**In The Matter Of:**

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

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*Vol. 1*

*January 24, 2023*

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BEFORE THE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C.

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| 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 Tuesday , January 24, 2023, at 9:00 a.m.

APPEARANCES:

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I N D E X

| WITNESS | DIRECT | CROSS | REDIRECT | RECROSS |
|---|---|---|---|---|
| Christina Wendel | 34 | 36 | 85 | 87 |
| Stephen Wente | 91 | 93 | 138 | -- |
| Jill Bloom | 142 | 143 | 218 | -- |

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P R O C E E D I N G S

(9:01 a.m.)

JUDGE BIRO: Good morning. I'm Susan Biro, Chief Administrative Law Judge for the Environmental Protection Agency. Counsel for the petitioner, can you please identify yourself for the record?

MR. WEINBERG: Your Honor, my name is David Weinberg. I am lead counsel for AMVAC and with me at the counsel table at this point are Hume Ross and Mark Sweet.

JUDGE BIRO: Good morning.

MR. WEINBERG: In addition, you will be seeing my colleague Tracy Heinzman, pardon me, who will also have a speaking role, and we have a number of other personnel here to observe, most notably the General Counsel of AMVAC Tim Donnelly and -- I could introduce the rest of the team to you if you find it useful, but they won't be speaking up.

JUDGE BIRO: That's not necessary. Thank you.

JUDGE BIRO: Agency?

MR. PITTMAN: Good morning, Your Honor. My name is Forrest Pittman. With me at counsel table here is Erin Koch.

JUDGE BIRO: Good morning. I understand that you invoke the rule of sequestration in this proceeding, so I would like to teach you a little bit about what that

means, for everybody that's in the courtroom. The idea of the rule is that everybody should testify from their own personal knowledge, what they remember.

It may not be perfect, but it's their personal memory and the rule of sequestration suggests that people stay apart so they don't get a joint memory, and that joint memory might not be more accurate than anybody's individual memory, so it's not very helpful. So we invoke the rule so each person testifies from their memory and everybody else is not present and then they testify from their memory, and until witnesses are released, you must maintain that silence, that restriction.

Don't talk about your testimony with anybody else. Don't talk about anybody else's testimony with them. You shouldn't convey even with your counsel to prepare for perhaps further direct or cross examination on breaks. It's supposed to be one, continuous opportunity for you to just tell your story, okay?

And we ask everybody to honor that, but if they fail to honor it, it generally means that we strike your testimony, the person who violated it and perhaps the person who we talk to on the record, which is a huge loss for whichever party you're testifying on behalf. So, I really ask you sincerely to try to abide by this rule, as

difficult as it can be sometimes and, you know, maintain that confidence.

If there's any issue that comes up where you feel somebody did not maintain their confidence, then of course, you know, please bring it to my attention.

MR. WEINBERG: Your Honor, if I may?

JUDGE BIRO: Yes.

MR. WEINBERG: We certainly understood what you just said. I do understand the sequestration rule does not apply to expert witnesses?

JUDGE BIRO: No. No, of course --

MR. WEINBERG: We do have our only expert with us sitting here.

JUDGE BIRO: Right. Of course. Expert witnesses can stay in the courtroom the whole time because generally their testimony is not based on personal knowledge, and also a representative for the company can stay in the courtroom at all times. He's also bound by the rules, but he's here to participate as an assistant to each side.

And the agency can also have a representative if they would like at their table to represent them. In this proceeding there is a specific order in which we go. The agency will have the burden of going forward, but the ultimate burden is on the petitioners. We are conducting

this hearing while we continue to have an ongoing pandemic.

I can't do anything to require you to wear a mask or use, you know, any kind of sterilizing lotion or take any COVID test, but my hope is that I can stay healthy enough and everybody else can stay healthy enough to finish this hearing. I personally am going to test every morning to make sure that I am not ill. If any of you would test, I'd be grateful.

If it turns out that you are ill, you know, there will be no punishment. We will find a way to accommodate you so that you can continue to participate in the hearing, if you're up to that and we'll go on. But, you know, not exposing other people to the virus is what I'm trying to do in this proceeding.

So, if you can wear a mask all the time, you're not actively participating, I would greatly appreciate it. If you need a personal break in this proceeding at any time for whatever personal reason you have, we want to do that. Just indicate that to me. Wave, shout, whatever you need to do, and we will be glad to do it.

It's not an endurance contest and we're trying to be flexible. On the other hand, we also only have a few days to do this hearing. So, we're going to try to be as efficient as possible. You know, take breaks at a

certain time and I'd really appreciate if everybody came back to start again on that time that we agree to so we can get done in this one week we have.

I really appreciate the cooperation that the attorneys for both sides have shown up until now and I hope we can continue that throughout the hearing. I've been practicing law for 40 years and I've been a judge for 30 years and I can assure you that it does not help anybody to be belligerent or grandiose or any, you know, yelling, screaming, insulting during the hearing process.

It doesn't help your case in any way. We granted the petitioners an opportunity to do an opening statement. You have the right to do it now, after the agency, if you would like, or you can wait until the start of your case. What would you like to do?

MR. WEINBERG: Your Honor, if the government is not going to make an opening statement, I would like to make mine at this point, please.

JUDGE BIRO: Okay. Does the government wish to make an opening statement?

MR. PITTMAN: I did have a few brief remarks, but I didn't know do you want to handle stipulation of exhibits prior to that preliminary matter. Whatever order you prefer.

JUDGE BIRO: Yeah. Let's just do opening

statements first, unless there are any other preliminary matters you want to deal with first.

MR. WEINBERG: We do have on the line, Your Honor, Counsel Cristen Rose who is not here personally today because of some personal issues and she may want to identify herself so that you're aware of that.

JUDGE BIRO: That's a great point. Thank you so much for mentioning that. Is that Ms. Rose?

MR. WEINBERG: Unfortunately, we can't hear her.

JUDGE BIRO: Oh, we can't hear you. Can we fix it so we can? Ms. Rose, can you hear us?

MS. ROSE: I can hear you.

