice to see you.

10 A. Good morning.

11 Q. Thank you for making the trip out here. I have
12 a handful of questions for you.

13 MR. PITTMAN: Ms. Koch, could you bring up
14 JX-37. Could you scroll to the, the top of that?

15 MS. KOCH: Which exhibit was it?

16 MR. PITTMAN: JX-37.

17 BY MR. PITTMAN:

18 Q. So Dr. McMahon, are you familiar with this
19 document?

20 A. Yes.

21 Q. And this was provided to AMVAC on about
22 March 17, 2017. Correct?

23 A. That's correct. Yes.

24 Q. So in your statement, you state that because
25 EPA sometimes took a long period to respond to AMVAC's

1 waiver requests, AMVAC believed that those studies at
2 issue would likely not be required based on the results
3 of other studies.

4 A. Mm-hmm.

5 Q. So if we could turn to page 6 of JX-37 here?
6 Thank you. So could you read very quickly the section
7 for the 835.4400 to yourself.

8 A. The entire section?

9 Q. I'm sorry, not read into the record. Can you
10 just read it for yourself for a moment, please.

11 A. Okay. It's gone from -- oh, here we go. And
12 you want me to read the first section 835 --

13 Q. I just -- I was going to ask you a question
14 about it. I wanted to make sure that you are familiar
15 with it. Are you familiar with this, this phrasing here,
16 both the stated AMVAC request for a waiver and the
17 response?

18 A. Yes. Yes.

19 Q. So if I understand it correctly, the quoted
20 rationale for AMVAC's request to waive this particular
21 TPA data requirement is that OPP should use anaerobic
22 aquatic metabolism data for the parent compound DCPA to
23 meet this data requirement. Correct?

24 A. Yes. So the AMVAC comment comes from a
25 previous document that AMVAC had submitted. And then you

1 see the EFED response underneath, yep.

2 Q. But the rationale is that OPP should use the
3 DCPA data essentially?

4 A. Yes. And in the bridging mechanism, too, read
5 across the data, correct.

6 Q. So in this document, OPP's response states that
7 understanding and dissipation of TPA is a critical risk
8 assessment question. Correct?

9 A. Say that one more time.

10 Q. So in the -- it's labeled EFED response, the
11 paragraph. And understanding dissipation of TPA is a
12 critical risk assessment question.

13 A. Yep, that's what it says.

14 Q. So you would interpret the statement from OPP
15 that it is not intending to waive this particular data
16 requirement. Correct?

17 A. In the bold statements, yeah. That recommends
18 that PRD deny the waiver request. And I would assume
19 that is from the justification given above. Yes.

20 Q. So after receiving this document, did you
21 interpret OPP's position to be that the TPA study would
22 likely not be required based on the results of the DCPA
23 studies?

24 A. Say that one more time.

25 Q. When AMVAC received this document, would you

1 have interpreted it -- would you have interpreted
2 OPP's --

3 MR. ROSS: I'm going to object to foundation.
4 Just based on the phrasing, he's asking for a
5 contemporaneous interpretation and Dr. McMahon just
6 testified that she reviewed the documentation concerning
7 the DCPA after the fact and would not have had an
8 interpretation contemporaneously.

9 MR. PITTMAN: I'll rephrase.

10 JUDGE BIRO: Okay, restate it.

11 BY MR. PITTMAN:

12 Q. Reading this document today, do you interpret
13 OPP's position as reflected in this document to be that
14 the TPA study would likely not be required after the day
15 this was delivered to AMVAC based on the results of that
16 DCPA study?

17 A. So if I had read the document that it was based
18 on initially, the AMVAC information that was given, and
19 then I would look at this comment, and then I would move
20 on through the entire record. Then knowing the full
21 story, then I would say that that is a denial of a
22 waiver.

23 Q. So from this document, you understand that
24 OPP's position as of May -- sorry, as of March 2017 was
25 that the 835.4400 study for TPA was still needed?

1 A. Whose opinion did you ask me to --

2 Q. OPP's.

3 A. OPP. I would say that's EFED's opinion and
4 they are informing PRD and OPP, yes.

5 MR. PITTMAN: Okay. Ms. Koch, could you pull
6 up JX-67?

7 BY MR. PITTMAN:

8 Q. Dr. McMahon, are you familiar with this
9 document?

10 A. Yes.

11 Q. So this document was sent to OPP from AMVAC in
12 2018. Correct?

13 A. Say that again.

14 Q. This document, AMVAC sent this document to OPP
15 in 2018? I believe the date is in February. Can you
16 scroll up a little?

17 A. In February, yes. It went from AMVAC to OPP.

18 Q. This document contains AMVAC's responses to a
19 number of waiver denials. Correct?

20 A. I think it's a mixed document. There's quite a
21 lot of information in there. So it's, it's kind of -- it
22 gathered together again a lot of the information that was
23 outstanding or was uncertain, unclear. So it really does
24 mix a lot of different studies at different stages at
25 that time.

1 Q. But in part this document does contain AMVAC's
2 responses to prior OPP waiver denials, at least in part?

3 A. At least in part, yes. If you scroll down, you
4 can see the full list of studies. I can't remember
5 off-hand -- yes, I think that's accurate.

6 MR. PITTMAN: Ms. Koch, could you scroll down
7 to page 15. I think is it one up? The page discussing
8 835.4400. I think one -- perhaps I have my pagination
9 wrong. Yes, this one. So apologies, it is page -- can
10 we confirm just for the record what page of X this is? I
11 believe my pagination was wrong in my notes.

12 JUDGE BIRO: I think it is, isn't it, 15 --
13 oh, 14.

14 MR. PITTMAN: 14.

15 BY MR. PITTMAN:

16 Q. So if you could just take a moment to, to look
17 at this?

18 A. Okay.

19 Q. So in this document, AMVAC is again requesting
20 that OPP consider the results of other studies before OPP
21 would require AMVAC to submit this TPA study. Correct?

22 A. Yes. So they discuss some studies, yeah, and
23 they want data to be looked at before they submit this.

24 Q. So following OPP's 2017 document or however you
25 character -- the document sent from an EPA subdivision in

1 2017 that we just reviewed a few minutes ago, in that
2 document OPP stated that the data was still needed for
3 this particular study. Correct?

4 A. Say that one more time. Sorry.

5 Q. So the document JX-37 that we read a few
6 minutes ago.

7 A. Yes.

8 Q. You agreed that OPP's -- that EPA's position as
9 stated in that document was that this particular study
10 was still required.

11 A. That this particular study was what?

12 Q. Was still required.

13 A. Required, yes.

14 Q. But, so instead of conducting that study or
15 initiating that study, AMVAC submitted this document and
16 opted instead to provide more information in support of
17 its initial waiver request?

18 A. I think this is referring to data that was
19 already at the agency.

20 Q. So your position is that this is not actually a
21 new waiver request. It is reiterating the original
22 waiver request.

23 A. I don't think it's a rebuttal. It's a position
24 statement or a statement position of, of where AMVAC was
25 at that time.

1 Q. Sorry, not rebuttal, but reiterating. I
2 understood that you just said it's essentially
3 reiterating the same documents and the same position that
4 AMVAC initially made?

5 A. I would have to go back and look at the AMVAC
6 documents of the original position from I think it was
7 the 90-day response.

8 Q. But it would be similar. It's essentially
9 advancing a similar argument to AMVAC's initial request
10 to waive this data?

11 A. I'd have to look at the pre -- go back to the
12 document that put out the original position. Because
13 what you've shown me is just a quick statement, yeah.

14 MR. PITTMAN: Okay. Ms. Koch, can we turn to
15 JX-21, please.

16 BY MR. PITTMAN:

17 Q. Dr. McMahon, are you familiar with this
18 document?

19 A. Yes. This is the one that is from October of
20 2020.

21 Q. Yes, the Respondent has been referring to it as
22 the data delay letter throughout this.

23 MR. PITTMAN: So could we turn to page 3 of
24 this document, Ms. Koch?

25 BY MR. PITTMAN:

1 Q. So about a halfway down the page in this table
2 here again discussing the 835.4400 TPA study, Dr.
3 McMahon, you would agree that this letter states that the
4 waiver request for that study is denied?

5 A. That's what it says, yes.

6 Q. So in reading this document, you understand
7 OPP's position as of October 2020 was that an 835.4400
8 study and TPA was still required. Correct?

9 A. Yes. And there's an outstanding footnote. Can
10 you drop down to the footnote? So that was the, the
11 information, the basis for that waiver from the 2014
12 document that you've already showed me, right, that you
13 got in 2017?

14 Q. Correct. I believe that was JX-37. It is
15 dated 2014 in this footnote. But we stipulated this
16 document was provided to AMVAC not until 2017. But the
17 question remains is that in this document OPP is
18 reflecting that the, the data is still outstanding and
19 that the waiver request has been denied. Correct?

20 A. Yep, that's what the table says.

21 Q. So from reading these documents this morning,
22 it doesn't appear that OPP's position changed between
23 2017 and 2020. Correct?

24 A. Whose position?

25 Q. EPA.

1 A. EPA's position from 2017, when you saw that
2 first document, to this one, no, it did not change.

3 Q. Thank you.

4 MR. PITTMAN: Ms. Koch, could we call attention
5 to JX-78?

6 BY MR. PITTMAN:

7 Q. Dr. McMahon, are you familiar with this
8 document?

9 A. I'm not familiar with this document. I haven't
10 read this document.

11 MR. PITTMAN: Okay. Ms. Koch, could you just
12 pull up JX-21 again? So can you go to the last page of
13 the table here.

14 BY MR. PITTMAN:

15 Q. Dr. McMahon, with respect to Special Study
16 1072, I believe the parties have been referring to it as
17 the leptochairus study thus far. This table reflects
18 that the waiver request is denied and the -- and that the
19 data is outstanding. Correct?

20 A. That's what it says, yes.

21 Q. So this document also states again that the
22 Guideline 850.1740, 10-day toxicity study may proceed in
23 the interim and that the results may allow EPA to
24 reconsider the waiver request for this leptochairus
25 study. Correct?

1 A. That's what it says, yes.

2 MR. PITTMAN: Your Honor, I would like to
3 approach the witness with a copy of what's been labeled
4 as Respondent's Exhibit 21.

5 JUDGE BIRO: Okay.

6 (Respondent's RX-21 identified.)

7 BY MR. PITTMAN:

8 Q. Dr. McMahon, do you recognize this document?

9 A. Yes. That is my testimony from -- there's no
10 date on it.

11 Q. I believe on the signature page.

12 A. Yes. This is my testimony from June.

13 Q. So this is a -- this is a verified written
14 statement that you prepared and signed in June 2022 for
15 this case. Correct?

16 A. Correct.

17 Q. Is it a true and accurate copy?

18 A. It looks like that that was submitted at that
19 time, yes.

20 Q. Thank you. And so when you signed the
21 statement, Dr. McMahon, it was closer in time to the
22 events discussed in your statement than the statement
23 that you submitted a few weeks ago in January of this
24 year?

25 A. Closer in time to what?

1 Q. Closer in time to the events that are discussed
2 in your statements, your respective statements.

3 A. Right. And so the, you know, I learned all of
4 this after April 2022. So I was working through the
5 records and looking at all the documentation in April.
6 So working pretty hard on, on building this, yes, so my
7 knowledge would be from the records at that time.

8 Q. I can sympathize. I understand getting through
9 all of these documents. So --

10 A. I'm sorry?

11 Q. I said I can sympathize. Okay, thank you.

12 MR. PITTMAN: Mrs. Koch, can we turn to this
13 statement, RX-21, and can we turn to page 5. Can you
14 scroll down a little bit more? Thank you.

15 BY MR. PITTMAN:

16 Q. So Dr. McMahon, on this page, you stated that -
17 - at the time, you stated AMVAC intended to perform the
18 850.1740 study. Correct?

19 A. Yes.

20 Q. And so you stated that AMVAC understands EPA
21 will reconsider its denial of the special study, the
22 special leptochairus study waiver request based on the
23 outcome of that 1740 study?

24 A. Correct, yes.

25 Q. So --

1 A. I mean we went, went through at that time, we
2 were looking at the difference between the 10-day study
3 and the guidelines study. There had been issues with
4 the, the guideline study in earlier years. But the
5 information that we got in April was that the decision
6 was that we should do this study as an interim to help
7 the waiver for the, the guideline study.

8 Q. Thank you. And so you also state in the
9 statement that AMVAC's understanding is based on the
10 October 2020 letter that we looked at a few minutes ago.
11 Correct?

12 A. Say that one more time.

13 Q. Could you just read perhaps the sentence
14 beginning with AMVAC understands?

15 A. Sure. AMVAC understands that EPA will
16 reconsider its waiver request for SS-1072 in view of
17 these results, as stated in EPA's October 16, 2020,
18 correspondence, given that EPA did not specifically state
19 that it would not so reconsider in the 2022 EPA
20 ecological effects waiver response.

21 Q. Thank you. So that statement reflects that
22 AMVAC -- sorry, that you understood that in 2020, this
23 2020 document, EPA might waive the leptochirus study
24 based on the outcome of the 1740 study. Correct?

25 A. From the 2020 document.

1 Q. I'm essentially asking the -- your
2 understanding of why AMVAC would perform the 1740 study
3 was based on the rationale laid out in EPA's October 2020
4 letter.

5 A. But there was no rationale on that. There was
6 no memos and detailed technical information around this
7 study. To me, the October 2020 is a summary of a status,
8 as opposed to a rationale as to why you would or would
9 not conduct a certain study, at a certain time, to do a
10 certain thing.

11 Q. So can you explain to me what you mean by as
12 stated in EPA's October 16, 2020 correspondence? What
13 were you trying to convey with that statement?

14 A. That, to me, that's the status. That is the
15 actual summary of what is the situation in October 2020.

16 Q. Thank you. So AMVAC did not initiate the 1740
17 alternative study prior to OPP issuing the NOITS.
18 Correct?

19 A. That is correct.

20 Q. And AMVAC has not at any point initiated the
21 leptochairus plumulosus special study. Correct?

22 A. Say that one more time.

23 Q. AMVAC has not at any point either before or
24 after OPP issued the NOITS, has not at any point
25 initiated the original special study, SS-1072.

1 A. The original special study, no. Yet, we
2 discussed whether we would propose the protocol to EPA as
3 was requested for the special study. We know that there
4 are still concerns and issues around the guidelines study
5 in its performance, and difficulty doing that. So we did
6 discuss, you know, during the summer, after the NOITS,
7 whether we would do that special study in its full and
8 complete situation, and whether we'd get something from
9 it as it --if it has technical difficulties. What we
10 decided then was that we would not submit the protocol to
11 review and spend that time waiting for a protocol to come
12 back. We would go towards what was proposed as an
13 interim activity, which was to do the 10-day study rather
14 than doing the special study, and follow the proposal of
15 the interim study to be conducted. And that study has
16 started.

17 Q. Thank you, understood.

18 MR. PITTMAN: Mrs. Koch, could we pull up
19 JX-22, please?

20 BY MR. PITTMAN:

21 Q. Dr. McMahon, are you familiar with this
22 document?

23 A. Scroll down a little more, please. Yes, I know
24 the document.

25 Q. Would it be fair to say that this document

1 contains a response from AMVAC to OPP's October 2020
2 communication?

3 A. That was the intent of the document, yes.

4 MR. PITTMAN: Ms. Koch, could you scroll down
5 to I believe -- my page number, I'm positive on this, the
6 discussion of SS-1072.

7 BY MR. PITTMAN:

8 Q. Dr. McMahon, if you would just take a minute
9 and see are you familiar with this section of the
10 document?

11 A. Okay.

12 Q. So here AMVAC is specifically recognizing that
13 OPP was, quote, retaining the requirement for the chronic
14 study, unquote.

15 A. Which line is that? Okay, yes, I see it, yeah.
16 And my review of the records, I have not been able to
17 work out where that understanding came from. So I wasn't
18 there at the time. So I've looked at all the records, as
19 many as I found during the -- working for this case, but
20 I've not been able to determine where that understanding
21 came from, was it a verbal conversation or not. So I
22 don't understand or I can't be able -- I can't tell you
23 or help you with this particular understanding where it
24 came from, how the discussion went at that time.

25 Q. But this document reflects that AMVAC had such

1 an understanding at the time. Correct?

2 A. Yes. They've expressed that they had an
3 understanding, yes.

4 Q. And so --

5 A. As I say, I don't know where that came from.

6 Q. In this document, AMVAC also states that it
7 will wait for OPP to take other actions before it
8 initiates any study. Correct?

9 A. Where is the other actions?

10 Q. Specifically, validation of the special study
11 or issuance of a DCI.

12 A. I don't know if it was specific to the agency
13 taking those actions. The labs, themselves, were having
14 problems with the study. So it may have been a
15 combination of the, the labs and the -- and the agency.

16 Q. So when you're referring -- sorry. Are you
17 familiar with the concept of study validation?

18 A. Not in detail. I'm not an ecotoxicologist or a
19 toxicologist. But I understand the concept of guidelines
20 and that they are validated, even the draft guidelines.
21 And new guidelines get introduced into regulatory
22 requirements not very often, but it does happen, and they
23 take time to be utilized, and perform well, and reliably.

24 Q. So it's fair to say that your understanding of
25 what validation means in this context would be to take

1 the special study and leptocheirus, and presumably for
2 OCSPP to adopt that as a Series 850 ecotox guideline.
3 Right?

4 A. As I say, that's not my expertise.

5 MR. ROSS: Objection. Beyond the scope.

6 MR. PITTMAN: I'll move on.

7 JUDGE BIRO: Okay.

8 BY MR. PITTMAN:

9 Q. So AMVAC's rationale for this decision that
10 it's not going to take further action as stated in this
11 document is based on the belief that the very low
12 toxicity of DCPA to aquatic organisms. Correct?

13 A. That that would not delay their conclusions
14 concerning this organism, yes.

15 Q. So this document reflects AMVAC's position that
16 a data requirement is not outstanding if the company
17 believes that the data are not required for OPP to
18 conduct a risk assessment.

19 A. I think what's missing here is the link -- er
20 why AMVAC had the conversation in the first place is that
21 this, the study that was proposed or the interim study
22 was not on the DCI. And so it was the basis around being
23 asked to conduct a study that was not on the data
24 call-in, in the first place. I think that was more the
25 discussion that had happened in the past. Again, I

1 wasn't there. But that was my understanding that it
2 wasn't validated. The study on the DCI was not a
3 validated study. People were having difficulty doing it.
4 And this was proposed as an interim, but it was an
5 informal interim. There may be some confusion of whether
6 it was a study to be done instead of or to build to a
7 waiver. And I think it took AMVAC a little while to
8 understand that it was to build towards a waiver and not
9 a direct swap of studies from one to the other. I think
10 some of that conversation that happened there, those
11 earlier discussions were more about it being an official
12 requested study through a DCI, as opposed to an interim
13 proposal for a study that's difficult to conduct.

14 Q. So AMVAC was reticent to perform the
15 alternative study because it had not been officially
16 requested through the DCI procedure?

17 A. They asked that question, is my understanding.
18 They asked it for a more formal request for that, yes.

19 Q. So based on that understanding, what was
20 AMVAC's position as to the outstanding nature of the
21 original special study as I understand it, that was
22 requested through the DCI?

23 A. My understanding was that they wanted that
24 study to be -- they wanted more definition about what was
25 actually being asked and proposed for that special study.

1 Q. When you say they, who do you mean?

2 A. So it was on the DCI as a special study. It
3 was expected there would be difficulties performing that
4 study. And so this was proposed, but it was never
5 formally asked through the DCI, and how it would connect
6 in with the formal DCI was not clear. I think that was
7 what the intent was here is to ask for clarity to add it
8 to the DCI.

9 Q. I'm willing to accept AMVAC's position here
10 that it did not want to perform the 1740 study. But I'm
11 talking about -- well, let's just accept that for
12 purposes of argument here that AMVAC doesn't want to do
13 that study. In this document, JX-22, what is AMVAC's
14 position concerning the original study, the one that was
15 included in the DCI?

16 A. It only references earlier discussions. So you
17 have to look back at the previous documents of where
18 AMVAC had discussed that with the agency before.

19 Q. But so -- does AMVAC in this document, is it
20 reflecting a belief that this special study is not -- no
21 longer outstanding?

22 A. I don't think that's what it's saying, no.

23 Q. Thank you.

24 MR. PITTMAN: I have no further questions, Your
25 Honor.

1 JUDGE BIRO: Mr. Ross?

2 MR. ROSS: May I proceed?

3 JUDGE BIRO: Yes, please proceed.

4 REDIRECT EXAMINATION

5 BY MR. ROSS:

6 Q. Good morning, Dr. McMahon. Just a few
7 questions about the two data requirements on which Mr.
8 Pittman's questioning focused. Mr. Pittman's line of
9 questioning concerning -- the first line was concerning
10 the 835.4400. Correct?

11 A. Correct.

12 Q. And you'll recall that Mr. Pittman was asking
13 you to characterize whether or not the agency's position
14 had changed as between two documents. Correct?

15 A. Yes.

16 MR. ROSS: Mr. Sayres, can you bring up Joint
17 Exhibit 79, please?

18 BY MR. ROSS:

19 Q. Ms. McMahon, based on your review of the
20 record, do you recognize this document?

21 A. Yes. We received that in April of 2022, yeah.

22 Q. So this was received after you became involved
23 with DCPA. Correct?

24 A. Correct. Yes.

25 Q. And to your knowledge, is this the most recent

1 document that AMVAC has received concerning certain
2 scientific discussions or document from EFED concerning
3 certain data requirements in the DCI?

4 A. Yes. There was I think two or three documents
5 at the same time in April 2022 from EFED.

6 Q. And specifically with regard to the 835.4400
7 guideline, is this -- do you -- do you understand this to
8 be the most recent document that AMVAC has received that
9 states EFED's position?

10 A. Can you scroll down just a little?

11 MR. ROSS: Yeah. Mr. Sayres, if you could go
12 to page -- it is enumerated 5 --

13 THE WITNESS: Yes, I see it. Yes.

14 MR. ROSS: -- in the footer. Also, 5 of 12, I
15 believe, correct? Conveniently.

16 THE WITNESS: Yep, I saw the table that
17 referenced the study you're talking about.

18 MR. ROSS: And Mr. Sayres, could you flip over
19 to page 6, please.

20 BY MR. ROSS:

21 Q. Ms. McMahon, do you recall EFED's conclusion
22 beginning in the second paragraph here concerning the
23 4400 because of the uncertainty?

24 A. Yes, yes. Aquatic exposure.

25 Q. Is there anything in this paragraph that to

1 your recollection, based on your review of the record,
2 that it was the first time that EFED was suggesting
3 anything in this paragraph?

4 A. I don't know the, the content in detail from
5 the previous document to this document to see if there
6 was a difference between them. Is that what you're
7 asking, that there's a difference?

8 Q. Correct. Just if you -- if as you sit here
9 today do you recall if there was anything with respect to
10 EFED's discussion of this study that EFED had not
11 previously proposed.

12 A. No, I don't know.

13 Q. Do you recall EFED previously proposing at any
14 point that a longer-than-standard study duration might be
15 needed in order to obtain useful data?

16 A. No, I don't. I think this was the first time
17 that that was stated. The guidelines are typically
18 shorter than, than that, yes. And I remember seeing the
19 statement as well in the attachment to the NOITS, the
20 explanatory attachments. It was a very similar statement
21 and I saw that there as well. But that, again, came in
22 April of 2022.

23 Q. Dr. McMahon, do you understand it to be the
24 agency's current position concerning the leptocheirus
25 study that a guideline -- that the acute 1740 study may

1 proceed as an interim step towards potentially satisfying
2 that requirement?

3 A. I think it's a not guaranteed that it will meet
4 that guideline. And if you're talking about the SS-1072,
5 I think it's not a guarantee. And I've acknowledged that
6 it's not a guarantee, in that it isn't a direct
7 substitute for that study. But it is an interim step.
8 The word interim, we understand that to mean that it can
9 be used and there is potential that we won't have to do
10 the SS-1072, but it will depend on the study and the
11 outcome of the study.

12 Q. Gotcha. Do you recall if EPA restated that the
13 acute 1740 could proceed as an interim step at the time
14 that it issued the NOITS?

15 A. I'd have to look at the actual -- I think there
16 it is in one of the EFED memos that that is correct, yes.

17 Q. Yes, I mean if --

18 A. But I don't know which EFED memo it's in.

19 Q. So to the best of your recollection it was
20 stated at the time of the NOITS that the 1740 could
21 proceed as an interim step?

22 A. Yes. And there was some extra details around
23 it. Yeah, I'm remembering that there is -- it was
24 discussed and there was some extra details as well around
25 that labs had -- a few labs had been successful in doing

1 that, the SS-1072. So, yes, there was some text in
2 there, I remember, yes.

3 Q. Correct. As it -- as it relates to the
4 guideline study. But with respect to the acute interim
5 alternative, to the best of your recollection, EPA
6 restated that that could proceed in the interim.

7 A. Oh, yes. Yes, yes.

8 MR. ROSS: No further questions, Your Honor.

9 JUDGE BIRO: Okay. Any recross?

10 MR. PITTMAN: No.

11 JUDGE BIRO: Dr. McMahon, I have a few
12 questions to ask. I'm a bit -- I just want to clarify
13 when exactly did your involvement with DCPA begin?

14 THE WITNESS: Yep. So the regulatory manager
15 before me was retiring at the end of April. EPA was
16 informed about mid-April that he was retiring. And they
17 asked for the new contact and he gave them my name as a
18 contact. I then did a couple of transition, internal
19 transition meetings with the former regulatory manager
20 kind of middle of April time so he was getting me
21 prepped.

22 At that time, we talked about the last studies
23 that were ongoing, but hadn't been yet submitted.

24 Q. JUDGE BIRO: And what other actions?

25 A. THE WITNESS: He, he went through, the labels,

1 pending actions, to give me an understanding of the
2 chemistry and what was coming up. And then he told me
3 that the preliminary draft risk assessment was the next
4 thing coming and he talked about the labels, that there
5 were pending labels at the agency as well. So he kind of
6 gave me that tour if you will, a typical transition
7 meeting to get me ready for taking that on.

