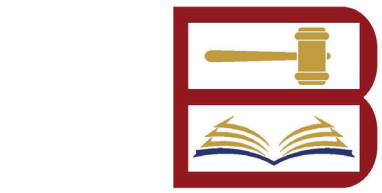
In The Matter Of:

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

Vol. 2

January 25, 2023



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BEFORE THE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C.

IN RE:	:	
FIFRA SECTION 3(c)(2)(B) NOTICE OF INTENT TO SUSPEND DIMETHYL TETRACHLOROTEREPHTHALATE (DCPA) TECHNICAL REGISTRATION	:	DOCKET NUMBER: FIFRA-HQ-2022-0002
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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I N D E X

EXHIBITS

EXHIBIT	DESCRIPTION	IDENT.	RCVD.
COURT'S			
C-1	Joint stipulations	379	379
C-2, C-3 and C-4	Stipulations	455	455
RESPONDENT'S			
R-13 to 16	Agency documents	257	258
R-20	Gur June Statement	395	408
R-21	McMahon June Statement	273	308
R-27	Bloom Statement	(prev ID)	449
PETITIONER AMVAC'S			
PAX-46	Agency documents	257	258
PAX-48	Emails	257	258
PAX-50	Emails	257	258
PAX-52 to 56	Emails	257	258
PAX-85	SETAC Publication	257	258
PAX-87	Data evaluation record	452	452
PAX-93	McMahon January Statement	307	307
PAX-94	Freedlander Statement	311	311
PAX-95	Jonynas January Statement	382	382
PAX-96	Ranganath Statement	386	387
PAX-97 & 97(a)	Gur January Statement & CV	408	408

EXHIBITS

(Continued)

EXHIBIT	DESCRIPTION	IDENT.	RCVD.
PETITIONER GROWERS'			
PGX-1 to 5	Attachments to PGX-6 to 8	377	377
PGX-6 to 8	Statements of Valadez, Fennimore, & Smith	377	377
PGX-7(a)	Updated Fennimore Statement	378	449

P R O C E E D I N G S

(9:02 a.m.)

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

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

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

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

JUDGE BIRO: And who is that?

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

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

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

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

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

JUDGE BIRO: Just give me --

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

JUDGE BIRO: Yeah, just give me the numbers

that we're agreeing to admit.

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

(Petitioner's PAX-46 identified.)

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

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

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

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

(Petitioner's PAX-85 identified.)

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

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

MR. ROSS: Thank you, Your Honor.

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

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

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

(Petitioner's PAX-85 received.)

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

MR. ROSS: Correct.

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

MS. ROSE: Yes, Your Honor.

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

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

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

JUDGE BIRO: Is there any other preliminary matters?

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

JUDGE BIRO: Okay.

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

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

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

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

JUDGE BIRO: Is there any objection to that?

MR. ROSS: No objection, Your Honor.

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

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

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

MS. ROSE: Okay, okay. Thank you.

JUDGE BIRO: Thank you, Ms. Rose.

MS. ROSE: Thank you.

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

MR. PITTMAN: Yes, Your Honor.

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

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

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

MR. ROSS: Ms. Porter's --

JUDGE BIRO: Yes.

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

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

DR. McMAHON: Yes.

(Whereupon,

CATHERINE NIAMH McMAHON,

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

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

DIRECT EXAMINATION

BY MR. ROSS:

Q. Good morning, Dr. McMahon.

A. Good morning.

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

A. Yep, Catherine Niamh McMahon.

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

A. I do.

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

please?

THE WITNESS: Yes, I see it.

BY MR. ROSS:

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

A. I do.

Q. -- in front of you?

A. Yes.

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

A. It is.

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

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

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

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

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

registration review and the NOITS?

A. Yes.

MR. ROSS: I tender the witness.

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

MR. PITTMAN: Yes, Your Honor.

CROSS-EXAMINATION

BY MR. PITTMAN:

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

A. Good morning.

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

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

MS. KOCH: Which exhibit was it?

MR. PITTMAN: JX-37.

BY MR. PITTMAN:

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

A. Yes.

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

A. That's correct. Yes.

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

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

A. Mm-hmm.

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

A. The entire section?

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

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

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

A. Yes. Yes.

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

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

see the EFED response underneath, yep.

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

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

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

A. Say that one more time.

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

A. Yep, that's what is says.

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

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

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

A. Say that one more time.

Q. When AMVAC received this document, would you

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

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

MR. PITTMAN: I'll rephrase.

JUDGE BIRO: Okay, restate it.

BY MR. PITTMAN:

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

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

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

A. Whose opinion did you ask me to --
Q. OPP's.
A. OPP. I would say that's EFED's opinion and they are informing PRD and OPP, yes.
MR. PITTMAN: Okay. Ms. Koch, could you pull up JX-67?
BY MR. PITTMAN:
Q. Dr. McMahon, are you familiar with this document?
A. Yes.
Q. So this document was sent to OPP from AMVAC in 2018. Correct?
A. Say that again.
Q. This document, AMVAC sent this document to OPP in 2018? I believe the date is in February. Can you scroll up a little?
A. In February, yes. It went from AMVAC to OPP.
Q. This document contains AMVAC's responses to a number of waiver denials. Correct?
A. I think it's a mixed document. There's quite a lot of information in there. So it's, it's kind of -- it gathered together again a lot of the information that was outstanding or was uncertain, unclear. So it really does mix a lot of different studies at different stages at that time.

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

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

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

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

MR. PITTMAN: 14.

BY MR. PITTMAN:

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

A. Okay.

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

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

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

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

A. Say that one more time. Sorry.

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

A. Yes.

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

A. That this particular study was what?

Q. Was still required.

A. Required, yes.

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

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

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

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

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

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

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

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

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

BY MR. PITTMAN:

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

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

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

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

BY MR. PITTMAN:

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

A. That's what it says, yes.

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

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

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

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

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

A. Whose position?

Q. EPA.

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

Q. Thank you.

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

BY MR. PITTMAN:

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

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

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

BY MR. PITTMAN:

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

A. That's what it says, yes.

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

A. That's what it says, yes.

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

JUDGE BIRO: Okay.

(Respondent's RX-21 identified.)

BY MR. PITTMAN:

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

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

Q. I believe on the signature page.

A. Yes. This is my testimony from June.

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

A. Correct.

Q. Is it a true and accurate copy?

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

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

A. Closer in time to what?

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

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

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

A. I'm sorry?

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

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

BY MR. PITTMAN:

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

A. Yes.

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

A. Correct, yes.

Q. So --

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

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

A. Say that one more time.

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

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

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

A. From the 2020 document.

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

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

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

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

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

A. That is correct.

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

A. Say that one more time.

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

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

Q. Thank you, understood.

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

BY MR. PITTMAN:

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

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

Q. Would it be fair to say that this document

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

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

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

BY MR. PITTMAN:

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

A. Okay.

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

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

Q. But this document reflects that AMVAC had such

an understanding at the time. Correct?

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

Q. And so --

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

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

A. Where is the other actions?

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

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

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

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

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

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

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

MR. ROSS: Objection. Beyond the scope.

MR. PITTMAN: I'll move on.

JUDGE BIRO: Okay.

BY MR. PITTMAN:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. Thank you.

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

JUDGE BIRO: Mr. Ross?

MR. ROSS: May I proceed?

JUDGE BIRO: Yes, please proceed.

REDIRECT EXAMINATION

BY MR. ROSS:

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

A. Correct.

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

A. Yes.

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

BY MR. ROSS:

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

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

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

A. Correct. Yes.

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

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

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

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

A. Can you scroll down just a little?

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

THE WITNESS: Yes, I see it. Yes.

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

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

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

BY MR. ROSS:

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

A. Yes, yes. Aquatic exposure.

Q. Is there anything in this paragraph that to

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

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

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

A. No, I don't know.

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

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

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

proceed as an interim step towards potentially satisfying that requirement?

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

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

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

Q. Yes, I mean if --

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

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

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

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

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

A. Oh, yes. Yes, yes.

MR. ROSS: No further questions, Your Honor.

JUDGE BIRO: Okay. Any recross?

MR. PITTMAN: No.

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

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

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

Q. JUDGE BIRO: And what other actions?

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

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

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

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

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

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

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

THE WITNESS: Yes, yes.

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

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

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

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

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

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

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

THE WITNESS: To the work plan, the preliminary?

JUDGE BIRO: Yeah, proposed work plan.

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

JUDGE BIRO: AMVAC never responds to those?

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

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

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

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

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

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

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

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

THE WITNESS: Right.

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

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

JUDGE BIRO: Is it sold in all those countries?

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

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

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

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

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

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

THE WITNESS: Often, yes. Yeah.

JUDGE BIRO: Okay. Were you involved in any

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

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

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

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

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

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

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

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

THE WITNESS: It was a question --

JUDGE BIRO: -- that talks about that understanding?

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

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

THE WITNESS: Yes.

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

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

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

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

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

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

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

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

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

THE WITNESS: Yes.

JUDGE BIRO: Daphnid study.

THE WITNESS: Yes.

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

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

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

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

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

THE WITNESS: Okay.

JUDGE BIRO: And maybe somebody could bring that up.

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

there is a table on the ecotox study requirements.

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

THE WITNESS: Yes.

JUDGE BIRO: -- to the DCI.

THE WITNESS: Yes.

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

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

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

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

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

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

JUDGE BIRO: Okay.

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

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

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

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

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

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

JUDGE BIRO: Just give me a round figure.

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

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

THE WITNESS: Yes.

JUDGE BIRO: Metabolism.

THE WITNESS: Yep.

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

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

JUDGE BIRO: Okay. So 3 of them --

THE WITNESS: 120, 150.

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

THE WITNESS: Yes.

JUDGE BIRO: -- all together.

THE WITNESS: All together, yes.

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

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

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

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

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

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

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

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

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

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

JUDGE BIRO: Right. And getting your report.

THE WITNESS: Yes.

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

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

JUDGE BIRO: Bear with me one moment.

THE WITNESS: Sure.

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

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

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

JUDGE BIRO: Right.

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

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

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

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

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

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

THE WITNESS: Correct.

JUDGE BIRO: And you go back and forth.

THE WITNESS: Yes.

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

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

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

THE WITNESS: Yes.

JUDGE BIRO: That's it, right?

THE WITNESS: Yeah. Yes.

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

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

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

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

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

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

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

MR. PITTMAN: No, Your Honor.

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

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

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

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

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

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

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

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

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

JUDGE BIRO: What are we marking her testimony as?

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

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

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

MR. ROSS: A and B.

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

MR. PITTMAN: Yes, Your Honor.

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

MS. ROSE: Yes, no objection.

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

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

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

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

MR. ROSS: No objection.

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

objection.

(Respondent's RX-21 received.)

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

MR. ROSS: Yes, Your Honor.

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

THE WITNESS: Thank you.

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

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

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

MS. ROSE: No, no worries.

(Witness excused.)

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

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

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

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

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

you like to call your next witness?

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

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

(Whereupon,

RICHARD SCOTT FREEDLANDER,

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

DIRECT EXAMINATION

BY MR. ROSS:

Q. Good morning, Dr. Freedlander.

A. Good morning.

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

A. Yes. Richard Scott Freedlander.

Q. What is your current position at AMVAC?

A. I'm the director of environmental science.

Q. How long have you been in that role?

A. Approximately, 11 years.

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

A. Well, I'd certainly been reviewing documents

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

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

BY MR. ROSS:

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

A. I do.

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

A. I have one right here in this binder.

Q. Can you identify this document?

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

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

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

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

A. That's correct.

MR. ROSS: I will tender the witness with a

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

THE WITNESS: A little closer? Is this better?