JUDGE BIRO: We can.

MR. WEINBERG: Yes. Yes.

MS. ROSE: Yes. (Indiscernible) Your Honor (indiscernible).

JUDGE BIRO: I'm sorry. The court reporter is having a little trouble hearing you, but I think you completed your identification and that should be sufficient. There is no need to apologize about appearing by videoconference. We were happy to accommodate you and thank you for being so cautious. Okay. Any other preliminary matters?

MR. WEINBERG: No, Your Honor.

JUDGE BIRO: Thank you. Agency, would you like to make an opening statement?

MR. PITTMAN: Thank you, Your Honor. It is our -- this case is about OPP's clear statutory authority to obtain the data needed to reassess risks posed by pesticide products. That authority includes making a determination about what additional data is needed and it requires OPP to issue a DCI to registrants who must then submit that data.

Those DCIs contain instructions for submission, including times in which data should be submitted and it requires commitments from registrants to take steps towards satisfying the data requirements. Importantly, the Agency's DCI authority also contains an enforcement mechanism such that if registrants fail to take appropriate steps OPP can suspend the registration until the registrant does so.

Despite considerable briefing in this matter concerning other issues, the scope of this hearing is in fact is quite narrow under the statute. I believe the evidence to be introduced will show that AMVAC failed to take appropriate steps within the time required by OPP as to the remaining nine data requirements.

For each of those requirements OPP informed AMVAC the data was still required, including as

communicated in an October 2020 compilation of then outstanding data. However, rather than initiate studies after OPP informed it that the data was still required, AMVAC continued to contest the need for those data.

While OPP's regulations and practice allow registrants to make the case that certain data is not needed, the ultimate determination and necessity must always rest with OPP. The fact that OPP has both in the past and in the instant case, entertained ongoing conversation with registrants about the need for data, does not impair its ability to enforce compliance with the DCI.

Such attempts to work with registrants do not represent the agency changing its mind as to what is required to satisfy data requirements or whether the data are required at all. As confirmed by this proceeding, the process to seek a suspension represents a considerable resource commitment. Which OPP attempts to avoid if at all possible. However, OPP does not have unlimited time to ensure the data requirements are satisfied and must eventually use the tools available to it.

When evaluating petitioner's testimony, it is important to keep in mind that neither Section 3, nor the board require this court to examine the parties' course of performance on a universal basis or to evaluate whether

AMVAC's conduct was broadly typical of other registrants.

The question of what constitutes appropriate steps does not turn on those matters. The evidence will also show that the parties were not confused as to the status of various data requirements. While AMVAC may have been surprised that OPP would actually take a step of initiating the suspension proceeding, the evidence cannot be made to show that the company misunderstood the import of various OPP communications.

They clearly understood that OPP was not waiving the requirements for those data and acted accordingly by attempting to rebut the agency's determinations. Furthermore, petitioners agree that OPP was not required to provide a warning before initiating the suspension proceeding, but in effect asked this court to create just such a requirement.

When hearing testimony this week we should bear in mind that there is no requirement for OPP to inform a registrant that a given waiver denial is the final step, that all data is absolutely still required, no questions asked, no further conversations entertained.

There's also no requirement that OPP justify for registrants that it cannot make risk assessments without certain data or for OPP to actually attempt to make a risk assessment with incomplete data before

informing a registrant that that data is actually needed.

This case is also not about steps that a registrant takes after OPP issues a notice of intent to suspend. While such steps are certainly important in the context of lifting a suspension, the initiation of data generation in reaction to an enforcement action cannot be considered an appropriate step.

Contrary to petitioner's assertions, the fact that OPP is no longer pursuing 11 of the original 20 data requirements, is not an endorsement of this view. OPP's continued willingness to work with registrants, even during an enforcement proceeding, should not be construed as a waiver of that enforcement authority.

Lastly, this case is decidedly not about whether suspension of a pesticide product would cause market disruption or whether a registrant's investment in that product shield it from suspension. Both the statutory authority and OPP's long-standing policy provides that registrants generally should not be allowed to sell or distribute product during the course of the suspension.

Consideration of such economic factors is beyond the narrow statutory scope of this hearing. While OPP understands that users benefit from the use of DCPA, this court is already -- has already noted that the surest way to mitigate any harm from suspension would be

for AMVAC to comply with the DCI. Thank you.

JUDGE BIRO: Thank you, Mr. Pittman. Mr. Weinberg?

MR. WEINBERG: Thank you, Your Honor.

First of all, thank you. We very much appreciate you allowing opening statements this morning. This is an unusual and very important case. Indeed, we believe it's the first DCI suspension hearing that ever has been held.

Certainly, to the best of our knowledge, it is the first that involves a company that has been deeply engaged with the EPA and has been spending millions of dollars on studies to support its product registration.

I may also say preliminarily, in light of your prior comments about health that I can assure you I do not have COVID.

I did have exposure to some very young children in the last week and I'm paying the price for that.

The AMVAC witnesses from whom you will be hearing over the next couple of days continue to work with EPA on an ongoing basis, and that's important. They do so not only on DCPA, the product that's at issue in this case, but in connection with many other active ingredients in products, and they value those relationships with the professionals at EPA.

Until they received a notice of intent to suspend that initiated this proceeding last April, they didn't think they had any reason -- that the EPA had any reason to question their commitment to working with the agency and in any event, as their testimony will indicate, they continue to hope to be able to work with the agency. But there are a few things that we wanted to touch on as this hearing begins because we wanted to provide context in particular for considering the cross-examination and responses that EPA witnesses will be giving to our cross-examination when we begin to get that opportunity.

So, over the next -- over the next few minutes during this opening statement, I hope to put the dispute as it has evolved into the context that we believe is relevant to what we for simplicity's sake will call the "appropriate steps" analysis. AMVAC's substantial efforts to address these studies since the DCI was indicated, was issued, is very, very important in our view.

First some background about why we are down to addressing only 20 of the studies initially noticed when the DCI was initiated.