8 Then on the 27th, I was copied into the email
9 for the NOITS with the former manager. And then I had a
10 conversation with EPA on the same date. They asked me to
11 acknowledge that we had received the NOITS. So the
12 former manager wasn't available that day and so I signed
13 off that, yes, we received this. The Federal Notice then
14 came and the additional documents that came with the
15 NOITS, you know, the waivers, the DERs, everything that
16 went into the docket subsequent to that. That was the
17 first real touch of -- that I had with DCPA.

18 JUDGE BIRO: Okay. So before April of 2022,
19 you had never been involved with DCPA at all, in any
20 aspect?

21 THE WITNESS: I had in one meeting, just
22 because my chemistry that I was working on was very
23 similar to something and we were preparing for a PMRA
24 meeting. But that was probably a year earlier and very
25 tangential. It just happens that we're trying to do the

1 same thing with the chemistry. He, the former manager,
2 was working on that one. I was working a different
3 chemical. And it just happened it was convenient to do
4 that. That was my only experience with DCPA.

5 JUDGE BIRO: Did you have experience working
6 with EPA on other chemicals for AMVAC?

7 THE WITNESS: Yes, yes.

8 JUDGE BIRO: Okay. How many other chemicals
9 have you --

10 THE WITNESS: So my portfolio is typically 8 to
11 10 active ingredients. Some of those are AMVAC as the
12 primary registrant. Some were generic and were in a task
13 force. Those were building data sets, etc., for data
14 call-ins. I'd had some experience both at AMVAC and a
15 previous employer working on registration review.

16 Sometimes you're, you're doing it from start to
17 finish, you know, it's a -- it's a long process. But
18 most of the time I've done either front-end of this and
19 been moved onto something else, or picked it up from
20 somebody else. So it's quite typical to pick something
21 up from other regulatory managers.

22 JUDGE BIRO: And how long did those
23 registration reviews take?

24 THE WITNESS: So usually they start with the
25 preliminary problem formulation. And then there is a

1 lag. And then you, you get the DCI and then you start to
2 generate some data. And depending on --

3 JUDGE BIRO: Do you -- let me just interrupt.
4 Has AMVAC ever responded to that preliminary problem
5 formulation or a -- what did they call it, proposed --

6 THE WITNESS: To the work plan, the
7 preliminary?

8 JUDGE BIRO: Yeah, proposed work plan.

9 THE WITNESS: For the cases that I'm aware of,
10 no.

11 JUDGE BIRO: AMVAC never responds to those?

12 THE WITNESS: I, I can't answer that because I
13 don't know. I haven't looked at each on in detail.

14 JUDGE BIRO: But any of them that you worked
15 on, they haven't?

16 THE WITNESS: Not the cases I have. I picked
17 up some others, but it was after that period of time.
18 And I know for that particular case, they did not.

19 JUDGE BIRO: Okay. Proceed. You were going to
20 talk about the process?

21 THE WITNESS: Oh, oh, the timing, yeah. So
22 usually depending on the complexity of the studies and
23 the length of the studies, a registration review can go
24 for quite a long period of time. There is a schedule
25 published in the preliminary work plan. I think that's -

1 - it does deviate from that as depending on how long,
2 data takes to generate.

3 In the case of dacthal, the data from just the
4 CTA study was a long and involved, complex study. So
5 that automatically makes it a little longer. But in, in
6 general, they take somewhere between 3 1/2 to 7 years, is
7 kind of -- it really is all over the board. But 3 1/2
8 years I would consider short and 7 years is, is starting
9 to get to the long side, yes. But it really varies on
10 the chemistry.

11 JUDGE BIRO: In one of the documents that AMVAC
12 submitted, I think it was their 90-day response, they
13 indicated that they intended to submit data generated for
14 a foreign registration for this fish early life tox
15 study, one of these 850-1400.

16 THE WITNESS: Right.

17 JUDGE BIRO: Where else is DCPA registered,
18 what other countries?

19 THE WITNESS: I wouldn't know exactly. I can
20 probably tell you a few of the countries. I'm pretty
21 sure that it's registered in South Africa. It is
22 registered -- I'm trying to go from where I've seen
23 labels for the countries. I think there's some Caribbean
24 countries that it's registered in. It is registered in
25 Canada. Anything after that I'd be guessing, yeah.

1 JUDGE BIRO: Is it sold in all those countries?

2 THE WITNESS: I don't know, yeah. I, I can
3 tell you for Canada that, yes, it is. But I don't know
4 for the others. I've seen active production of labels
5 and production, so I would assume that it's sold there.
6 But I don't know for 100 percent sure.

7 JUDGE BIRO: And does it go through
8 re-registration processes in those countries?

9 THE WITNESS: Some countries, yes. Like PMRA
10 would have a re-evaluation process. Some of the other
11 countries may or may not. It depends on their regulatory
12 structure. But typically agencies do some sort of
13 re-evaluation over a period of time to catch up with the
14 science, and to learn and understand if any studies have
15 been generated and how they can regulate the chemical.

16 JUDGE BIRO: Have you been involved in those
17 re-registrations in other countries?

18 THE WITNESS: Only for Canada, because my remit
19 is U.S. and Canada, so we have a different group within
20 AMVAC that does the international registrations.

21 JUDGE BIRO: Okay. And do you use the same
22 studies in those re-registration processes, same
23 scientific studies as you use for EPA?

24 THE WITNESS: Often, yes. Yeah.

25 JUDGE BIRO: Okay. Were you involved in any

1 way with the DCIs that were issued to AMVAC earlier in
2 1987, or '92, or '95?

3 THE WITNESS: No. I've only read the
4 documents, the RED documents, the outcomes, because often
5 they're relevant to the, the DCI that you're getting.
6 Because everything builds on, you know, former
7 discussion. Registration review takes what's there, and
8 looks for the gaps, and builds the data on top of that.
9 So the outcome of a previous evaluation is always the
10 starting point for the next evaluation.

11 JUDGE BIRO: Okay. I think you said that you
12 couldn't determine where the understanding came from that
13 AMVAC apparently alleged it had at one point that the
14 acute testing for leptospirosis would substitute for the
15 chronic study.

16 THE WITNESS: Yes. There was a comment in some
17 notes from a March 2017, it was a check-in meeting
18 between AMVAC and EPA.

19 JUDGE BIRO: It was, I'm sorry, a check-in?

20 THE WITNESS: Like a status check of where the
21 agency and the registrant met. And I don't know the
22 specific objective of that meeting, but it was used to
23 kind of cross-reference where everything was and do a
24 status check. And there were some notes in there that
25 the -- that AMVAC had asked EPA to, to check certain

1 things. And that is the last record that I've seen where
2 AMVAC had asked that question would it be -- could that
3 interim study, which it now understands to be an interim
4 study, could that be placed into the DCI, because it's
5 not on the DCI. It's not a formal request to do that.
6 And then the next document in which we see a reference to
7 it is some of the documents seen here this morning, but I
8 don't know where that understanding came from.

9 JUDGE BIRO: Okay. So there's nothing in that
10 note particularly --

11 THE WITNESS: It was a question --

12 JUDGE BIRO: -- that talks about that
13 understanding?

14 THE WITNESS: No. It was a question to the
15 agency. So the agency must have answered it, but I have
16 no record of the answer because later documents reference
17 then that there is that understanding. But I don't know
18 where it came from.

19 JUDGE BIRO: So the only reference is AMVAC
20 asking the agency--

21 THE WITNESS: Yes.

22 JUDGE BIRO: -- could we substitute one study
23 for another?

24 THE WITNESS: Yes. And then clearly the answer
25 must have been given, because you saw the -- that

1 previous discussions and an understanding was there. But
2 I, I don't know how that occurred, how the answer came to
3 come back.

4 JUDGE BIRO: Were there other notes of interim
5 conversations that were had in the process?

6 THE WITNESS: More by email. Nearly everything
7 else I found is in the written record either by email or
8 documents like you've seen this morning with responses
9 and then memos from the Agency. There is a few -- there
10 was a check-in as well in the October 2020, around --
11 around that time in 2020. There was some discussions --
12 what's your understanding of the status. And you saw
13 that table that kind of summarizes everyone's
14 understanding of the table. It's a communication to
15 understand -- does everybody, you know, -- there's a lot
16 of studies in a registration review, making sure that
17 everything is covered.

18 JUDGE BIRO: Right. You would expect if the
19 agency had consented to substituting one study for
20 another, that would have been in an email or a letter.
21 There would be some documentation, wouldn't you think?

22 THE WITNESS: Yes. And there wasn't. It was -
23 - but it was an interim study that would, could be used
24 to waive the, the other study. And whether AMVAC
25 understood it as a waiver initially or a direct

1 substitution -- it's hard to tell from the record.

2 JUDGE BIRO: Okay. You were aware that AMVAC
3 did this -- I may be -- daphnid. I'm not sure I'm
4 pronouncing that right.

5 THE WITNESS: Yes.

6 JUDGE BIRO: Daphnid study.

7 THE WITNESS: Yes.

8 JUDGE BIRO: And that was also I think an acute
9 study versus a chronic.

10 THE WITNESS: I don't know. I'm sorry.

11 JUDGE BIRO: Okay. Do you know if that study
12 was in the DCI?

13 THE WITNESS: I believe it was. And I'm not
14 100 percent sure. Dr. Freedlander would be able to tell
15 you. I think it was and maybe there was -- I can
16 actually check if you want me to, to check. It would be
17 in the, the table, the initial response whether that was
18 there in the DCI. And our initial response would be
19 quoted.

20 JUDGE BIRO: Okay. Well, the DCI is JX-4.

21 THE WITNESS: Okay.

22 JUDGE BIRO: And maybe somebody could bring
23 that up.

24 THE WITNESS: I could go by the -- I could go
25 by the guideline number. I have JX-5. I'm sorry, JX-5,

1 there is a table on the ecotox study requirements.

2 JUDGE BIRO: Okay. That's AMVAC's response --

3 THE WITNESS: Yes.

4 JUDGE BIRO: -- to the DCI.

5 THE WITNESS: Yes.

6 JUDGE BIRO: Okay. And does it say that the
7 daphnid study is required?

8 THE WITNESS: So if it's 850-1300, on page 22
9 of JX-5, it said that there was a waiver. So the 90-day
10 response would have been a waiver for that study.

11 JUDGE BIRO: Okay. I'm not asking -- so they
12 wanted to waive that. So the request was in the study
13 that they do the daphnid acute study?

14 THE WITNESS: I see -- I see -- I'm looking at
15 the chronic study. I think they waived the chronic
16 study. And then, then there is the response from EPA
17 that that data could be used to tier or to bridge, and
18 they proceeded with that study.

19 JUDGE BIRO: So EPA asked AMVAC to do a chronic
20 daphnid study, but it went onto accept AMVAC just doing
21 an acute study?

22 THE WITNESS: No. I think they're probably two
23 separate study requirements.

24 JUDGE BIRO: Okay.

25 THE WITNESS: I don't know, I'm sorry. I'd

1 have to go by guideline and I'm not an expert on ecotox.

2 JUDGE BIRO: Do you remember AMVAC at any time
3 asking that the DCI be amended to include the acute
4 daphnid study?

5 THE WITNESS: Not the acute daphnid study.
6 They did for the leptocheirus. That was the question can
7 the DCI be amended for the leptocheirus study. But I
8 don't believe so for daphnid.

9 JUDGE BIRO: Okay. Do you know what the cost
10 is of doing the leptocheirus study, this special study?

11 THE WITNESS: I should know, because we, we
12 started the study. And I have a schedule and a quotation
13 from the lab. I think it's --

14 JUDGE BIRO: Just give me a round figure.

15 THE WITNESS: Okay. Yeah, it's probably about
16 \$100,000, so somewhere between \$80 to \$120,000. It's
17 around that.

18 JUDGE BIRO: How about the other kinds of
19 studies that we were looking for, the soil and aquatic
20 metabolism study.

21 THE WITNESS: Yes.

22 JUDGE BIRO: Metabolism.

23 THE WITNESS: Yep.

24 JUDGE BIRO: Metabolism study. How much do
25 those kind of tests cost?

1 THE WITNESS: So they vary a little. And
2 you've got to do some prework as well, because you've got
3 to make some radiolabeled material to be able to run the
4 study. But they typically, for all three would be around
5 \$400,000 to \$450,000. I think one of them is a little
6 cheaper than the others, but an average is -- divide that
7 by three and you can get the idea for a study.

8 JUDGE BIRO: Okay. So 3 of them --

9 THE WITNESS: 120, 150.

10 JUDGE BIRO: -- about \$400,000 --

11 THE WITNESS: Yes.

12 JUDGE BIRO: -- all together.

13 THE WITNESS: All together, yes.

14 JUDGE BIRO: And the fish studies that they
15 were the ecotoxicology studies on these sheepshead
16 minnows and such.

17 THE WITNESS: Yes. They vary as well depending
18 on the species. And they kind of vary again between 150
19 to 250k, thousand dollars. I think again one of the
20 species is very expensive compared to the others, so it's
21 an average of about \$120,000 to \$130,000.

22 JUDGE BIRO: And from the time they start these
23 tests till they end, how long does it generally take?

24 THE WITNESS: So when you're working with the
25 contract research lab, it takes some time to schedule

1 those studies and get them into their ongoing work. You
2 have some technical discussions. Sometimes, there will
3 be a protocol requirement and that lab would write a
4 protocol. And the Agency takes a review, etc.

5 But in general, the in-life phase which is
6 where they're really doing the experiment on the organism
7 is relatively short in the whole scheme of the entire
8 study, right out to the final report. It can be anything
9 from -- like in the case of leptocheirus, we would say a
10 10-day study because that's the actual time length of the
11 in-life phase. So a lot of it is the prep work before
12 that. And then writing -- doing a lot of analysis. A
13 lot of analysis is needed to make sure that the
14 concentrations are correct, that the assessment of the
15 tissues is correct. And so a lot of analytics goes on
16 behind that.

17 So usually those studies can vary from a year,
18 just over a year is the typical length to get to the
19 final report that you're submitting.

20 JUDGE BIRO: From the day you call up the lab
21 and say we --

22 THE WITNESS: No. I would take from the day
23 you call up the lab to getting it actually started is
24 usually depending on their schedule, is probably 2, 3, 4
25 months, because you have to have some technical

1 discussions, what are you trying to achieve. And then
2 from thereon it's probably 9, 10 months to the final
3 report that's ready for submission. It's been reviewed,
4 and QA checked, and all of those things.

5 JUDGE BIRO: Right. And getting your report.

6 THE WITNESS: Yes.

7 JUDGE BIRO: So it's about a year, year and a
8 half?

9 THE WITNESS: Yeah, that's usual, yeah, for a
10 study that -- even though it has a short in-life phase,
11 that would be, yeah.

12 JUDGE BIRO: Bear with me one moment.

13 THE WITNESS: Sure.

14 JUDGE BIRO: In your experience, how often can
15 you ask EPA or have you asked EPA to waive a requirement?
16 In other -- in other pesticides, have you submitted two
17 or three requests for waiver in a row?

18 THE WITNESS: I don't think I have any examples
19 where I've done waivers and, and submitted -- usually,
20 it's more of a conversation where you're discussing a
21 position, and then you build the documentation and the
22 science for that position. So you can elaborate on, many
23 times, your position. And I think that's what's here is
24 that a position is being taken and then you, you work
25 towards, does the EPA agree with your position.

1 And then you'll, you'll bolster your argument
2 with more science and more data. You build a case more,
3 yeah. So official waivers, you know, doing one and then
4 doing another, I usually see those more as a discussion,
5 a technical discussion where you come to an agreement, as
6 opposed to you do a waiver, then you do a waiver, then
7 you do a waiver.

8 JUDGE BIRO: Right.

9 THE WITNESS: It really is an evolution of the
10 data. Because during registration review, you're
11 building data sets. You're understanding more about the,
12 the ingredient that you're working on, the chemical that
13 you're working on. And so more data comes available to
14 put the story together. So, you know, and that can
15 either bolster your argument or your position in the
16 first case, that waiver position, or it can actually do
17 the opposite. And then you, you react and act based on
18 that, yes.

19 JUDGE BIRO: Do you see your role representing
20 AMVAC to try to maintain as broad a use for your
21 chemicals as you can?

22 THE WITNESS: Typically, you're trying to
23 maintain what you have as you go into registration
24 review. When you're expanding uses and building your,
25 your chemistry, you know, to, to broaden your chemistry,

1 you don't really do that during registration review.
2 Registration review is very much about defending, and
3 explaining, and checking the risk for what you already
4 have. And so you're building a data set to do a risk
5 assessment or looking to see if it's safe for use for
6 what you currently have.

7 And you look at the use patterns, clarify the
8 use patterns. If there is uncertainty or unclarity, it's
9 an opportunity as well to sharpen up your label, sharpen
10 up your directions to the user. And a lot of that gets
11 done during registration review to make sure that the
12 users are safe, that the risk assessors are coming out to
13 a conclusion that the data that they have, that they're
14 assessing that you've built over a registration review to
15 get to the, the best label as you're moving out of
16 registration review.

17 JUDGE BIRO: So you were talking about, you
18 have a position and EPA has a position.

19 THE WITNESS: Correct.

20 JUDGE BIRO: And you go back and forth.

21 THE WITNESS: Yes.

22 JUDGE BIRO: Who has the last word in that
23 discussion?

24 THE WITNESS: I think as a regulating agency,
25 the EPA has that last word.

1 JUDGE BIRO: Okay. So if they come back and
2 say you know we understand, Dr. McMahon, everything you
3 said, but we want this study.

4 THE WITNESS: Yes.

5 JUDGE BIRO: That's it, right?

6 THE WITNESS: Yeah. Yes.

7 JUDGE BIRO: Regardless of whether you agree
8 with that and, and think it's useful, that's the end.

9 THE WITNESS: So you know the full process is
10 that every piece of data is contributing to the risk
11 assessment and contributes to the rationale and the
12 understanding of the chemistry. But you hope that all
13 the studies that are asked for contribute to the
14 regulatory decision that's being made. I mean you have
15 the data-call-in, but you don't know the outcome of those
16 studies in advance. That's why we're doing the studies.

17 So some of those may be redundant to building a
18 regulatory decision. But as I say, you always hope that
19 the studies that you are doing are going towards
20 contributing to that regulatory decision. And they don't
21 always do that. And that's many times why a waiver is
22 requested. It's a -- it's an approach at the start. You
23 don't know what you don't know. And then as you build
24 the information that you're -- through the studies, you
25 may have an opportunity for, for a waiver. Or your, your

1 position may be substantiated with the data that you've
2 generated.

3 JUDGE BIRO: So you were -- when you're -- this
4 iterative process, it's you and other scientists like you
5 on the other side. Right?

6 THE WITNESS: Correct. Now I'm not the
7 scientist in this. I'm the manager. So we could be
8 hearing from the scientists for some of this later or
9 from the other testimony. So yes, typically, you work
10 together on a peer-to-peer when you have the opportunity.
11 Typically, you have to request that kind of technical
12 meeting to be able to have your peers, the experts, the
13 technical peers who are the experts. They know the
14 guidelines, and know what these things are, and the
15 importance to the regulatory decision. They'll talk
16 together, yes.

17 JUDGE BIRO: All right. Thank you very much.
18 Hold on. Did my questions raise any questions for you,
19 Mr. Pittman?

20 MR. PITTMAN: No, Your Honor.

21 JUDGE BIRO: Okay. How about you, Mr. Ross?

22 MR. ROSS: Only, only if Your Honor would like
23 Ms. McMahon to possibly testify further about the daphnid
24 studies and whether or not they were included in the DCI,
25 or why are they not. We can I believe handle that from

1 the record, if you'd like to hear from us or --

2 JUDGE BIRO: Okay. I don't -- if you can point
3 it out in the record, we'll go from there.

4 MR. ROSS: Certainly. And the second matter,
5 just procedurally I'd like to move the exhibits to Ms.
6 McMahan's testimony into the record. There are two of
7 them. I will represent to the Court and the parties that
8 the Exhibit B is just an update in time of Exhibit A. If
9 you'd like, I can run through the reason for that update
10 with Ms. McMahan, but if desired --

11 MR. PITTMAN: Just so I understand, you would
12 be attempting to move both statements into evidence?

13 MR. ROSS: No. Ms. McMahan's January testimony
14 was originally submitted with an Exhibit A. That
15 reflected the status of study acceptance as of January
16 9th. That had changed by January 23rd and so that
17 statement was amended. And that's Exhibit B. It
18 reflects that the four residue studies were --

19 MR. PITTMAN: If I understand, the exhibit to
20 her statement, we would have no objection to that.

21 MR. ROSS: We would move that Exhibits A and B
22 to Ms. McMahan's January 9th testimony be admitted into
23 the evidence.

24 JUDGE BIRO: What are we marking her testimony
25 as?

1 MR. ROSS: That would be Petitioner AMVAC's
2 exhibit -- just a moment. Petitioner AMVAC's Exhibit 93,
3 Your Honor.

4 (Petitioner's PAX-93(a) and 93(b) identified.)

5 JUDGE BIRO: Okay. We're going to admit PAX-93
6 with attachment --

7 MR. ROSS: A and B.

8 JUDGE BIRO: -- A and B. Mr. Pittman, are we
9 in agreement on that?

10 MR. PITTMAN: Yes, Your Honor.

11 JUDGE BIRO: Okay. How about Ms. Rose, any
12 objection?

13 MS. ROSE: Yes, no objection.

14 JUDGE BIRO: PAX-93 with Exhibits A and B
15 attached are admitted.

16 (Petitioner's PAX-93(a) and 93(b) received.)

17 JUDGE BIRO: Would you like the right to recall
18 Dr. McMahon at a later point?

19 MR. PITTMAN: If you would, Your Honor. I --
20 sorry, in a similar oversight, also did not request to
21 move Ms. McMahon's June statement labeled as RX-21 into
22 evidence.

23 MR. ROSS: No objection.

24 JUDGE BIRO: Okay. So RX-21 -- do you want
25 this back -- is admitted into the record without

1 objection.

2 (Respondent's RX-21 received.)

3 JUDGE BIRO: Can we release Dr. McMahon to go
4 back to wherever she is?

5 MR. ROSS: Yes, Your Honor.

6 JUDGE BIRO: Okay. Thank you so much for your
7 testimony.

8 THE WITNESS: Thank you.

9 JUDGE BIRO: Oh, Ms. Rose, did I not give you
10 an option for questioning? I'm so sorry. Dr. McMahon,
11 hold on. Do you have any questions?

12 MS. ROSE: I do not. I will speak up. I know
13 I'm far away. I will speak up.

14 JUDGE BIRO: I am so sorry. You're never on my
15 screen and so I, I really apologize. Thank you.

16 MS. ROSE: No, no worries.

17 (Witness excused.)

18 JUDGE BIRO: Mr. Ross, would you like to take a
19 break or do you want to call your next witness?

20 MR. ROSS: We would ask for a 5-minute recess.

21 JUDGE BIRO: Sure. What time is it now? It's
22 10:29. Come back in 15 minutes. Okay. I keep looking
23 at this clock which doesn't move.

24 (Off the record from 10:21 a.m. to 10:36 a.m.)

25 JUDGE BIRO: Please be seated. Mr. Ross, would

1 you like to call your next witness?

2 MR. ROSS: Yes. AMVAC will call Dr. Richard
3 Freedlander.

4 JUDGE BIRO: Good morning, Dr. Freedlander. If
5 you would just stand in the witness box and raise your
6 right hand? Mr. Reporter, would you please swear the
7 witness.

8 (Whereupon,

9 RICHARD SCOTT FREEDLANDER,
10 having been first duly sworn, was called as a witness
11 herein and testified as follows:)

12 DIRECT EXAMINATION

13 BY MR. ROSS:

14 Q. Good morning, Dr. Freedlander.

15 A. Good morning.

16 Q. Can you please state your full name for the
17 record?

18 A. Yes. Richard Scott Freedlander.

19 Q. What is your current position at AMVAC?

20 A. I'm the director of environmental science.

21 Q. How long have you been in that role?

22 A. Approximately, 11 years.

23 Q. How long have you been involved with the
24 registration review of dacthal?

25 A. Well, I'd certainly been reviewing documents

1 that were coming out prior to the data call-in. But
2 maybe since 2009 I've been looking at these type of
3 documents.

4 MR. ROSS: Mr. Sayres, could you please bring
5 up the testimony?

6 BY MR. ROSS:

7 Q. Dr. Freedlander, do you recognize this
8 document?

9 A. I do.

10 Q. And do you by any chance have a written copy of
11 this document that you have with you?

12 A. I have one right here in this binder.

13 Q. Can you identify this document?

14 A. Yes. That's my testimony concerning the trial
15 here today and provides, I think, the relevant
16 information concerning what we'll discuss.

17 Q. Do you also recognize there are three
18 attachments there to the statement?

19 A. I'm aware there's three attachments as well,
20 yes.

21 Q. And looking at the statement and the
22 attachments to it, do they appear to be true and accurate
23 copies of your witness statement and its attachments?

24 A. That's correct.

25 MR. ROSS: I will tender the witness with a

1 reminder just if you could pull your microphone over
2 slightly just to enable -- make it easier for other folks
3 to hear.

4 THE WITNESS: A little closer? Is this better?

5 MR. ROSS: Yes. You'll find, find the
6 distance.

7 JUDGE BIRO: Are we going to admit his
8 statement as PAX-94?

9 MR. ROSS: Yes, please, 94, along with its
10 exhibits.

11 (Petitioner's PAX-94 identified.)

12 JUDGE BIRO: Is there any objection?

13 MR. PITTMAN: No objection.

14 JUDGE BIRO: Okay. PAX-94 is admitted into the
15 record.

16 (Petitioner's PAX-94 received.)

17 JUDGE BIRO: Please proceed with cross, Mr.
18 Pittman.

19 CROSS-EXAMINATION

20 BY MR. PITTMAN:

21 Q. Good morning, Dr. Freedlander.

22 A. Good morning, sir.

23 Q. My name is Forrest Pittman and I'm representing
24 the Office of Pesticide Programs here, and I'll just have
25 a handful of questions for you.