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

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

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

(Petitioner's PAX-94 identified.)

JUDGE BIRO: Is there any objection?

MR. PITTMAN: No objection.

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

(Petitioner's PAX-94 received.)

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

CROSS-EXAMINATION

BY MR. PITTMAN:

Q. Good morning, Dr. Freedlander.

A. Good morning, sir.

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

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

BY MR. PITTMAN:

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

A. I am.

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

A. I've discussed it, yes.

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

A. Yes.

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

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

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

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

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

BY MR. PITTMAN:

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

A. Yes, that's correct.

Q. Thank you.

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

BY MR. PITTMAN:

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

A. Yes, I am, sir.

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

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

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

BY MR. PITTMAN:

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

A. Yes, sir.

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

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

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

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

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

A. Right.

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

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

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

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

Q. Okay.

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

BY MR. PITTMAN:

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

A. I am, sir.

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

A. Yes.

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

BY MR. PITTMAN:

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

A. That is correct.

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

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

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

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

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

completes the 850.1740 acute tox study. Correct?

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

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

A. Okay.

Q. The 10-day --

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

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

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

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

BY MR. PITTMAN:

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

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

Q. Thank you.

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

BY MR. PITTMAN:

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

A. That's correct.

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

A. Yes, that's correct.

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

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

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

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

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

outcome of the 1740. Correct?

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

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

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

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

A. The acute study, that's correct.

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

BY MR. PITTMAN:

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

A. Yes, I am, sir.

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

BY MR. PITTMAN:

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

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

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

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

A. That's correct.

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

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

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

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

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

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

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

A. Yeah.

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

A. Yes, I am, sir.

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

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

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

considered a validated bit with respect to that particular requirement.

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

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

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

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

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

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

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

MR. ROSS: Objection, vague.

JUDGE BIRO: Vague?

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

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

JUDGE BIRO: Okay.

BY MR. PITTMAN:

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

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

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

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

MR. PITTMAN: No further questions, Your Honor.

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

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

JUDGE BIRO: Okay. Please proceed.

MR. ROSS: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. ROSS:

Q. Dr. Freedlander, has it been your general

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

completion of a risk assessment notwithstanding any outstanding data?

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

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

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

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

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

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

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

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

myself here, today.

MR. ROSS: No further questions, Your Honor.

JUDGE BIRO: Is there any recross?

MR. PITTMAN: Nothing further.

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

THE WITNESS: Certainly, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

allowed them to make such an assessment.

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

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

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

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

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

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

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

to that preliminary work plan --

THE WITNESS: Yes.

JUDGE BIRO: -- they issued.

THE WITNESS: Yep.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE WITNESS: No.

JUDGE BIRO: -- best interest?

THE WITNESS: No, Your Honor.

JUDGE BIRO: Okay.

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

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

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

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

THE WITNESS: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

highly conservative manner.

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

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

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

We were there to assist the agency in

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

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

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

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

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

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

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

requirement, we would do it.

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

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

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

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

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

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

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

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

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

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

THE WITNESS: Well --

JUDGE BIRO: Which might be helpful.

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

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

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

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

THE WITNESS: Not both.

JUDGE BIRO: No.

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

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

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

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

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

THE WITNESS: Sure.

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

THE WITNESS: Is that with regard to a specific study, the leptocheirus, because --

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

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

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

THE WITNESS: The bi --

JUDGE BIRO: Prior to 2016.

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

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

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

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

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

JUDGE BIRO: In 2022?

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

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

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

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

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

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

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

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

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

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

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

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

JUDGE BIRO: Sure, take a few minutes, of

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

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

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

THE WITNESS: Thank you.

(Pause.)

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

JUDGE BIRO: Okay.

CONTINUED REDIRECT EXAMINATION

BY MR. ROSS:

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

A. Yes.

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

A. Yes, that's true.

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

A. Yes, that's true.

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

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

A. Yes, that is true.

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

A. That's correct, sir. Yes.

MR. ROSS: No further questions.

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

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

JUDGE BIRO: Let's see.

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

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

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

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

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

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

JUDGE BIRO: And then we could break for lunch.

MR. ROSS: Yes.

JUDGE BIRO: And then you could cross.

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

JUDGE BIRO: Let's do that.

CONTINUED REDIRECT EXAMINATION

BY MR. ROSS:

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

A. That's correct.

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

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

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

A. It was. It was, yes.

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

A. Besides that study?

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

A. Of TPA, itself, no.

Q. TPA, itself.

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

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

A. Yes. That's correct.

MR. ROSS: No further questions.

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

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

being referred to here?

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

JUDGE BIRO: MRID number.

MR. PITTMAN: Sure, that would be acceptable.

JUDGE BIRO: Okay.

(Pause.)

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

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

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

THE WITNESS: Yes.

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

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

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

THE WITNESS: Yes.

JUDGE BIRO: The study done in England.

THE WITNESS: Yes.

JUDGE BIRO: And is there any other documents?

THE WITNESS: No.

JUDGE BIRO: No.

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

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

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

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

JUDGE BIRO: 1,200 days?

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

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

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

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

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

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

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

THE WITNESS: No.

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

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

JUDGE BIRO: It did at one time.

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

JUDGE BIRO: Okay.

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

JUDGE BIRO: How old were these studies?

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

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

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

JUDGE BIRO: Okay.

THE WITNESS: I hope that helps.

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

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

JUDGE BIRO: Okay, great.

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

CONTINUED REDIRECT EXAMINATION

BY MR. ROSS:

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

A. I do, indeed.

Q. And what document do you recognize this as?

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

Q. And, and do you see the aerobic soil --
A. I do.
Q. -- data requirement on this exhibit.
A. For TPA, I do, yes, sir.
Q. And the aerobic soil metabolism for TPA?
A. Yes.
Q. And in this document, we can all see EPA's response states, does it not, that a study was accepted as supplemental and additional data was not required?
A. That's correct.
Q. And there are two footnotes. Correct?
A. There are.
Q. And if we might scroll to the footnotes, those were -- the footnotes were 2 and 3. Dr. Freedlander, can you see that there is an MRID in footnote 3?
A. Yes. I see an MRID list that is 49307516.
Q. And that would appear also to refer to this data evaluation record issued in connection with this study?
A. Yes.
Q. And the data evaluation record would necessarily have been issued by EPA. Correct?
A. Yes.
Q. Dr. Freedlander, do you recall when this particular study was submitted to EPA?

A. I don't.

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

BY MR. ROSS:

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

A. I do.

Q. What do you recognize it as?

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

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

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

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

A. Yes.

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

THE WITNESS: Yes, sir.

BY MR. ROSS:

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

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

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

BY MR. ROSS:

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

A. Yes, I do.

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

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

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

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

A. Yes. That's correct.

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

A. That's correct.

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

A. That's correct.

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

A. That's correct.

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

A. I'm sorry, did I urge the agency?

Q. Have you advocated that the agency should specifically use the half-lives calculated from this study in their risk assessment for DCPA in the United States?

A. No, I have not. I have not.

MR. ROSS: No further questions, Your Honor.

JUDGE BIRO: Mr. Pittman?

MR. PITTMAN: One moment to discuss?

JUDGE BIRO: Oh, of course.

(Pause.)

JUDGE BIRO: Oh, sorry, Mr. Pittman.

MR. PITTMAN: It's okay. No further questions, at this time.

JUDGE BIRO: Okay. Do we want to reserve the right to -- oh, wait. Ms. Rose, do you have any questions?

MS. ROSE: I do not. Thank you, Your Honor.

JUDGE BIRO: Thank you. Do we want to reserve the right to -- and by we, I mean you, reserve the right to recall Dr. Freedlander?

MR. ROSS: In connection with potential rebuttal testimony, yes, Your Honor.

JUDGE BIRO: Okay. So, Dr. Freedlander, please don't discuss any of your testimony with anyone until the

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

THE WITNESS: Yes, Your Honor.

JUDGE BIRO: Thank you. You can step down.

THE WITNESS: Thank you.

(Witness excused.)

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

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

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

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

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

MR. ROSS: Not from AMVAC, Your Honor.

JUDGE BIRO: No, okay, great.

MR. ROSS: We have counsel for Growers.

JUDGE BIRO: Yes. Ms. Rose?

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

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

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

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

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

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

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

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

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

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

JUDGE BIRO: 6, 7, and 8.

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

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

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

JUDGE BIRO: Okay.

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

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

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

JUDGE BIRO: Of relevance.

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

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

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

MS. ROSE: That's acceptable.

JUDGE BIRO: Ms. Rose, is that okay?

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

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

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

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

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

(Court's C-1 identified.)

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

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

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

JUDGE BIRO: Okay.

MR. ROSS: But I have no objection to marking

the joint stipulations as --

MR. PITTMAN: No objection.

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

MS. ROSE: No, Your Honor.

(Court's C-1 received.)

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

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

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

(Whereupon,

ANN JONYNAS,

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

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

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

JUDGE BIRO: Okay, perfect. Please proceed.

DIRECT EXAMINATION

BY MR. ROSS:

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

A. Just about morning, yes.
Q. Could you please state your full name for the record, please?
A. My full name is Ann Jonynas. Can you hear me well enough?
Q. Yes, we can. We can hear you well, thank you.
MR. ROSS: Mr. Sayres, could you bring up the -- Ms. Jonynas' statement.
JUDGE BIRO: I'm just correcting the spelling on the name.
BY MR. ROSS:
Q. Dr. Jonynas, are you able to see the document that is now on the screen?
A. Yes, I can.
Q. Do you recognize this document?
A. Yes, I do.
Q. And what do you recognize this document as?
A. My witness statement.
MR. ROSS: We move to admit the January 9th statement of Dr. Jonynas into the record of the proceeding.
JUDGE BIRO: Isn't the majority of this not really relevant anymore? This all goes to the CTA.
MR. ROSS: We -- our proffer as to the relevance of Dr. Jonynas' testimony is that the conduct

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

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

JUDGE BIRO: Hasn't the study been completed?

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

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

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

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

(Petitioner's PAX-95 identified.)

JUDGE BIRO: Do you have any objection?

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

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

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

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

(Petitioner's PAX-95 received.)

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

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

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

MR. ROSS: No, Your Honor.

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

THE WITNESS: Thank you.

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

MR. ROSS: We do not, Your Honor.

JUDGE BIRO: Okay. Thank you, doctor. You're released.

THE WITNESS: Thank you.

(Witness excused.)

JUDGE BIRO: Okay. Would you like to call your next witness?

MR. ROSS: Yes, Your Honor. AMVAC calls Suneet Ranganath. While Mr. Ranganath is connecting, I will note that Mr. Ranganath's written testimony as it has been submitted contains a portion that has been designated as confidential business information. Only if cross-exam is expected to get into the specifics of that information would we have any need to restrict access to the courtroom. If not then there will be no need to restrict access.

MR. PITTMAN: Your Honor, we do not intend to cross-exam Mr. Ranganath.

JUDGE BIRO: Okay. Maybe you could always just

refer it to as the number identified in his statement and not use the specific number, you know, if that becomes necessary. Dr. Ranganath, can you hear me?