Those studies, those nine studies, include only one that uses as a test substance DCPA that is the active

ingredient in the AMVAC products. The others all involve a degradate of DCPA known as TPA, and I'll say a little bit more about TPA in a minute.

Initially, though, I want to say that there's various ways to quantify the amounts of studies, and you may already have a question about how many studies are issued here versus how many guidelines, or some different numbers that have been tossed around in various briefs. Do we have the opportunity to put up that chart? (Referring to McMahon Ex. B).

Your Honor, I assume you can see these in front of me?

JUDGE BIRO: Well, right now I'm seeing --

MR. WEINBERG: Right. The DCI identified a number of study components using what EPA refers to as its guidelines. Those are detailed, numbered definitions of the studies, or as "special studies" where they were not typical studies for which guidelines had been established. And, as the chart shows, in total there were 74 studies required in the original data call-in.

They fit into different guidelines and that's the reason for some of the confusion on this that we have talked about.

After it received the DCI, AMVAC promptly began to work on those 20 studies -- pardon me, began work and

ultimately satisfied EPA with regard to 11 of the 20 studies that were the focus of the DCI and so there are a substantial number of study requirements as it shows in blue that now aren't even at issue in this case.

This company spent a lot of time and effort submitting those, and of course EPA has now made clear that they are not suggesting that AMVAC didn't take appropriate steps as to any but the nine studies that are still in the case.

Over time EPA had responded very slowly to some of the requests for waivers for studies, which are authorized, and we'll talk about in the hearing, as we will show, that are related to those nine. In fact, at the same time that EPA issued the notice of intent to suspend last year, it provided long overdue information on the issues associated with eight of those nine studies, which were the first responses that the company had had to their requests regarding those studies and for the reasons that they had for not doing the studies.

When AMVAC received the information from EPA a year or so ago, not quite a full year ago, but last April, it immediately took steps to deal with the 20 studies that were then considered still outstanding, to either initiate the missing studies or provide additional data to EPA or to remove the need for some of the studies

by changing the label on the product.

If you change the label, you take off certain uses. The elimination of those uses means that the EPA doesn't have to evaluate the impact of those uses. So that takes away certain of the studies if you do the label changes. And that's why we are down to nine studies now, because a lot of them were finished up.

So, as a result of all of this, the question in front of you today is whether EPA can lawfully suspend the registration of DCPA products, notwithstanding the significant impacts on the company and on American farmers. And our testimony that you will be hearing, some of which you have seen already, and in cross-examination of which you will be hearing, explains that.

It's very important to keep in mind that in the EAB ruling in this case earlier, the EAB instructed that AMVAC's waiver request and the responses thereto may be relevant as to whether AMVAC took appropriate steps to produce the data required. And that's why the testimony of Dr. McMahon, Dr. Freedlander, Mr. Gur, will indicate the most fundamental reasons for these nine studies still being at issue was principally EPA's often years long delays in responding to AMVAC's waiver requests and its scientific discussions between AMVAC and governmental scientists with regard to the need for those studies.

And, in addition, a second related reason is that EPA just didn't communicate with AMVAC or suggest any of the positions that they're taking in this case, such as the idea that a registrant gets only one chance to ask for a waiver and if that's denied that's the end of the game.

Now, interestingly, during the pendency of the preceding years, EPA personnel, scientific personnel have been quite open to talking with the company's scientific personnel. Talking may be the wrong word. Communicating. These days so much communication is by email rather than talk. I have to be more careful.

But, for example, for five of the nine studies still at issue, EFED, the Environmental Fate Division of the EPA had suggested to AMVAC's people that they follow a particular limited test approach to avoid having to do all of those studies. And, AMVAC did that and submitted the data from that effort to EPA in August 2020. Submitted the data in August, a report on what that data said in December 2020. But EPA only informed AMVAC essentially simultaneously with the publication of the notice of intent to suspend that, based on the work that had been done, it believed further tests had to be done.

This alternative approach EPA suggested did not fulfill the requirement. So AMVAC immediately turned and initiated those studies which it had hoped to be able to

demonstrate were not necessary, but respected EPA's views, obviously, and had to do the studies. They started them right after EPA responded to the information AMVAC had provided 18 months or so before EPA responded to them.

EPA makes a good deal out of the fact that AMVAC several times asked EPA to reconsider positions with regard to waivers. Mr. Gur, our expert witness, will explain that serious agency attention to further justifications for waivers is typical of the registration review program, and is good scientific and regulatory practice.

And AMVAC never was told by EPA not to continue this effort. EPA could have simply said, look, we're not going to consider any further argument, whether you're right or wrong. We're not convinced, so do the studies. In fact, EPA came back and responded to the inquiries that Dr. Freedlander and others will testify about.

But in fact the appropriateness of the steps that AMVAC was taking in dealing with this, and trying to convince EPA of the fact that some studies were not needed to obtain a waiver, is evidenced by the fact that the AMVAC scientists convinced the agency scientists to recommend granting several waivers.

And some of those were even at issue

concurrently with the issue -- with the issuance of the notice of intent to suspend.

There are a number of other arguments that have been advanced by EPA in its pretrial briefs which are unprecedented suggestions that the registrant should only get one opportunity to seek a waiver; these are inconsistent with guidance documents that EPA has published and made available in this case in discovery as well as more publicly.

There is no basis for that argument and several of EPA's others based on history or what EPA has previously told registrants in its regulations and its guidance documents.

Well, the other thing I want to be sure that I can get to this morning, I know we've got limited time -- is just very briefly to mention the TPA studies.

As I said, eight of the nine studies still outstanding used as the test substance the degradate of DCPA. The degradate is called TPA. That is what it changes to in the environment. The testimony from Dr. Freedlander explains that there is good reason to believe that those studies would not be necessary, based on what was known prior to initiating the studies about the issues associated with TPA, DCPA and how no issues associated with the fact that DCPA was not more toxic and

was no more persistent than DCPA. And, as we will explain in testimony and also address in some of the cross-examination, it was important that EPA stated to AMVAC, as it has said repeatedly to other companies, that if data is not produced we will have to go forward with our risk assessments, but we'll make the most conservative possible assumption -- meaning we'll have to assume there is no reduction in the amount of TPA in the environment, that it is toxic -- and the AMVAC scientists were sufficiently confident that doing that would not result in excessive limitations on the products.