1 MR. PITTMAN: Mrs. Koch, could we pull up
2 JX-66, please?

3 BY MR. PITTMAN:

4 Q. Dr. Freedlander, are you familiar with this
5 document?

6 A. I am.

7 Q. And you discuss this document in your
8 statement. Correct?

9 A. I've discussed it, yes.

10 Q. So could we turn to -- sorry, your statement
11 rather describes this document as containing EFED
12 recommendations. Correct?

13 A. Yes.

14 Q. So you believe when you reviewed this document
15 that OPP had not yet formally denied AMVAC's request to
16 waive certain studies, particularly the 835.4400 data
17 requirement?

18 A. I understood that there were certain data
19 requirements being waived within this document, yeah.

20 Q. I'm sorry. Can you repeat that?

21 A. If I understood what you're saying, it's a
22 little difficult, to be honest, to hear you, is that I --
23 that this was the agency document that basically talked
24 about the requirements, and what would be required, and
25 what sort of studies would -- might be waived as well.

1 MR. PITTMAN: Ms. Koch, could you pull up Dr.
2 Freedlander's statement that was just admitted? So could
3 you turn to page 13, paragraph 66? So in this -- and if
4 you can go down a little bit further, Ms. Koch?

5 BY MR. PITTMAN:

6 Q. So in paragraphs 66 and 67 displayed before you
7 here, is it accurate to describe your statement that,
8 that JX-66 represented recommendations from EFED
9 concerning the 835.4400 data requirement?

10 A. Yes, that's correct.

11 Q. Thank you.

12 MR. PITTMAN: Ms. Koch, can you pull up JX-69,
13 please?

14 BY MR. PITTMAN:

15 Q. Dr. Freedlander, are you familiar with this
16 statement -- or, sorry, this document?

17 A. Yes, I am, sir.

18 Q. And you also discuss this document in your
19 statement. Correct?

20 A. Yes. I do discuss it in my statement, yes.

21 MR. PITTMAN: So can we turn to page 2 of
22 JX-69?

23 BY MR. PITTMAN:

24 Q. If you could just take a moment and look at
25 this.

1 A. Yes, sir.

2 Q. So when you reviewed this document from 2022,
3 you believed that OPP had not yet formally denied AMVAC's
4 request to waive the five outstanding data requirements?

5 A. I understood that the agency had denied waiving
6 certain requirements, yes.

7 Q. So you do understand this document as
8 containing denials of AMVAC's waiver requests. Correct?

9 A. I'm sorry. I'm having trouble hearing you.

10 Q. You understand this document as containing
11 OPP's denial of AMVAC's waiver requests. Correct?

12 A. Right.

13 Q. Okay. Has AMVAC taken any steps to submit the
14 data that was denied by this document?

15 A. We provided just information concerning why we
16 felt the data didn't need to be provided based on our
17 assessment of what the agency had said earlier to us.

18 Q. Okay. And just -- sorry, I just want to ask
19 this one more time. You do understand this document as
20 containing OPP's, the Office of Pesticide Programs,
21 denial of AMVAC's waiver requests?

22 A. Yeah, I, I understand that, sir.

23 Q. Okay.

24 MR. PITTMAN: Ms. Koch, can you turn to JX-74,
25 please?

1 BY MR. PITTMAN:

2 Q. Dr. Freedlander, are you familiar with this
3 document?

4 A. I am, sir.

5 Q. And so this, this document is in response to
6 AMVAC's waiver request for the leptochairus study from
7 March 15, 2016.

8 A. Yes.

9 MR. PITTMAN: And so can we turn to page 3, Ms.
10 Koch?

11 BY MR. PITTMAN:

12 Q. And so this document states that it does not
13 constitute a waiver request, does not constitute a
14 waiver. Correct?

15 A. That is correct.

16 Q. The response here, this document states that
17 the leptochairus study will remain an outstanding. You
18 see that requirement, correct?

19 A. That's what the agency is saying, yes, sir.

20 Q. So would you agree with me that those
21 statements are clear statements that OPP was not waiving
22 the SS-1072?

23 A. I think they were clear statements, yes, sir.

24 Q. This document states that in the alternative, a
25 waiver may be considered at a later date if AMVAC

1 completes the 850.1740 acute tox study. Correct?

2 A. You're talking about the ecological, the
3 ecological studies at this point. So I --

4 Q. Yes, sir. I'm referring to the 850.1740 study.

5 A. Okay.

6 Q. The 10-day --

7 A. Yeah, the agency indicated that, you know, at
8 this point there wasn't a waiver being granted, but they
9 would consider in the future.

10 Q. And this document states that OPP encourages
11 AMVAC to conduct the 1740 study as expeditiously as
12 possible. Correct?

13 A. They -- the agency did state that, yes, sir.

14 MR. PITTMAN: Ms. Koch, could you turn to
15 JX-21, please?

16 BY MR. PITTMAN:

17 Q. Dr. Freedlander, are you familiar with this
18 document? Perhaps scroll down to see.

19 A. Let's see, this is -- yes, I am, sir.

20 Q. Thank you.

21 MR. PITTMAN: Ms. Koch, could you turn to, I
22 believe it's page 4, the last page of the table. I'm
23 sorry. For the record, this would be at page 6 of this
24 document, of JX-21.

25 BY MR. PITTMAN:

1 Q. Dr. Freedlander, looking at the table that's
2 provided here, this document states that the waiver
3 request for Special Study 1072 is denied.

4 A. That's correct.

5 Q. And this letter reiterates the point that we
6 just discussed in the last document, that the 1740 study
7 may proceed in the interim, at which point EPA would
8 consider another, another waiver based on those results?

9 A. Yes, that's correct.

10 Q. So is it correct to say that EPA informed AMVAC
11 on two separate occasions that the SS-1072 was not
12 waived?

13 A. They made it clear that that was the case, yes,
14 sir.

15 Q. And on both of those occasions, EPA informed
16 AMVAC that the results of the 1740 study could lead to
17 EPA waiving the SS-1072 at a later date. Right?

18 A. They did for the most part. But then at one
19 point within one of the agency's document, they indicated
20 that the requirement for a chronic study was very
21 different than the acute study, suggesting to me that the
22 acute study could not serve for meeting the requirement
23 for the chronic study.

24 Q. But EPA indicated that it would consider
25 AMVAC's request to waive the special study based on the

1 outcome of the 1740. Correct?

2 A. They said they would consider that, yes, sir.

3 Q. So AMVAC never initiated the special study
4 1072. Correct?

5 A. We never initiated, but we certainly in the
6 beginning started the process of trying to initiate the
7 study.

8 Q. But so since I believe -- I'm not entirely sure
9 of the date. But AMVAC has recently initiated the 1740
10 study. Correct?

11 A. The acute study, that's correct.

12 MR. PITTMAN: Ms. Koch, could you please bring
13 up JX-22?

14 BY MR. PITTMAN:

15 Q. Dr. Freedlander, are you familiar with this
16 document?

17 A. Yes, I am, sir.

18 MR. PITTMAN: Ms. Koch, could you turn to
19 page 3, please. I'm sorry, I believe I have the page
20 number incorrect. Yes, let the record show it's page 2.

21 BY MR. PITTMAN:

22 Q. Dr. Freedlander, if you'd like a second to just
23 look at the discussion of SS-1072 here.

24 A. Thank you. Yes, sir, I've read it.

25 Q. Thank you. So Dr. Freedlander, this letter

1 from AMVAC acknowledges that EPA was retaining the
2 requirement for the leptocheirus study. Correct?

3 A. That's correct.

4 Q. But in the same paragraph, this document states
5 that AMVAC would not be conducting either SS-1072 or the
6 alternative 1740 study. Correct?

7 A. No, I don't believe that's what it says, sir.
8 AMVAC indicated that if the chronic study that was
9 requested as a part of the original 2013 DCI had been
10 properly validated, we certainly would have done the
11 study. And we also went on further to indicate that we
12 would be willing to do the acute study, if the acute
13 study was directly related to the chronic study. And if
14 the results were clean, could fulfill that requirement.
15 So AMVAC provided basically two states of condition by
16 which it was willing to move forward in terms of
17 conducting the study.

18 Q. So AMVAC is not -- just to be correct, AMVAC in
19 this statement is -- in this document is not stating that
20 it will be moving forward with one of those two studies,
21 right? It's saying it will move forward if EPA takes
22 certain steps?

23 A. So if the study was properly validated such
24 that a successful study could be performed, a chronic
25 study.

1 Q. Dr. Freedlander, would you consider that step
2 of validating to involve EPA needing to take some step?

3 A. I think we would be looking to the agency for
4 guidance that they felt now this study could be properly
5 performed and, and that it was a study that was, was
6 rigorous, that it no longer had to seek the acute study.
7 So, yes.

8 Q. But so, I'm sorry, I'm just trying to get a
9 sense. When --

10 A. Yeah.

11 Q. You're familiar with this document. Are you
12 familiar with the concept of validation of a study?

13 A. Yes, I am, sir.

14 Q. Can you give me your understanding of what
15 validation involves?

16 A. Well, I know that even specifically with regard
17 to this study, it needed to be demonstrated that multiple
18 laboratories could perform the study and meet the
19 specifications that it normally set for an appropriate
20 study. So, for example, in using a control group, that
21 you can show that they can survive through the duration
22 of the study. That's just an example of the criteria to
23 be validated.

24 And if that can be shown repeatedly within
25 several different laboratories, then it would be

1 considered a validated bit with respect to that
2 particular requirement.

3 Q. So, I -- sorry. I understood what you just
4 said here that does involve input, i.e. a step from OPP.
5 Correct?

6 A. Well, I think what we were looking for is --
7 our understanding, we felt that if the agency believed
8 that the chronic study could go forward and there was no
9 longer a need to take this intermediate step, which I
10 think they recognized AMVAC was hesitant to do, that the
11 agency had informed us that, look, we believe this study,
12 there's been sufficient progress, we think that at this
13 point you can go forward with that study, we would have
14 done so.

15 Q. So is that -- is that related to the statement
16 in here concerning, I guess the last sentence of the
17 second paragraph displayed here, considering the very low
18 toxicity associated, AMVAC believes that this data will
19 not impact the agency's conclusions.

20 A. That was -- that was a technical assessment
21 concerning the study and how it would relate to the
22 registration. That was a, a separate statement we were
23 making. And we felt that the agency could move forward
24 in an appropriate manner with regard to the risk
25 assessment. They had, as we had pointed out, data that

1 pointed to this type of study. And we felt that the
2 agency could do so in a comfortable and reliable manner.
3 That's what we were more or less trying to state to the
4 agency.

5 Q. So AMVAC's position as reflected in this
6 document, as of December of 2020, is at least partially
7 based on its belief that this data is not needed, that
8 OPP did not need this data?

9 A. No. We're not saying that's --

10 MR. ROSS: Objection, vague.

11 JUDGE BIRO: Vague?

12 MR. ROSS: He referred to AMVAC's position
13 without allowing the witness to characterize or explain
14 what position he was asking him to describe was supported
15 by one or --

16 MR. PITTMAN: I'll, I'll rephrase.

17 JUDGE BIRO: Okay.

18 BY MR. PITTMAN:

19 Q. So Dr. Freedlander, the position that I am
20 referring to here as reflected in this, this document, I
21 believe you testified a few minutes ago that AMVAC in
22 this document was reflecting a position that it would not
23 conduct either the SS-1072 or the 1740 study.

24 A. No. That's not what I said, sir. I said that
25 if the study was validated and the agency had given us a

1 sign that going forward made sense, we would have
2 certainly undertaken the study. That was our initial
3 intent at the issuance of the DCI. We also indicated
4 that the agency felt that it was more appropriate to
5 perform the acute study, we would do that. But what we
6 were seeking was an appropriate process in terms of
7 asking us for that information.

8 So the point was we were looking for a formal,
9 you know, data call-in that says, look, this is a
10 separate, different requirement from the chronic, but we
11 as the agency are asking for that. And we weren't doing
12 that to be obstinate. It was something that's really
13 important in terms of data compensation considerations.
14 We were just asking for the agency to help us in that
15 regard, to stay true to what we understand the agency's
16 processes for requesting the data.

17 MR. PITTMAN: No further questions, Your Honor.

18 JUDGE BIRO: Maybe we should give a chance to
19 Ms. Rose. Do you have any questions?

20 MS. ROSE: No, Your Honor. Thank you.

21 JUDGE BIRO: Okay. Please proceed.

22 MR. ROSS: Thank you, Your Honor.

23 REDIRECT EXAMINATION

24 BY MR. ROSS:

25 Q. Dr. Freedlander, has it been your general

1 experience that when a registrant requests waivers, there
2 may be a technical scientific discussion between the
3 registrant and EFED?

4 A. Yes. Certainly there has to be many times an
5 exchange of information as to what is behind the agency's
6 thinking, what's behind the registrant's thinking, and to
7 try to come to a meeting of the minds.

8 Q. And would you characterize with respect to the
9 few data requirements that Mr. Pittman just discussed,
10 would you characterize that as what occurred here?

11 A. We felt that there was very slow progress in
12 terms of coming to terms with each other's understanding.
13 It took -- slowly different points were made that were
14 providing some enlightenment in terms of what the agency
15 was thinking about. We felt that some of our most
16 critical points were not coming across well and we
17 endeavored to try to do a better job as we continued to
18 respond to the data call-in.

19 Q. But did EFED at least, slowly perhaps, provide
20 you with information that enabled you to, in your view,
21 better explain to them your position?

22 A. Yeah. The agency -- I'm sorry, could you
23 please ask the question again? I'm not sure I --

24 Q. Certainly. In the course of this DCI, did you
25 receive information from EFED that enabled you to focus

1 in on the specific concerns that they were articulating
2 and then provide them with additional information?

3 A. Yes. Through the process, we did go sometimes
4 to considerable lengths to try to provide additional
5 information, to try to as best as we could understand
6 address the agency's concerns, to try to understand why
7 they weren't in sync with our thinking. You know, we
8 felt that because the process had been elongated, it was
9 challenging to be able to, to have that communication.
10 But we tried to provide some key documents to help to put
11 our position together. And where the agency had raised
12 some concerns, try to address it with as much clarity and
13 as much information as we could provide.

14 Q. So these documents that provided you with
15 additional information, that enabled you to respond, were
16 some of them also denominated as a recommendation that
17 EPA deny the waiver?

18 A. You know the way I understood it in my thinking
19 was the agency -- we were basically putting -- we had
20 basically responded in the DCI with how we intended to
21 respond to the data requirements and put forward waivers.
22 The agency referred to the fact that they were still
23 denying the waivers. We were trying to provide a
24 technical understanding of how we saw the requirements.

25 We also understood, I think it's important, is

1 that we saw the agency indicating paths they would follow
2 if we didn't meet the requirements. And we felt that in
3 some ways, although the agency felt that it would not be
4 as reflective in terms of how to conduct the risk
5 assessment, we thought the agency's approach or early,
6 very early on in terms of for example looking at the fact
7 that this particular degradate we're talking about is
8 stable.

9 We were trying to basically maintain you're
10 correct and, therefore, you know, whether you waive the
11 requirement or not, you've said that you're going to go
12 forward in your assessment and assume it's stable. We
13 thought that was an appropriate path. We didn't believe
14 that we needed a waiver to be satisfied. We saw that
15 direction the agency was warning us they were going to
16 take and, and we thought actually it was appropriate to
17 move forward in that way.

18 We appreciated the fact the agency was trying
19 to alert us that there could be concerns if they
20 conducted the risk assessment in a certain manner. And
21 we were trying to respond and say we understand what
22 you're saying, but we think that you can proceed forward.
23 And that's what we were trying to establish there.

24 Q. And prior to receipt of the NOITS, did you
25 understand that the agency was proceeding towards

1 completion of a risk assessment notwithstanding any
2 outstanding data?

3 A. Absolutely. We made it very clear that if they
4 didn't have the certain data that we're talking about
5 here for which the agency has been seeking that, they had
6 a pathway they were ready to follow. They were confident
7 they could conduct the risk assessment. They were just
8 saying that the risk assessment may be highly
9 conservative, in their view. And we understood what they
10 were saying. And we felt that we took that into account
11 as we moved forward.

12 Q. And in your experience is that a path that the
13 agency has taken in the past to state that conservative
14 assumptions will be made, but proceed to risk assessment
15 nonetheless?

16 A. Yeah. They do it all the time. I think the,
17 the agency's job is to make sure that the assessment is
18 protective. And if we're not going to take certain steps
19 in terms of providing them certain data that they believe
20 would help to refine it, then we do at our own risk.
21 Because the agency is not deterred from making a decision
22 that is safeguarding the environment and the public.
23 They were just giving us opportunity to help to refine
24 that understanding.

25 Q. And when you say at your own risk, do you mean

1 at the risk that the risk assessment would conclude a
2 certain label amendment was necessary?

3 A. Correct. Or even the fact that a registration
4 wasn't justified. The agency normally moves forward in a
5 risk-benefit situation. And the exceedances would be
6 looked at appropriately. We felt that the agency was
7 going down a pathway that made sense to us. They didn't
8 do that -- although they put these studies out requesting
9 them in the data call-in, they had their own clear
10 pathway anyway if they didn't get the data.

11 They at least indicated to me in terms of their
12 earlier writing that they suspected things that AMVAC was
13 trying to convey were accurate in terms of toxicity and
14 in terms of persistency. We thought the agency was
15 moving down the right pathway. We were just trying to do
16 our duty to provide as much information as we could so
17 that the agency understood why we were taking the action
18 we were.

19 It wasn't -- it wasn't that we, we were
20 snubbing the agency. We were trying to explain that we
21 felt the data was already there that they were looking
22 for. And we continuously tried to make those points by
23 pointing them at the data, providing additional
24 information. And we felt that everything was moving in
25 an appropriate manner. I'm rather surprised to find

1 myself here, today.

2 MR. ROSS: No further questions, Your Honor.

3 JUDGE BIRO: Is there any recross?

4 MR. PITTMAN: Nothing further.

5 JUDGE BIRO: Dr. Freedlander, I have just a few
6 questions for you, if you can help me.

7 THE WITNESS: Certainly, Your Honor.

8 JUDGE BIRO: You said that AMVAC came to the
9 conclusion that it would be acceptable to it, to go with
10 a highly conservative risk assessment. That the agency
11 basically said unless you provide this data, we're going
12 to go with this conservative risk assessment and it may
13 not work in your interest. Can you point me to any
14 documentation, any letter that AMVAC sent to the agency
15 indicating that that was acceptable to it?

16 THE WITNESS: No. I think, Your Honor, we, you
17 know, in terms of perhaps all aspects of our thinking,
18 we, we did not provide that. We were really focused on
19 trying to fill in what gaps the EPA had in terms of a
20 point we were trying to make. We thought they were part
21 way there. And we were trying to endeavor to continue so
22 they could arrive at the conclusion.

23 And the other thing, Your Honor, is although
24 the agency characterized this as a conservative
25 assessment, for example, saying that the compound is

1 highly stable and, therefore, it can build up and
2 everything. We believed it was an accurate assessment.
3 It wasn't that we -- even if we had done the studies, we
4 felt that it would be simply wasting EPA's time in terms
5 of reviewing it, wasting their resources and also AMVAC's
6 resources.

7 But we, we didn't want to just appear not to be
8 responsive. We kept trying to indicate these are the
9 facts, you know. But I think that if I had understood
10 that there was, you know, something missing in terms of
11 trying to explain to the agency, if the agency ever came
12 to me and said we still don't understand, why aren't you
13 doing this? Do you really want a highly conservative
14 assessment? Is that in the best interest of your
15 compound? I think that type of question would have
16 spurred me to go further and sort of explain were we just
17 appearing to be stubborn. Although, I thought we weren't
18 being.

19 We were continuously trying to amass
20 information, to put it together in a way the agency could
21 see it, understand it, to listen to the type of questions
22 they had. And whatever they were saying, try to say,
23 well, this is, you know, we've seen this data a lot more
24 than you have. You're bouncing back and forth through
25 this long process. We're trying to help you to see the

1 position. We're not just saying we're not going to do
2 it, go ahead and do it. We were very active trying to
3 respond back to the agency in a sincere manner, Your
4 Honor.

5 JUDGE BIRO: I'm not a scientist, but I
6 understand that one of the issues that EPA had was some
7 risk they thought it could be from TPA being stable, or
8 persistent in the sense that it just built up over time,
9 but it could break down further.

10 THE WITNESS: Yeah. I, I think, Your Honor,
11 the way I looked at it is there were some very legitimate
12 questions with regard to the registered product. It's an
13 older product. These days, you don't tend to see many
14 persistent products being put on the market. And it was
15 going to take to another level to discuss this issue of
16 what is the persistency. You know, the agency had, had
17 shown us very late in the process that they had looked at
18 this build up and all that. And they said you could
19 eventually reach concentrations that are problematic.

20 And I think in the simple tier, initial
21 analysis, you would come to that conclusion. Then the
22 question would be, well, how would you answer that. And
23 we provided throughout the documents, say, look, it's
24 persistent within the course of doing these shorter-term
25 laboratory studies. But in the environment, I went to

1 lengths to try to provide them examples of how things can
2 change. So something that is persistent in year 1 may
3 not be as persistent year 2, may not be persistent in
4 year 3. And essentially what happens is the soil is
5 adaptable. So in the real environment, that type of
6 build up wouldn't occur.

7 And I've actually provided, even though the
8 agency wasn't -- in the time we were responding before
9 the -- before the NOITS came out, I had already started
10 that discussion in terms of explaining that the short-
11 term type of persistency doesn't necessarily mean long-
12 term persistency, provided them examples of how they
13 should really think of it in a more sophisticated manner.
14 And my view is, is that the way this process should have
15 gone is the agency say, you know, we need some higher-
16 tier work in the field. If this is what you're saying,
17 this is what you're believing, let's look at that. And
18 that's where refinement I think was really due.

19 And I was trying to move the process to a point
20 to answering what I thought were the real questions,
21 which came out in terms of the persistency issue right at
22 the end, where EFED issued the document and say, look, we
23 have this build up. It would have been -- if that
24 dialogue had continued, it would have gone forward in
25 what I thought was appropriate to really look at it

1 holistically, not just to say, well, it's persistent, it
2 might be a problem, but what that would yield.

3 And if the risk assessment was done, to show
4 how that would be a problem and then say, well, AMVAC,
5 what do you say about that? Is your compound, you know,
6 does it have these problems? Show us a mechanism to put
7 it into proper perspective. But, Your Honor, I couldn't
8 do it in terms of these simple laboratory tests.

9 Matter of fact, we had -- the evidence was
10 right there. And I don't want to get too technical, but
11 just to give you a view of my thinking is I would -- we
12 had conducted many years ago and it was actually a
13 predecessor company, studies where you put this compound
14 into soil and it breaks right down to TPA, which is what
15 we're talking about. And the TPA just sits there, 197
16 days.

17 So in -- so in 30 days, if you think of it, 50
18 percent of this chemical has already degraded to this
19 degradant we're talking about, and it just sits there
20 and, and it doesn't degrade. And that's really the true
21 nature of it. You know, the laboratory studies that EPA
22 designs in terms of the guidelines doesn't allow you to
23 acclimate the soil, to get the soil microbes conditioned
24 to the degradate you have. They don't have -- I mean it
25 makes sense they don't want that.

1 But in this type of chemistry, you know, the
2 conclusion is, is if you don't acclimate it, it's not
3 going to degrade. And that is true. You just acclimate
4 the soil. And I provided evidence as to how long it
5 would take, cases and the literature, sometimes several
6 months before you start to see degradation. Or it could
7 be a year. That information I tried to put forward to
8 the agency so they could -- so they could look at it and
9 see that the pathway they had indicated to me, we're
10 going to do the risk assessment, that's really step 1.
11 That should have been done.

12 And then after that, there would have been
13 questions that would have required a more higher-tiered
14 level of thinking, important questions for the agency to
15 answer. And that's what I was preparing to deal with. I
16 wanted to move forward to the risk assessment and try to
17 get both what I saw as the, the issues of concern, to get
18 the agency scientists thinking along with me so we could
19 address that.

20 And I felt that the last response that came
21 through was very telling. It was a shame I wasn't able
22 to continue that dialogue. It was the first time the
23 agency said, look, this is what happens. And that's the
24 type of dialogue I was trying to evoke throughout the
25 process.

1 JUDGE BIRO: So when you talk about this sort
2 of long-term persistent stable in soil, is that also true
3 in water?

4 THE WITNESS: Yeah. You know you could get
5 very technical to try to explain why in water it would
6 even be more stable. There was data to indicate that.
7 There was, because just like we had these studies on the
8 parent compound in soil, there were also studies on the
9 parent compound in a sediment system, where TPA is once
10 again forming and you don't see degradation. And the key
11 was that even the formation of TPA, itself, is delayed in
12 an aquatic environment due to the chemistry of it. So it
13 would be even worse in a sediment system.

14 JUDGE BIRO: Okay. So they seem to be very
15 focused, and when I said they, EPA, OPP on this no
16 observable adverse effect concentration or something like
17 that. Do you know that term?

18 THE WITNESS: Yeah. They were -- they were
19 looking to, to say that it wasn't an exceedance. It met
20 our safety criteria fully. And in those cases you don't
21 even have to do a risk benefit assessment. As FIFRA
22 typically allows, you can just say we don't see risk. So
23 we don't even have to take another step, yeah.

24 JUDGE BIRO: Okay. So they were focused on
25 that. And it seemed that they did not feel the data

1 allowed them to make such an assessment.

2 THE WITNESS: You know the thing is, Your
3 Honor, it seemed that even before the data call-in was
4 issued, they recognized the properties of these -- of
5 this compound. They recognized that it wasn't as toxic
6 as dacthal. And they recognized it was persistent.
7 Asking for more data to be more confirmatory, that's
8 fine. You know, I didn't have any problem with that.

9 But, you know, I, I did -- I felt that the
10 agency really should become comfortable with the approach
11 they indicated they were going to take from the start.
12 If what I can understand is normally a registrant is
13 doing everything they can to refine the data, and we do
14 that regularly with many chemicals. We don't want the
15 risk to be overstated. It can be a problem with a
16 chemical.