DR. RANGANATH: Yes, I can. I can hear you.

JUDGE BIRO: Can you raise your right hand so the court reporter can swear you in?

(Whereupon,

SUNEET RANGANATH,

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

JUDGE BIRO: Is anyone else present with you where you are testifying from?

THE WITNESS: No, they're not.

JUDGE BIRO: Please proceed.

DIRECT EXAMINATION

BY MR. ROSS:

Q. Good afternoon, Mr. Ranganath.

A. Hi, good afternoon.

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

A. Suneet Ranganath.

Q. What is your position with AMVAC?

A. I'm vice president of global supply chain and operations.

MR. ROSS: Mr. Sayres, could you please bring

up the first page of Mr. Ranganath's witness statement.

BY MR. ROSS:

Q. Mr. Ranganath, do you recognize this document?

A. Yes.

Q. Do you understand it to be a true and accurate copy of your verified witness statement?

A. Yes, I do.

Q. I have only one, one further question for you. Mr. Ranganath, since you prepared this statement, have there been any, any changes to any of the numbers that you reported at any point in this statement?

A. No, not as of -- not as of the 9th, no.

MR. ROSS: No further questions, Your Honor.

JUDGE BIRO: Okay. Is there any cross-examination?

MR. PITTMAN: Your Honor, we would object to the admission of Dr. Ranganath's statement on grounds of relevance concerns. We don't believe that it's within the narrow statutory scope of this hearing. But otherwise no cross-examination.

JUDGE BIRO: Why isn't what they make available to the public and sell relevant? How much of it?

MR. PITTMAN: Your Honor, we believe that under FIFRA Section 3(c)(2)(B) and EPA's existing stocks policy specifically concerning suspensions under that section

that questions of market disruption or availability are not relevant to the context of whether or not a product should be suspended. EPA is not contesting the -- that market effects may occur, but simply that they are not relevant to the scope of this hearing.

MR. ROSS: Your Honor, if I may?

JUDGE BIRO: Okay.

MR. ROSS: The statute specifically creates a right for entities other than the registrant to request a hearing and specifically provides that the -- whether or not the existing stocks policy is consistent with FIFRA, is part of the statutory scope of the hearing. We think that evidence is a clear -- not only clearly from the text of FIFRA, but from the fact that they chose to allow entities other than the registrant to request a hearing, a clear intent to bring questions of market disruption within the scope of this hearing.

JUDGE BIRO: Well, we let the Growers' statements in and that all has to do with it. And whether it comes within the statute or not is a legal decision I'll have to address in my decision. So I'll admit it. What -- are we up to PAX-96?

MR. ROSS: 96, Your Honor.

(Petitioner's PAX-96 identified.)

JUDGE BIRO: Okay. We'll admit Mr. Ranganath's

statement as PAX-96 over the agency's objection.

(Petitioner's PAX-96 received.)

JUDGE BIRO: Okay. Is there cross-examination you want to make?

MR. PITTMAN: No, Your Honor.

JUDGE BIRO: Ms. Rose, do you have any questions you'd like to ask?

MS. ROSE: I do not, Your Honor.

JUDGE BIRO: Okay. I have a few questions I'd like to ask. Mr. Ranganath, can you tell me where dacthal is sold?

THE WITNESS: I manage the supply chain, so I don't have full knowledge of where all it is sold.

MR. ROSS: Apologies, Your Honor, if I might? I'm not certain that the witness heard the initial explanation concerning whether or not the courtroom is closed. And so I'd simply advise the witness that if he wishes to testify to something that he considers to be confidential business information, to please advise the Court before doing so.

JUDGE BIRO: Yeah. So I'm -- I don't want confidential business information, but I don't think where you sell your product is confidential business information. So do you sell it beyond the United States?

THE WITNESS: Yes. So, again, we, we do, but I

don't have particular knowledge of where we do, as I'm managing the supply chain inbound and production. That would be with our commercial team.

JUDGE BIRO: So do you know how many pounds or units, I don't know how you measure it, of dacthal is sold every year?

THE WITNESS: I have a general idea, yes.

JUDGE BIRO: Do you consider that confidential business information?

THE WITNESS: It had been marked that way, yes.

JUDGE BIRO: Can you give me a range then?

THE WITNESS: I would -- it is north of 100,000 gallons of end-use product.

JUDGE BIRO: Of end-use product in total every year?

THE WITNESS: Annually, yes.

JUDGE BIRO: And is it a product in which your company makes a profit?

THE WITNESS: Yes.

JUDGE BIRO: Have you increased the amount of product you are producing, end-use product you are producing over the past year?

THE WITNESS: No.

JUDGE BIRO: Okay. I don't have any further questions.

(Pause.)

JUDGE BIRO: I know you might not be able to see it, but maybe you can, Mr. Ross is just having a little sidebar.

THE WITNESS: I cannot see it.

JUDGE BIRO: Okay. I'm sorry. I don't want you to think we're ignoring you.

THE WITNESS: Yes, thank you.

MR. ROSS: We have no further questions, Your Honor.

JUDGE BIRO: Mr. Pittman?

MR. PITTMAN: None for me.

JUDGE BIRO: Ms. Rose?

MS. ROSE: No questions, Your Honor.

JUDGE BIRO: Thank you very much for your attendance at our hearing. Is there any reason to retain the right to recall?

MR. ROSS: There is not.

JUDGE BIRO: No? Okay. Thank you, you're released. I really appreciate you accommodating us.

THE WITNESS: Thank you.

(Witness excused.)

MR. ROSS: AMVAC would next call Ephraim Gur to the stand.

JUDGE BIRO: Good afternoon, Dr. Gur.

DR. GUR: Good afternoon.

JUDGE BIRO: Could you please take the stand, remain standing, raise your right hand?

(Whereupon,

EPHRAIM GUR,

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

DIRECT EXAMINATION

BY MR. ROSS:

Q. Good afternoon, Mr. Gur.

A. Good afternoon.

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

A. Ephraim Gur.

Q. Could you please briefly summarize your career as it relates to pesticide regulation, the pesticide industry?

A. Yes, I'll do that. I began my career almost 40 years ago as a toxicologist in a contract lab doing GLP studies for this industry and the pharmaceutical industry. Worked my way from the role of a study director to the head of general tox in that lab. Eight years later, which about 31 years ago, I moved into our industry and basically since then I've been managing global regulatory departments around the world.

In the last about 8 years, I've been a consultant and also an employee of Gowan Company, consulting companies on EPA and regulatory requirements, and all sort of activities. And within Gowan Company, I am the chief scientist, which is the head of the global regulatory team, as well as other managerial functions.

MR. ROSS: Mr. Sayres, could you bring up Mr. Gur's statement, please?

BY MR. ROSS:

Q. Mr. Gur, do you recognize this document?

A. Yes.

Q. And what do you recognize it as?

A. This is my expert witness affidavit.

MR. ROSS: Your Honor, because -- the parties have agreed as concerning a stipulation as to Mr. Gur's expertise. Only because it has not been formally submitted, yet, I would ask if you would like me to read the stipulation into the record prior to formally submitting it.

JUDGE BIRO: Okay.

MR. ROSS: The parties stipulate that based on his training and experience as set forth in his written -- verified written statement, AMVAC offers Mr. Gur's testimony as an expert witness in the areas of pesticide registration, re-registration, and registration review

under FIFRA, including but not limited to the following:

First, responding to data call-ins.

Second, data development including but not limited to involvement in analysis of data requirements, study design, protocol development, data generation, and interpretation of study results.

And, three, interfacing with EPA and other regulatory agencies regarding all of the above.

With that, I will tender the witness.

JUDGE BIRO: Have, have you agreed to that expertise?

MR. PITTMAN: Yes, Your Honor.

JUDGE BIRO: Okay.

MR. PITTMAN: That's what we've agreed to.

JUDGE BIRO: And Ms. Rose, are you in agreement to stipulating to Mr. Gur as an expert in designated fields that the stipulation covers?

MS. ROSE: Yes, I am.

JUDGE BIRO: Okay. So designated. Please proceed.

CROSS-EXAMINATION

BY MR. PITTMAN:

Q. Good afternoon, Mr. Gur. My name is Forrest Pittman. I believe you've been here and seen that I've been counsel for OPP today. I just have a handful of

questions for you.

MR. PITTMAN: Mrs. Koch, could we please pull up page 14 of Mr. Gur's statement, the January statement. Can you scroll down to paragraph 49?

BY MR. PITTMAN:

Q. Mr. Gur, could I ask that you read the first sentence of paragraph 49 into the record?

A. Yes.

Q. Can you read it into the record?

A. Oh, read it out loud?

Q. Yes, please.

A. Sorry. I thought you were meaning --

Q. That's fine, thank you.

A. You want me to read it out loud.

Q. If you would. Can you read "Often when EFED or HED . . ."?

A. All the paragraph. Often when EFED or HED recommends denying a waiver, the reviewer will indicate the basis for the recommendation. The explanation may identify an issue that could be answered with additional information. The registrant may be able to provide the additional information so that the scientific issue is resolved and the waiver could then be approved. Thus, it is common for registrant to make further submissions after it receives EFED and HED's initial response from

additional exchanges between the registrant and agency personnel to continue thereafter, both verbally and in writing.

Q. So I, I think that that's a -- I really wanted the reading of the first sentence.

MR. PITTMAN: If you could scroll back up just a little bit, Ms. Koch?

BY MR. PITTMAN:

Q. So in this document, the first sentence that you just read in, you're discussing EFED and HED reviews of AMVAC's waiver request or actually I think of registrant waiver request --

A. Yeah.

Q. -- more generally.

A. Correct.

Q. So is it your position that these documents that are signed last by EFED or HED, they represent only recommendations?

A. Correct.

Q. And so when these are transmitted to AMVAC or to another registrant but there is not a separate transmittal memo attached to it that these documents only represent recommendations still to that point?

A. I would think so, based on my experience, yes.

MR. PITTMAN: Ms. Koch, can you please pull up

what's been marked as RX-20? May I approach the witness, Your Honor?

(Respondent's RX-20 identified.)

BY MR. PITTMAN:

Q. Mr. Gur, do you recognize this document? Take a moment to review it, of course.

A. Yes.

Q. What is this document?

A. That is the previous version of my testimony, I think.

Q. So is this a true and accurate copy of --

A. I can't proofread every word, but I would expect it is, yes.

Q. So if you'd like to -- if you'd like to read it, we have all the time, I believe, today.

A. Well, I'll need to see the original one if I want to proofread every word. But --

MR. PITTMAN: I would ask perhaps this is -- this document is not -- this is not the first time this document has been presented. Would AMVAC stipulate at least to authenticity of this document?

MR. ROSS: To address Mr. Gur's concern of whether this is, in fact, a particular version of his verified statement?

MR. PITTMAN: The June 17 version.

MR. ROSS: We could provide him with an electronic copy of what we would be -- his legal team would represent to him was an accurate copy of it.

JUDGE BIRO: Why don't you look at this document and compare it to your copy and see if it's consistent.

MR. ROSS: We can also do that.

MR. PITTMAN: Would you like a written --

MR. ROSS: We are not aware that OPP would have the ability to access any version of this document other than --

JUDGE BIRO: To change it.

MR. ROSS: -- the prior version.

JUDGE BIRO: Okay. So let's just stipulate. Can we agree to stipulate that this is an accurate copy of his prior -- draft of his prior statement?