So, they relied on the fact that EPA had said, you don't have to do these studies. We'll just make these assumptions. The EPA then said, with regard to the Notice, they would disagree with that and they were going to require these studies notwithstanding everything they previously had said about making conservative assumptions. And, in fact, the Notice -- the documentation with the Notice -- was the first time, compared to many previous times, that EPA had said we can't do this risk analysis without this data. Every previous time they had said we can make assumptions and the assumptions will allow us to do the risk analysis we need to do for our registration review.

Now there are a number of other things that are

going to be addressed in the course of the hearing and the cross-examination, but we obviously have a limited amount of time here this morning, so I just at this point want to express our appreciation for the opportunity to do this introductory statement and look forward to addressing in the cross-examination of the EPA witnesses a number of these issues, as well as presenting our witnesses for cross-examination. Thank you, Your Honor.

JUDGE BIRO: Thank you, Mr. Weinberg. Ms. Rose, would you like to make an opening statement now or would you like to reserve your opportunity to do it at the beginning of your case?

MS. ROSE: I think in light of the potential technical issues and the court reporter having difficulty hearing me, I might defer and work these issues out during a morning break because I'm also getting a fair amount of echo and feedback when I speak, and I reserve my opening for later when we have technical issues resolved.

JUDGE BIRO: Well, that's very generous, but I think we've worked out the technical issues. You're actually coming through quite well now. If that changes your mind at all, or we can --

MS. ROSE: I can go ahead and deliver the opening now. Good morning, Your Honor, once again thank

you for allowing me to appear remotely. I represent the Growers Association of Central California, J&D Produce, Ratto Brothers and Huntington Farms. The Grower's Association is a regional trade association founded in 1930 based in California Salinas Valley.

It has approximately 300 members who are farmers, shippers and processors and vegetable producers in Monterey, Santa Cruz and San Benito and San -- counties. Because implementing effective disease effects management strategies is a continual challenge for farmers the Grower-Shipper Association works collaboratively with local farm advisors and experts, universities and its members on crop protection issues. These issues are critical not only to farmers but also the farmer's ability to provide affordable and healthy produce to American consumers.

My remaining clients J&D Produce, Ratto Brothers and Huntington Farms are family-owned businesses which operate farms in Texas and California. These family farms grow a variety of fruits and vegetables including onions, ground rooted vegetables and other specialty crops. For the Grower-Shipper Association and the family farms I represent, DCPA is critical.

DCPA is a critical, indeed in some places irreplaceable foundational tool for weed control.

Blocking of access for DCPA would have significant adverse impact on the crops that rely on it for weed control as well as the impact on cropping systems. In particular, DCPA is vital in production for certain crops for which there are no viable, practical or economical alternatives for weed control.

As permitted by the notice of intent of this hearing, the growers have objected and requested this hearing so they can demonstrate that the administrator's determination regarding existing stocks of DCPA is not reasonable, rational or consultative.

This demonstration will be based on fact testimony provided by Christopher Valadez and expert testimony provided by two university professors, Richard Smith and Stephen Fennimore. Mr. Valadez is president of the Grower-Shipper Association. Mr. Smith and Dr. Fennimore are experts in weed science and related strategy for weed management in vegetable crops as well as the availability and efficacy or lack thereof of alternative tools and means to control weeds in crops for which DCPA is used.

Consideration of the information provided in the testimony of Mr. Valadez and Mr. Smith and Dr. Fennimore is essential to the analysis of whether the existing stocks provision of the suspension is

reasonable, rational and consistent with that thought. Among other things, the testimony will demonstrate that the loss of DCPA as a critical crop protection tool would result from a unique market structure in supply and distribution of DCPA, an issue which is addressed in the testimony of petitioner AMVAC witnesses.

Growers submit that an existing stocks provision that fails to account for distinctive market situations of DCPA as well has the Administrator's failure to consider the benefits of the product in conjunction with the Administrator's associated risk in seeking to justify the provision is not consistent with that part. Thank you.

JUDGE BIRO: Thank you, Ms. Rose. I think we talked about introducing exhibits. Can we proceed to that or do you want to take a break? We're good? Okay. Let's go.

MR. PITTMAN: Thank you, Your Honor. I have a list that Mr. Ross provided, if I get the numbers wrong here. Pursuant to stipulations I would -- I guess I'll move these in in chunks, if that's the easiest way to do it, so I would move that joint exhibits 1 through 48 and 50 through 92 to be admitted to the record.

MR. WEINBERG: No objection.

JUDGE BIRO: Okay. Joint Exhibits one through

48 and 50 through 92 are admitted into the record.

(Joint Exhibit 1 through 48 and 50 to 92 are admitted)

MR. PITTMAN: I would next move that Respondent's exhibits one through 12, 17 to 18 and 24 be admitted to the record for stipulation.

JUDGE BIRO: Is there any objection.

MR. ROSS: No objection.

JUDGE BIRO: Okay.

MS. ROSE: No objection.

JUDGE BIRO: Sorry, Ms. Rose. I'm so sorry. Please feel free to speak up any time I forget to include you because you're not physically here and I really apologize. Respondent's exhibits one through 12, 17 to 18 and 24 are admitted into the record without objection.

(Respondent Exhibits 1 to 12, 17 to 18 and 24 are admitted)

MR. PITTMAN: So next would be AMVAC and I move that AMVAC exhibits 1 through 43, 45, 47, 49, 51, 78 through 82, 89, 91 and 92 be admitted per stipulation.

JUDGE BIRO: I assume there is no objection to that?

MR. ROSS: No objection, Your Honor.

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

MS. ROSE: No objections.

JUDGE BIRO: Okay. So, Petitioner's Exhibits one through 43 -- these are Petition AMVAC exhibits one through 43, 45, 47, 49, 51, 78 through 82, 89, 91 and 92 are admitted into the record.