17 But if the properties of the chemical are such
18 that basically it's an accurate reflection, you've got to
19 own it. And then you've got to say where persistency is
20 normally a problem, how do you justify the registration
21 of this chemical under those conditions. And there you
22 have to first say, well, how risky is it if this build-up
23 occurs. And if it is risky, and that's all you have to
24 say about it, is that risk too great? Or if, if there
25 are other mitigating issues like I talked about the soil

1 microbial population changing where all of a sudden it
2 could manage it, this build-up wouldn't occur over long
3 periods of time.

4 And the interesting thing to recognize in terms
5 of this molecule, it's not that toxic to begin with, even
6 the parent compound. So you can have a certain level of
7 build-up before, you know, you reach levels that, you
8 know, would be clearly toxic to fish and such. I'm not
9 saying that, you know, I fully characterize the toxicity.
10 But relatively speaking compared to a lot of pesticides
11 we looked at, this compound is not so toxic on an acute
12 basis, even the EPA says it's not toxic on an acute
13 basis. In other words, the fish aren't going to die or
14 even the little invertebrates, they're not going to die.

15 But there is also the risk of chronic risk,
16 which is more subtle. There could be problems there.
17 And, you know, we were basically -- they, they recognized
18 that the chemical was not, you know, as toxic as such an
19 insecticide that they were willing to grant the fact that
20 maybe we don't need all of this data. They, themselves,
21 were saying right from the beginning, even before the
22 data call-in was issued, they said we could live with a
23 smaller set of data. They pointed that. I never thought
24 there was an --

25 JUDGE BIRO: Right. You're, you're referring

1 to that preliminary work plan --

2 THE WITNESS: Yes.

3 JUDGE BIRO: -- they issued.

4 THE WITNESS: Yep.

5 JUDGE BIRO: So why didn't AMVAC respond to
6 that preliminary work plan?

7 THE WITNESS: Yeah, that's a good question,
8 Your Honor. And the answer to that I've got to say is we
9 were not exactly geared up to doing that. I wasn't with
10 the company at that time. And it's not -- I know it's
11 not, you know, it may have been helpful if we had put
12 forward some of our thinking earlier on. But that
13 thinking wasn't available to the company until later on
14 and we were actually engaged in requirements. That's
15 when I was within the company.

16 And, you know, normally, especially for larger
17 companies and what I'm used to is you do want to respond
18 early on. You do. But, but once again, we would have
19 just confirmed the fact -- your thinking about this is
20 correct. You're saying the chemical is persistent. You,
21 yourself, the agency, have said that. It's persistent
22 under aerobic conditions or even under anaerobic
23 conditions. And, and then saying we don't -- we sort of
24 see that this degradate, although we're going to ask you,
25 you know, they don't say it, but although later on there

1 is some requirements, we think you can run with a smaller
2 set of data.

3 And as a matter of fact, when the agency,
4 themselves, put forward -- we want you to do two studies,
5 I thought that was a rather minimal data set. We would
6 have been happy to have where the agency ended up at the
7 end of the day and said, well, we'd also like you to do
8 some fish. We'd like you to do this marine diatom. If
9 they had asked for that up front to say this is the
10 amount of data we require to be comfortable, we would
11 have done it.

12 But we thought we were at the agency's
13 judgment. They said do these studies and follow along
14 our path. My suggestion initially when the data call-in
15 was in is say let's look at all the data for the parent
16 compound. Let's, let's look over the universe of data
17 and then decide what to do. The agency rightfully had,
18 had the authority to say, no, no, we don't want to do
19 that. We want you to start moving on things now, but
20 here's a path where you can take. Specifically, do these
21 two studies.

22 And my understanding from that is if we do
23 these studies and if everything the agency had thought
24 was likely to occur and what we were affirming should
25 occur, then we were on safe ground. You know, as long as

1 there were no surprises, we had basically provided the
2 agency with the information they wanted. And the -- and
3 the fact was the data did indicate that.

4 But as the agency started to think more -- I'm
5 sort of putting myself out in terms of what they're
6 thinking. And they said, geez, maybe we could use a bit
7 more data as we start to think about this. You know,
8 maybe we want this particular fish study. We want that.
9 If this process had continued -- we weren't trying not to
10 do data. We were trying to give all the data we, we
11 believed that was necessary for the agency to conduct
12 their business. We would have done it. We would have
13 done it at the end of the day or -- sorry, Your Honor.
14 We would have done it right up front.

15 The fact that the agency, it seemed to me, had
16 a change of heart in terms of how they wanted to look at
17 this, it's fine. I, I never felt it was -- I never felt
18 it was a promise. I felt that the agency was working as
19 a partner in this and it was our responsibility to be a
20 good faith partner in it. If you want these studies,
21 this is what you want, we, we would have certainly talked
22 about it.

23 But I thought it was a rather -- what the
24 agency had called for in terms of allowing them to come
25 to their conclusion on the ecotox was perhaps a little

1 short-sighted. Maybe they didn't have the amount of time
2 that I had spent on it. And, and they had just asked for
3 a few studies. They could have asked for more.

4 I still think and I -- and I would affirm that
5 it's not going to change anything. And at this point in
6 time, obviously, because we're pushed in terms of the
7 fact that the agency has taken action that we didn't
8 expect, we're not even thinking about whether the data is
9 required or not. We're just doing it.

10 If we had -- if the agency had said, listen, if
11 you don't do this, we're going to -- we're going to
12 suspend you, I mean there would have been no doubt. But
13 we, we thought that we were on a path that made -- that
14 made sense to them and us. They're just warning us if
15 you don't do these things, we're going to basically go
16 down this path. And we're trying to explain why we think
17 that's okay. So sorry if that's a bit long-winded, Your
18 Honor.

19 JUDGE BIRO: No, it is great. So you did not
20 expect a highly-conservative assumptions to work against
21 AMVAC's --

22 THE WITNESS: No.

23 JUDGE BIRO: -- best interest?

24 THE WITNESS: No, Your Honor.

25 JUDGE BIRO: Okay.

1 THE WITNESS: We, we thought that the more
2 complicated issues were yet to come. In other words,
3 when it's -- if it's persistent in these studies, how can
4 you have a persistent chemical in the environment. To
5 continue that line of discussion. If it builds up
6 forever, it's eventually going to reach a point of a
7 problem. But even the agency, themselves, had pointed to
8 the facts to say, look, even we know that if you put the
9 chemical in the pond, you know, the sediment, we'll go
10 over it, we'll bury it, you know, we're aware there are
11 processes.

12 But to me the big issue for this chemistry and
13 why it works is that although soils are not able to
14 manage this chemistry initially, once it's out in the
15 field for a year or two then there is degradation going
16 on. And even the agency had said at an earlier time
17 we've seen data and where the chemical has been put out
18 year after year, and then there is a three year lag. The
19 agency actually cited this. And they said we still find
20 the chemical. And they're right, because it's
21 persistent.

22 But then it becomes a question was that level
23 brought down to a manageable level. But the -- even the
24 agency brought up data that showed it was highly
25 persistent, I felt.

1 JUDGE BIRO: Okay. So you wanted them to do
2 their risk assessment. And then let's say they put out
3 their preliminary risk assessment. You would get to
4 comment on that preliminary --

5 THE WITNESS: Yes.

6 JUDGE BIRO: -- risk assessment. And was your
7 intent to comment about having further studies to, to
8 narrow the assessment or to clarify the assessment?

9 THE WITNESS: I think the fact is, is the -- is
10 the agency is working with the data it asked in the data
11 call-in. And we, we, ourselves, wanted to see how the
12 agency was doing a risk assessment to see what questions
13 were being brought forward, which particular organisms
14 might there be problems with. Is it an issue for just
15 the soil or under these conditions the sediment?

16 So we felt that with the risk assessment as a
17 tool, seeing the agency's -- not only a bit of their
18 thinking, but how exactly they're going to build these
19 models -- we say parametrize these models, to understand
20 what the issues are. And we would then respond with
21 regard to our thinking to try to see whether or not we
22 can remediate any concerns the agency raised.

23 We're not ever completely sure how the agency
24 is going to view it until they provide the risk
25 assessment. So, so we really felt that we had to get to

1 that point. And if the agency still had concerns and if
2 the benefits weren't sufficient, we would have to address
3 it.

4 But we felt that we had no choice. The studies
5 we were being asked to perform were just not going to --
6 were not going to provide the compound in a sophisticated
7 light. It was going to suggest what the agency suspected
8 that under these conditions in a laboratory, the chemical
9 is persistent. And so we felt that we had to go through
10 the risk assessment process and try to continue dialoging
11 with the agency.

12 We thought the agency was getting it. I
13 thought that the reviews that came back to us at the same
14 time as the -- as the NOITS were very informative, were
15 well thought out, made sense to me the type of things.
16 They were starting to get I thought in tune with us. I
17 felt that that dialogue would just continue, there
18 wouldn't be a problem.

19 JUDGE BIRO: Are you aware or did the agency
20 make you aware of any particular water body, or soil
21 samples, or something out in the real world that had been
22 contaminated, had reached what they thought was the
23 maximum contamination?

24 THE WITNESS: The agency did bring up the issue
25 that, look, we've seen monitoring studies where they were

1 talking about the parent at that point in time. But I
2 would give you that the degradate seen had relatively
3 high concentration, especially in ground water. They
4 brought that to our attention. And I address that in the
5 response.

6 So one of the things that I was trying to point
7 the agency to is when they're talking about groundwater
8 concentrations, that is not by the agency's own
9 definition an ecological risk. In other words, that's a
10 human health risk. People get water from the wells. But
11 there's not fish down there and everything. And so I
12 said, well, the first thing you should do is look at the
13 right type of data, which is surface water data.

14 And the indication was that there have been
15 spurious levels of, of the chemical even that far itself
16 that have been picked up in certain areas. It was a
17 question that was worthy of discussion. I, I don't deny
18 that. That's exactly, you know, because that's looking
19 at taking it from a laboratory setting to a real world
20 setting. Well, you know, what about that data. And
21 then, then you could say, yeah, that can indeed happen.

22 But then you go are those levels that you see,
23 that have actually been monitored -- and monitoring data,
24 you have to be a little skeptical because they're not EPA
25 robust studies. You say do those levels create concern.

1 And I, I would say, Your Honor, that that hasn't been
2 shown. The agency didn't show, say, look at this TPA
3 level, it's been seen in water. These organisms are
4 going to be -- have to deal with those, that level,
5 that's a real risk.

6 The agency never went to that point. There
7 wasn't that type of data in the real world to say it's a
8 clear-cut risk. I don't know if that helps you to --

9 JUDGE BIRO: But I mean in the end who is the
10 final call on these studies? I mean who, who makes the
11 final judgment, you or EPA, of what's needed?

12 THE WITNESS: I think EPA makes it, the
13 judgment in terms, absolutely in terms of what's needed.
14 But when the agency says to us we have a pathway forward
15 even if you don't do the studies, maybe it wasn't
16 appropriate for us to interpret that -- interpret that as
17 saying it's okay if you don't do it. The agency is
18 saying we thought saying we're not going to suspend you,
19 we're going to do this risk assessment. And we thought
20 that we were basically, although we were trying to
21 explain why we were doing it, the agency said this is
22 what we're going to do. We have our path. We're going
23 to follow this path. If you don't provide this data,
24 it's not that we can't assess the safety of this
25 chemical. We're going to do it as they believed in a

1 highly conservative manner.

2 JUDGE BIRO: But you didn't proactively make
3 that clear to them, to, to EPA. You didn't say, yes, we
4 agree, do the conservative assessment. We are not going
5 to do these studies.

6 THE WITNESS: You know I think, Your Honor, we
7 weren't specific in saying, you know, look EPA, go
8 forward and just do that. I think it wouldn't have set
9 the right tone. I thought it was more important to stick
10 towards the points they were making about the studies and
11 what the studies would yield in terms of information.
12 You know, I, I thought it was -- it just wasn't an
13 appropriate way to respond to the agency.

14 I thought if they can understand the technical
15 findings of the study in the way that I did, and I was
16 very convinced. Sometimes, you know, there's different
17 interpretation. I thought it was extremely clear in
18 terms of the, for example, the stability, the
19 persistence. I thought we were almost there. If we
20 could just get over that hump, there would be -- I didn't
21 want to say, look, we're not getting to talk to you
22 anymore, just do your darn analysis the way you're saying
23 and we'll leave it to that. We didn't think that would
24 be appropriate.

25 We were there to assist the agency in

1 understanding things. We didn't want to say we don't
2 care, just run it. We didn't want to say, you know,
3 we'll talk to you after you run it. We were trying to
4 bring the agency throughout the process up to the
5 technical understanding we had as to why it made sense.
6 To me it was better to explain to the agency why it made
7 sense to go forward, rather than tell them just go
8 forward.

9 JUDGE BIRO: Okay. You mentioned some data
10 compensation considerations. I don't know what that
11 means in this circumstance. Who are you getting
12 compensation from?

13 THE WITNESS: You never know, Your Honor, as to
14 when another registrant would have the -- which they do
15 have the right to basically step in and say we want to
16 start selling this product. EPA allows for that sort of
17 freedom. There's no, you know, safe -- there's no
18 safeguard for a company to say you can't come into this
19 market with me. It's free market stuff.

20 At the point they do allow you in, the agency,
21 themselves, stipulates that you have to fairly compensate
22 the old company for all the work the old company did.
23 The old company and the new company are arguing over
24 what's appropriate. A lot of times, as I've been
25 involved, myself, I said, well, we did all this thinking.

1 We did this special consideration. None of that
2 typically ends up as justification in court. It usually
3 comes down to a stipulation by EPA says you've got to do
4 this, this data, and you've done it.

5 So the concern, I think, if you're talking now
6 about the -- this was an issue for the leptochairus, that
7 single study. My concern was as I couldn't link it to
8 the requirement, because the agency had said there are
9 end points in this study that will not be met by doing
10 this short-term. You're just going to satisfy us short-
11 term. You're not fulfilling the DCI requirement. That's
12 the way I understood it.

13 I kept saying if -- the message I was trying to
14 convey is if you think that way, fine. We'll do the
15 study, but please issue it as a requirement. Because if
16 you don't and someone comes in, another company at some
17 point, and says, okay, we're going to pay you for the
18 studies the agency requires, it hasn't been affirmed in
19 the right way, the normal way the agency does to say this
20 is a formal requirement. And all we were seeking is
21 saying if you're really insisting on us doing it, it's
22 different than what you issued in the data call-in.
23 Although you're saying you might consider it, it's a
24 different study you're talking about. Just issue us a
25 formal requirement. And then if it's a formal

1 requirement, we would do it.

2 We did two other species that are very similar
3 to the one we're talking about. Those study protocols
4 are well advanced. It works. We did the studies. We
5 would have done the third study if we could have. But if
6 they want this special study, which in some cases I think
7 makes sense. I'm not so sure it made sense in our case.
8 But we were saying and we were talking to the agency not
9 just in writing, but saying, look, just indicate it as a
10 -- as a formal requirement and then we'll do it, if you
11 really feel that we need to do it.

12 I wrote a long case as to why, to try to
13 explain to the agency why that data wasn't particularly
14 useful, because it wasn't a very sensitive species. That
15 doesn't mean that the agency doesn't have a right to ask
16 about that. But it sort of puts it into perspective.
17 But the -- and because it's not such a sensitive species,
18 just to give you a little bit of our thought process, an
19 acute study is not as informative as a chronic study.

20 EPA has already said the chemical is not
21 acutely toxic, so doing an acute study just on that basis
22 doesn't make so much sense. The real need, if they
23 wanted the data, and they said it, is a chronic study to
24 look at issues such as reproduction and such. That's
25 really what they needed. We gave them two studies to

1 show that it wasn't risky for at least two other similar
2 organisms.

3 The only thing that really made sense to do I
4 think for this chemical was to say, look, once this data
5 requirement is sorted out and studies can be done in a
6 reliable manner, we're going to come back to you and, and
7 insist that you do it. To me, that would have been
8 perfectly appropriate.

9 The agency did say that some studies had been
10 done in the past. And counsel had assisted me to look
11 and see, well, what studies have other people tried to do
12 and submit to the agency on this. We found and it's in
13 my testimony, one example with this chemical fipronil.
14 And it's clear within that study that there were all
15 sorts of problems. It didn't make sense. It didn't run
16 well.

17 So it just sort of reaffirmed why it made sense
18 for the agency to be asking registrants in general do the
19 acute study because the chronic study isn't available.
20 But for a compound that's not acutely toxic, it's not
21 really helpful in my view. We had established for two
22 other species, although they weren't marine species, that
23 it's not very toxic.

24 I think the right way or the way I would have
25 handled it, I'm not going to say the right way. That's

1 not for me to judge. But the way that I would have made
2 sense technically is to say, look, we reserve the study.
3 And that's many times what they say -- we reserve the
4 right to ask you to do the study at a later date.

5 JUDGE BIRO: Okay. I understand that, what you
6 said. But you were trying, it seems to me, to ask the
7 agency to accept an acute study you knew would likely
8 lead to very little useful information in lieu of a
9 chronic study.

10 THE WITNESS: Well --

11 JUDGE BIRO: Which might be helpful.

12 THE WITNESS: Well, we, we said we would -- we
13 would proceed on two fronts. We did say that with regard
14 to the chronic study, if the agency said you guys may not
15 know, but we can point you at three studies and the
16 laboratories who is doing this stuff, we would have
17 jumped in. But --

18 JUDGE BIRO: Would you have jumped in even if
19 the DCI had not changed or --

20 THE WITNESS: Yep. Well, the DCI was for that
21 chronic study. And if we would have --

22 JUDGE BIRO: Right. But would you have done
23 both studies?

24 THE WITNESS: Not both.

25 JUDGE BIRO: No.

1 THE WITNESS: Because really the agency was
2 seeking the chronic studies, just that it -- the study
3 was not -- the, the way to do the study in an acceptable
4 manner hadn't been established. You couldn't do it. We
5 saw that in terms of at least one other compound where a
6 registrant had tried. So, so it -- what we said is, you
7 know, that was our preference.

8 Once again, if you were to ask me did you state
9 that's your preference? No, we didn't. But I did
10 indicate that if you are intent on requiring this
11 particular study, which was a bit special and we looked
12 at that as separate from the other ecological studies,
13 we'll do it. You know, we didn't want to be -- it's not
14 that we wouldn't do -- even if some information we felt
15 wasn't relevant, it wasn't that we were going to draw a
16 hard line in the sand. We were trying to come to terms
17 with the agency.

18 If they wanted this acute study, even though to
19 me it didn't make any sense, there we said we'll do the
20 study, just make it formal for us in terms of data
21 call-in. I had already written a paper why it didn't
22 make sense. They had reviewed it and they still felt the
23 need for it. Well, then we'll do this study under
24 conditions where we think it's fair. If you're going to
25 ask us for a requirement, EPA, do it in your normal

1 manner so we don't have a problem. Issue us a data call-
2 in for it and we'll do it.

3 JUDGE BIRO: Okay. If you could indulge me
4 just one minute.

5 THE WITNESS: Sure.

6 JUDGE BIRO: I think in your expert's
7 statement, Mr. Gur, he indicated that EPA had been doing
8 bi-yearly, twice a year meetings with registrants. Did
9 you engage in any of those meetings with EPA?

10 THE WITNESS: Is that with regard to a specific
11 study, the leptochairus, because --

12 JUDGE BIRO: No. I think he said generally
13 during I think a DCI.

14 THE WITNESS: Well, I, I would say, Your Honor,
15 that I do play a role in -- with CLA, which is the
16 industry's spokes group in terms of trying to clarify
17 requirements. I head up the group that's involved in
18 drinking water assessments and how to progress that
19 science further. I'm not involved in every aspect of
20 everything. And but I certainly try to engage with the
21 agency in, in a manner that even goes beyond my own
22 company to try to assist the agency.

23 JUDGE BIRO: Do you know whether AMVAC, any of
24 your employees in your department participated in those
25 twice yearly meetings?

1 THE WITNESS: The bi --

2 JUDGE BIRO: Prior to 2016.

3 THE WITNESS: I'll be honest with you, Your
4 Honor, not only I'm not sure, I'm not really sure which
5 meetings, you know, the name of the meetings or the
6 specific need of the meetings. But if they are technical
7 in nature, what I tend to do, because there's a lot of
8 forward-thinking in terms of trying to deal with agency
9 problems in many different issues. And what I do is in
10 many of these cases, I collect that information at the
11 back end through CLA. Sometimes, I'll even give my own
12 viewpoint. But many times I've got a lot of very bright
13 colleagues that are intimately involved in the issue at
14 hand and they will -- they will typically have covered it
15 as well. But I will follow that discussion.

16 You know many times within the industry, we
17 have common needs, even with the agency. And we make
18 changes as we progress. I've done so with regard to the
19 human risk assessing drinking water. The agency has
20 relatively recently made changes as to how they model.
21 That's where I spend my time. And then the information
22 out of what my group does within the industry is passed
23 onto others. And they do the same.

24 JUDGE BIRO: So yesterday there was some
25 testimony about there being a number of successful

1 leptocheirus studies since about 2017. When did you
2 become aware of those?

3 THE WITNESS: The agency had stated that and I
4 think I, I wasn't aware of that until the agency stated
5 that.

6 JUDGE BIRO: In 2022?

7 THE WITNESS: Yeah, I'm not exact, to be honest
8 with you. I'd have to look to see when it is. But it
9 was relatively recently. Because it was one of the last
10 actions I got involved with the legal team to help me
11 find what are these studies, let's look for them, and
12 maybe someone has them. And I know that our attorneys
13 were rather extensive in terms of their searching. I
14 didn't do this, myself. But they were able to find just
15 one study. And I reviewed that study and explained to
16 counsel in terms of what the study showed. And it
17 absolutely was a disaster in terms of it raised more
18 questions than it answered. Why is this different than
19 the acute study -- I'm sorry, Your Honor.

20 JUDGE BIRO: So you just became aware of those
21 studies in -- well, let's whenever, very recently when
22 EPA advised you of them. You weren't aware of --

23 THE WITNESS: I wasn't -- I wasn't aware that
24 even the agency thought so. And once the agency said it,
25 I was keen to try to see let's see some of those studies.

1 Because I'd worked closely with the laboratories on this.
2 And the laboratories were having significant trouble.
3 Matter of fact, you know, maybe it's a little bit off the
4 subject, it's actually more problematic to do it now than
5 it used to be, because the source of the organisms has
6 changed. And that's really at the heart of it. You have
7 to have hearty organisms. That's how the agency picks
8 what to test. Organisms that are reliable to survive and
9 reproduce, so you can compare it with a decent specimen.

10 JUDGE BIRO: So you weren't aware that your
11 lab, SMD, at least your lab in this instance was
12 conducting those tests and submitting their results to
13 EPA, and getting approval of their process?

14 THE WITNESS: No. I was not, Your Honor. I
15 was not aware that -- that I -- I saw that the EPA had
16 been issuing this separate pathway of doing acute study
17 as a direct response that they felt uncomfortable with
18 what was going on. You know it wasn't a normal course.
19 But that's the best that the agency could do with the
20 science at hand. And it's the same course I would have
21 taken.

22 But the fact that some people, as the agency
23 has indicated, found that they could successfully do the
24 study, to this day I don't know what studies are being
25 referred to. Because the -- as I said, the only study I

1 found was submitted, but had a lot of problems with it,
2 the type you would expect for a study that was not rugged
3 in nature.

4 JUDGE BIRO: So is your understanding that
5 AMVAC continues to -- anticipates continuing to sell
6 dacthal and the products, the end-use products from it?

7 THE WITNESS: Well, we hope to, Your Honor. I
8 mean that's why we're going to the separate -- matter of
9 fact, the new studies we've been initiated is to say,
10 look, if, if it ends up that we are suspended on it, it's
11 no longer a question of trying to convince the agency
12 that they don't need these studies. We just have to do
13 them. Because now we're at, in a type of risk situation
14 that we didn't anticipate and it has become serious, and
15 there's no time to educate or deliberate. We just
16 basically launched doing it. I expect, it's not that I
17 think our views will be vindicated, but you know I think
18 we're going to basically confirm for the agency what
19 we've been saying all along.

20 JUDGE BIRO: Okay. And I don't think I have
21 any more questions. Did my questions raise any questions
22 for you, Mr. Ross?

23 MR. ROSS: Potentially, Your Honor. Allow me
24 to confer with co-counsel for a minute.

25 JUDGE BIRO: Sure, take a few minutes, of

1 course. Dr. Freedlander, would you like some water?

2 THE WITNESS: Oh, thank you. No, I'm fine.
3 Thank you, though. I'm more concerned at my age of
4 having to run to the bathroom than I am keeping hydrated.

5 JUDGE BIRO: If you need to do that, too, we're
6 happy to take a break.

7 THE WITNESS: Thank you.

8 (Pause.)

9 MR. ROSS: A brief set of questions, Your
10 Honor.

11 JUDGE BIRO: Okay.

12 CONTINUED REDIRECT EXAMINATION

13 BY MR. ROSS:

14 Q. Dr. Freedlander, you answered some questions
15 from the presiding officer concerning the work plan, do
16 you recall?

17 A. Yes.

18 Q. And specifically the fact that AMVAC had not in
19 this instance provided comments on the work plan.

20 A. Yes, that's true.

21 Q. Was one of the core forecasts, if you will, of
22 the work plan that EPA might have to assume persistence
23 of the chemical?

24 A. Yes, that's true.

25 Q. Was one of the core forecasts of the work plan

1 that EPA might be willing to accept a limited set of TPA
2 data in lieu of a full set?

3 A. Yes, that is true.

4 Q. And AMVAC agreed with both of those
5 presumptions. Correct?

6 A. That's correct, sir. Yes.

7 MR. ROSS: No further questions.

8 JUDGE BIRO: Okay, thank you. Mr. Pittman?

9 MR. PITTMAN: Yes, Your Honor. I have
10 discussed with my co-counsel here. But apologies, I'm
11 still not exactly sure how to, to couch this. But Dr.
12 Freedlander, during his testimony to you, stated that he
13 had provided information to EPA that TPA would actually
14 break down in the context of the conservative
15 assumptions. I'm just, I suppose, requesting from AMVAC
16 we be pointed to specific documents admitted into the
17 record that reflect that. And just to give us a chance
18 to respond either here or in briefing.