MR. PITTMAN: And with one objection. I'd -- OPP would not characterize this as a draft. This is a signed version delivered in the pre-hearing exchange on June 17th of last year. OPP does not, as Mr. Ross pointed out, have access to any pre-signature drafts, or something like that.

JUDGE BIRO: You have a signed copy? He said this is not signed.

MR. PITTMAN: This bears signatures of both --

this document bears signatures from both Mr. Gur and Mr. Ross.

JUDGE BIRO: Okay. So can we stipulate that this is an accurate copy of the statement that was delivered with his pre-hearing exchange, with AMVAC's pre-hearing exchange?

MR. ROSS: yes, as far as I'm concerned. I didn't want to speak for my -- for my witness.

JUDGE BIRO: Okay. So stipulated. Go ahead.

MR. PITTMAN: Mrs. Koch, could we turn to the bottom of page 10, on page 11.

BY MR. PITTMAN:

Q. So Mr. Gur, can you read the first, just the first sentence that runs from the beginning of paragraph 42 and to the first word of the following page?

A. Often when a waiver is denied by EPA, the reviewer denying the waiver will indicate the basis for the denial, which might be an issue that could be answered with additional information.

Q. So if you would also note into the record, but just take a second and read the remainder of paragraph 42 and perhaps for your own purposes compare it to paragraph 49 of your, your January written statement.

A. So the registrant may be able to provide the additional information so that the scientific issue is

resolved and the waiver could be approved. AMVAC's waivers -- waiver request for DCPA are typical of this approach. The approach is scientifically valid and efficient as it saves EPA resources in reviewing complex studies that may be found redundant or unnecessary.

Q. So this paragraph 42 of your June statement is substantially similar in most respects to paragraph 49 of your January statement?

A. Yes.

Q. The one change that really stands out here is that in your January statement, you changed the wording of this first sentence. Correct?

A. Correct.

Q. So whereas in June you referred to EPA denying the waiver, you are now characterizing that as EFED simply recommending a waiver or, sorry, recommending denial of a waiver?

A. Correct.

Q. So is it -- is it accurate to state that your June statement suggests you are discussing EPA denials, right, as in a, a final statement that a waiver is denied.

A. Yes.

Q. So, Mr. Gur, what about the facts of this case changed between June and January?

A. I don't think the facts have changed. But in the first version which we did pretty hurried, because when I got called in June, we needed to -- needed to opine on a very broad set of issues. We created this document based on what I could see and regard then.

When the matter focused on nine, only nine studies, I had the ability to hone into those issues and read all the documents in much more care, and see that in fact all I could see where the EPA memos -- sorry, the EFED's memos to PRD, which basically do say that EFED recommends. And that's what initiated the change.

Q. So you say you reviewed them. Was it your idea to make this language change from, from denied to recommended denial?

A. In most cases, yes. It has been my idea to make changes, yes.

Q. So you're just saying sometime in the last 6 months you have changed your interpretation of the documents submitted by EPA during the pendency of this DCI?

A. I was asked to focus on only nine studies and, therefore, I could read much more carefully all the documents.

Q. Okay.

MR. PITTMAN: Mrs. Koch, if we could turn back

to the -- oh, sorry, the January statement. So if we could scroll up to paragraph 41.

BY MR. PITTMAN:

Q. Mr. Gur, if you could take a look at this. Are you familiar with that statement, paragraph 41?

A. Yes, I read that.

Q. So here you're stating that some data requirements are driven by risk assessments. So by that I assume you mean prior risk assessments, like for example those conducted during EPA's let's say re-registration, processes that predated registration review?

A. Yes.

Q. Okay. So your position is not that OPP would say normally conduct a risk assessment during registration review before determining if data is actually required?

A. Normally, they wouldn't. But they could call you and say we need more data, yes.

Q. But they normally would not do that. This order of processes is DCI issued, data submitted, risk assessment is performed. Correct?

A. Correct. And then possible refined, which is when the additional data might be required.

MR. PITTMAN: Mrs. Koch, if you could turn to

paragraph 64, pages 18 to 19, I believe.

BY MR. PITTMAN:

Q. Mr. Gur, if you could just read that paragraph 64?

A. Yes, I read it.

Q. So in this statement you say that EPA for the first time in I believe 2022, if I understand JX-69, but in 2022, EPA for the first time presented modeling to AMVAC indicating that assumption of stability would lead to a gradual increase in environmental concentrations.

A. Yes.

Q. So wouldn't it follow from these statements that AMVAC has been pointing to throughout the course of this hearing that an assumption of stability is naturally going to lead to an increase in environmental concentration. Correct?

A. I'm sorry. I can't -- I didn't hear that.

Q. So isn't it natural to assume that if EPA assumes stability, the environmental concentration is going to essentially increase.

A. Could be, yes.

Q. So if --

MR. ROSS: I'm going to object. This is a line of questioning primarily ecological in nature. Mr. Gur is a witness primarily as to the registration process.

JUDGE BIRO: Overruled. Go ahead.

BY MR. PITTMAN:

Q. So I, I think I'm not following here. So if OPP were to assume stability, that means that the -- whatever chemical it's talking about is not breaking down. Correct?

A. Is not?

Q. It's not breaking down, being metabolized, degrading, whatever terminology you'd prefer.

A. Yes.

Q. So if it's not degrading then it is essentially going to build up in the environment without some mechanism of removal.

A. It could potentially, yes. But what I'm trying to say here is when you assume a product is stable, that number -- it creates a number that gets fed into the risk assessment. I think Dr. Freedlander spoke about that a lot. And that's when you know if you have a problem or not.

Q. But all I'm trying to get at here is in your statement, paragraph 64, this reads to me, and characterize it how you would, but this reads to me as AMVAC saying that it was blindsided by EPA stating that it's going to assume very large environmental concentrations.

A. I'm not sure. I think it's a different concern that EPA raised. That's what I'm trying to say in this paragraph. Assuming it's stable is the input parameter that goes into the modeling for either ecological risk assessments or human health groundwater, which the assessment -- it's the number that plugs into the model. Assuming it concentrates is, is there a food chain bioconcentration issue, which is two different problems.

And that's what I was trying to say. They raise a whole new issue here in this -- in this assumption that it's accumulating in the environment and you would address them differently, just as Dr. Freedlander said. If you just assume stability and you assume the number plugged into the risk assessment would still indicate safe use, you don't have to worry about it. If it doesn't, you have to mitigate it.

If you assume bioconcentration in environment, then you start answering the issue. It's totally different. It's a whole different question. And that's what I think I was referring to in this paragraph.

Q. So Mr. Gur, you're saying that OPP provided some data that -- not that concentrations would increase in the environment just from repeated applications of DCPA and its not breaking down, but you believe this OPP document was discussing a trophic accumulation? You

mentioned the food chain.

A. Could be. It could be. But sometimes we guess. That's part of our problem with this issue. That's why we need the dialogue. Because we're making assumptions on the -- on the, you know, two words or two sentences, and we ask and we clarify what your concern is so we can address it correctly. So again, assuming it's stable has to me a whole different impact than it's accumulates, because I don't think their models I think day-to-day take into account accumulation over years except through their models, not through actual testing.

Q. So I think I'm still just not really --

A. Okay. The --

Q. I'm not understanding the connection that you are making here. So EPA's conservative assumptions as discussed throughout the rest of your statement here, it's not conservative assumptions about food chain accumulation. It's my understanding that has not been an issue discussed during this hearing. Correct?

A. I'm very -- I'm finding it very hard to hear you, I'm sorry.

Q. I'm sorry.

A. If you can speak to the speaker, that would be very helpful.

Q. It seemed like Mr. Freedlander had an easier

time hearing me. I will take my mask off, if this makes it easier for you.

A. Yes, it does.

Q. It has not been my understanding as I sit in this courtroom that when the parties are discussing conservative assumptions about the stability of TPA, that that is a discussion of like trophic accumulation --

A. Correct.

Q. -- through the food chain.

A. Correct. We're saying the same thing, yes.

Q. So I, I am -- again, I'm not getting the connection here.

A. Okay, okay. Let me -- let me try to explain. Stability is one thing. Gradual accumulation is another thing. Stability, when I see stability and the EPA is saying we'll take a conservative assumption, it means they have a level that they won't show any let's say hydrolysis or any break down. And they will use that level.

Accumulation is a whole new ball game. It says we -- that's how I read this sentence. Again, I might be making wrong assumptions. But what they're saying is gradual increase in accumulations, that leads to a whole different discussion of would it really increase or not, and how much.

And it's, it's got nothing to do or very different issues to do than the stability. And that's what I was meaning in this thing. It opens a whole new question. That's addressed in a whole different way, by the way.

Q. So you understand EPA's communication in JX-69 and perhaps we should switch to that in a moment, but you understood that document as, as discussing increase in concentration in some context other than just DCPA into --

A. Yes.

Q. -- an environmental area --

A. Yeah, one thing --

Q. -- because of no degradation TPA will eventually build up in that?

A. Yeah. That's what I -- that's what I read when I see gradual increase in environmental concentrations. I immediately see a totally different concern.

MR. PITTMAN: Your Honor, if I could have one moment with my co-counsel?

(Pause.)

BY MR. PITTMAN:

Q. Mr. Gur, I just want to clarify one thing. One last question here. So your belief is that EPA for the first time raised an issue about environmental

accumulation that did not involve just a simple input versus degradation calculation for TPA?

A. Yes. Yeah, I thought they are introducing a new question, yes.

MR. PITTMAN: No further questions, Your Honor.

JUDGE BIRO: Ms. Rose, do you have any questions you'd like to ask?

MS. ROSE: No, Your Honor.

JUDGE BIRO: Sorry, Ms. Rose. Okay.

MR. ROSS: One moment, Your Honor.

JUDGE BIRO: Okay.

(Pause.)

MR. PITTMAN: Your Honor, just in the course of this I forgot to request that JX-21 be admitted to the record -- JX-20, I'm sorry, RX-20. I got it right that time. It's RX-20.

JUDGE BIRO: Okay. First, is there any objection to RX-20 being admitted into the record?

MR. ROSS: There is not, Your Honor.

JUDGE BIRO: Okay. So RX-20 is admitted into the record. Ms. Rose, I spoke too soon. Do you have any objection to RX-20?

MS. ROSE: I do not. Thank you, Your Honor.

JUDGE BIRO: Confirmed and entered into the record. Go ahead.

(Respondent's RX-20 received.)

MR. ROSS: No redirect, Your Honor. However, I believe I failed to actually admit his current statement into the record, which I would like to do so as Petitioner AMVAC's Exhibit 97 and also include a separate document which is Exhibit A to his statement, which is his CV.

(Petitioner's PAX-97 and 97(a) identified.)

JUDGE BIRO: Is there any objection?

MR. PITTMAN: No objection.

JUDGE BIRO: Okay. So PAX-97 -- Ms. Rose, any objection?

MS. ROSE: No objection.

JUDGE BIRO: PAX-97 with Exhibit A, the CV of Mr. Gur, admitted into the record.

(Petitioner's PAX-97 and 97(a) received.)

JUDGE BIRO: Mr. Gur, can I ask you just a couple of questions.

THE WITNESS: Yes, Your Honor.

JUDGE BIRO: I thought I read in your statement that up until 2016, EPA was meeting with registrants undergoing DCI's I think once or twice a year to touch base.