(Petition AMVAC Exhibits 1 through 43, 45, 47, 49, 51, 78 through 82 and 91 and 92 are admitted)

MR. PITTMAN: So, the next chunk I would move that AMVAC Exhibits 57, 63 through 77 and 84 be admitted to the record. OPP at this point would like to preserve its right to object to their use on cross-examination, but we're generally stipulating to their admissibility.

JUDGE BIRO: Okay. I assume there's no objections. How about Ms. Rose? Do you have any objection?

MS. ROSE: No objection.

JUDGE BIRO: Okay. AMVAC additional exhibits -- these are Petitioner AMVAC 57, 63 through 77 and 84 are admitted into the record.

(Petition AMVAC Exhibits 57, 63 through 77 and 84 are admitted)

MR. PITTMAN: And then one final matter for me is while we don't have a written stipulation to provide at this point, the parties do have an agreement in principle with respect to expert witness qualifications.

I think given the order in which they will be called we should be able to provide a written stipulation to Your Honor before that time would come.

JUDGE BIRO: Okay. If it's not in writing, we'll just put it on the record.

MR. PITTMAN: Okay.

JUDGE BIRO: Great. Are there any additional exhibits you would like to move into the evidence?

MR. ROSS: The parties had discussed, Your Honor, that reference might be made to any of the documents in the regulations.gov docket for the dacthal registration review. Those, to the extent they've not been identified already as a JX or PAX exhibit, many of them have, to the extent they've not already been identified, they would likely to be referred to by their regulations.gov document tracking ID, so certainly we could either move the entire docket into the record and provide those documents or if you would prefer to take notice of the docket, if you will, such that those documents could be referenced in briefing or in cross.

MR. PITTMAN: No objection to any of those, Judge.

JUDGE BIRO: Okay. Ms. Rose, do you have any opinion on that?

MS. ROSE: No. No, Your Honor.

JUDGE BIRO: Okay. So, I think it would be probably easier to just take an official notice and not have to move a whole bunch of documents into the record, assuming that we can all have access to that and if you would just identify them by document number, we'll get access to them.

MR. ROSS: And as far as a preliminary matter, it may be that there is an additional document or two that we can reach the same stipulation that Mr. Pittman just referenced, but I would propose that any further documents we can handle at the opening of AMVAC's case as to those records.

JUDGE BIRO: Okay. Thank you, Mr. Ross. Ms. Rose, do you have any exhibits you would like to move into the evidence now?

MS. ROSE: We have five exhibits. I understand that the agency has relevance objections to the documents but -- and correct me if I'm wrong, does not object to the authenticity of the document so I'm not sure if we need to reserve that until the witnesses appear later.

JUDGE BIRO: Are you continuing without objection?

MR. PITTMAN: That is correct, yes. We --

JUDGE BIRO: Okay. So, we'll you wait until you present them later on. Okay. I have looked over

every document you have offered in this record, every pleading, every exhibit, literally everything over the past two weeks.

Does that mean I remember every detail, no, I don't, but I have a good understanding of all of them. So if we could just identify them in some, you know, common way that we have been in all of our pleadings, that would be really helpful.

Are there any witnesses in the room that you intend to call that would be subject to the sequester order? No?

Okay. Well, then let's proceed. Unless do you want to take a break now, gentlemen.

MR. PITTMAN: It might be a few minutes; both of the OPP in person witnesses are sequestered here in their respective offices here at EPA East, but they will walk down the hall for an elevator ride.

JUDGE BIRO: Okay. So why don't we take a 10 minute break. I'm not exactly sure what time it is now. 9:44. So we could come back at 10. Okay. We will stand in recess until 10 o'clock. Thank you.

(Off the record)

JUDGE BIRO: Please be seated. Hopefully we're all back tech wise. Okay. Mr. Pittman, would you like to call your first witness?

MR. PITTMAN: Your Honor, if I could call Christina Wendel. Ms. Wendel, would you please take a seat right there and remain -- well, actually remain standing so the court reporter can swear you in.

(Whereupon,

CHRISTINA WENDEL,

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

JUDGE BIRO: Please be seated. Are you ready to proceed? Okay. Go ahead.

DIRECT EXAMINATION

BY MR. PITTMAN:

Q. Good morning, Ms. Wendel. Would you please state your name and current title for the record?

A. Christina Wendel, biologist.

Q. So, I'm going to be showing you what has been marked as the witness statement of Christina Wendel. Do you recognize this document?

A. Yes.

Q. How do you recognize it?

A. I was the author of the document.

Q. So, what is it?

A. Oh, sorry.

Q. What is the document?

A. The document is my witness statement.

Q. Is it a true and accurate copy?

A. That's correct, yes.

Q. I move that the written statement of Christina Wendel be admitted into the record. I'm sorry. I just moved that the witness statement of Christina Wendel be admitted into the record.

JUDGE BIRO: Okay. Is there any objection to Ms. Wendel's statement dated June 17, 2022?

MR. ROSS: No, Your Honor.

JUDGE BIRO: Thank you. Ms. Rose, do you have any --

MS. ROSE: No, Your Honor.

JUDGE BIRO: Thank you. Okay. We'll admit Ms. Wendel's statement. What exhibit number would you like me to --

MR. PITTMAN: I suppose this would become RX-25, if we're going to designate it such.

JUDGE BIRO: Respondent Exhibit 25 did you say?

MR. PITTMAN: 25. Yes.

JUDGE BIRO: Okay. Respondent Exhibit 25 is admitted into the record.

(Respondent Exhibit 25 is admitted)

JUDGE BIRO: Please proceed.

MS. ROSE: Thank you.

JUDGE BIRO: Okay. Mr. Hume, right? Please proceed?

MR. ROSS: Yes, Your Honor. Thank you. A moment to bring my --

JUDGE BIRO: Mr. Ross. I'm sorry.

MR. ROSS: May I proceed?