19 JUDGE BIRO: Let's see.

20 MR. ROSS: Your Honor, we believe that we, the
21 counsel team, know what documents that Dr. Freedlander
22 was referring to. So at your option, we can provide what
23 we believe or we can all them --

24 JUDGE BIRO: Yeah, why don't you tell Dr.
25 Freedlander what those exhibits are and see if those are

1 the same ones that he's referring to. Would that answer
2 your question?

3 MR. PITTMAN: Your Honor, we would -- this is
4 to our knowledge the first time that this particular
5 argument has been made. We would just like some time to
6 review those documents and provide some opportunity
7 potentially to recross Dr. Freedlander.

8 JUDGE BIRO: Okay. So why don't we -- we could
9 break early for lunch.

10 MR. ROSS: Well, perhaps if I could -- I could
11 question Mr. Freedlander in such a way that the identity
12 of that document might be made known and --

13 JUDGE BIRO: And then we could break for lunch.

14 MR. ROSS: Yes.

15 JUDGE BIRO: And then you could cross.

16 MR. PITTMAN: That's acceptable, thank you.

17 JUDGE BIRO: Let's do that.

18 CONTINUED REDIRECT EXAMINATION

19 BY MR. ROSS:

20 Q. Dr. Freedlander, you referred during the course
21 of your testimony to certain studies that had been
22 performed in England. Correct?

23 A. That's correct.

24 Q. And those studies you testified may have been
25 performed in acclimated soils?

1 A. Yes. The aerobic soil metabolism study for TPA
2 that was done in Europe, my view is it was likely done in
3 an acclimated soil, yes.

4 Q. And that study report was submitted to the
5 agency in the course of this data call-in. Correct?

6 A. It was. It was, yes.

7 Q. Do you recall any other documents to which you
8 might have been referring that would have specifically
9 demonstrated break down of TPA in soils or allowed a
10 half-life to be --

11 A. Besides that study?

12 Q. Another study that would have allowed a
13 half-life to be specifically calculated.

14 A. Of TPA, itself, no.

15 Q. TPA, itself.

16 A. That's the only study I -- that I recall at
17 this moment where there was any sign of degradation.

18 Q. And that was the one to which you referred in
19 your testimony. Correct?

20 A. Yes. That's correct.

21 MR. ROSS: No further questions.

22 JUDGE BIRO: Okay. Mr. Ross -- Mr. Pittman,
23 does that answer your question?

24 MR. PITTMAN: I'm sorry. Has counsel
25 identified the document by perhaps exhibit number that's

1 being referred to here?

2 MR. ROSS: I believe given a moment we could
3 identify it by MRID.

4 JUDGE BIRO: MRID number.

5 MR. PITTMAN: Sure, that would be acceptable.

6 JUDGE BIRO: Okay.

7 (Pause.)

8 JUDGE BIRO: Mr. Pittman, assuming that's the
9 one study, are you familiar with it enough to go ahead
10 with cross-examination without time to prepare or do you
11 still need time?

12 MR. PITTMAN: No, Your Honor. Sorry, the
13 nature of my question is that I believe that there was
14 some discussion at some point. I'm not doubting Dr.
15 Freedlander's testimony here. This is not something that
16 has been previously briefed. It has generally been --
17 I'm sorry to paraphrase. OPP has understood AMVAC's
18 position more along the lines of you should go ahead and
19 proceed with the conservative assumption and it will be,
20 you know, accurate, I think is how Dr. Freedlander
21 described it. But then also there is testimony today
22 that actually maybe it's not accurate because it would
23 break down.

24 JUDGE BIRO: Well, I know that in all the
25 documents I read there was something in some document --

1 THE WITNESS: Yes.

2 JUDGE BIRO: -- that said it broke down or it
3 could. I don't think it said for certain. I think that
4 there was some evidence at the very end of more
5 short-term tests that suggested that it might break down.

6 THE WITNESS: Would you like me to respond to
7 that, Your Honor?

8 JUDGE BIRO: Well, I think the documents you
9 were relying on for that is this English study?

10 THE WITNESS: Yes.

11 JUDGE BIRO: The study done in England.

12 THE WITNESS: Yes.

13 JUDGE BIRO: And is there any other documents?

14 THE WITNESS: No.

15 JUDGE BIRO: No.

16 THE WITNESS: That was the only study that
17 there was evidence of degradation of this degradate TPA.

18 JUDGE BIRO: Okay. And was that an acute study
19 or a chronic study?

20 THE WITNESS: Well, that was a -- that was an
21 aerobic soil metabolism study. And matter of fact, just
22 to help provide a little bit of background on that study,
23 there were actually three soils that were looked at. The
24 half-lives of three soils varied significantly. One was
25 like approximately 100 days half-life. The other one was

1 approximately 200 days. And the third one was
2 approximately 1,200 days.

3 JUDGE BIRO: 1,200 days?

4 THE WITNESS: 1,200 days. And the requirements
5 in Europe are different than the U.S. EPA is very clear
6 and stipulates in a way unlike Europe that you have to
7 make sure you do the study in an unacclimated soil. You
8 have to basically have the field history of where you're
9 collecting your soil to make sure of that.

10 The way Europe does it is they have what they
11 have are certain characteristic soils they ask everyone
12 to do the work on. And there is no thinking in terms of
13 making sure that the soils are not acclimated. And,
14 therefore, there is -- and I can understand a little bit
15 of confusion between the aerobic TPA study that's done in
16 Europe that showed for some of the soils there was
17 degradation, whereas when you looked at the three soils
18 that were done on dacthal where TPA is formed right away
19 there's absolutely no degradation.

20 And to me knowing what mechanism is involved,
21 this acclimation thing, that it's basically my belief
22 that because these soils had not been validated as being
23 unacclimated and the fact that it's very disparate data,
24 one case 100 days, one 1,200, that some of these soils
25 had been acclimated. And it doesn't have to be to

1 dacthal. It just has to be of general chlorinated
2 chemistry, for example.

3 So, you know, I, I think that's where there is
4 degradation indicated. But once again, the reason for
5 that and the reason if you do -- if you look at the U.S.
6 version, it's different. It sort of says different
7 things is because of the simple issue of acclimation.
8 EPA says you're not allowed to do it in acclimated soils.
9 European soils were not validated to say that they were.
10 And, therefore, there was some degradation.

11 And I've always asserted the fact that if you
12 leave the chemical out there for a long enough period or
13 similar chemistry, yeah, then the soil can degrade those
14 compounds. That's how it happens long-term. The soil
15 adjusts.

16 JUDGE BIRO: So are -- is AMVAC selling its
17 products in England and Europe generally?

18 THE WITNESS: No.

19 JUDGE BIRO: No, okay. Did it ever --

20 THE WITNESS: It did at one -- it did at one
21 time, Your Honor.

22 JUDGE BIRO: It did at one time.

23 THE WITNESS: To explain why it was done, yes.
24 It wasn't done for U.S. registration.

25 JUDGE BIRO: Okay.

1 THE WITNESS: But when the data call-in came
2 out, we grabbed a few studies that happened to be in
3 Europe that also include the acute daphnia, there was an
4 acute fish study. So we provided the agency with --
5 since they wanted information on ecotox for, as well as
6 EPA, we brought in the studies we had on-hand that were
7 used in Europe.

8 JUDGE BIRO: How old were these studies?

9 THE WITNESS: Pretty old. Probably at least 25
10 years. You know, I -- you know, they weren't recent
11 studies. But, you know, I think the findings are
12 reliable in a general sense, you know, as there was
13 degradation seen, which, you know, in hindsight may have
14 caused some confusion that, you know, as to does it.
15 Because I think for counsel it says, well, wait, does it
16 degrade or does it not degrade.

17 In our -- what we have basically said in our
18 position is in an EPA study where soils cannot be
19 acclimated, it doesn't degrade. But if you pick up a
20 soil randomly, you may find degradation. But that's not
21 what EPA demands in conducting the studies. So although
22 the studies fit the category of aerobic soil, they could
23 be misleading in that regard, may have misled the agency,
24 and maybe I was a bit derelict in not pointing that out
25 to them and say, oh, by the way, if you're wondering on

1 this point, you know, it just never came up. I kept
2 pointing to the U.S. studies.

3 JUDGE BIRO: Okay.

4 THE WITNESS: I hope that helps.

5 JUDGE BIRO: It does, thank you. Mr. Ross?

6 MR. ROSS: If I may, I think with some
7 questioning we may be able to get the specific MRID on
8 the record.

9 JUDGE BIRO: Okay, great.

10 MR. ROSS: Mr. Sayres, could you bring up Joint
11 Exhibit 21, please. And turn to page 3 of 6.

12 CONTINUED REDIRECT EXAMINATION

13 BY MR. ROSS:

14 Q. Dr. Freedlander, do you recognize this document
15 based on just what you're looking at on the screen right
16 now?

17 A. I do, indeed.

18 Q. And what document do you recognize this as?

19 A. Well, this is, you know, a status document as
20 to where the agency is in terms of considering the study,
21 whether they've reviewed it, whether or not it's a waiver
22 request and they look at it as being denied, or whether
23 or not they're looking at the data and saying, well, it
24 doesn't fulfill the requirement completely, but it's
25 helpful and, therefore, we --

1 Q. And, and do you see the aerobic soil --

2 A. I do.

3 Q. -- data requirement on this exhibit.

4 A. For TPA, I do, yes, sir.

5 Q. And the aerobic soil metabolism for TPA?

6 A. Yes.

7 Q. And in this document, we can all see EPA's
8 response states, does it not, that a study was accepted
9 as supplemental and additional data was not required?

10 A. That's correct.

11 Q. And there are two footnotes. Correct?

12 A. There are.

13 Q. And if we might scroll to the footnotes, those
14 were -- the footnotes were 2 and 3. Dr. Freedlander, can
15 you see that there is an MRID in footnote 3?

16 A. Yes. I see an MRID list that is 49307516.

17 Q. And that would appear also to refer to this
18 data evaluation record issued in connection with this
19 study?

20 A. Yes.

21 Q. And the data evaluation record would
22 necessarily have been issued by EPA. Correct?

23 A. Yes.

24 Q. Dr. Freedlander, do you recall when this
25 particular study was submitted to EPA?

1 A. I don't.

2 MR. ROSS: Mr. Sayres, could you bring up Joint
3 Exhibit 27, please.

4 BY MR. ROSS:

5 Q. Dr. Freedlander, do you recognize this
6 document?

7 A. I do.

8 Q. What do you recognize it as?

9 A. Basically, it's a document from the EPA. It's
10 called a, you know, a 12-month response document. It's
11 referring back to the original DCI and the status of
12 certain requirements associated with the DCI at that
13 particular point.

14 Q. So is this an -- is this an AMVAC letter to Ms.
15 Bloom?

16 A. Oh, I'm sorry. Yes, it is. It's our -- it's
17 our document, I apologize. It's our, our update in terms
18 of where the studies are.

19 Q. And it's dated in January of 2014. Correct?

20 A. Yes.

21 MR. ROSS: Mr. Sayres, could you sort of scroll
22 down so we can -- Dr. Freedlander can see the context of
23 this document.

24 THE WITNESS: Yes, sir.

25 BY MR. ROSS:

1 Q. And now you've had a moment to review some
2 additional portions of the document, what do you
3 understand this document to be?

4 A. Well, once again it's sort of our update in
5 terms of where we see things at this point in time. It
6 says somewhere in the middle AMVAC is still anticipating
7 a response from EPA regarding several guidelines. It's a
8 status report that was produced to indicate where we are
9 with regard to the different requirements. My
10 understanding it's provided to the agency to make sure
11 that we're in tune with them in terms of where they are
12 in their review.

13 MR. ROSS: Mr. Sayres, if you could turn to
14 page 3 of 7, please. And zoom in on the bit of text in
15 front of the second table, please.

16 BY MR. ROSS:

17 Q. Just read into the record the document -- in
18 regards to the promised existing data, please find three
19 copies of the following documents enclosed. Do you see
20 that, Dr. Freedlander?

21 A. Yes, I do.

22 Q. Do you recognize from, from the documents that
23 follow an indicating of the transmittal of the aerobic --
24 or anaerobic soil metabolism study?

25 A. Yes. That's, that's listed as the -- well, the

1 second item is, is for TPA, which I think you're
2 referring to, is 100-MET-011. Is that correct? As
3 opposed to the one that's highlighted is for dacthal.
4 And if we're talking about the European study, that is
5 100-MET-011.

6 Q. And based on your review of EPA's document
7 referring to the DER, is it your belief that the study
8 indicated as having been submitted here on -- in January
9 of 2014 is the study that was later assigned MRID
10 49307516?

11 A. Yes. That's correct.

12 Q. And you discussed briefly some differences
13 between U.S. and English regulatory requirements with
14 respect to soil acclimation. Correct?

15 A. That's correct.

16 Q. Now EPA accepted or rather issued a DER for
17 this study. Correct?

18 A. That's correct.

19 Q. And based on this DER, EPA determined that no
20 further data would be required in connection with this
21 particular data requirement. Yes?

22 A. That's correct.

23 Q. Have you ever urged EPA to adopt the results of
24 this study with respect to TPA in connection with its
25 persistence?

1 end of this hearing and you hear from Mr. Ross.

2 THE WITNESS: Yes, Your Honor.

3 JUDGE BIRO: Thank you. You can step down.

4 THE WITNESS: Thank you.

5 (Witness excused.)

6 JUDGE BIRO: It's 12:14. Could we break for
7 lunch now and come back, what time, 1:15. Do you need an
8 hour? Is everybody over there taking -- in unison,
9 that's great, okay. We'll come back in an hour at 1:15.

10 (Whereupon, at 12:14 p.m., a lunch recess was
11 taken.)

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24 A F T E R N O O N S E S S I O N

25 (Time Noted: 1:16 p.m.)

1 JUDGE BIRO: You're going to call your next
2 witness, unless there's any preliminary matters.

3 MR. ROSS: Not from AMVAC, Your Honor.

4 JUDGE BIRO: No, okay, great.

5 MR. ROSS: We have counsel for Growers.

6 JUDGE BIRO: Yes. Ms. Rose?

7 MS. ROSE: Yes. I did just want to follow-up
8 on the preliminary matter we discussed this morning. We
9 will submit the testimony of the three witnesses, the
10 exhibits, as well in to the record and will not be
11 intending to call them since they will not be
12 cross-examined. There is one small piece of information
13 that Dr. Fennimore wanted to add to this testimony that
14 he was going to do orally. He has supplemented the
15 written testimony, so I will provide that to counsel for
16 AMVAC and OPP this evening. And assuming no objections,
17 we can submit everything to Your Honor in the morning.

18 JUDGE BIRO: Okay. Is that agreeable to the
19 agency and to AMVAC?

20 MR. PITTMAN: Your Honor, it would be, I
21 assume, Ms. Rose, the testimony would be of the same --
22 sorry, thank you. Sorry. The testimony would be of the
23 same general type as what are contained in the current
24 witness statement as to the economic benefits of dacthal?

25 MS. ROSE: That's correct. And just as a brief

1 proffer, it relates to the impact of unpredictable
2 weather events, such as California has experienced in the
3 last few months, and the need for weed protection systems
4 that have multiple components to it, to protect in those
5 sorts of events.

6 MR. PITTMAN: Your Honor, OPP would stipulate
7 to that update subject to the same objection we have now.

8 JUDGE BIRO: Relevancy, okay. If you could
9 even get a draft to the agency and to AMVAC of that
10 tonight, you know, as soon as possible, so we can make
11 sure that there is no objection. And we can go ahead as
12 we planned. That would be lovely, Ms. Rose. I'd really
13 appreciate it.

14 MS. ROSE: Yes. I can do that now, actually.
15 I just wasn't sure if they had the availability to review
16 it.

17 JUDGE BIRO: Okay. Yeah, sure, no problem.
18 And then why don't we go ahead and admit -- can we admit
19 these documents now? Is there any reason we can't?
20 Okay. So we're going to admit the direct testimony of
21 Christopher Valadez, Stephen Fennimore, and Richard
22 Smith. And we're going to mark those as -- what did we
23 call them?

24 MS. ROSE: PGX, PGX-6, 7, and 8.

25 JUDGE BIRO: 6, 7, and 8.

1 (Petitioner's PGX-6, 7 and 8 identified.)

2 JUDGE BIRO: And you said you had exhibits to
3 go with them?

4 MS. ROSE: Yes, PGX-1 through 3, and then 4 and
5 5 as well are the CVs.

6 JUDGE BIRO: Okay.

7 (Petitioner's PGX-1 to 5 identified.)

8 JUDGE BIRO: So without objection, we're going
9 to admit into the record PGX-1 through 5 -- 1 through 8.
10 No objection?

11 MR. PITTMAN: Subject to EPA's objection,
12 but --

13 JUDGE BIRO: Of relevance.

14 (Petitioner's PGX-1 through 8 received.)

15 MS. ROSE: And the updated version of the, the
16 testimony of Dr. Fennimore, would that be PGX-7 that you
17 just admitted or shall we hold off on that one until it's
18 actually received?

19 JUDGE BIRO: You can mark it for identification
20 as like 7(a), is that in lieu of -- with 7 being his
21 testimony and maybe we'll swap that out for his
22 testimony. Does that work for you?

23 MS. ROSE: That's acceptable.

24 JUDGE BIRO: Ms. Rose, is that okay?

25 MS. ROSE: Yes, that's, that's okay. Yes.

1 (Petitioner's PGX-7(a) identified.)

2 JUDGE BIRO: So we'll wait to see on 7(a) and
3 its admissibility after you give the parties a chance --
4 the other parties a chance to look at it. Is there any
5 other preliminary matter? No, okay. Let's proceed.

6 MR. ROSS: AMVAC will next call Ann Jonynas.
7 She is testifying telephonically. I have her on the line
8 dialing in.

9 JUDGE BIRO: While we're waiting on her, do you
10 want to mark the joint stipulations as an exhibit? I can
11 mark them just as Court's Exhibit 1.

12 (Court's C-1 identified.)

13 MR. ROSS: You're referring to the docket 47,
14 the previously submitted joint stipulations that are 48
15 or 50 paragraphs, something of that nature?

16 JUDGE BIRO: I think there's only one set in
17 this case. 51 paragraphs.

18 MR. ROSS: Yes. I recall -- I know the
19 specific document you're referring to. I believe there
20 is one prior joint status report that does also discuss
21 some stipulations as to document relevance and
22 authenticity as well. And we can provide the docket
23 reference numbers for that also.

24 JUDGE BIRO: Okay.

25 MR. ROSS: But I have no objection to marking

1 the joint stipulations as --

2 MR. PITTMAN: No objection.

3 JUDGE BIRO: Okay. So I'll just admit it into
4 the record as Court's Exhibit 1, just because it will
5 probably be easier when you cite it. All right. Ms.
6 Rose, you don't have any objection to that, do you?

7 MS. ROSE: No, Your Honor.

8 (Court's C-1 received.)

9 JUDGE BIRO: Okay. Hello, Ms. Jonynas. How
10 are you?

11 MS. JONYNAS: Good afternoon. Good, thank you.

12 JUDGE BIRO: Would you please raise your right
13 hand and let the court reporter swear you in.

14 (Whereupon,

15 ANN JONYNAS,

16 having been first duly sworn, was called as a witness
17 herein and testified as follows:)

18 JUDGE BIRO: Can you tell me who is with you
19 where you are testifying?

20 THE WITNESS: Nobody. I'm, I'm at home.

21 JUDGE BIRO: Okay, perfect. Please proceed.

22 DIRECT EXAMINATION

23 BY MR. ROSS:

24 Q. Good afternoon, Dr. Jonynas, or is it perhaps
25 good morning where you are located still.

1 A. Just about morning, yes.

2 Q. Could you please state your full name for the
3 record, please?

4 A. My full name is Ann Jonynas. Can you hear me
5 well enough?

6 Q. Yes, we can. We can hear you well, thank you.

7 MR. ROSS: Mr. Sayres, could you bring up the -
8 - Ms. Jonynas' statement.

9 JUDGE BIRO: I'm just correcting the spelling
10 on the name.

11 BY MR. ROSS:

12 Q. Dr. Jonynas, are you able to see the document
13 that is now on the screen?

14 A. Yes, I can.

15 Q. Do you recognize this document?

16 A. Yes, I do.

17 Q. And what do you recognize this document as?

18 A. My witness statement.

19 MR. ROSS: We move to admit the January 9th
20 statement of Dr. Jonynas into the record of the
21 proceeding.

22 JUDGE BIRO: Isn't the majority of this not
23 really relevant anymore? This all goes to the CTA.

24 MR. ROSS: We -- our proffer as to the
25 relevance of Dr. Jonynas' testimony is that the conduct

1 of the CTA study, which was novel and very complex,
2 effectively forms the backbone of certain interactions
3 between the agency and EPA. It was ongoing throughout
4 the entirety of this DCI. And so we do think that
5 establishing through the record the conduct of the CTA
6 study remains relevant to establishing AMVAC has been
7 taking appropriate steps potentially as to other data
8 requirements through the conduct of the CTA study.

9 Additionally, Your Honor, the NOITS was
10 explicitly premised on deficiencies in the CTA study and
11 the lack of the CTA study. And the NOITS has never been
12 amended. As it stands today, it refers in large part to
13 the absence of the CTA study. So we think that having a
14 robust record concerning AMVAC's attempts to conduct and
15 complete that study is highly relevant.

16 JUDGE BIRO: Hasn't the study been completed?

17 MR. ROSS: It has been completed. And OPP has,
18 as a legal matter, deemed it to be satisfied. However,
19 we heard testimony from Ms. Bloom on the stand that OPP
20 had certain reservations concerning the study and that
21 OPP had not yet provided any formal response to AMVAC
22 concerning the study or derived any data from it. And so
23 another reason why we would like this in the record.

24 JUDGE BIRO: Okay. I think it's nominally
25 relevant. I understand you think it forms the backbone

1 and I think you're right on that point. I think it did,
2 because that reflected the health risk and that was the
3 greatest risk that I think the agency recognized. But
4 how it relates to the other requirements I'm not really
5 persuaded on that. But I'll admit it. What are -- what
6 are we identifying this as?

7 MR. ROSS: One moment, Your Honor. 95, Your
8 Honor.

9 (Petitioner's PAX-95 identified.)

10 JUDGE BIRO: Do you have any objection?

11 MR. PITTMAN: Excuse me, Your Honor, thank you.
12 We would object on the grounds that you've already made
13 clear.

14 JUDGE BIRO: Ms. Rose, do you have any
15 objection?

16 MS. ROSE: Sorry, technical issues. No, Your
17 Honor, I do not.

18 JUDGE BIRO: Okay. I'll admit PAX-95.

19 (Petitioner's PAX-95 received.)

20 MR. ROSS: I will tender the witness to Mr.
21 Pittman.

22 MR. PITTMAN: No cross-examination, Your Honor.

23 JUDGE BIRO: Okay. Ms. Rose, do you have any
24 questions you'd like to ask the doctor?

25 MR. ROSS: No, Your Honor.

1 JUDGE BIRO: Okay, thank you. Thank you so
2 much, Dr. Jonynas. I really appreciate it for your time
3 and calling in.

4 THE WITNESS: Thank you.

5 JUDGE BIRO: Does anyone reserve the right to
6 recall her for any reason?

7 MR. ROSS: We do not, Your Honor.

8 JUDGE BIRO: Okay. Thank you, doctor. You're
9 released.

10 THE WITNESS: Thank you.

11 (Witness excused.)

12 JUDGE BIRO: Okay. Would you like to call your
13 next witness?

14 MR. ROSS: Yes, Your Honor. AMVAC calls Suneet
15 Ranganath. While Mr. Ranganath is connecting, I will
16 note that Mr. Ranganath's written testimony as it has
17 been submitted contains a portion that has been
18 designated as confidential business information. Only if
19 cross-exam is expected to get into the specifics of that
20 information would we have any need to restrict access to
21 the courtroom. If not then there will be no need to
22 restrict access.

23 MR. PITTMAN: Your Honor, we do not intend to
24 cross-exam Mr. Ranganath.

25 JUDGE BIRO: Okay. Maybe you could always just

1 refer it to as the number identified in his statement and
2 not use the specific number, you know, if that becomes
3 necessary. Dr. Ranganath, can you hear me?

4 DR. RANGANATH: Yes, I can. I can hear you.

5 JUDGE BIRO: Can you raise your right hand so
6 the court reporter can swear you in?

7 (Whereupon,

8 SUNEET RANGANATH,

9 having been first duly sworn, was called as a witness
10 herein and testified as follows:)

11 JUDGE BIRO: Is anyone else present with you
12 where you are testifying from?

13 THE WITNESS: No, they're not.

14 JUDGE BIRO: Please proceed.

15 DIRECT EXAMINATION

16 BY MR. ROSS:

17 Q. Good afternoon, Mr. Ranganath.

18 A. Hi, good afternoon.

19 Q. Can you please state your full name for the
20 record?

21 A. Suneet Ranganath.

22 Q. What is your position with AMVAC?

23 A. I'm vice president of global supply chain and
24 operations.

25 MR. ROSS: Mr. Sayres, could you please bring

1 up the first page of Mr. Ranganath's witness statement.

2 BY MR. ROSS:

3 Q. Mr. Ranganath, do you recognize this document?

4 A. Yes.

5 Q. Do you understand it to be a true and accurate
6 copy of your verified witness statement?

7 A. Yes, I do.

8 Q. I have only one, one further question for you.
9 Mr. Ranganath, since you prepared this statement, have
10 there been any, any changes to any of the numbers that
11 you reported at any point in this statement?