THE WITNESS: Yes. It's been my experience and I've learned that from colleagues and peers in the

industry that you -- it makes a lot of sense to meet EPA as an individual registrant, in my experience twice a year. Other companies probably did it more or less. And not just the data call-ins, but also other divisions, the other division, and go over all the ongoing projects that you have together to make sure that you're aligned and that everyone is updated, everyone understands the other's priorities, what to -- what to focus on.

And I practiced it for many years and it was very useful in various roles. And sometime in 2016, I was told "our workload has gone crazy and we just can't do it, and for many reasons." We, we tried to change the format. I insisted that we do it, in my personal roles, so it ended up being maybe meetings only with the head of divisions or maybe just calls. And I think now after the pandemic we are starting to try to do it again and so forth.

Now I'm aware that not every company does that. But, yes, it's something that we found very useful and very helpful, yes.

JUDGE BIRO: So that was something your company initiated with EPA?

THE WITNESS: Yes.

JUDGE BIRO: Do you know whether that's something AMVAC --

THE WITNESS: I'm not aware of that, ma'am.

JUDGE BIRO: You don't know, okay. And when you couldn't do it after 2016, did you maintain status checks with the agency through emails, or phone calls, or letters?

THE WITNESS: We tried to have these catch-up meetings or alignment meetings either via phone calls or just sort of almost one-on-one basis with the -- with the heads of divisions. And they would, when they see -- obviously, you don't come in and just start talking. You give them an agenda in advance. And they could invite branch chiefs or CRMs to those meetings, and go over all those topics. So I'm -- I was able to maintain that at least until the pandemic and other changes in their workload occurred, yes.

JUDGE BIRO: When you're working with EPA, you indicated it's an iterative process where you go back and forth. Who has the last word on whether a study is going to be done or not?

THE WITNESS: Obviously, EPA.

JUDGE BIRO: And when a company decides to -- strike that. If EPA says, look, if you don’t do these studies, we'll be left to do conservative assumptions. Is it your practice to reach out and, and tell EPA, okay, we're not going to do them, do your conservative

assumptions?

THE WITNESS: Not necessarily. It might come up in one of those meetings, but not necessarily because for me the conservative assumption is the default. So if they say we're going to assume it's stable, just like I just addressed with the counsel, for me, again, I visualize this risk assessment as the number is going to be this number is going to be plugged in. It's a default. And I just don't have to comment on it anymore from my perspective.

JUDGE BIRO: Do you just tell them I'm not going to do the studies or you say nothing?

THE WITNESS: In writing, I usually wouldn't say anything. I would address all the other concerns. For me, this concern I can address it by doing the study or not, by having the default factor. That's the practice.

JUDGE BIRO: So how does EPA know to move forward and use the conservative assumption?

THE WITNESS: I think they just do it. I don't think they ask me for permission or anything. They just do it.

JUDGE BIRO: After a certain period of time or I mean like --

THE WITNESS: When they do the risk assessment.

That's their -- their deadline is the risk assessment. And we've seen it in -- we've been talking about one specific set of studies which are, you know, stability. But we've seen that in, for example, the registration review asked for -- this is -- this is a pretty common one by the way. It asks for additional soils in existing, because they changed their requirements from two soils to four soils, for example, one soil to four soils. And they would say if you don't submit them, we will just add a factor of three to the DT50 soil.

So if you have a short-lived active ingredient that a factor of three doesn't impact the risk assessment in any significant way, you basically just keep that requirement. Or if you are in a meeting, you say I'm not going to do the study. But if you don't, you just skip that requirement and suffer the - suffer consequences, you know, the default of extra three factor on the DT50.

JUDGE BIRO: So again I'm sort of wondering when the agency would know like you've completed all the things that you're going to do and they can move forward. I mean what, what is the deadline that's used?

THE WITNESS: We don't know that. They have an internal deadline for the risk assessment that they have to issue.

JUDGE BIRO: I was a little confused about your

discussion about stability and accumulation. When something is stable, doesn't -- that means it, it doesn't degrade. It just remains. Is that correct?

THE WITNESS: That's, yeah, that's a simple --

JUDGE BIRO: Doesn't it always build up over time, accumulate over time?

THE WITNESS: No, not at all. And that's I think Dr. Freedlander --

JUDGE BIRO: Explain that to me. That's where I lose -- I lose it.

THE WITNESS: So Dr. Freedlander talked about acclimatization of soil and that microbes may build up, that suddenly know how to degrade that product. That happens in nature. But maybe a more simple way for me to address and also addresses how I responded to the counsel there is in Europe it is pretty common when they see a long DT50, it is pretty common to ask for a soil bioaccumulation study. And I've, I've seen a few of them in my lifetime.

You do a study and see what we call the chainsaw effect. You see accumulation, and then it drops, and a little bit accumulation, and then it drops, because again it's seasonal and it depends on microbial activity in that soil. And Europe would basically plot some sort of an either maximum level over let's say a

period of 3 to 5 years. So yes, it is stable, but it doesn't accumulate, because at some stage it might degrade.

I don't think I've seen products that are forever accumulating, but I'm not an expert in soil sciences. I can't speak to that.

JUDGE BIRO: So what causes -- so what -- in these studies, you're looking for what breaks it down over time? It must degrade, right?

THE WITNESS: Yeah. Well, first of all, we're looking at the active ingredient to see that it's there and at what level. And that's the -- that's the ultimate endpoint. We don't try to identify which microbes degraded it. But if there are degradation products, we do try to identify them so that we know what's, what's being created. And in many cases they just -- when they degrade, they degrade all the way to H2O and CO2. So, but that's not always the case.

But, yeah, we just look at that maximum value or plot a curve so that they can statistically define what they would use in their risk assessment. And based on the accumulation, mitigation measures may occur.

JUDGE BIRO: So when you talk about degradation, are you talking about in soil or in water?

THE WITNESS: Both.

JUDGE BIRO: Both. So we had some discussion earlier where they talked about studies that did tests using acclimated and non-acclimated soil. So maybe you could define those terms for me. What, what is acclimated soil?

THE WITNESS: Acclimated soil means there are microbes there that might identify your chemical. That's, that's all the difference that Dr. Freedlander was trying to talk about. We don't --

JUDGE BIRO: Is that -- would that be similar to soil you might find out in the natural environment?

THE WITNESS: Yes. If they've been exposed, if that soil has been exposed to similar chemistry, not necessarily identical but similar enough and it can identify some structures in that molecule, it can -- it can attack it and degrade it. If you have sterilized soil, which is the extreme because there's no microbial activity, you don't have in it any microbial degradation.

Now not all degradation is microbial. Some of it is chemical. Could be just light, or water, or air that degrades it. But usually microbial is the -- is the biggest contributor. But again I am not a soil scientist. I can't speak as a soil scientist.

JUDGE BIRO: So if you do a test -- is non-acclimated soil sterilized soil?

THE WITNESS: I'm not sure of the specific requirement in the guideline, whether it's sterilized or just has to prove that it has low microbial activity. I'm not sure about that.

JUDGE BIRO: So when you talk about degradation, you're talking about a test that would be performed on acclimated soil?

THE WITNESS: EPA requires that it's not acclimated. Europe doesn't have that clause so you may -- you may -- you don't intentionally acclimate it. You may have soil that you collected somewhere that has been exposed to similar chemical, similar chemistry.

JUDGE BIRO: In your CV -- in your statement, you said that the time lines that EPA normally provides in their DCA often underestimates how long it takes.

THE WITNESS: Yes.

JUDGE BIRO: And it's -- we had some discussions about the time periods for doing these studies. Why do you think they underestimate? Is that just your personal experience to get them done or --

THE WITNESS: First of all -- sorry. First of all, yes, it is my personal experience that it takes in many cases much longer than it takes to get a study done. And in some cases, especially, and I think that's what I say in my testimony, special studies, it's probably

never. You never meet those deadlines, because EPA requires to approve a protocol, which usually doesn't take a matter of weeks or months. Could take very long, in my experience, especially if they have to comment and those comments go back to the CRO, and you start trying to find the practical way of conducting the study per those comments. I can talk about a few examples, if you want.

And secondly, you have to then, only after the protocol is finalized, you can start -- and you heard from someone else about -- you start developing a protocol. You have to get in line for the lab. And then so it's very difficult to see any study, even a very short study being done in 12 to 14, 24 months when, when that requirement exists. And again, special studies also have -- there are other reasons. You heard a lot about the leptocheirus, of course.

The other -- the other example I want to give which I think is very telling is the DCIs that we've seen since the RED review, almost all of them included high-tier bee studies. And I guess, and I'm not criticizing, EPA didn't want to run around and do DCIs whenever they, they had a concern, and they just added them to these DCIs.

Now when you have a high-tier bee study, you

need to do the tier 1, which is very simple lab study. Tier 2, which could be either in a tunnel or, or a semi-field, or some condition. And tier 3 might be a full field study with a lot of observations. EPA also required to review those protocols, because those are very complex studies. Conducting those studies are also seasonal. You can only start them in April, May. You can't test these in December.

So assuming you can get through these three tiers with approval of protocols along the line in a manner of even 36 months is extremely -- well, it's impossible. There's no way to do it. So, and the deadline says 36 months. I've actually talked with colleagues at EPA several times told them why don't you say "to be determined?" Why do you keep that number there which doesn't make any sense? None of the DCIs could meet these deadlines. So that's the kind of things I was referring to.

JUDGE BIRO: So is it -- you talked about special studies taking especially long. How about the other more routine studies where there are guidelines, do they -- do the timelines set basically apply in those cases? Are they reasonable?

THE WITNESS: Of course. Sorry, yeah. Yeah, for some of them, yes. It again depends on the chemical.

Not all chemicals are identical. So doing the studies requires understanding how to deliver the compound. So some compounds are very easy. If you do a fish study and you just pour it into the water and it stays there, and it's stable in water, for example, and you can analyze it easy, those studies are pretty routine and I guess those deadlines could be met. That's not a big deal.

But you have a product that's very lipophilic, which means it likes the oily part and not the water part, then it's very hard to administer it into an aquarium and get the right doses. Those could take months and years to establish just the methodology and the analytical methodology to expose the animal. So those, those you won't meet. So it's sort of a depends on the molecule. But you can in some instances meet those deadlines, sure.

JUDGE BIRO: Bear with me one minute. Have you ever in your process of representing a company asked that they revise their DCI to accommodate a study they've requested?

THE WITNESS: No, I don't remember that.

JUDGE BIRO: I don't have any further questions. Mr. Ross, do you have any questions?

MR. ROSS: Yes, Your Honor. Or I should say it depends. I believe the witness may have misunderstood

your final question, which I will attempt to restate and you can tell me if, if I understood it.

REDIRECT EXAMINATION

BY MR. ROSS:

Q. As I understood the question, it was in your experience, Mr. Gur, have you seen instances where you or someone else has asked that EPA formally add a data requirement to a DCA -- to a DCI or otherwise?

A. No. Again, not the -- not add a formal data requirement, but add another DCI. That's different, yes.

Q. So you've seen instances in which a registrant was asked to perform a study that was not in the DCI?

A. Yes. Yes, but it's not, not necessarily linked to the DCI. I've seen instances where a registrant asked EPA to issue a DCI in order to maintain its intellectual property rights. Those are the data compensation issues that Dr. Freedlander talked about, yes.