CROSS EXAMINATION

BY MR. ROSS:

Q. Good morning, Ms. Wendel. My name is Hume Ross. I'm an attorney with Wiley Rein representing AMVAC Chemical Corporation and I will be asking you a few questions concerning the verified written witness statement that was just offered into evidence.

First, a few introductory questions just concerning the scope of your testimony, your written testimony. Are you aware that this proceeding is examining AMVAC's compliance or noncompliance with a particular statutory standard?

A. Yes.

Q. The testimony, the written testimony that you provided, does that testimony provide any opinion, your opinion as to the meaning of, or AMVAC's compliance with, that statutory standard?

A. To the best of my knowledge, yes.

Q. So, within your witness statement, you reach a

conclusion as to whether or not AMVAC took appropriate steps under 7 U.S.C. 136a?

A. I'm sorry. Could you repeat the question?

Q. Certainly. The testimony that you were offering in your written witness statement is factual in nature, correct?

A. That is correct, yes.

Q. So, you were not testifying as to whether any particular legal standard has or has not been satisfied, correct?

A. That is correct. Yes.

Q. And you are not personally testifying as to whether any particular action or inaction of AMVAC was part of OPP's reasoning for issuing a notice of intent to suspend or its basis for issuing a notice of intent to suspend, are you?

A. That's correct, no.

Q. Do you have a copy of your written statement available to you? I may refer to it. I will try to do so by page number throughout the examination.

On page one of your statement, you indicate that it is based on your personal knowledge and the records of respondent. Can you elaborate on what records you consulted, if any, beyond the documents that you referred to in the statement?

A. The documents that are referred to in the statement are what I referenced and utilized to formulate this document.

Q. On the second page of your statement you discuss the responsibilities of the Environmental Fate and Effects Division within the Office of Pesticide Programs; isn't that correct?

A. That's correct, yes.

Q. And a specific task that you refer to is EFED's obligation to develop risk assessments, correct?

A. That's correct.

Q. There is another division within OPP, the Pesticide Re-evaluation Division or PRD, which is the division that primarily interacts with pesticide registrants like AMVAC, correct?

A. Correct.

Q. And PRD is also the division that would use a risk assessment developed by EFED in the registration review process, correct?

A. Correct.

Q. Throughout your statement you discuss various documents that were exchanged between the Office of Pesticide Programs and AMVAC during the course of the response to this DCI, correct?

A. Correct.

Q. Can you describe the process of how a document provided by a registrant, let's say a waiver request, is ultimately sent to the Environmental Fate and Effects Division for review?

A. Through the PRD pesticide division, we receive a BEAN or a means to instruct us that we have something that requires an action on our part and that is how the effects division would receive the information, whether it's for instance a waiver request of how to -- or what we need to complete.

Q. So, it would not be ordinary for a registrant to transmit a document directly to EFED, bypassing PRD, correct?

A. That's correct. It goes through the registration, PRD, or the registration divisions before it would come to us.

Q. And so, the purpose of PRD forwarding a particular document that PRD has received from a registrant to EFED is so that EFED can apply its scientific judgment to that document and render some sort of conclusion as to it, correct?

A. Correct. We provide our feedback back to PRD.

Q. And as you stated, under I think it was the BEAN process or the BEAN?

A. BEAN, b-e-a-n. It's a term that we use.

Q. Under the BEAN process, the purpose of PRD sending a document is because it requires action by EFED, correct?

A. That's correct.

Q. And so, if PRD were to receive a document that either did not require scientific review or -- well, if EFED or PRD determined that that document did not require scientific review, there's no obligation that PRD send that document to EFED?

A. I'm not privy to all of PRD's actions so I couldn't justify all of the rationale that they utilize when sending documents to the other scientific divisions.

Q. But it's your understanding that PRD has the option of whether to BEAN a particular document to EFED for action or not?

A. As far as I'm aware, but there could be other items that I'm not privy to. I'm just a scientist in the science division.

Q. To confirm your response, as far as you're aware, there could be documents that PRD would elect not to forward to EFED because no action was required on them, correct?

A. Possibly, yes.

Q. Does PRD provide any sort of timeframe when it BEANS a document to EFED? Is there a timeframe that EFED

is requested or required to provide a response within?

A. Sometimes. And sometimes it's renegotiated.

Q. So, to explore that for a moment, a document would come from PRD and PRD would say, we would like EFED's scientific opinion of this document within a certain timeframe, correct?

A. Correct.

Q. And there might be a response from EFED indicating that that was achievable or that EFED would prefer to have more time?

A. That's correct, from my understanding.

Q. Are there default time frames for review of various types of documents?

A. I don't know that information.

Q. In your employment with EFED, for how long have you been in a position where you would have been receiving these requests for scientific review from PRD?

A. They're part of the process in general. They are filtered through other players in EFED before they would get to the scientists, management or branch chief but since probably since I began, I became aware of this process on how actions are completed and transmitted between the divisions.

Q. So, you would understand the general timeframes for certain types of documents, for instance a waiver

request, and scientific study, correct?

A. Correct.

Q. And can you tell me approximately how long does PRD typically request that EFED respond with its recommendation concerning a waiver request?

A. I've had different experiences, but sometimes six months, a year. I couldn't hone in on the exact number.

Q. And what about for a review of a scientific study that is submitted?

A. I don't know if they provide specific dates unless there's an action, but for the most part I couldn't tell you a timeframe if there was one provided.

Q. You mentioned a waiver request that might be six months or a year in terms of the requested response date. Is there a similar ordinary timeframe of the request for a scientific study?

A. I couldn't tell you. I don't know.

Q. Are some studies provided and it's open ended? There is no --

A. It's my understanding.

Q. -- date indicated? Your written testimony discusses 12 different data requirements or studies, correct?

A. Correct.

Q. And they are enumerated in your statement beginning on page three and concluding on page 9, correct?

A. Correct.

Q. And under the nomenclature that you have used, the enumeration, if a particular OCSPP guideline is required to be performed on both the active ingredient and the degradate, that would be two separate studies or requirements under your nomenclature, correct?