12 A. No, not as of -- not as of the 9th, no.

13 MR. ROSS: No further questions, Your Honor.

14 JUDGE BIRO: Okay. Is there any
15 cross-examination?

16 MR. PITTMAN: Your Honor, we would object to
17 the admission of Dr. Ranganath's statement on grounds of
18 relevance concerns. We don't believe that it's within
19 the narrow statutory scope of this hearing. But
20 otherwise no cross-examination.

21 JUDGE BIRO: Why isn't what they make available
22 to the public and sell relevant? How much of it?

23 MR. PITTMAN: Your Honor, we believe that under
24 FIFRA Section 3(c)(2)(B) and EPA's existing stocks policy
25 specifically concerning suspensions under that section

1 that questions of market disruption or availability are
2 not relevant to the context of whether or not a product
3 should be suspended. EPA is not contesting the -- that
4 market effects may occur, but simply that they are not
5 relevant to the scope of this hearing.

6 MR. ROSS: Your Honor, if I may?

7 JUDGE BIRO: Okay.

8 MR. ROSS: The statute specifically creates a
9 right for entities other than the registrant to request a
10 hearing and specifically provides that the -- whether or
11 not the existing stocks policy is consistent with FIFRA,
12 is part of the statutory scope of the hearing. We think
13 that evidence is a clear -- not only clearly from the
14 text of FIFRA, but from the fact that they chose to allow
15 entities other than the registrant to request a hearing,
16 a clear intent to bring questions of market disruption
17 within the scope of this hearing.

18 JUDGE BIRO: Well, we let the Growers'
19 statements in and that all has to do with it. And
20 whether it comes within the statute or not is a legal
21 decision I'll have to address in my decision. So I'll
22 admit it. What -- are we up to PAX-96?

23 MR. ROSS: 96, Your Honor.

24 (Petitioner's PAX-96 identified.)

25 JUDGE BIRO: Okay. We'll admit Mr. Ranganath's

1 statement as PAX-96 over the agency's objection.

2 (Petitioner's PAX-96 received.)

3 JUDGE BIRO: Okay. Is there cross-examination
4 you want to make?

5 MR. PITTMAN: No, Your Honor.

6 JUDGE BIRO: Ms. Rose, do you have any
7 questions you'd like to ask?

8 MS. ROSE: I do not, Your Honor.

9 JUDGE BIRO: Okay. I have a few questions I'd
10 like to ask. Mr. Ranganath, can you tell me where
11 dacthal is sold?

12 THE WITNESS: I manage the supply chain, so I
13 don't have full knowledge of where all it is sold.

14 MR. ROSS: Apologies, Your Honor, if I might?
15 I'm not certain that the witness heard the initial
16 explanation concerning whether or not the courtroom is
17 closed. And so I'd simply advise the witness that if he
18 wishes to testify to something that he considers to be
19 confidential business information, to please advise the
20 Court before doing so.

21 JUDGE BIRO: Yeah. So I'm -- I don't want
22 confidential business information, but I don't think
23 where you sell your product is confidential business
24 information. So do you sell it beyond the United States?

25 THE WITNESS: Yes. So, again, we, we do, but I

1 don't have particular knowledge of where we do, as I'm
2 managing the supply chain inbound and production. That
3 would be with our commercial team.

4 JUDGE BIRO: So do you know how many pounds or
5 units, I don't know how you measure it, of dacthal is
6 sold every year?

7 THE WITNESS: I have a general idea, yes.

8 JUDGE BIRO: Do you consider that confidential
9 business information?

10 THE WITNESS: It had been marked that way, yes.

11 JUDGE BIRO: Can you give me a range then?

12 THE WITNESS: I would -- it is north of 100,000
13 gallons of end-use product.

14 JUDGE BIRO: Of end-use product in total every
15 year?

16 THE WITNESS: Annually, yes.

17 JUDGE BIRO: And is it a product in which your
18 company makes a profit?

19 THE WITNESS: Yes.

20 JUDGE BIRO: Have you increased the amount of
21 product you are producing, end-use product you are
22 producing over the past year?

23 THE WITNESS: No.

24 JUDGE BIRO: Okay. I don't have any further
25 questions.

1 (Pause.)

2 JUDGE BIRO: I know you might not be able to
3 see it, but maybe you can, Mr. Ross is just having a
4 little sidebar.

5 THE WITNESS: I cannot see it.

6 JUDGE BIRO: Okay. I'm sorry. I don't want
7 you to think we're ignoring you.

8 THE WITNESS: Yes, thank you.

9 MR. ROSS: We have no further questions, Your
10 Honor.

11 JUDGE BIRO: Mr. Pittman?

12 MR. PITTMAN: None for me.

13 JUDGE BIRO: Ms. Rose?

14 MS. ROSE: No questions, Your Honor.

15 JUDGE BIRO: Thank you very much for your
16 attendance at our hearing. Is there any reason to retain
17 the right to recall?

18 MR. ROSS: There is not.

19 JUDGE BIRO: No? Okay. Thank you, you're
20 released. I really appreciate you accommodating us.

21 THE WITNESS: Thank you.

22 (Witness excused.)

23 MR. ROSS: AMVAC would next call Ephraim Gur to
24 the stand.

25 JUDGE BIRO: Good afternoon, Dr. Gur.

1 DR. GUR: Good afternoon.

2 JUDGE BIRO: Could you please take the stand,
3 remain standing, raise your right hand?

4 (Whereupon,

5 EPHRAIM GUR,
6 having been first duly sworn, was called as a witness
7 herein and testified as follows:)

8 DIRECT EXAMINATION

9 BY MR. ROSS:

10 Q. Good afternoon, Mr. Gur.

11 A. Good afternoon.

12 Q. Can you please state your full name for the
13 record?

14 A. Ephraim Gur.

15 Q. Could you please briefly summarize your career
16 as it relates to pesticide regulation, the pesticide
17 industry?

18 A. Yes, I'll do that. I began my career almost 40
19 years ago as a toxicologist in a contract lab doing GLP
20 studies for this industry and the pharmaceutical
21 industry. Worked my way from the role of a study
22 director to the head of general tox in that lab. Eight
23 years later, which about 31 years ago, I moved into our
24 industry and basically since then I've been managing
25 global regulatory departments around the world.

1 In the last about 8 years, I've been a
2 consultant and also an employee of Gowan Company,
3 consulting companies on EPA and regulatory requirements,
4 and all sort of activities. And within Gowan Company, I
5 am the chief scientist, which is the head of the global
6 regulatory team, as well as other managerial functions.

7 MR. ROSS: Mr. Sayres, could you bring up Mr.
8 Gur's statement, please?

9 BY MR. ROSS:

10 Q. Mr. Gur, do you recognize this document?

11 A. Yes.

12 Q. And what do you recognize it as?

13 A. This is my expert witness affidavit.

14 MR. ROSS: Your Honor, because -- the parties
15 have agreed as concerning a stipulation as to Mr. Gur's
16 expertise. Only because it has not been formally
17 submitted, yet, I would ask if you would like me to read
18 the stipulation into the record prior to formally
19 submitting it.

20 JUDGE BIRO: Okay.

21 MR. ROSS: The parties stipulate that based on
22 his training and experience as set forth in his written -
23 - verified written statement, AMVAC offers Mr. Gur's
24 testimony as an expert witness in the areas of pesticide
25 registration, re-registration, and registration review

1 under FIFRA, including but not limited to the following:

2 First, responding to data call-ins.

3 Second, data development including but not
4 limited to involvement in analysis of data requirements,
5 study design, protocol development, data generation, and
6 interpretation of study results.

7 And, three, interfacing with EPA and other
8 regulatory agencies regarding all of the above.

9 With that, I will tender the witness.

10 JUDGE BIRO: Have, have you agreed to that
11 expertise?

12 MR. PITTMAN: Yes, Your Honor.

13 JUDGE BIRO: Okay.

14 MR. PITTMAN: That's what we've agreed to.

15 JUDGE BIRO: And Ms. Rose, are you in agreement
16 to stipulating to Mr. Gur as an expert in designated
17 fields that the stipulation covers?

18 MS. ROSE: Yes, I am.

19 JUDGE BIRO: Okay. So designated. Please
20 proceed.

21 CROSS-EXAMINATION

22 BY MR. PITTMAN:

23 Q. Good afternoon, Mr. Gur. My name is Forrest
24 Pittman. I believe you've been here and seen that I've
25 been counsel for OPP today. I just have a handful of

1 questions for you.

2 MR. PITTMAN: Mrs. Koch, could we please pull
3 up page 14 of Mr. Gur's statement, the January statement.
4 Can you scroll down to paragraph 49?

5 BY MR. PITTMAN:

6 Q. Mr. Gur, could I ask that you read the first
7 sentence of paragraph 49 into the record?

8 A. Yes.

9 Q. Can you read it into the record?

10 A. Oh, read it out loud?

11 Q. Yes, please.

12 A. Sorry. I thought you were meaning --

13 Q. That's fine, thank you.

14 A. You want me to read it out loud.

15 Q. If you would. Can you read "Often when EFED or
16 HED . . ."?

17 A. All the paragraph. Often when EFED or HED
18 recommends denying a waiver, the reviewer will indicate
19 the basis for the recommendation. The explanation may
20 identify an issue that could be answered with additional
21 information. The registrant may be able to provide the
22 additional information so that the scientific issue is
23 resolved and the waiver could then be approved. Thus, it
24 is common for registrant to make further submissions
25 after it receives EFED and HED's initial response from

1 additional exchanges between the registrant and agency
2 personnel to continue thereafter, both verbally and in
3 writing.

4 Q. So I, I think that that's a -- I really wanted
5 the reading of the first sentence.

6 MR. PITTMAN: If you could scroll back up just
7 a little bit, Ms. Koch?

8 BY MR. PITTMAN:

9 Q. So in this document, the first sentence that
10 you just read in, you're discussing EFED and HED reviews
11 of AMVAC's waiver request or actually I think of
12 registrant waiver request --

13 A. Yeah.

14 Q. -- more generally.

15 A. Correct.

16 Q. So is it your position that these documents
17 that are signed last by EFED or HED, they represent only
18 recommendations?

19 A. Correct.

20 Q. And so when these are transmitted to AMVAC or
21 to another registrant but there is not a separate
22 transmittal memo attached to it that these documents only
23 represent recommendations still to that point?

24 A. I would think so, based on my experience, yes.

25 MR. PITTMAN: Ms. Koch, can you please pull up

1 what's been marked as RX-20? May I approach the witness,
2 Your Honor?

3 (Respondent's RX-20 identified.)

4 BY MR. PITTMAN:

5 Q. Mr. Gur, do you recognize this document? Take
6 a moment to review it, of course.

7 A. Yes.

8 Q. What is this document?

9 A. That is the previous version of my testimony, I
10 think.

11 Q. So is this a true and accurate copy of --

12 A. I can't proofread every word, but I would
13 expect it is, yes.

14 Q. So if you'd like to -- if you'd like to read
15 it, we have all the time, I believe, today.

16 A. Well, I'll need to see the original one if I
17 want to proofread every word. But --

18 MR. PITTMAN: I would ask perhaps this is --
19 this document is not -- this is not the first time this
20 document has been presented. Would AMVAC stipulate at
21 least to authenticity of this document?

22 MR. ROSS: To address Mr. Gur's concern of
23 whether this is, in fact, a particular version of his
24 verified statement?

25 MR. PITTMAN: The June 17 version.

1 MR. ROSS: We could provide him with an
2 electronic copy of what we would be -- his legal team
3 would represent to him was an accurate copy of it.

4 JUDGE BIRO: Why don't you look at this
5 document and compare it to your copy and see if it's
6 consistent.

7 MR. ROSS: We can also do that.

8 MR. PITTMAN: Would you like a written --

9 MR. ROSS: We are not aware that OPP would have
10 the ability to access any version of this document other
11 than --

12 JUDGE BIRO: To change it.

13 MR. ROSS: -- the prior version.

14 JUDGE BIRO: Okay. So let's just stipulate.
15 Can we agree to stipulate that this is an accurate copy
16 of his prior -- draft of his prior statement?

17 MR. PITTMAN: And with one objection. I'd --
18 OPP would not characterize this as a draft. This is a
19 signed version delivered in the pre-hearing exchange on
20 June 17th of last year. OPP does not, as Mr. Ross
21 pointed out, have access to any pre-signature drafts, or
22 something like that.

23 JUDGE BIRO: You have a signed copy? He said
24 this is not signed.

25 MR. PITTMAN: This bears signatures of both --

1 this document bears signatures from both Mr. Gur and Mr.
2 Ross.

3 JUDGE BIRO: Okay. So can we stipulate that
4 this is an accurate copy of the statement that was
5 delivered with his pre-hearing exchange, with AMVAC's
6 pre-hearing exchange?

7 MR. ROSS: yes, as far as I'm concerned. I
8 didn't want to speak for my -- for my witness.

9 JUDGE BIRO: Okay. So stipulated. Go ahead.

10 MR. PITTMAN: Mrs. Koch, could we turn to the
11 bottom of page 10, on page 11.

12 BY MR. PITTMAN:

13 Q. So Mr. Gur, can you read the first, just the
14 first sentence that runs from the beginning of paragraph
15 42 and to the first word of the following page?

16 A. Often when a waiver is denied by EPA, the
17 reviewer denying the waiver will indicate the basis for
18 the denial, which might be an issue that could be
19 answered with additional information.

20 Q. So if you would also note into the record, but
21 just take a second and read the remainder of paragraph 42
22 and perhaps for your own purposes compare it to paragraph
23 49 of your, your January written statement.

24 A. So the registrant may be able to provide the
25 additional information so that the scientific issue is

1 resolved and the waiver could be approved. AMVAC's
2 waivers -- waiver request for DCPA are typical of this
3 approach. The approach is scientifically valid and
4 efficient as it saves EPA resources in reviewing complex
5 studies that may be found redundant or unnecessary.

6 Q. So this paragraph 42 of your June statement is
7 substantially similar in most respects to paragraph 49 of
8 your January statement?

9 A. Yes.

10 Q. The one change that really stands out here is
11 that in your January statement, you changed the wording
12 of this first sentence. Correct?

13 A. Correct.

14 Q. So whereas in June you referred to EPA denying
15 the waiver, you are now characterizing that as EFED
16 simply recommending a waiver or, sorry, recommending
17 denial of a waiver?

18 A. Correct.

19 Q. So is it -- is it accurate to state that your
20 June statement suggests you are discussing EPA denials,
21 right, as in a, a final statement that a waiver is
22 denied.

23 A. Yes.

24 Q. So, Mr. Gur, what about the facts of this case
25 changed between June and January?

1 A. I don't think the facts have changed. But in
2 the first version which we did pretty hurried, because
3 when I got called in June, we needed to -- needed to
4 opine on a very broad set of issues. We created this
5 document based on what I could see and regard then.

6 When the matter focused on nine, only nine
7 studies, I had the ability to hone into those issues and
8 read all the documents in much more care, and see that in
9 fact all I could see where the EPA memos -- sorry, the
10 EFED's memos to PRD, which basically do say that EFED
11 recommends. And that's what initiated the change.

12 Q. So you say you reviewed them. Was it your idea
13 to make this language change from, from denied to
14 recommended denial?

15 A. In most cases, yes. It has been my idea to
16 make changes, yes.

17 Q. So you're just saying sometime in the last 6
18 months you have changed your interpretation of the
19 documents submitted by EPA during the pendency of this
20 DCI?

21 A. I was asked to focus on only nine studies and,
22 therefore, I could read much more carefully all the
23 documents.

24 Q. Okay.

25 MR. PITTMAN: Mrs. Koch, if we could turn back

1 to the -- oh, sorry, the January statement. So if we
2 could scroll up to paragraph 41.

3 BY MR. PITTMAN:

4 Q. Mr. Gur, if you could take a look at this. Are
5 you familiar with that statement, paragraph 41?

6 A. Yes, I read that.

7 Q. So here you're stating that some data
8 requirements are driven by risk assessments. So by that
9 I assume you mean prior risk assessments, like for
10 example those conducted during EPA's let's say re-
11 registration, processes that predated registration
12 review?

13 A. Yes.

14 Q. Okay. So your position is not that OPP would
15 say normally conduct a risk assessment during
16 registration review before determining if data is
17 actually required?

18 A. Normally, they wouldn't. But they could call
19 you and say we need more data, yes.

20 Q. But they normally would not do that. This
21 order of processes is DCI issued, data submitted, risk
22 assessment is performed. Correct?

23 A. Correct. And then possible refined, which is
24 when the additional data might be required.

25 MR. PITTMAN: Mrs. Koch, if you could turn to

1 paragraph 64, pages 18 to 19, I believe.

2 BY MR. PITTMAN:

3 Q. Mr. Gur, if you could just read that
4 paragraph 64?

5 A. Yes, I read it.

6 Q. So in this statement you say that EPA for the
7 first time in I believe 2022, if I understand JX-69, but
8 in 2022, EPA for the first time presented modeling to
9 AMVAC indicating that assumption of stability would lead
10 to a gradual increase in environmental concentrations.

11 A. Yes.

12 Q. So wouldn't it follow from these statements
13 that AMVAC has been pointing to throughout the course of
14 this hearing that an assumption of stability is naturally
15 going to lead to an increase in environmental
16 concentration. Correct?

17 A. I'm sorry. I can't -- I didn't hear that.

18 Q. So isn't it natural to assume that if EPA
19 assumes stability, the environmental concentration is
20 going to essentially increase.

21 A. Could be, yes.

22 Q. So if --

23 MR. ROSS: I'm going to object. This is a line
24 of questioning primarily ecological in nature. Mr. Gur
25 is a witness primarily as to the registration process.

1 JUDGE BIRO: Overruled. Go ahead.

2 BY MR. PITTMAN:

3 Q. So I, I think I'm not following here. So if
4 OPP were to assume stability, that means that the --
5 whatever chemical it's talking about is not breaking
6 down. Correct?

7 A. Is not?

8 Q. It's not breaking down, being metabolized,
9 degrading, whatever terminology you'd prefer.

10 A. Yes.

11 Q. So if it's not degrading then it is essentially
12 going to build up in the environment without some
13 mechanism of removal.

14 A. It could potentially, yes. But what I'm trying
15 to say here is when you assume a product is stable, that
16 number -- it creates a number that gets fed into the risk
17 assessment. I think Dr. Freedlander spoke about that a
18 lot. And that's when you know if you have a problem or
19 not.

20 Q. But all I'm trying to get at here is in your
21 statement, paragraph 64, this reads to me, and
22 characterize it how you would, but this reads to me as
23 AMVAC saying that it was blindsided by EPA stating that
24 it's going to assume very large environmental
25 concentrations.

1 A. I'm not sure. I think it's a different concern
2 that EPA raised. That's what I'm trying to say in this
3 paragraph. Assuming it's stable is the input parameter
4 that goes into the modeling for either ecological risk
5 assessments or human health groundwater, which the
6 assessment -- it's the number that plugs into the model.
7 Assuming it concentrates is, is there a food chain
8 bioconcentration issue, which is two different problems.

9 And that's what I was trying to say. They
10 raise a whole new issue here in this -- in this
11 assumption that it's accumulating in the environment and
12 you would address them differently, just as Dr.
13 Freedlander said. If you just assume stability and you
14 assume the number plugged into the risk assessment would
15 still indicate safe use, you don't have to worry about
16 it. If it doesn't, you have to mitigate it.

17 If you assume bioconcentration in environment,
18 then you start answering the issue. It's totally
19 different. It's a whole different question. And that's
20 what I think I was referring to in this paragraph.

21 Q. So Mr. Gur, you're saying that OPP provided
22 some data that -- not that concentrations would increase
23 in the environment just from repeated applications of
24 DCPA and its not breaking down, but you believe this OPP
25 document was discussing a trophic accumulation? You

1 mentioned the food chain.

2 A. Could be. It could be. But sometimes we
3 guess. That's part of our problem with this issue.
4 That's why we need the dialogue. Because we're making
5 assumptions on the -- on the, you know, two words or two
6 sentences, and we ask and we clarify what your concern is
7 so we can address it correctly. So again, assuming it's
8 stable has to me a whole different impact than it's
9 accumulates, because I don't think their models I think
10 day-to-day take into account accumulation over years
11 except through their models, not through actual testing.

12 Q. So I think I'm still just not really --

13 A. Okay. The --

14 Q. I'm not understanding the connection that you
15 are making here. So EPA's conservative assumptions as
16 discussed throughout the rest of your statement here,
17 it's not conservative assumptions about food chain
18 accumulation. It's my understanding that has not been an
19 issue discussed during this hearing. Correct?

20 A. I'm very -- I'm finding it very hard to hear
21 you, I'm sorry.

22 Q. I'm sorry.

23 A. If you can speak to the speaker, that would be
24 very helpful.

25 Q. It seemed like Mr. Freedlander had an easier

1 time hearing me. I will take my mask off, if this makes
2 it easier for you.

3 A. Yes, it does.

4 Q. It has not been my understanding as I sit in
5 this courtroom that when the parties are discussing
6 conservative assumptions about the stability of TPA, that
7 that is a discussion of like trophic accumulation --

8 A. Correct.

9 Q. -- through the food chain.

10 A. Correct. We're saying the same thing, yes.

11 Q. So I, I am -- again, I'm not getting the
12 connection here.

13 A. Okay, okay. Let me -- let me try to explain.
14 Stability is one thing. Gradual accumulation is another
15 thing. Stability, when I see stability and the EPA is
16 saying we'll take a conservative assumption, it means
17 they have a level that they won't show any let's say
18 hydrolysis or any break down. And they will use that
19 level.

20 Accumulation is a whole new ball game. It says
21 we -- that's how I read this sentence. Again, I might be
22 making wrong assumptions. But what they're saying is
23 gradual increase in accumulations, that leads to a whole
24 different discussion of would it really increase or not,
25 and how much.

1 And it's, it's got nothing to do or very
2 different issues to do than the stability. And that's
3 what I was meaning in this thing. It opens a whole new
4 question. That's addressed in a whole different way, by
5 the way.

6 Q. So you understand EPA's communication in
7 JX-69 and perhaps we should switch to that in a moment,
8 but you understood that document as, as discussing
9 increase in concentration in some context other than just
10 DCPA into --

11 A. Yes.

12 Q. -- an environmental area --

13 A. Yeah, one thing --

14 Q. -- because of no degradation TPA will
15 eventually build up in that?

16 A. Yeah. That's what I -- that's what I read when
17 I see gradual increase in environmental concentrations.
18 I immediately see a totally different concern.

19 MR. PITTMAN: Your Honor, if I could have one
20 moment with my co-counsel?

21 (Pause.)

22 BY MR. PITTMAN:

23 Q. Mr. Gur, I just want to clarify one thing. One
24 last question here. So your belief is that EPA for the
25 first time raised an issue about environmental

1 accumulation that did not involve just a simple input
2 versus degradation calculation for TPA?

3 A. Yes. Yeah, I thought they are introducing a
4 new question, yes.

5 MR. PITTMAN: No further questions, Your Honor.

6 JUDGE BIRO: Ms. Rose, do you have any
7 questions you'd like to ask?

8 MS. ROSE: No, Your Honor.

9 JUDGE BIRO: Sorry, Ms. Rose. Okay.

10 MR. ROSS: One moment, Your Honor.

11 JUDGE BIRO: Okay.

12 (Pause.)

13 MR. PITTMAN: Your Honor, just in the course of
14 this I forgot to request that JX-21 be admitted to the
15 record -- JX-20, I'm sorry, RX-20. I got it right that
16 time. It's RX-20.

17 JUDGE BIRO: Okay. First, is there any
18 objection to RX-20 being admitted into the record?

19 MR. ROSS: There is not, Your Honor.

20 JUDGE BIRO: Okay. So RX-20 is admitted into
21 the record. Ms. Rose, I spoke too soon. Do you have any
22 objection to RX-20?

23 MS. ROSE: I do not. Thank you, Your Honor.

24 JUDGE BIRO: Confirmed and entered into the
25 record. Go ahead.

1 (Respondent's RX-20 received.)

2 MR. ROSS: No redirect, Your Honor. However, I
3 believe I failed to actually admit his current statement
4 into the record, which I would like to do so as
5 Petitioner AMVAC's Exhibit 97 and also include a separate
6 document which is Exhibit A to his statement, which is
7 his CV.

8 (Petitioner's PAX-97 and 97(a) identified.)

9 JUDGE BIRO: Is there any objection?

10 MR. PITTMAN: No objection.

11 JUDGE BIRO: Okay. So PAX-97 -- Ms. Rose, any
12 objection?

13 MS. ROSE: No objection.

14 JUDGE BIRO: PAX-97 with Exhibit A, the CV of
15 Mr. Gur, admitted into the record.

16 (Petitioner's PAX-97 and 97(a) received.)

17 JUDGE BIRO: Mr. Gur, can I ask you just a
18 couple of questions.

19 THE WITNESS: Yes, Your Honor.

20 JUDGE BIRO: I thought I read in your statement
21 that up until 2016, EPA was meeting with registrants
22 undergoing DCI's I think once or twice a year to touch
23 base.

24 THE WITNESS: Yes. It's been my experience and
25 I've learned that from colleagues and peers in the

1 industry that you -- it makes a lot of sense to meet EPA
2 as an individual registrant, in my experience twice a
3 year. Other companies probably did it more or less. And
4 not just the data call-ins, but also other divisions, the
5 other division, and go over all the ongoing projects that
6 you have together to make sure that you're aligned and
7 that everyone is updated, everyone understands the
8 other's priorities, what to -- what to focus on.

9 And I practiced it for many years and it was
10 very useful in various roles. And sometime in 2016, I
11 was told "our workload has gone crazy and we just can't
12 do it, and for many reasons." We, we tried to change the
13 format. I insisted that we do it, in my personal roles,
14 so it ended up being maybe meetings only with the head of
15 divisions or maybe just calls. And I think now after the
16 pandemic we are starting to try to do it again and so
17 forth.

18 Now I'm aware that not every company does that.
19 But, yes, it's something that we found very useful and
20 very helpful, yes.

21 JUDGE BIRO: So that was something your company
22 initiated with EPA?

23 THE WITNESS: Yes.

24 JUDGE BIRO: Do you know whether that's
25 something AMVAC --

1 THE WITNESS: I'm not aware of that, ma'am.

2 JUDGE BIRO: You don't know, okay. And when
3 you couldn't do it after 2016, did you maintain status
4 checks with the agency through emails, or phone calls, or
5 letters?