Q. But a request is provided from the registrant that there be a formal document stating we, the agency, require you to do study X as a matter under FIFRA?

A. Correct. But I'll, I'll try to -- I'll try to insist on a DCI, not just when you say formal document. A memo could be helpful. But if I -- I've negotiated a lot of data comp negotiations, so I'm fairly familiar with this issue. And if you want to have a clean

negotiation without having to involve arbitrations and all that stuff, if you have a DCI it's almost non-negotiable. They will compensate you for that study. If you just have a formal letter, it's a bit different.

Q. So if you enter a FIFRA arbitration with a DCI requirement, that's basically -- that would be the gold standard of, "I should be compensated for those?"

A. It might even avoid an arbitration, let me take it as far as that.

Q. And anything other than that, you'd be fighting --

A. Yes.

Q. -- over whether or not it was necessary.

A. Absolutely correct.

JUDGE BIRO: Okay. Any other questions?

RECROSS-EXAMINATION

BY MR. PITTMAN:

Q. Mr. Gur, I have to say over the course of this testimony, I've become less certain about what you mean by stability. When, when you read a statement from OPP that the U.S. EPA will assume stability, you understand that to mean that EPA will assume the chemical is not breaking down?

A. Correct.

Q. But you also said that essentially you

understand that the chemical will break down.

A. It might. I don't know that for sure. Can, can I explain again? I may be -- I'm not a modeler. In our life, we have modelers who plug the numbers into models.

Q. Yeah, I accept that you're --

A. Stability is -- directs that number.

Q. I, I understand that's not your area of expertise. But in the context of seeing an EPA statement that it will assume stability, is that not natural to assume that if a stability is assumed but use is continued that environment concentration is increased, to say nothing of trophic accumulation, but just based purely on continued use and no degradation, that environment concentrations would increase.

A. That, that could be. But it doesn't -- that's not what I would think of when I see stability. I see it in the context of the risk assessment only.

Q. No further questions.

A. That's the goal of the -- of the -- that's the deliverable EPA has to produce, right, the risk assessment.

JUDGE BIRO: Ms. Rose, do you have any questions?

MS. ROSE: No, Your Honor.

JUDGE BIRO: Do you have additional questions?

MR. ROSS: Yes, Your Honor. Going to the --

JUDGE BIRO: Can I interrupt you. I'm sorry. You mentioned before, Mr. Gur, about lipophilic tests on something, oil in water, I think. Is DCPA a lipophilic product, I mean chemical?

THE WITNESS: I don't remember. I apologize.

JUDGE BIRO: Okay.

THE WITNESS: I don't remember.

JUDGE BIRO: All right. Go ahead, sorry to interrupt.

FURTHER REDIRECT EXAMINATION

BY MR. ROSS:

Q. Mr. Gur, if the agency stated to you prior to a risk assessment that it would assume stability of a particular compound, would you understand that to refer to the chemical properties of that compound, that it would not be expected to degrade in a study?

A. Yes.

Q. If EPA stated to you that after they had performed a modeling analysis in the context of a risk assessment, if they said to you then the environmental concentrations of this chemical will remain stable, you would understand that differently. Correct?

MR. PITTMAN: Objection. That's misreading

stability, trying to apply stability of environmental concentration levels versus stability from degradation.

MR. ROSS: Well, I think I'm attempting to elucidate the exact difference in terminology that the objection --

JUDGE BIRO: Okay. Well, I'll let you come back and -- it's not clear, go ahead.

BY MR. ROSS:

Q. If the agency was to provide you the results of modeling after they've performed a risk assessment, and those modeling results showed that the expected environmental concentrations of the chemical were over time, over a long time horizon not decreasing or, or were increasing, that's using the term stability in a different sense. Correct?

A. Yeah, but that's not what they show us. I mean maybe I'm -- I couldn't explain myself. The purpose of those studies is to determine a DT50. That DT50 gets plugged into a model, that then helps them analyze how much would be in surface water, groundwater, and so forth. And when I hear stability, I know that the modeler will put let's say 1,000 days. I'm not sure, but I'm making an assumption. And that's the entire purpose of the study. It's not to look at what happens tomorrow.

The model then, when I mention 30 years, the

model then assumes 30 years of usage. It's based on rain, and weather, and all those issues, to determine how much leakage, so --

Q. So are there --

A. Looking into the future is not something that I have to do.

Q. Are there other parameters that are put into the model beyond the chemical stability of the compound which affect how that compound will increase or decrease in the environment over time --

A. I don't know. I don’t think so.

Q. -- in a particular location?

A. Soil types, yes. But again, we don't look at the increase over time. We look at what -- how does it break down. Soil type is -- I don't remember all the parameters for the model. I can't tell you that. Hydrolysis is obviously one. Soil characteristics is obviously another. But I can't remember them all. Solubility.

Q. Are there other lines of evidence that an EPA risk assessor -- either an EPA modeler or an EPA risk assessor might look at when they were -- if they were and when they were considering the long-term accumulation or not of a chemical? Are there other lines of evidence that they might look at other than the chemical -- the

chemical stability?

A. They would look at lipophilicity, maybe. That's in animals. That's in fish or in birds. They would look at those kind of things to see what happens in the environment. But again not from these studies that we are talking about, not the anaerobic degradation study --or metabolism study, sorry.

MR. ROSS: No further questions.

JUDGE BIRO: Mr. Pittman, do you have any further questions?

MR. PITTMAN: Nothing further, Your Honor.

JUDGE BIRO: Are we going to reserve the right to recall Mr. Gur?

MR. ROSS: Yes, Your Honor.

JUDGE BIRO: Okay. Ms. Rose, I'm so sorry, do you have any questions you want to add?

MS. ROSE: No, Your Honor. And I will speak up if I ever do and don't get called upon.

JUDGE BIRO: All right. Thank you, Mr. Gur.

THE WITNESS: Thank you.

JUDGE BIRO: You remain to be recalled, so please don't discuss anything -- well, actually, you get to stay here indefinitely so that's not a problem.

(Witness excused.)

JUDGE BIRO: If you'd like to call your next

witness?

MR. ROSS: We have no further direct witnesses.

JUDGE BIRO: How about Mr. Wood?

MR. ROSS: Oh, Mr. Wood will not be called.

JUDGE BIRO: Is there any other documents you wish to put into evidence?

MR. ROSS: If we might request a 5-minute recess --

JUDGE BIRO: Oh, of course, sure.

MR. ROSS: -- before answering that question.

JUDGE BIRO: Sure. It's 2:35. How long do you need? Do you want to go to 3:00?

MR. ROSS: That would work. Thank you.

JUDGE BIRO: Okay. We'll stand in recess till 3:00.

(Off the record from 2:35 p.m. to 3:00 p.m.)

JUDGE BIRO: Please be seated. Okay, Mr. Ross, where are we? Do we have any exhibits we're going to introduce?

MR. ROSS: We do not have any further exhibits to introduce.

JUDGE BIRO: Okay. Does the Petitioner rest, Petitioner AMVAC?

MR. ROSS: But for potential rebuttal, yes.

JUDGE BIRO: Okay. Ms. Rose?

MS. ROSE: Yes, Your Honor.

JUDGE BIRO: Do you have any exhibits that you would like to put in as considered part of your direct case?

MS. ROSE: Beyond the ones that we handled earlier, only PGX-7(a), which I supplied to counsel for the other parties and subject to their objection. That would be the only one.

JUDGE BIRO: So let's try to remember to get back to that before the end of today or tomorrow.

Okay, Mr. Pittman, do you have any rebuttal witnesses?

MR. PITTMAN: Your Honor, no, we do not intend to call anybody on rebuttal.

JUDGE BIRO: Okay.

MR. ROSS: We'd like to call Mr. Gur for brief rebuttal, Your Honor.

JUDGE BIRO: What are you rebutting, because they're not putting on any rebuttal witnesses.

MR. ROSS: Cross-examination testimony provided by Ms. Bloom, Your Honor.

JUDGE BIRO: All right. Shouldn't this have been something we got out of him on cross-examination before or your direct testimony before?

MR. ROSS: Well, it -- the three areas that I

hope to briefly cover were not within the --

JUDGE BIRO: Scope?

MR. ROSS: They were not within the scope of Mr. Pittman's cross and they relate to issues commented on by Ms. Bloom.

JUDGE BIRO: Okay. Mr. Gur, could you take the stand again? Thank you for indulging us. You remain under oath.

MR. GUR: Sure.

(Whereupon,

EPHRAIM GUR,

having been previously sworn, was recalled as a witness herein and testified as follows:)

DIRECT EXAMINATION

BY MR. ROSS:

Q. Good afternoon, Mr. Gur.

A. Afternoon.

Q. You've been with us in the hearing room through the testimony. Correct?

A. Correct.

Q. And you observed the cross-examination testimony of OPP's witness, Ms. Jill Bloom. Correct?

A. Correct.

Q. During the examination of Ms. Bloom, there was a discussion of commenting on EPA preliminary work plans.

Do you recall that --

A. Yes.

Q. -- discussion? Do you have experience commenting on EPA work plans?

A. Yes, I do.

Q. And what is the general nature of comments that a registrant might supply on an EPA work plan?

A. So some registrants would want to comment in any case. Some would comment ad hoc on whether they have anything to say. Some of them would be very general, like say we agree, or we'll -- we will comply, or we will wait for the DCI. And some would really address some of the requirements. It's really very different in the industry on, on what you see in terms of how they address this. And some simply ignore it if they either don't want to or don't need to comment.

Q. And for those registrants that do choose to comment on preliminary work plans, would you characterize their comments as more commonly being directed to the broad themes, EPA's general approach, or would the comments on the work plan be to the need for specific data requirements?

A. I would think generally it'll be more general than specific data requirements. And, and the reasons would be probably two, two reasons. One is, not always

would those work plans that say we expect to have these studies in the DCI, actually have all those studies in the DCI. So you might feel that there's redundancy in making comments. Sometimes, assumptions that are made in these work plans about what studies would end up in the DCI don't, don't happen.

And, two, in many cases, EPA would probably disregard them basically. They'll sort of politely acknowledge that we received comments, but the scientists of EPA wouldn't want to start reviewing those studies again. They'll wait for a DCI and say submit the waiver, and then we'll address your comment. They will want to see the formal process of a -- of a waiver.

Q. So with respect to the broader category of comments going to EPA's general work plan, if you will, if a registrant did not have a substantive concern with the general direction in which EPA was headed, they would not even have a reason to supply comments, would they?

A. Yes.

Q. Have you ever seen a registrant attempt to take a very narrow approach of saying you're, you know, I'm using a hypothetical, but you're -- you say you're going to require a tier 1 X study. We don't think you should. Please remove it from the work plan. Have you seen something like that?

A. I don't think I've ever seen anything that specific, that narrow, yeah.

Q. What about I mean challenging any data requirement by, by name, if you will?

A. I'm trying to remember if I've seen anything or done anything that specific. Maybe very rarely, if, if at all.

Q. To the extent that you recall such an instance, do you recall the agency's response to that sort of comment on a preliminary work plan?

A. So that kind of thing would usually come up, in my experience, in those six monthly meetings where because the work plan says a DCI will be issued at a certain date and since the beginning of the registration review, EPA was always 6 to 12 months late on those, on those dates. We always had time to say we've seen the work plan. We sort of could discuss maybe not in detail, but say, you know, we think we don't need this. We think we don't need that.