A. Yes.

Q. And likewise, if a single guideline study was to be required on multiple species of test animal, that would be listed in your statement as three distinct requirements, correct?

A. That's correct.

Q. And is that in part because in fact multiple studies would need to be conducted potentially or a waiver request submitted to satisfy that guideline?

A. That's correct.

Q. Are you aware that OPP is no longer alleging that AMVAC failed to take appropriate steps in connection with half, that is six of the 12 data requirements that you discussed in your verified witness statement?

A. Yes.

Q. And when did you become aware of that?

A. Less than a month ago.

Q. Did you consider revising your testimony in view of the fact that half of the studies that it originally discussed are no longer at issue in this matter?

A. No. I was not, no.

Q. Are you aware of the basis on which OPP is no longer alleging that AMVAC failed to take appropriate steps with the other six?

A. Not to specific details, no.

Q. You said not to specific details.

A. Not to detail. I was told -- I was informed that those were no longer being incorporated into the hearing.

Q. To your knowledge, was anyone in EFED consulted about the decision to retract the allegation that AMVAC had failed to take appropriate steps with respect to six of the 12 data requirements still at issue?

A. I don't have any information about that.

Q. Ms. Wendel, you are the signatory of a waiver response that was issued to AMVAC around the time that the notice of intent to suspend, correct?

A. That's correct.

Q. Which was the most recent, formal communication that you were aware of from EFED concerning the TPA

ecotox studies, correct?

A. Correct.

Q. And do you remain involved in the risk assessment development for DCPA?

A. I remain assigned to the chemical.

Q. So, if PRD had consulted EFED concerning PRD's decision to retract its allegation, would you expect that you would have been consulted about that decision?

A. I don't know. Sometimes -- no, I don't know.

Q. But to confirm, you're not aware. Neither you nor anyone that you are aware of was -- that EFED was consulted about that decision, correct?

A. I don't know either way.

Q. For purposes of the record and just our discussion for the rest of this cross examination I would just like to quickly run through the enumeration in your statement so that we can identify the data requirements which remain at issue. If I have this correct, they are number two, that is the 850.1350 TPA mysid study. That is the study that remains at issue, correct?

A. Correct.

Q. The guideline 850.1400 fish early life stage studies for TPA which are enumerated as data requirements five, six and seven in your testimony?

A. Correct.

Q. The guideline 850.4500 algal toxicity test for TPA enumerated as number 10 in your testimony?

A. That's correct.

Q. And finally, the non-guideline for special study chronic sediment toxicity for estuarine/marine species Leptocheirus number 12, correct?

A. Correct.

Q. To your knowledge, have any studies or other clarifying information that were received from AMVAC after the date of the NOITS, have they been BEAN'd to EFED at any point since the NOITS?

A. Yes. The fish -- or the ELS studies for DCPA.

Q. To your knowledge, has any other studies or clarifying information been BEAN'd to EFED from PRD?

A. Response to comments for the mysid study.

Q. And what is the status of EFED's review of this material?

A. They have been completed.

Q. Does EFED's review of any of this material impact EFED's view about the necessity of any particular data in connection with the six remaining studies at issue in this matter?

A. It confirms the need for them or doesn't remove them but they stay as a data need.

Q. Has EFED taken any steps to communicate this

conclusion to PRD?

A. Yes. We informed them.

Q. To your knowledge, has PRD informed AMVAC of this?

A. I have no knowledge of that.

Q. Of the remaining six studies, all but the last, that is the one enumerated 12, relate to a degradate of DCPA known -- a degradate of DCPA known as TPA, correct?

A. Correct.

Q. It's possible I may refer to these five collectively as the TPA ecotox data requirements. Is that a broadly accurate term in your view?

A. Probably, yes.

Q. And the remaining one, number 12, relates to a chronic study of the effects of DCPA on a particular marine amphipod, the leptocheirus, correct?

A. Correct.

Q. I may refer to this as the leptocheirus data requirement. As between DCPA and TPA, EFED has observed on several occasions that the available data showed TPA is no more toxic than DCPA, correct?

A. Correct.

Q. And that in many cases it is less or substantially less toxic for certain categories of test species, correct?

A. Correct.

Q. And so long as it could reasonably be assumed that TPA is no more toxic than DCPA, a conservative risk assessment could be performed by assuming that the toxicity of TPA was equal to the toxicity of DCPA, correct?

A. It's a possibility. There are limitations to it, but it is possible.

Q. It would produce, if anything, a conservative risk assessment, correct?

A. Correct. And it cannot be refined.

Q. And when you say it cannot be refined, would it be correct to say that you are saying there is a degree of uncertainty inherent in making these conservative assumptions that without additional data could not be reduced, correct?

A. Correct.

Q. But to the extent there is uncertainty, it is only a question of how conservative the risk assessment would be, correct?

A. Correct.

Q. At several points in your testimony, and I'm speaking now about the five TPA ecotox studies, you referred to waiver requests submitted by AMVAC in 2013, 2014 and 2020. Examples of this, if you would like to

take a brief review, are on page three of your testimony near the bottom. There is a parenthetical first at 2013, 2014, 2020, and at the top of page six, the same reference; isn't that, right?

A. Correct.

Q. Your testimony however does not specify what those individual communications were, at least not in every instance that they're referred to, correct?

A. Correct.

Q. Do you recall the nature of the 2013 document that you referred to?

A. Those were a response of the DCI in relation to the regular review process. Those were a submission of the data waivers for the studies that were requested as part of the DCI.

Q. Mr. Sayres, could you bring up Joint Exhibit 5, please? If we could have control of the -- there we go. Ms. Wendel, is the document in front of you on the screen a copy of the document that you understand to be the 2013 document that's referred to in your testimony?

A. Yes, to my understanding.

Q. And this was AMVAC's initial request for waivers of several data requirements, correct?

A. To my knowledge, yes.

Q. And this was made in AMVAC's so-called 90 day

response to the DCI, correct?