6 THE WITNESS: We tried to have these catch-up
7 meetings or alignment meetings either via phone calls or
8 just sort of almost one-on-one basis with the -- with the
9 heads of divisions. And they would, when they see --
10 obviously, you don't come in and just start talking. You
11 give them an agenda in advance. And they could invite
12 branch chiefs or CRMs to those meetings, and go over all
13 those topics. So I'm -- I was able to maintain that at
14 least until the pandemic and other changes in their
15 workload occurred, yes.

16 JUDGE BIRO: When you're working with EPA, you
17 indicated it's an iterative process where you go back and
18 forth. Who has the last word on whether a study is going
19 to be done or not?

20 THE WITNESS: Obviously, EPA.

21 JUDGE BIRO: And when a company decides to --
22 strike that. If EPA says, look, if you don't do these
23 studies, we'll be left to do conservative assumptions.
24 Is it your practice to reach out and, and tell EPA, okay,
25 we're not going to do them, do your conservative

1 assumptions?

2 THE WITNESS: Not necessarily. It might come
3 up in one of those meetings, but not necessarily because
4 for me the conservative assumption is the default. So if
5 they say we're going to assume it's stable, just like I
6 just addressed with the counsel, for me, again, I
7 visualize this risk assessment as the number is going to
8 be this number is going to be plugged in. It's a
9 default. And I just don't have to comment on it anymore
10 from my perspective.

11 JUDGE BIRO: Do you just tell them I'm not
12 going to do the studies or you say nothing?

13 THE WITNESS: In writing, I usually wouldn't
14 say anything. I would address all the other concerns.
15 For me, this concern I can address it by doing the study
16 or not, by having the default factor. That's the
17 practice.

18 JUDGE BIRO: So how does EPA know to move
19 forward and use the conservative assumption?

20 THE WITNESS: I think they just do it. I don't
21 think they ask me for permission or anything. They just
22 do it.

23 JUDGE BIRO: After a certain period of time or
24 I mean like --

25 THE WITNESS: When they do the risk assessment.

1 That's their -- their deadline is the risk assessment.
2 And we've seen it in -- we've been talking about one
3 specific set of studies which are, you know, stability.
4 But we've seen that in, for example, the registration
5 review asked for -- this is -- this is a pretty common
6 one by the way. It asks for additional soils in
7 existing, because they changed their requirements from
8 two soils to four soils, for example, one soil to four
9 soils. And they would say if you don't submit them, we
10 will just add a factor of three to the DT50 soil.

11 So if you have a short-lived active ingredient
12 that a factor of three doesn't impact the risk assessment
13 in any significant way, you basically just keep that
14 requirement. Or if you are in a meeting, you say I'm not
15 going to do the study. But if you don't, you just skip
16 that requirement and suffer the - suffer consequences,
17 you know, the default of extra three factor on the DT50.

18 JUDGE BIRO: So again I'm sort of wondering
19 when the agency would know like you've completed all the
20 things that you're going to do and they can move forward.
21 I mean what, what is the deadline that's used?

22 THE WITNESS: We don't know that. They have an
23 internal deadline for the risk assessment that they have
24 to issue.

25 JUDGE BIRO: I was a little confused about your

1 discussion about stability and accumulation. When
2 something is stable, doesn't -- that means it, it doesn't
3 degrade. It just remains. Is that correct?

4 THE WITNESS: That's, yeah, that's a simple --

5 JUDGE BIRO: Doesn't it always build up over
6 time, accumulate over time?

7 THE WITNESS: No, not at all. And that's I
8 think Dr. Freedlander --

9 JUDGE BIRO: Explain that to me. That's where
10 I lose -- I lose it.

11 THE WITNESS: So Dr. Freedlander talked about
12 acclimatization of soil and that microbes may build up,
13 that suddenly know how to degrade that product. That
14 happens in nature. But maybe a more simple way for me to
15 address and also addresses how I responded to the counsel
16 there is in Europe it is pretty common when they see a
17 long DT50, it is pretty common to ask for a soil
18 bioaccumulation study. And I've, I've seen a few of them
19 in my lifetime.

20 You do a study and see what we call the
21 chainsaw effect. You see accumulation, and then it
22 drops, and a little bit accumulation, and then it drops,
23 because again it's seasonal and it depends on microbial
24 activity in that soil. And Europe would basically plot
25 some sort of an either maximum level over let's say a

1 period of 3 to 5 years. So yes, it is stable, but it
2 doesn't accumulate, because at some stage it might
3 degrade.

4 I don't think I've seen products that are
5 forever accumulating, but I'm not an expert in soil
6 sciences. I can't speak to that.

7 JUDGE BIRO: So what causes -- so what -- in
8 these studies, you're looking for what breaks it down
9 over time? It must degrade, right?

10 THE WITNESS: Yeah. Well, first of all, we're
11 looking at the active ingredient to see that it's there
12 and at what level. And that's the -- that's the ultimate
13 endpoint. We don't try to identify which microbes
14 degraded it. But if there are degradation products, we
15 do try to identify them so that we know what's, what's
16 being created. And in many cases they just -- when they
17 degrade, they degrade all the way to H₂O and CO₂. So,
18 but that's not always the case.

19 But, yeah, we just look at that maximum value
20 or plot a curve so that they can statistically define
21 what they would use in their risk assessment. And based
22 on the accumulation, mitigation measures may occur.

23 JUDGE BIRO: So when you talk about
24 degradation, are you talking about in soil or in water?

25 THE WITNESS: Both.

1 JUDGE BIRO: Both. So we had some discussion
2 earlier where they talked about studies that did tests
3 using acclimated and non-acclimated soil. So maybe you
4 could define those terms for me. What, what is
5 acclimated soil?

6 THE WITNESS: Acclimated soil means there are
7 microbes there that might identify your chemical.
8 That's, that's all the difference that Dr. Freedlander
9 was trying to talk about. We don't --

10 JUDGE BIRO: Is that -- would that be similar
11 to soil you might find out in the natural environment?

12 THE WITNESS: Yes. If they've been exposed, if
13 that soil has been exposed to similar chemistry, not
14 necessarily identical but similar enough and it can
15 identify some structures in that molecule, it can -- it
16 can attack it and degrade it. If you have sterilized
17 soil, which is the extreme because there's no microbial
18 activity, you don't have in it any microbial degradation.

19 Now not all degradation is microbial. Some of
20 it is chemical. Could be just light, or water, or air
21 that degrades it. But usually microbial is the -- is the
22 biggest contributor. But again I am not a soil
23 scientist. I can't speak as a soil scientist.

24 JUDGE BIRO: So if you do a test -- is
25 non-acclimated soil sterilized soil?

1 THE WITNESS: I'm not sure of the specific
2 requirement in the guideline, whether it's sterilized or
3 just has to prove that it has low microbial activity.
4 I'm not sure about that.

5 JUDGE BIRO: So when you talk about
6 degradation, you're talking about a test that would be
7 performed on acclimated soil?

8 THE WITNESS: EPA requires that it's not
9 acclimated. Europe doesn't have that clause so you may -
10 - you may -- you don't intentionally acclimate it. You
11 may have soil that you collected somewhere that has been
12 exposed to similar chemical, similar chemistry.

13 JUDGE BIRO: In your CV -- in your statement,
14 you said that the time lines that EPA normally provides
15 in their DCA often underestimates how long it takes.

16 THE WITNESS: Yes.

17 JUDGE BIRO: And it's -- we had some
18 discussions about the time periods for doing these
19 studies. Why do you think they underestimate? Is that
20 just your personal experience to get them done or --

21 THE WITNESS: First of all -- sorry. First of
22 all, yes, it is my personal experience that it takes in
23 many cases much longer than it takes to get a study done.
24 And in some cases, especially, and I think that's what I
25 say in my testimony, special studies, it's probably

1 never. You never meet those deadlines, because EPA
2 requires to approve a protocol, which usually doesn't
3 take a matter of weeks or months. Could take very long,
4 in my experience, especially if they have to comment and
5 those comments go back to the CRO, and you start trying
6 to find the practical way of conducting the study per
7 those comments. I can talk about a few examples, if you
8 want.

9 And secondly, you have to then, only after the
10 protocol is finalized, you can start -- and you heard
11 from someone else about -- you start developing a
12 protocol. You have to get in line for the lab. And then
13 so it's very difficult to see any study, even a very
14 short study being done in 12 to 14, 24 months when, when
15 that requirement exists. And again, special studies also
16 have -- there are other reasons. You heard a lot about
17 the leptocheirus, of course.

18 The other -- the other example I want to give
19 which I think is very telling is the DCIs that we've seen
20 since the RED review, almost all of them included
21 high-tier bee studies. And I guess, and I'm not
22 criticizing, EPA didn't want to run around and do DCIs
23 whenever they, they had a concern, and they just added
24 them to these DCIs.

25 Now when you have a high-tier bee study, you

1 need to do the tier 1, which is very simple lab study.
2 Tier 2, which could be either in a tunnel or, or a
3 semi-field, or some condition. And tier 3 might be a
4 full field study with a lot of observations. EPA also
5 required to review those protocols, because those are
6 very complex studies. Conducting those studies are also
7 seasonal. You can only start them in April, May. You
8 can't test these in December.

9 So assuming you can get through these three
10 tiers with approval of protocols along the line in a
11 manner of even 36 months is extremely -- well, it's
12 impossible. There's no way to do it. So, and the
13 deadline says 36 months. I've actually talked with
14 colleagues at EPA several times told them why don't you
15 say "to be determined?" Why do you keep that number
16 there which doesn't make any sense? None of the DCIs
17 could meet these deadlines. So that's the kind of things
18 I was referring to.

19 JUDGE BIRO: So is it -- you talked about
20 special studies taking especially long. How about the
21 other more routine studies where there are guidelines, do
22 they -- do the timelines set basically apply in those
23 cases? Are they reasonable?

24 THE WITNESS: Of course. Sorry, yeah. Yeah,
25 for some of them, yes. It again depends on the chemical.

1 Not all chemicals are identical. So doing the studies
2 requires understanding how to deliver the compound. So
3 some compounds are very easy. If you do a fish study and
4 you just pour it into the water and it stays there, and
5 it's stable in water, for example, and you can analyze it
6 easy, those studies are pretty routine and I guess those
7 deadlines could be met. That's not a big deal.

8 But you have a product that's very lipophilic,
9 which means it likes the oily part and not the water
10 part, then it's very hard to administer it into an
11 aquarium and get the right doses. Those could take
12 months and years to establish just the methodology and
13 the analytical methodology to expose the animal. So
14 those, those you won't meet. So it's sort of a depends
15 on the molecule. But you can in some instances meet
16 those deadlines, sure.

17 JUDGE BIRO: Bear with me one minute. Have you
18 ever in your process of representing a company asked that
19 they revise their DCI to accommodate a study they've
20 requested?

21 THE WITNESS: No, I don't remember that.

22 JUDGE BIRO: I don't have any further
23 questions. Mr. Ross, do you have any questions?

24 MR. ROSS: Yes, Your Honor. Or I should say it
25 depends. I believe the witness may have misunderstood

1 your final question, which I will attempt to restate and
2 you can tell me if, if I understood it.

3 REDIRECT EXAMINATION

4 BY MR. ROSS:

5 Q. As I understood the question, it was in your
6 experience, Mr. Gur, have you seen instances where you or
7 someone else has asked that EPA formally add a data
8 requirement to a DCA -- to a DCI or otherwise?

9 A. No. Again, not the -- not add a formal data
10 requirement, but add another DCI. That's different, yes.

11 Q. So you've seen instances in which a registrant
12 was asked to perform a study that was not in the DCI?

13 A. Yes. Yes, but it's not, not necessarily linked
14 to the DCI. I've seen instances where a registrant asked
15 EPA to issue a DCI in order to maintain its intellectual
16 property rights. Those are the data compensation issues
17 that Dr. Freedlander talked about, yes.

18 Q. But a request is provided from the registrant
19 that there be a formal document stating we, the agency,
20 require you to do study X as a matter under FIFRA?

21 A. Correct. But I'll, I'll try to -- I'll try to
22 insist on a DCI, not just when you say formal document.
23 A memo could be helpful. But if I -- I've negotiated a
24 lot of data comp negotiations, so I'm fairly familiar
25 with this issue. And if you want to have a clean

1 negotiation without having to involve arbitrations and
2 all that stuff, if you have a DCI it's almost non-
3 negotiable. They will compensate you for that study. If
4 you just have a formal letter, it's a bit different.

5 Q. So if you enter a FIFRA arbitration with a DCI
6 requirement, that's basically -- that would be the gold
7 standard of, "I should be compensated for those?"

8 A. It might even avoid an arbitration, let me take
9 it as far as that.

10 Q. And anything other than that, you'd be
11 fighting --

12 A. Yes.

13 Q. -- over whether or not it was necessary.

14 A. Absolutely correct.

15 JUDGE BIRO: Okay. Any other questions?

16 RE-CROSS-EXAMINATION

17 BY MR. PITTMAN:

18 Q. Mr. Gur, I have to say over the course of this
19 testimony, I've become less certain about what you mean
20 by stability. When, when you read a statement from OPP
21 that the U.S. EPA will assume stability, you understand
22 that to mean that EPA will assume the chemical is not
23 breaking down?

24 A. Correct.

25 Q. But you also said that essentially you

1 understand that the chemical will break down.

2 A. It might. I don't know that for sure. Can,
3 can I explain again? I may be -- I'm not a modeler. In
4 our life, we have modelers who plug the numbers into
5 models.

6 Q. Yeah, I accept that you're --

7 A. Stability is -- directs that number.

8 Q. I, I understand that's not your area of
9 expertise. But in the context of seeing an EPA statement
10 that it will assume stability, is that not natural to
11 assume that if a stability is assumed but use is
12 continued that environment concentration is increased, to
13 say nothing of trophic accumulation, but just based
14 purely on continued use and no degradation, that
15 environment concentrations would increase.

16 A. That, that could be. But it doesn't -- that's
17 not what I would think of when I see stability. I see it
18 in the context of the risk assessment only.

19 Q. No further questions.

20 A. That's the goal of the -- of the -- that's the
21 deliverable EPA has to produce, right, the risk
22 assessment.

23 JUDGE BIRO: Ms. Rose, do you have any
24 questions?

25 MS. ROSE: No, Your Honor.

1 JUDGE BIRO: Do you have additional questions?

2 MR. ROSS: Yes, Your Honor. Going to the --

3 JUDGE BIRO: Can I interrupt you. I'm sorry.
4 You mentioned before, Mr. Gur, about lipophilic tests on
5 something, oil in water, I think. Is DCPA a lipophilic
6 product, I mean chemical?

7 THE WITNESS: I don't remember. I apologize.

8 JUDGE BIRO: Okay.

9 THE WITNESS: I don't remember.

10 JUDGE BIRO: All right. Go ahead, sorry to
11 interrupt.

12 FURTHER REDIRECT EXAMINATION

13 BY MR. ROSS:

14 Q. Mr. Gur, if the agency stated to you prior to a
15 risk assessment that it would assume stability of a
16 particular compound, would you understand that to refer
17 to the chemical properties of that compound, that it
18 would not be expected to degrade in a study?

19 A. Yes.

20 Q. If EPA stated to you that after they had
21 performed a modeling analysis in the context of a risk
22 assessment, if they said to you then the environmental
23 concentrations of this chemical will remain stable, you
24 would understand that differently. Correct?

25 MR. PITTMAN: Objection. That's misreading

1 stability, trying to apply stability of environmental
2 concentration levels versus stability from degradation.

3 MR. ROSS: Well, I think I'm attempting to
4 elucidate the exact difference in terminology that the
5 objection --

6 JUDGE BIRO: Okay. Well, I'll let you come
7 back and -- it's not clear, go ahead.

8 BY MR. ROSS:

9 Q. If the agency was to provide you the results of
10 modeling after they've performed a risk assessment, and
11 those modeling results showed that the expected
12 environmental concentrations of the chemical were over
13 time, over a long time horizon not decreasing or, or were
14 increasing, that's using the term stability in a
15 different sense. Correct?

16 A. Yeah, but that's not what they show us. I mean
17 maybe I'm -- I couldn't explain myself. The purpose of
18 those studies is to determine a DT50. That DT50 gets
19 plugged into a model, that then helps them analyze how
20 much would be in surface water, groundwater, and so
21 forth. And when I hear stability, I know that the
22 modeler will put let's say 1,000 days. I'm not sure, but
23 I'm making an assumption. And that's the entire purpose
24 of the study. It's not to look at what happens tomorrow.

25 The model then, when I mention 30 years, the

1 model then assumes 30 years of usage. It's based on
2 rain, and weather, and all those issues, to determine how
3 much leakage, so --

4 Q. So are there --

5 A. Looking into the future is not something that I
6 have to do.

7 Q. Are there other parameters that are put into
8 the model beyond the chemical stability of the compound
9 which affect how that compound will increase or decrease
10 in the environment over time --

11 A. I don't know. I don't think so.

12 Q. -- in a particular location?

13 A. Soil types, yes. But again, we don't look at
14 the increase over time. We look at what -- how does it
15 break down. Soil type is -- I don't remember all the
16 parameters for the model. I can't tell you that.
17 Hydrolysis is obviously one. Soil characteristics is
18 obviously another. But I can't remember them all.
19 Solubility.

20 Q. Are there other lines of evidence that an EPA
21 risk assessor -- either an EPA modeler or an EPA risk
22 assessor might look at when they were -- if they were and
23 when they were considering the long-term accumulation or
24 not of a chemical? Are there other lines of evidence
25 that they might look at other than the chemical -- the

1 chemical stability?

2 A. They would look at lipophilicity, maybe.
3 That's in animals. That's in fish or in birds. They
4 would look at those kind of things to see what happens in
5 the environment. But again not from these studies that
6 we are talking about, not the anaerobic degradation study
7 --or metabolism study, sorry.

8 MR. ROSS: No further questions.

9 JUDGE BIRO: Mr. Pittman, do you have any
10 further questions?

11 MR. PITTMAN: Nothing further, Your Honor.

12 JUDGE BIRO: Are we going to reserve the right
13 to recall Mr. Gur?

14 MR. ROSS: Yes, Your Honor.

15 JUDGE BIRO: Okay. Ms. Rose, I'm so sorry, do
16 you have any questions you want to add?

17 MS. ROSE: No, Your Honor. And I will speak up
18 if I ever do and don't get called upon.

19 JUDGE BIRO: All right. Thank you, Mr. Gur.

20 THE WITNESS: Thank you.

21 JUDGE BIRO: You remain to be recalled, so
22 please don't discuss anything -- well, actually, you get
23 to stay here indefinitely so that's not a problem.

24 (Witness excused.)

25 JUDGE BIRO: If you'd like to call your next

1 witness?

2 MR. ROSS: We have no further direct witnesses.

3 JUDGE BIRO: How about Mr. Wood?

4 MR. ROSS: Oh, Mr. Wood will not be called.

5 JUDGE BIRO: Is there any other documents you
6 wish to put into evidence?

7 MR. ROSS: If we might request a 5-minute
8 recess --

9 JUDGE BIRO: Oh, of course, sure.

10 MR. ROSS: -- before answering that question.

11 JUDGE BIRO: Sure. It's 2:35. How long do you
12 need? Do you want to go to 3:00?

13 MR. ROSS: That would work. Thank you.

14 JUDGE BIRO: Okay. We'll stand in recess till
15 3:00.

16 (Off the record from 2:35 p.m. to 3:00 p.m.)

17 JUDGE BIRO: Please be seated. Okay, Mr. Ross,
18 where are we? Do we have any exhibits we're going to
19 introduce?

20 MR. ROSS: We do not have any further exhibits
21 to introduce.

22 JUDGE BIRO: Okay. Does the Petitioner rest,
23 Petitioner AMVAC?

24 MR. ROSS: But for potential rebuttal, yes.

25 JUDGE BIRO: Okay. Ms. Rose?

1 MS. ROSE: Yes, Your Honor.

2 JUDGE BIRO: Do you have any exhibits that you
3 would like to put in as considered part of your direct
4 case?

5 MS. ROSE: Beyond the ones that we handled
6 earlier, only PGX-7(a), which I supplied to counsel for
7 the other parties and subject to their objection. That
8 would be the only one.

9 JUDGE BIRO: So let's try to remember to get
10 back to that before the end of today or tomorrow.

11 Okay, Mr. Pittman, do you have any rebuttal
12 witnesses?

13 MR. PITTMAN: Your Honor, no, we do not intend
14 to call anybody on rebuttal.

15 JUDGE BIRO: Okay.

16 MR. ROSS: We'd like to call Mr. Gur for brief
17 rebuttal, Your Honor.

18 JUDGE BIRO: What are you rebutting, because
19 they're not putting on any rebuttal witnesses.

20 MR. ROSS: Cross-examination testimony provided
21 by Ms. Bloom, Your Honor.

22 JUDGE BIRO: All right. Shouldn't this have
23 been something we got out of him on cross-examination
24 before or your direct testimony before?

25 MR. ROSS: Well, it -- the three areas that I

1 hope to briefly cover were not within the --

2 JUDGE BIRO: Scope?

3 MR. ROSS: They were not within the scope of
4 Mr. Pittman's cross and they relate to issues commented
5 on by Ms. Bloom.

6 JUDGE BIRO: Okay. Mr. Gur, could you take the
7 stand again? Thank you for indulging us. You remain
8 under oath.

9 MR. GUR: Sure.

10 (Whereupon,

11 EPHRAIM GUR,

12 having been previously sworn, was recalled as a witness
13 herein and testified as follows:)

14 DIRECT EXAMINATION

15 BY MR. ROSS:

16 Q. Good afternoon, Mr. Gur.

17 A. Afternoon.

18 Q. You've been with us in the hearing room through
19 the testimony. Correct?

20 A. Correct.

21 Q. And you observed the cross-examination
22 testimony of OPP's witness, Ms. Jill Bloom. Correct?

23 A. Correct.

24 Q. During the examination of Ms. Bloom, there was
25 a discussion of commenting on EPA preliminary work plans.

1 Do you recall that --

2 A. Yes.

3 Q. -- discussion? Do you have experience
4 commenting on EPA work plans?

5 A. Yes, I do.

6 Q. And what is the general nature of comments that
7 a registrant might supply on an EPA work plan?

8 A. So some registrants would want to comment in
9 any case. Some would comment ad hoc on whether they have
10 anything to say. Some of them would be very general,
11 like say we agree, or we'll -- we will comply, or we will
12 wait for the DCI. And some would really address some of
13 the requirements. It's really very different in the
14 industry on, on what you see in terms of how they address
15 this. And some simply ignore it if they either don't
16 want to or don't need to comment.

17 Q. And for those registrants that do choose to
18 comment on preliminary work plans, would you characterize
19 their comments as more commonly being directed to the
20 broad themes, EPA's general approach, or would the
21 comments on the work plan be to the need for specific
22 data requirements?

23 A. I would think generally it'll be more general
24 than specific data requirements. And, and the reasons
25 would be probably two, two reasons. One is, not always

1 would those work plans that say we expect to have these
2 studies in the DCI, actually have all those studies in
3 the DCI. So you might feel that there's redundancy in
4 making comments. Sometimes, assumptions that are made in
5 these work plans about what studies would end up in the
6 DCI don't, don't happen.

7 And, two, in many cases, EPA would probably
8 disregard them basically. They'll sort of politely
9 acknowledge that we received comments, but the scientists
10 of EPA wouldn't want to start reviewing those studies
11 again. They'll wait for a DCI and say submit the waiver,
12 and then we'll address your comment. They will want to
13 see the formal process of a -- of a waiver.

14 Q. So with respect to the broader category of
15 comments going to EPA's general work plan, if you will,
16 if a registrant did not have a substantive concern with
17 the general direction in which EPA was headed, they would
18 not even have a reason to supply comments, would they?

19 A. Yes.

20 Q. Have you ever seen a registrant attempt to take
21 a very narrow approach of saying you're, you know, I'm
22 using a hypothetical, but you're -- you say you're going
23 to require a tier 1 X study. We don't think you should.
24 Please remove it from the work plan. Have you seen
25 something like that?

1 A. I don't think I've ever seen anything that
2 specific, that narrow, yeah.

3 Q. What about I mean challenging any data
4 requirement by, by name, if you will?

5 A. I'm trying to remember if I've seen anything or
6 done anything that specific. Maybe very rarely, if, if
7 at all.

8 Q. To the extent that you recall such an instance,
9 do you recall the agency's response to that sort of
10 comment on a preliminary work plan?

11 A. So that kind of thing would usually come up, in
12 my experience, in those six monthly meetings where
13 because the work plan says a DCI will be issued at a
14 certain date and since the beginning of the registration
15 review, EPA was always 6 to 12 months late on those, on
16 those dates. We always had time to say we've seen the
17 work plan. We sort of could discuss maybe not in detail,
18 but say, you know, we think we don't need this. We think
19 we don't need that.

20 So we would have had the opportunity to raise
21 that in those kind of settings and see if EPA would be
22 willing to entertain that discussion before a DCI is
23 issued or not. I think in most cases, EPA would say,
24 yeah, that's interesting, please submit the waiver when
25 the DCI is issued, because that's easier for them just to

1 follow process and not start having things jump in the
2 middle on one hand.

3 Q. There was also testimony, Mr. Gur, if you
4 recall, regarding the -- from Ms. Bloom, about the
5 expected or average duration of a DCI from initiation to
6 completion. Do you recall that testimony?

7 A. Yes.

8 Q. Do you happen to recall the rough window that
9 she provided for a short versus a long DCI?

10 A. I think I remember 3 years or something like
11 that, but I am not sure.

12 Q. As the -- as the shorter window? Or sort of
13 she --

14 A. I don't remember the exact number. I
15 apologize. I remember what the witness today said, but
16 not what Jill said yesterday.