So we would have had the opportunity to raise that in those kind of settings and see if EPA would be willing to entertain that discussion before a DCI is issued or not. I think in most cases, EPA would say, yeah, that's interesting, please submit the waiver when the DCI is issued, because that's easier for them just to

follow process and not start having things jump in the middle on one hand.

Q. There was also testimony, Mr. Gur, if you recall, regarding the -- from Ms. Bloom, about the expected or average duration of a DCI from initiation to completion. Do you recall that testimony?

A. Yes.

Q. Do you happen to recall the rough window that she provided for a short versus a long DCI?

A. I think I remember 3 years or something like that, but I am not sure.

Q. As the -- as the shorter window? Or sort of she --

A. I don't remember the exact number. I apologize. I remember what the witness today said, but not what Jill said yesterday.

Q. Based on the 3-year estimate that she provided, do you suspect that she was referring to DCIs from a particular --

MR. PITTMAN: Objection. The witness that said that 3-year estimate was from today's witness, which I believe is referring to Ms. McMahon, who provided a 3-year estimate.

MR. ROSS: I believe there was a separate timeframe offered by Ms. McMahon. I asked Mr. Gur if he

recalled an estimate being provided by Ms. Bloom.

JUDGE BIRO: Right. Well, he doesn't remember what she said. So you can ask him hypothetically, because he's an expert, hypothetically if it was 3 years.

BY MR. ROSS:

Q. I'm sorry. Do you -- do you recall that Ms. Bloom's response was 3 years?

A. I thought so. I'm not sure.

Q. Based on that response, do you think she might be referring to DCIs from a particular historical timeframe?

A. Yeah, I think 3 years is a -- is a very -- should be only a very simple DCI that has very simple and narrow requirements, and probably standard studies, very standard. I think it's very rare to see a DCI finalized in 3 years.

Q. Would you characterize the dacthal DCI as a simple DCI?

A. I think that is one of the more problematic and difficult ones, which we would have seen from products that were -- that have I would call it run over from the previous process, the RED process, and had to go through the registration review, relatively old molecules that had a lot of studies that had to be renewed.

In addition, dacthal has both parent and

metabolites. That creates another complexity. And it had a pretty complex study in it, which is the CTA, which is the type of studies that take, take a long time to finalize. They have a lot of stages that EPA wants to opine on as they go along. So you're dependent on EPA to provide you with approval for those steps.

Q. And so there, there might not -- there might exist, might they, other complex DCIs, correct?

A. I have had ones that are even more than 10 years.

Q. And so DCPA might be -- might share qualities with those. Correct?

A. Correct.

Q. Mr. Gur, based on your -- also as it relates to the overall duration, does the overall duration of a DCI, is that impacted by how quickly responses are received from EPA as well?

A. Absolutely, on various issues. First of all, approval of protocols. And then approval of stages of a study like the CTA and that example with other, other types of studies, not just the CTA, which I've personally never been involved in. And addressing waivers, which again if you get a waiver response quickly and you can clarify the agency's concern so that you can address it either by submitting additional data, or running the

study, or then that would speed up the process. If it takes a long time to get those responses, then obviously you are waiting to see what the exact issue is.

Q. And so with respect to waivers in particular, if a registrant did not receive a response to a waiver for hypothetically 33 or 44 months, 3, 4 years, whatever it is, that would necessarily extend the timeline for the DCI. Correct?

A. Yes.

Q. And finally, Mr. Gur, Ms. Bloom mentioned that in some instances the agency's response documents are made available on a docket. What docket did you understand her to be referring to?

A. The registration review docket, of the government dockets, regulations.gov.

Q. So she made reference to some other internal EPA systems. Correct?

A. Yes.

Q. But none of those are available to a registrant?

A. No.

Q. Is regulations.gov available to a registrant?

A. Yes.

Q. Have you reviewed the regulations.gov docket for the DCPA registration review?

A. Yes. I've had a look at it, yes.

Q. And in general can you describe the contents of that docket?

A. So it has about 79 documents posted in it. A few are between 2011 to 2015. And the rest after the NOITS. So if I remember well, the dates April 27/28 of 2022 for the majority of them in those two dates, actually, the first date and then the add-ons probably in the second date. So 27th of April. So between 2015 to April 2022, there were no, no documents, no postings on -- in the docket.

Q. Were a majority of the documents in the docket posted contemporaneous with the NOITS?

A. Yes.

Q. And prior to the documents that were posted contemporaneous with the NOITS, again if you could, approximately how far back was the next most recent document in the docket?

A. Seven years, 2015.

MR. ROSS: No further questions on rebuttal, Your Honor.

MR. PITTMAN: If, if I could have just one moment?

JUDGE BIRO: Mm-hmm.

(Pause.)

CROSS-EXAMINATION

BY MR. PITTMAN:

Q. Mr. Gur, just one question. So during your testimony here, you said that EPA often disregards comments submitted to regulations.gov dockets?

A. I'm not sure I said that. If I said that, I might --

MR. PITTMAN: Should we have the record read back -- should we have the record read back to refresh his memory?

JUDGE BIRO: If you want, but I, I think I recall that and it's in my notes. Right. Mr. Gur, is that your testimony that EPA doesn't respond to comments to preliminary -- I think it was preliminary work.

THE WITNESS: Work plan, yes.

MR. PITTMAN: I understood the question to be somewhat broader, to comments generally submitted to registration review dockets.

JUDGE BIRO: Oh, well, ask him.

THE WITNESS: I think it was comments to the work plan. Right?

JUDGE BIRO: Or we could ask the court reporter to find it. Mr. Reporter, could you go back to Mr. Gur's testimony on direct -- is it on direct?

MR. PITTMAN: Just moments ago, Your Honor.

(Off the record from 3:17 p.m. to 3:18 p.m.)

MR. ROSS: I believe the issue concerned a question that I --

JUDGE BIRO: On rebuttal, right. Okay.

MR. ROSS: I can either attempt to -- or we can go to the transcript.

MR. PITTMAN: I would prefer the transcript.

JUDGE BIRO: Okay.

MR. PITTMAN: I'm sorry. Am I -- do I need to ask you exactly -- Your Honor, I'm sorry. I don't know exactly how to do this, but I'm trying to get the comment. I distinctly remember EPA disregards comments. We can clarify the context in which it's asked. Perhaps my recollection needs refreshing. But I think this is an important point to address.

JUDGE BIRO: Mr. Reporter, could you find an answer from Mr. Gur to a question about the usefulness or generally the second on the usefulness of responding to the work plans?

MR. PITTMAN: And again I am willing to accept that perhaps my recollection of the exact context of this question is not correct. But I would like to know. So, I mean if it was a Gur statement, I would like to address it. I, I think that was his statement.

JUDGE BIRO: Okay, it's fine. We can take a

few minutes. Would you like to go onto something else? Well, I guess we can't. We'll torture the court reporter.

Q. MR. PITMMAN: This is my only question. So --

(Off the record from 3:20 p.m. to 3:25 p.m.)

JUDGE BIRO: Could you play back that little clip one more time and a little bit louder, if possible? Why don't you maybe move a little bit closer.

(Off the record from 3:25 p.m. to 3:27 p.m.)

BY MR. PITTMAN:

Q. Mr. Gur, I admit this entire little interlude here was because when I hear that EPA disregards comments submitted to a docket, that comes off as quite a serious allegation when I'm hearing it as counsel for EPA.

A. I understand.

Q. Are you aware, can you point me to any particular documents -- or sorry, sorry, any particular registration review cases that you've worked on where you feel that EPA has disregarded a comment submitted?

A. So what I said there if you heard is it disregards a specific comment that politely says we heard your comments and we'll address them. And I think that's a very generic term that I've seen a lot of times. I need to -- I don't know if I can point to a specific example. But it's certainly something that's pretty

generic in those work plan -- in the -- when EPA comments to -- sorry, addresses all the comments it receives, it many times says we received comments from the registrant saying this and this. We heard them. We'll take care of it when we do the risk assessment. It won't address all the specific comments.

You can say that about USDA. You can say that about grower groups. Thank you for your comments, we will consider them. And that's what I was saying. They politely say we heard you, which I believe they have, but they won't address a specific attempt to say let's say waive a -- waive a requirement or tell them that you think this requirement is redundant, or won't inform your risk assessment, which is why we generally don't put those requirements.

Q. Well, perhaps my recollection is a little different, but it seems like we're going to have to wait for the official transcript to come out. But just to follow-up on that, would you stand by that characterization of EPA acknowledging that comments have been submitted --

A. Yes.

Q. -- but disregarding them?

A. Yes.

MR. PITTMAN: Okay. No further questions.

THE WITNESS: Apologize.

JUDGE BIRO: Mr. Gur, can I ask a question. How long do you think a registrant should go after they submit a waiver before they contact EPA on the status of it? What's a good practice?

THE WITNESS: Well, it's a good question. Because the EPA did initiate at some stage following some OIG, I think, report, a requirement that we give them status reports. And we do send status report of the status. And I think Dr. Freedlander talked about or showed one of them, for example. And for us, unless we have another gathering or meeting, this is where they get an update. And so we might have a status report, and I've seen at least one in the docket somewhere when I reviewed the documents that I was supposed to comment on, where there was an appendix with, "this is the status." And on the waivers it said waivers pending. So per EPA, they request that typically every 3 months. So I think we do have a system where we do update. Unfortunately, it's not, as you indicated yesterday, it's not automatic. It's not sort of sophisticated system. It's a document that they're supposed to get, and distribute the need, and address.

JUDGE BIRO: So if I were a registrant and I got a DCI. I submitted a request for waiver in my

initial response. It was denied. Or it wasn't denied. Let's say it was I submitted a request for a waiver and I didn't hear anything, would I contact EPA? Would it be a good practice to contact EPA after 6 months or a year? Like how long do you wait?

THE WITNESS: Give or take 6 months would make sense. But again bear in mind there's a difference between a very relatively simple -- I've had DCIs where the compound was recently registered, so the DCI was relatively small, 10 studies, 15 studies. It's very easy to monitor and chase EPA on every individual study. Versus this DCI that had like 40 or 45 studies, and discussions were ongoing with different departments over all those studies. So it's very easy to sort of let the waiver stand there if you don't chase a specific waiver. So it changes.

JUDGE BIRO: Okay. So it would be easy for EPA to overlook it if somebody is not keeping up on it? Or it would be easy for the company to say I'll just let that go and sit?

THE WITNESS: Both, I guess. Both. But again in this instance, for example, there was an example that I saw. And I can find it, if needed, where a status report was sent and that waiver, the EFED's response was already there, but never communicated to the company. So

--

JUDGE BIRO: So in your experience, are you aware of the very convoluted process that OPP seems to have for communications?

THE WITNESS: Yes.

JUDGE BIRO: And do you take any action proactively because of that, that system of communications?

THE WITNESS: As an industry, we have. Not for leptocheirus, we haven't. But I've been a member of the Croplife registration committee for about 15 to 20 years, not, not that long, but until about 2019 or '18. And we have had visitors from EPA visit us and we have talked about improving their systems, and ensuring better training and ensuring consistency.

That's another problem that we have around product and CRM maybe behaving, behaving that way, or interpreting issues one way, the other interpreting issues the other way. And I think it's in, someplace in the testimony, EPA is now testing a new software called Salesforce. And I understand they've had a pilot. And that software is like for sales people so that everyone knows who talked to the client. So this is, I think, a similar software that will hopefully improve that situation.

JUDGE BIRO: So the whole industry is basically aware of the -- of the limitations of the current system?

THE WITNESS: Yes. But remember the industry is not working against EPA. It works with EPA.

JUDGE BIRO: Right.

THE WITNESS: It wants efficiency, wants to address the concerns, and wants to get on with doing their business. So we have an interest to see improvements in this area. We will support as much as we can. Publicly, it's hard to support EPA because then, of course, what activists will say -- will have something to say on that. So we're in a different -- we're in a difficult situation in that respect.

JUDGE BIRO: Right, okay. I understand. Mr. Gur, would you like some water?

THE WITNESS: I have some. Thank you very much.

JUDGE BIRO: Mr. Ross?

MR. ROSS: One brief follow-up perhaps, a brief series of follow-up questions to your line of questioning.

REDIRECT EXAMINATION

BY MR. ROSS:

Q. Mr. Gur, you testified that it would -- in many instances, registrants do follow-up with the agency if

they have not received a response to a waiver or something else for a long period of time. Correct? You've also testified, correct, that you have seen in the record such status reports in which AMVAC was communicating the current status as it understood it to EPA?

A. Correct.

Q. If a registrant were to receive a document from EPA indicating that a risk assessment would be completed in the near future, what would the next document that registrant would be expecting to see from EPA?

A. Today, it's a bit different than it used to be. But I think the next document would be a proposed decision and the risk assessment would be posted. In the past, we could have seen draft risk assessments so that we could at least address typos, or miscalculations, or stuff like that, you know, argue a lot of the science we find. And we have. I have in my experience at least twice found miscalculations.

Q. But putting, putting aside the particular characterization of the subsequent document, whether it was a proposed interim decision, or an interim final decision, or an interim registration review decision, or what have you, a registrant receiving that communication -- when the prior communication was that a risk

assessment will be performed using conservative assumptions if needed -- in less time than a study could possibly be completed hypothetically -- they would expect to see that risk assessment document next. Correct?

A. Correct.

MR. ROSS: No further questions.

JUDGE BIRO: Did my questions raise any questions for you, Mr. Pittman?

MR. PITTMAN: No further questions, Your Honor.

JUDGE BIRO: Ms. Rose, do you have any questions you'd like to ask?

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

THE WITNESS: Thank you.

(Witness excused.)

JUDGE BIRO: Is there another rebuttal witness? Is there another rebuttal witness you'd like to call?

MR. ROSS: No, Your Honor.

JUDGE BIRO: Is there any other witnesses? Ms. Rose? Anybody wants to call in this proceeding? Are we done? Everybody has had an opportunity? Okay. I want to go over what exhibits have been admitted into the record so that we're all on the same page.

I understand the stipulations have been admitted as Court's Exhibit 1.

I have Joint Exhibits 1 through 48, and 50

through 92. We all in agreement or should we go over, through all of them, then we'll take a break and look over your notes, and get back to me? Should we do that?

MR. PITTMAN: I think we can do this on the fly. I was just wondering are you going per category like JX in a row?

JUDGE BIRO: I was.

MR. PITTMAN: Okay.

JUDGE BIRO: Is that okay?

MR. PITTMAN: Yes, ma'am.

JUDGE BIRO: Okay. Those are the first two categories I did. And then PGX, which I have as Exhibits 1 through 8, with Exhibit 7(a) pending your approval. And I understand from Ms. Rose that you have a draft of that. And assuming that it's acceptable and you don't want to cross-examine a live witness, we'll admit that into the record.

MR. PITTMAN: If you'd -- if you'd like, Your Honor, I did have a chance to briefly look it over. It is consistent with -- I'm sorry, Ms. Rose, you can't hear me. It is consistent with the initial testimony and we would not have any further objection than the relevance one previously raised overall.

JUDGE BIRO: Okay. Does AMVAC have any objection?

MR. ROSS: No objection.

JUDGE BIRO: Okay. So we'll go ahead and admit 7(a). We have a draft copy of that, I believe an unsigned copy, and Ms. Rose if you will submit a signed copy, we'll swap it out for the record.

(Petitioner's PGX-7(a) received.)

JUDGE BIRO: So then in terms of PGX's exhibits, we have 1 through 7, and 7(a), and 8. Is that --

MS. ROSE: Yes, yes.

JUDGE BIRO: Okay. For -- let me go with RX, because it's not quite as long. So we have 1 through 14, 16 through 18, 20, 21, and 24. And I'm not sure about 27. That's Ms. Bloom's statement. Was that admitted into the record? Would you like it admitted into the record?

MR. PITTMAN: Your Honor, if it was not previously admitted, we would move that Ms. Bloom's direct testimony be admitted.

MR. ROSS: No objection.

JUDGE BIRO: Okay. Ms. Rose?

MS. ROSE: No objection.

JUDGE BIRO: Okay. 27 into the record.

(Respondent's RX-27 received.)

JUDGE BIRO: So then for RX, we have 1 through

14, 16 through 18, 20, 21, 24, and 27. Okay.

And then for PAX, Exhibits 1 through 43, 45 through 48 -- actually, it's 49, 45 through 49, 51 to 56 -- no, 57. Then we have 63 through 77, 84 to 85, and 94 through 97 including Exhibit A. Somehow, I feel I'm missing something. I think I'm missing what, 78 to 82? Oh, 93, Exhibits A and B, so it's really 93. Let's go over that again.

MR. PITTMAN: Can I consult with opposing counsel?

JUDGE BIRO: Yeah, why don't you discuss that.

(Pause.)

JUDGE BIRO: Okay. So Mr. Pittman, why don't you tell me what exhibits of AMVAC you believe have been admitted.

MR. PITTMAN: Your Honor, I believe it's correct. It is 93 to 94. I had not been cross-referencing their witness exhibits. There were documents labeled as PAX-93 and 94 that were not admitted. But I think it's been resolved.

JUDGE BIRO: Okay. So what am I missing?

MR. ROSS: We're aware there was at least one PAX skipped. I believe it was 50. If we could, we'll take a quick look for some others.

JUDGE BIRO: Okay. Why don't we take a

5-minute break and maybe we can get an agreement on what the set of exhibits are so we know what we're looking at to write our post-hearing memos. Thank you.

(Off the record from 3:44 p.m. to 3:53 p.m.)

JUDGE BIRO: Please be seated. Okay, ladies and gentlemen, have we reached an agreement on what the exhibits, the AMVAC's exhibits that were admitted are?

MR. ROSS: We just came to an internal agreement and we can see if we have a bilateral or trilateral agreement. Perhaps if I could read back so it's all in one place what we understood you to state was in the record as far as the PAX exhibits. 1 through 43, 45 through 57.

JUDGE BIRO: Okay.

MR. ROSS: Excepting 50.

JUDGE BIRO: Okay. Well, then go back to 45 through 49.

MR. ROSS: 45 through 49.

JUDGE BIRO: 51 through 57, okay.

MR. ROSS: 77, 84 to 85, and 94, 97. And then would you like me to identify the additional PAX that we believe were moved in?

JUDGE BIRO: Okay. Yes.

MR. ROSS: According to our notes, PAX-50 was moved in. I'll state the nature of that momentarily.

PAX-50 was one of the emails on which Jill Bloom was copied.

JUDGE BIRO: Yeah, okay, we have that. So we're all in agreement, 50, okay.

MR. ROSS: PAX -- we have in our notes that PAX-78 was moved in. It is a data evaluation record and as such appears in the docket. And so perhaps a decision was made to --

JUDGE BIRO: Oh, okay.

MR. ROSS: -- look to the docket instead.

JUDGE BIRO: Yep, we have it as admitted.

MR. ROSS: Likewise Exhibit 87 is another data evaluation record.

(Petitioner PAX-87 identified.)

JUDGE BIRO: Don't have that. Is there any --

MR. PITTMAN: We would stipulate to it.

JUDGE BIRO: Okay, 87.

(Petitioner's PAX-87 received.)

MR. ROSS: PAX-89 is another of the emails on which Ms. Bloom was copied.

JUDGE BIRO: Okay. We have that.

MR. ROSS: Finally, PAX-93 is the first of the witness statements of AMVAC's witnesses, the statement of Ms. McMahon.

MR. PITTMAN: No objection. We were -- our

reference was to the prior, prior supplied 93 and 94.

JUDGE BIRO: Okay. And is that the whole universe of PAX exhibits?

MR. ROSS: Additionally, Your Honor, we also have PAX-91 and 92, which are emails noted as being in.

JUDGE BIRO: Okay.

MR. ROSS: That is all of the additional exhibits that we identified.

JUDGE BIRO: Okay. So PAX Exhibits 1 through 43, 45 to 57, 63 through 78, 84, 85, 87, 89, 91, 92, 93, and Exhibits A and B to that document, 94 to 96, and 97 with Exhibit A attached. Are we in agreement? Okay. To the extent that any of those documents weren't previously admitted, without objection we're going to admit them in the record. That's correct?

MR. PITTMAN: Yes, Your Honor.

JUDGE BIRO: Okay. Ms. Rose, is that correct?

MS. ROSE: Yes, Your Honor.

JUDGE BIRO: Shaking your head yes. Okay. My statement of the Agency's exhibits, were those correct?

MR. PITTMAN: Yes, Your Honor.

JUDGE BIRO: Okay. Are there any other exhibits that we have somehow overlooked that need to be moved into evidence?

MR. ROSS: Just to confirm, 94 included three

exhibits as well, attachments to 94.

JUDGE BIRO: Okay. Is that correct?

MR. PITTMAN: No objection.

JUDGE BIRO: No objection, okay, 94 with those three attachments admitted, if it wasn't admitted before. Anything else?

MR. ROSS: Yes, Your Honor. You mentioned the one CV stipulations document. Correct?

JUDGE BIRO: Right.

MR. ROSS: I still suspect there may be at least one, if not two additional docket documents that also contain stipulations. And in addition, there will be the additional document we referenced this morning, which we will submit. To the extent we identified the others, we will send them to the Court's attention and propose the CV.

JUDGE BIRO: They can be Court's Exhibits 2, 3, and 4. That would be fine. Okay. Is there any other issues we have to address? Thank you so much for being so cooperative to narrow down the amount of live testimony we had to take in this proceeding. I know it's really time-consuming and expensive. And I'm really grateful for that.

And to Ms. Rose particular for being so cooperative about having her witnesses who are on the

West Coast and the time limits, you know, accept their testimony writing -- in writing.

We will get the transcript, the time to get it, and we will send it out to you to comment on and correct. And when we get that back, we'll then issue a scheduling order for post-decision briefs. And we will try to get our decision out as soon as we can after those briefs are in. It takes us some time. You know, I know that this is supposed to be a really short proceeding. But there's only two judges in my office and many, many cases. So we will try to get it out as soon as we can, which I can't make any promises on.

And then, of course, anybody is unhappy can appeal to my brethren at the EAB. I've seen it before. Somebody's likely to see them again. You're all likely to see them again. So, and if there's any post-hearing issues, if you decide to settle, if all the issues get resolved before we issue our decision, please tell me. That's wishful thinking, but it does happen rarely.

If there's nothing else, we'll go off the record. Thank you.

(Court's Exhibits C-2, C-3 and C-4 identified and received)

(Whereupon, at 4:02 p.m., the above-entitled matter was closed.)

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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