17 Q. Based on the 3-year estimate that she provided,
18 do you suspect that she was referring to DCIs from a
19 particular --

20 MR. PITTMAN: Objection. The witness that said
21 that 3-year estimate was from today's witness, which I
22 believe is referring to Ms. McMahon, who provided a 3-
23 year estimate.

24 MR. ROSS: I believe there was a separate
25 timeframe offered by Ms. McMahon. I asked Mr. Gur if he

1 recalled an estimate being provided by Ms. Bloom.

2 JUDGE BIRO: Right. Well, he doesn't remember
3 what she said. So you can ask him hypothetically,
4 because he's an expert, hypothetically if it was 3 years.

5 BY MR. ROSS:

6 Q. I'm sorry. Do you -- do you recall that Ms.
7 Bloom's response was 3 years?

8 A. I thought so. I'm not sure.

9 Q. Based on that response, do you think she might
10 be referring to DCIs from a particular historical
11 timeframe?

12 A. Yeah, I think 3 years is a -- is a very --
13 should be only a very simple DCI that has very simple and
14 narrow requirements, and probably standard studies, very
15 standard. I think it's very rare to see a DCI finalized
16 in 3 years.

17 Q. Would you characterize the dacthal DCI as a
18 simple DCI?

19 A. I think that is one of the more problematic and
20 difficult ones, which we would have seen from products
21 that were -- that have I would call it run over from the
22 previous process, the RED process, and had to go through
23 the registration review, relatively old molecules that
24 had a lot of studies that had to be renewed.

25 In addition, dacthal has both parent and

1 metabolites. That creates another complexity. And it
2 had a pretty complex study in it, which is the CTA, which
3 is the type of studies that take, take a long time to
4 finalize. They have a lot of stages that EPA wants to
5 opine on as they go along. So you're dependent on EPA to
6 provide you with approval for those steps.

7 Q. And so there, there might not -- there might
8 exist, might they, other complex DCIs, correct?

9 A. I have had ones that are even more than 10
10 years.

11 Q. And so DCPA might be -- might share qualities
12 with those. Correct?

13 A. Correct.

14 Q. Mr. Gur, based on your -- also as it relates to
15 the overall duration, does the overall duration of a DCI,
16 is that impacted by how quickly responses are received
17 from EPA as well?

18 A. Absolutely, on various issues. First of all,
19 approval of protocols. And then approval of stages of a
20 study like the CTA and that example with other, other
21 types of studies, not just the CTA, which I've personally
22 never been involved in. And addressing waivers, which
23 again if you get a waiver response quickly and you can
24 clarify the agency's concern so that you can address it
25 either by submitting additional data, or running the

1 study, or then that would speed up the process. If it
2 takes a long time to get those responses, then obviously
3 you are waiting to see what the exact issue is.

4 Q. And so with respect to waivers in particular,
5 if a registrant did not receive a response to a waiver
6 for hypothetically 33 or 44 months, 3, 4 years, whatever
7 it is, that would necessarily extend the timeline for the
8 DCI. Correct?

9 A. Yes.

10 Q. And finally, Mr. Gur, Ms. Bloom mentioned that
11 in some instances the agency's response documents are
12 made available on a docket. What docket did you
13 understand her to be referring to?

14 A. The registration review docket, of the
15 government dockets, regulations.gov.

16 Q. So she made reference to some other internal
17 EPA systems. Correct?

18 A. Yes.

19 Q. But none of those are available to a
20 registrant?

21 A. No.

22 Q. Is regulations.gov available to a registrant?

23 A. Yes.

24 Q. Have you reviewed the regulations.gov docket
25 for the DCPA registration review?

1 A. Yes. I've had a look at it, yes.

2 Q. And in general can you describe the contents of
3 that docket?

4 A. So it has about 79 documents posted in it. A
5 few are between 2011 to 2015. And the rest after the
6 NOITS. So if I remember well, the dates April 27/28 of
7 2022 for the majority of them in those two dates,
8 actually, the first date and then the add-ons probably in
9 the second date. So 27th of April. So between 2015 to
10 April 2022, there were no, no documents, no postings on -
11 - in the docket.

12 Q. Were a majority of the documents in the docket
13 posted contemporaneous with the NOITS?

14 A. Yes.

15 Q. And prior to the documents that were posted
16 contemporaneous with the NOITS, again if you could,
17 approximately how far back was the next most recent
18 document in the docket?

19 A. Seven years, 2015.

20 MR. ROSS: No further questions on rebuttal,
21 Your Honor.

22 MR. PITTMAN: If, if I could have just one
23 moment?

24 JUDGE BIRO: Mm-hmm.

25 (Pause.)

1 CROSS-EXAMINATION

2 BY MR. PITTMAN:

3 Q. Mr. Gur, just one question. So during your
4 testimony here, you said that EPA often disregards
5 comments submitted to regulations.gov dockets?6 A. I'm not sure I said that. If I said that, I
7 might --8 MR. PITTMAN: Should we have the record read
9 back -- should we have the record read back to refresh
10 his memory?11 JUDGE BIRO: If you want, but I, I think I
12 recall that and it's in my notes. Right. Mr. Gur, is
13 that your testimony that EPA doesn't respond to comments
14 to preliminary -- I think it was preliminary work.

15 THE WITNESS: Work plan, yes.

16 MR. PITTMAN: I understood the question to be
17 somewhat broader, to comments generally submitted to
18 registration review dockets.

19 JUDGE BIRO: Oh, well, ask him.

20 THE WITNESS: I think it was comments to the
21 work plan. Right?22 JUDGE BIRO: Or we could ask the court reporter
23 to find it. Mr. Reporter, could you go back to Mr. Gur's
24 testimony on direct -- is it on direct?

25 MR. PITTMAN: Just moments ago, Your Honor.

1 (Off the record from 3:17 p.m. to 3:18 p.m.)

2 MR. ROSS: I believe the issue concerned a
3 question that I --

4 JUDGE BIRO: On rebuttal, right. Okay.

5 MR. ROSS: I can either attempt to -- or we can
6 go to the transcript.

7 MR. PITTMAN: I would prefer the transcript.

8 JUDGE BIRO: Okay.

9 MR. PITTMAN: I'm sorry. Am I -- do I need to
10 ask you exactly -- Your Honor, I'm sorry. I don't know
11 exactly how to do this, but I'm trying to get the
12 comment. I distinctly remember EPA disregards comments.
13 We can clarify the context in which it's asked. Perhaps
14 my recollection needs refreshing. But I think this is an
15 important point to address.

16 JUDGE BIRO: Mr. Reporter, could you find an
17 answer from Mr. Gur to a question about the usefulness or
18 generally the second on the usefulness of responding to
19 the work plans?

20 MR. PITTMAN: And again I am willing to accept
21 that perhaps my recollection of the exact context of this
22 question is not correct. But I would like to know. So,
23 I mean if it was a Gur statement, I would like to address
24 it. I, I think that was his statement.

25 JUDGE BIRO: Okay, it's fine. We can take a

1 few minutes. Would you like to go onto something else?
2 Well, I guess we can't. We'll torture the court
3 reporter.

4 Q. MR. PITTMAN: This is my only question. So --
5 (Off the record from 3:20 p.m. to 3:25 p.m.)

6 JUDGE BIRO: Could you play back that little
7 clip one more time and a little bit louder, if possible?
8 Why don't you maybe move a little bit closer.

9 (Off the record from 3:25 p.m. to 3:27 p.m.)

10 BY MR. PITTMAN:

11 Q. Mr. Gur, I admit this entire little interlude
12 here was because when I hear that EPA disregards comments
13 submitted to a docket, that comes off as quite a serious
14 allegation when I'm hearing it as counsel for EPA.

15 A. I understand.

16 Q. Are you aware, can you point me to any
17 particular documents -- or sorry, sorry, any particular
18 registration review cases that you've worked on where you
19 feel that EPA has disregarded a comment submitted?

20 A. So what I said there if you heard is it
21 disregards a specific comment that politely says we heard
22 your comments and we'll address them. And I think that's
23 a very generic term that I've seen a lot of times. I
24 need to -- I don't know if I can point to a specific
25 example. But it's certainly something that's pretty

1 generic in those work plan -- in the -- when EPA comments
2 to -- sorry, addresses all the comments it receives, it
3 many times says we received comments from the registrant
4 saying this and this. We heard them. We'll take care of
5 it when we do the risk assessment. It won't address all
6 the specific comments.

7 You can say that about USDA. You can say that
8 about grower groups. Thank you for your comments, we
9 will consider them. And that's what I was saying. They
10 politely say we heard you, which I believe they have, but
11 they won't address a specific attempt to say let's say
12 waive a -- waive a requirement or tell them that you
13 think this requirement is redundant, or won't inform your
14 risk assessment, which is why we generally don't put
15 those requirements.

16 Q. Well, perhaps my recollection is a little
17 different, but it seems like we're going to have to wait
18 for the official transcript to come out. But just to
19 follow-up on that, would you stand by that
20 characterization of EPA acknowledging that comments have
21 been submitted --

22 A. Yes.

23 Q. -- but disregarding them?

24 A. Yes.

25 MR. PITTMAN: Okay. No further questions.

1 THE WITNESS: Apologize.

2 JUDGE BIRO: Mr. Gur, can I ask a question.
3 How long do you think a registrant should go after they
4 submit a waiver before they contact EPA on the status of
5 it? What's a good practice?

6 THE WITNESS: Well, it's a good question.
7 Because the EPA did initiate at some stage following some
8 OIG, I think, report, a requirement that we give them
9 status reports. And we do send status report of the
10 status. And I think Dr. Freedlander talked about or
11 showed one of them, for example. And for us, unless we
12 have another gathering or meeting, this is where they get
13 an update. And so we might have a status report, and
14 I've seen at least one in the docket somewhere when I
15 reviewed the documents that I was supposed to comment on,
16 where there was an appendix with, "this is the status."
17 And on the waivers it said waivers pending. So per EPA,
18 they request that typically every 3 months. So I think
19 we do have a system where we do update. Unfortunately,
20 it's not, as you indicated yesterday, it's not automatic.
21 It's not sort of sophisticated system. It's a document
22 that they're supposed to get, and distribute the need,
23 and address.

24 JUDGE BIRO: So if I were a registrant and I
25 got a DCI. I submitted a request for waiver in my

1 initial response. It was denied. Or it wasn't denied.
2 Let's say it was I submitted a request for a waiver and I
3 didn't hear anything, would I contact EPA? Would it be a
4 good practice to contact EPA after 6 months or a year?
5 Like how long do you wait?

6 THE WITNESS: Give or take 6 months would make
7 sense. But again bear in mind there's a difference
8 between a very relatively simple -- I've had DCIs where
9 the compound was recently registered, so the DCI was
10 relatively small, 10 studies, 15 studies. It's very easy
11 to monitor and chase EPA on every individual study.
12 Versus this DCI that had like 40 or 45 studies, and
13 discussions were ongoing with different departments over
14 all those studies. So it's very easy to sort of let the
15 waiver stand there if you don't chase a specific waiver.
16 So it changes.

17 JUDGE BIRO: Okay. So it would be easy for EPA
18 to overlook it if somebody is not keeping up on it? Or
19 it would be easy for the company to say I'll just let
20 that go and sit?

21 THE WITNESS: Both, I guess. Both. But again
22 in this instance, for example, there was an example that
23 I saw. And I can find it, if needed, where a status
24 report was sent and that waiver, the EFED's response was
25 already there, but never communicated to the company. So

1 --

2 JUDGE BIRO: So in your experience, are you
3 aware of the very convoluted process that OPP seems to
4 have for communications?

5 THE WITNESS: Yes.

6 JUDGE BIRO: And do you take any action
7 proactively because of that, that system of
8 communications?

9 THE WITNESS: As an industry, we have. Not for
10 leptocheirus, we haven't. But I've been a member of the
11 Croplife registration committee for about 15 to 20 years,
12 not, not that long, but until about 2019 or '18. And we
13 have had visitors from EPA visit us and we have talked
14 about improving their systems, and ensuring better
15 training and ensuring consistency.

16 That's another problem that we have around
17 product and CRM maybe behaving, behaving that way, or
18 interpreting issues one way, the other interpreting
19 issues the other way. And I think it's in, someplace in
20 the testimony, EPA is now testing a new software called
21 Salesforce. And I understand they've had a pilot. And
22 that software is like for sales people so that everyone
23 knows who talked to the client. So this is, I think, a
24 similar software that will hopefully improve that
25 situation.

1 JUDGE BIRO: So the whole industry is basically
2 aware of the -- of the limitations of the current system?

3 THE WITNESS: Yes. But remember the industry
4 is not working against EPA. It works with EPA.

5 JUDGE BIRO: Right.

6 THE WITNESS: It wants efficiency, wants to
7 address the concerns, and wants to get on with doing
8 their business. So we have an interest to see
9 improvements in this area. We will support as much as we
10 can. Publicly, it's hard to support EPA because then, of
11 course, what activists will say -- will have something to
12 say on that. So we're in a different -- we're in a
13 difficult situation in that respect.

14 JUDGE BIRO: Right, okay. I understand. Mr.
15 Gur, would you like some water?

16 THE WITNESS: I have some. Thank you very
17 much.

18 JUDGE BIRO: Mr. Ross?

19 MR. ROSS: One brief follow-up perhaps, a brief
20 series of follow-up questions to your line of
21 questioning.

22 REDIRECT EXAMINATION

23 BY MR. ROSS:

24 Q. Mr. Gur, you testified that it would -- in many
25 instances, registrants do follow-up with the agency if

1 they have not received a response to a waiver or
2 something else for a long period of time. Correct?
3 You've also testified, correct, that you have seen in the
4 record such status reports in which AMVAC was
5 communicating the current status as it understood it to
6 EPA?

7 A. Correct.

8 Q. If a registrant were to receive a document from
9 EPA indicating that a risk assessment would be completed
10 in the near future, what would the next document that
11 registrant would be expecting to see from EPA?

12 A. Today, it's a bit different than it used to be.
13 But I think the next document would be a proposed
14 decision and the risk assessment would be posted. In the
15 past, we could have seen draft risk assessments so that
16 we could at least address typos, or miscalculations, or
17 stuff like that, you know, argue a lot of the science we
18 find. And we have. I have in my experience at least
19 twice found miscalculations.

20 Q. But putting, putting aside the particular
21 characterization of the subsequent document, whether it
22 was a proposed interim decision, or an interim final
23 decision, or an interim registration review decision, or
24 what have you, a registrant receiving that communication
25 -- when the prior communication was that a risk

1 assessment will be performed using conservative
2 assumptions if needed -- in less time than a study could
3 possibly be completed hypothetically -- they would expect
4 to see that risk assessment document next. Correct?

5 A. Correct.

6 MR. ROSS: No further questions.

7 JUDGE BIRO: Did my questions raise any
8 questions for you, Mr. Pittman?

9 MR. PITTMAN: No further questions, Your Honor.

10 JUDGE BIRO: Ms. Rose, do you have any
11 questions you'd like to ask?

12 MS. ROSE: No, Your Honor. Thank you.

13 THE WITNESS: Thank you.

14 (Witness excused.)

15 JUDGE BIRO: Is there another rebuttal witness?
16 Is there another rebuttal witness you'd like to call?

17 MR. ROSS: No, Your Honor.

18 JUDGE BIRO: Is there any other witnesses? Ms.
19 Rose? Anybody wants to call in this proceeding? Are we
20 done? Everybody has had an opportunity? Okay. I want
21 to go over what exhibits have been admitted into the
22 record so that we're all on the same page.

23 I understand the stipulations have been
24 admitted as Court's Exhibit 1.

25 I have Joint Exhibits 1 through 48, and 50

1 through 92. We all in agreement or should we go over,
2 through all of them, then we'll take a break and look
3 over your notes, and get back to me? Should we do that?

4 MR. PITTMAN: I think we can do this on the
5 fly. I was just wondering are you going per category
6 like JX in a row?

7 JUDGE BIRO: I was.

8 MR. PITTMAN: Okay.

9 JUDGE BIRO: Is that okay?

10 MR. PITTMAN: Yes, ma'am.

11 JUDGE BIRO: Okay. Those are the first two
12 categories I did. And then PGX, which I have as Exhibits
13 1 through 8, with Exhibit 7(a) pending your approval.
14 And I understand from Ms. Rose that you have a draft of
15 that. And assuming that it's acceptable and you don't
16 want to cross-examine a live witness, we'll admit that
17 into the record.

18 MR. PITTMAN: If you'd -- if you'd like, Your
19 Honor, I did have a chance to briefly look it over. It
20 is consistent with -- I'm sorry, Ms. Rose, you can't hear
21 me. It is consistent with the initial testimony and we
22 would not have any further objection than the relevance
23 one previously raised overall.

24 JUDGE BIRO: Okay. Does AMVAC have any
25 objection?

1 MR. ROSS: No objection.

2 JUDGE BIRO: Okay. So we'll go ahead and admit
3 7(a). We have a draft copy of that, I believe an
4 unsigned copy, and Ms. Rose if you will submit a signed
5 copy, we'll swap it out for the record.

6 (Petitioner's PGX-7(a) received.)

7 JUDGE BIRO: So then in terms of PGX's
8 exhibits, we have 1 through 7, and 7(a), and 8. Is that
9 --

10 MS. ROSE: Yes, yes.

11 JUDGE BIRO: Okay. For -- let me go with RX,
12 because it's not quite as long. So we have 1 through 14,
13 16 through 18, 20, 21, and 24. And I'm not sure about
14 27. That's Ms. Bloom's statement. Was that admitted
15 into the record? Would you like it admitted into the
16 record?

17 MR. PITTMAN: Your Honor, if it was not
18 previously admitted, we would move that Ms. Bloom's
19 direct testimony be admitted.

20 MR. ROSS: No objection.

21 JUDGE BIRO: Okay. Ms. Rose?

22 MS. ROSE: No objection.

23 JUDGE BIRO: Okay. 27 into the record.

24 (Respondent's RX-27 received.)

25 JUDGE BIRO: So then for RX, we have 1 through

1 14, 16 through 18, 20, 21, 24, and 27. Okay.

2 And then for PAX, Exhibits 1 through 43, 45
3 through 48 -- actually, it's 49, 45 through 49, 51 to 56
4 -- no, 57. Then we have 63 through 77, 84 to 85, and 94
5 through 97 including Exhibit A. Somehow, I feel I'm
6 missing something. I think I'm missing what, 78 to 82?
7 Oh, 93, Exhibits A and B, so it's really 93. Let's go
8 over that again.

9 MR. PITTMAN: Can I consult with opposing
10 counsel?

11 JUDGE BIRO: Yeah, why don't you discuss that.

12 (Pause.)

13 JUDGE BIRO: Okay. So Mr. Pittman, why don't
14 you tell me what exhibits of AMVAC you believe have been
15 admitted.

16 MR. PITTMAN: Your Honor, I believe it's
17 correct. It is 93 to 94. I had not been cross-
18 referencing their witness exhibits. There were documents
19 labeled as PAX-93 and 94 that were not admitted. But I
20 think it's been resolved.

21 JUDGE BIRO: Okay. So what am I missing?

22 MR. ROSS: We're aware there was at least one
23 PAX skipped. I believe it was 50. If we could, we'll
24 take a quick look for some others.

25 JUDGE BIRO: Okay. Why don't we take a

1 5-minute break and maybe we can get an agreement on what
2 the set of exhibits are so we know what we're looking at
3 to write our post-hearing memos. Thank you.

4 (Off the record from 3:44 p.m. to 3:53 p.m.)

5 JUDGE BIRO: Please be seated. Okay, ladies
6 and gentlemen, have we reached an agreement on what the
7 exhibits, the AMVAC's exhibits that were admitted are?

8 MR. ROSS: We just came to an internal
9 agreement and we can see if we have a bilateral or
10 trilateral agreement. Perhaps if I could read back so
11 it's all in one place what we understood you to state was
12 in the record as far as the PAX exhibits. 1 through 43,
13 45 through 57.

14 JUDGE BIRO: Okay.

15 MR. ROSS: Excepting 50.

16 JUDGE BIRO: Okay. Well, then go back to 45
17 through 49.

18 MR. ROSS: 45 through 49.

19 JUDGE BIRO: 51 through 57, okay.

20 MR. ROSS: 77, 84 to 85, and 94, 97. And then
21 would you like me to identify the additional PAX that we
22 believe were moved in?

23 JUDGE BIRO: Okay. Yes.

24 MR. ROSS: According to our notes, PAX-50 was
25 moved in. I'll state the nature of that momentarily.

1 PAX-50 was one of the emails on which Jill Bloom was
2 copied.

3 JUDGE BIRO: Yeah, okay, we have that. So
4 we're all in agreement, 50, okay.

5 MR. ROSS: PAX -- we have in our notes that
6 PAX-78 was moved in. It is a data evaluation record and
7 as such appears in the docket. And so perhaps a decision
8 was made to --

9 JUDGE BIRO: Oh, okay.

10 MR. ROSS: -- look to the docket instead.

11 JUDGE BIRO: Yep, we have it as admitted.

12 MR. ROSS: Likewise Exhibit 87 is another data
13 evaluation record.

14 (Petitioner PAX-87 identified.)

15 JUDGE BIRO: Don't have that. Is there any --

16 MR. PITTMAN: We would stipulate to it.

17 JUDGE BIRO: Okay, 87.

18 (Petitioner's PAX-87 received.)

19 MR. ROSS: PAX-89 is another of the emails on
20 which Ms. Bloom was copied.

21 JUDGE BIRO: Okay. We have that.

22 MR. ROSS: Finally, PAX-93 is the first of the
23 witness statements of AMVAC's witnesses, the statement of
24 Ms. McMahon.

25 MR. PITTMAN: No objection. We were -- our

1 reference was to the prior, prior supplied 93 and 94.

2 JUDGE BIRO: Okay. And is that the whole
3 universe of PAX exhibits?

4 MR. ROSS: Additionally, Your Honor, we also
5 have PAX-91 and 92, which are emails noted as being in.

6 JUDGE BIRO: Okay.

7 MR. ROSS: That is all of the additional
8 exhibits that we identified.

9 JUDGE BIRO: Okay. So PAX Exhibits 1 through
10 43, 45 to 57, 63 through 78, 84, 85, 87, 89, 91, 92, 93,
11 and Exhibits A and B to that document, 94 to 96, and 97
12 with Exhibit A attached. Are we in agreement? Okay. To
13 the extent that any of those documents weren't previously
14 admitted, without objection we're going to admit them in
15 the record. That's correct?

16 MR. PITTMAN: Yes, Your Honor.

17 JUDGE BIRO: Okay. Ms. Rose, is that correct?

18 MS. ROSE: Yes, Your Honor.

19 JUDGE BIRO: Shaking your head yes. Okay. My
20 statement of the Agency's exhibits, were those correct?

21 MR. PITTMAN: Yes, Your Honor.

22 JUDGE BIRO: Okay. Are there any other
23 exhibits that we have somehow overlooked that need to be
24 moved into evidence?

25 MR. ROSS: Just to confirm, 94 included three

1 exhibits as well, attachments to 94.

2 JUDGE BIRO: Okay. Is that correct?

3 MR. PITTMAN: No objection.

4 JUDGE BIRO: No objection, okay, 94 with those
5 three attachments admitted, if it wasn't admitted before.
6 Anything else?

7 MR. ROSS: Yes, Your Honor. You mentioned the
8 one CV stipulations document. Correct?

9 JUDGE BIRO: Right.

10 MR. ROSS: I still suspect there may be at
11 least one, if not two additional docket documents that
12 also contain stipulations. And in addition, there will
13 be the additional document we referenced this morning,
14 which we will submit. To the extent we identified the
15 others, we will send them to the Court's attention and
16 propose the CV.

17 JUDGE BIRO: They can be Court's Exhibits 2, 3,
18 and 4. That would be fine. Okay. Is there any other
19 issues we have to address? Thank you so much for being
20 so cooperative to narrow down the amount of live
21 testimony we had to take in this proceeding. I know it's
22 really time-consuming and expensive. And I'm really
23 grateful for that.

24 And to Ms. Rose particular for being so
25 cooperative about having her witnesses who are on the

1 West Coast and the time limits, you know, accept their
2 testimony writing -- in writing.

3 We will get the transcript, the time to get it,
4 and we will send it out to you to comment on and correct.
5 And when we get that back, we'll then issue a scheduling
6 order for post-decision briefs. And we will try to get
7 our decision out as soon as we can after those briefs are
8 in. It takes us some time. You know, I know that this
9 is supposed to be a really short proceeding. But there's
10 only two judges in my office and many, many cases. So we
11 will try to get it out as soon as we can, which I can't
12 make any promises on.

13 And then, of course, anybody is unhappy can
14 appeal to my brethren at the EAB. I've seen it before.
15 Somebody's likely to see them again. You're all likely
16 to see them again. So, and if there's any post-hearing
17 issues, if you decide to settle, if all the issues get
18 resolved before we issue our decision, please tell me.
19 That's wishful thinking, but it does happen rarely.

20 If there's nothing else, we'll go off the
21 record. Thank you.

22 (Court's Exhibits C-2, C-3 and C-4 identified and
23 received)

24 (Whereupon, at 4:02 p.m., the above-entitled
25 matter was closed.)

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REPORTER'S CERTIFICATE

BEFORE THE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

IN RE: FIFRA SECTION 3(c)(2)(B) NOTICE OF INTENT TO
SUSPEND DIMETHYL TETRACHLOROTEREPHTHALATE (DCPA)
TECHNICAL REGISTRATION

AMVAC CHEMICAL CORPORATION; GROWER-SHIPPER ASSOCIATION OF
CENTRAL CALIFORNIA; SUNHEAVEN FARMS, LLC, ; J&D PRODUCE;
RATTO BROS, INC.; AND HUNTINGTON FARMS,

Petitioners-Appellants.

DOCKET NUMBER: FIFRA-HQ-2022-0002

Date: January 25, 2023

I hereby certify that the proceedings and
evidence herein are contained fully and accurately on the
audio and notes reported by me at the deposition in the
above case and that this is a true and correct transcript
of the case.

Date: February 1, 2023

/s/ Adrian Morris

Certified Court Reporter and Notary Public

My Commission Expires: October 17, 2027

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