A. Correct.

Q. Do you recall generally the 2014 document that you referred to in your testimony?

A. Vaguely, yes.

Q. Can you describe the nature of that document?

A. I believe it's a follow-up to this laying out additional responses to data waiver requests.

Q. In the document that you are thinking of, AMVAC was responding to a review from EFED, correct?

A. I don't know the submission, the rationale for the submission.

Q. Mr. Sayres, could you bring up Joint Exhibit 67, please? And Ms. Wendel, if you would like to -- when one of these documents is shown, if you would like to see a different portion of it, just let us know and we can scroll around. But the document apparently up on the screen states that it is a waiver request in support of the dacthal registration review provided in response to the agency's memorandum dated March 21, 2014, received March 17 of 2017, correct?

A. Correct. That's what it states.

Q. Is it possible that this is the document that you referred to several times in your testimony as the 2014 document?

A. It's either that or the final -- I believe it's the final date of -- our response from 2014.

Q. So, page three of your testimony at the bottom it says AMVAC submitted multiple data waivers for this data over the years and the parenthetical is 2013, 2014 and 2020, correct?

A. That's correct.

Q. This document we're looking at on the screen, which is dated in 2018, is not in that list, correct?

A. Correct.

Q. As you sit here, do you recall another document prior to this one that you've reviewed from AMVAC earlier in time than 2018?

A. Only the leptocheirus responses from 2016.

Q. But with respect to the five TPA ecotox documents, waiver requests, rather, you don't recall a 2014 waiver request?

A. Just our response.

Q. So, the 2014 in your parenthetical could be read as a reference to EFED's response to the initial waiver requests, correct?

A. Correct.

Q. And that document, you understand that to be based on the document there we're now looking at on the screen, what is referred to in the second highlighted

section as, quote, the agency's memorandum dated March 21, 2014?

A. Correct. Correct, yes.

Q. And this document continues, "received on March 17 of 2017." As you sit here today, are you aware that EFED's March 21, 2014, response was not provided to AMVAC until March 2017?

A. I don't know why, but it states it there.

Q. As you stated earlier, once EFED provides a document to PRD, EFED may not be aware of the subsequent history of that document where it's sent, correct?

A. Correct.

Q. Do you recall approximately when EFED's memorandum dated March 21, 2014, was provided to PRD from EFED?

A. The transmission date is March 21, 2014, around then is when it was logged out or sent to PRD. It's my understanding.

Q. If you could elaborate on that. You say logged out. Do you recall -- could you expand on that concept of being logged out?

A. When a document is finalized, the science division EFED provides our signatures of everybody that reviewed it and then it is logged out according to the DP barcode which we get from the BEAN and it's transmitted

to the division that opened the BEAN, whether PRD or RD and so -- and then it's also sent to our tracking team for placement in folders for reference and documentation.

Q. And the fact that a particular document had been logged out, someone from PRD received a notification that -- such as we might understand like an email -- or would they have to log into some sort of system?

A. Currently it's an email. We CC them on our logout emails, but back in 2014 it could have been a paper copy where we would sign and then it was left in a drawer and they come and pick up the documents that are logged out. So, it's a different process now with electronic signatures.

Q. Gotcha. When approximately would that procedure change?

A. I don't know the exact date of when it changed just solely on electronic signatures.

Q. Do you recall approximately the last time that you left an EFED paper copy in a drawer somewhere?

A. It's been a number of years.

Q. Was it near the beginning of this DCI?

A. No. It was after 2014, but I believe before 2016, but I'm not 100 percent sure on the dates for the transition.

Q. Mr. Sayres, if we could turn back to Joint

Exhibit 5, please. Ms. Wendel, this is what we have been referring to as the initial waiver request from 2013.

A. Okay.

Q. And talking now about the five TPA ecotox studies from your statement as we enumerated them earlier, this document requested that EPA waive each of those five data requirements, correct?

A. Correct.

Q. And Mr. Sayres, if you could bring up Joint Exhibit 66, please? Do you recognize this document, Ms. Wendel?

A. Yes.

Q. This is the March 21, 2014, memorandum that as we were just discussing AMVAC received in 2017, correct?

A. Correct.

Q. And this document contains EFED's scientific response as to all five of the TPA ecotox studies remaining at issue in the matter, correct?

A. Correct.

Q. And specifically, if we can look on page seven of nine? And if we could zoom in on the opening paragraph. This is a section of the report that discusses all five of those, correct?

A. Correct.

Q. And if we look at the -- if you can scroll up,

Mr. Sayres, that is apparent based on the fact that if we were to make everyone suffer through going into that list and reading through it, we would find all five of the guidelines, the OCSPP guidelines that we've been discussing, correct?

A. Correct.

Q. Mr. Sayres, if you could scroll down slightly to the bolded section and highlight the portion, the entirety of the paragraph, "EFED recommends" and then continuing on through the end of the paragraph.

So, this, what we're looking at is EFED's response in the 2014 memo received in 2017 concerning all five of the remaining ecotox data requirements, correct?

A. Correct.

Q. And just to read it into the record here it says, EFED recommends that PRD denies request to defer the data collection of TPA until DCPA studies are completed, with the intention of using DCPA toxicity data in lieu of TPA toxicity data. Toxicity data is needed for TPA.

Therefore, one possible solution is conducting a limited set of toxicity tests initially for TPA. For example, an acute and chronic toxicity study in daphnids and depending on the results of these initial studies, a full suite of studies may or not be subsequently

required, correct?

A. Correct.

Q. So as an initial matter, this document constitutes an EFED recommendation to PRD, correct?

A. Correct.

Q. It would be PRD, which would then determine whether or not to formally grant or deny the registrant's waiver request, correct?

A. Correct. That's my understanding. Yes.

Q. Are you aware of a PRD document in which PRD does grant or deny these waivers on the basis of EFED's recommendation as set forth in this document?

A. I'm not aware of one. I may not be aware of one, if there was one. We're not privy to the final decision.

Q. In your experience, does PRD sometimes issue formal documents in which it accepts or declines EFED's recommendation to grant or deny a waiver request?

A. I don't have any knowledge, or to provide either way. I'm not privy to PRD's practices.

Q. So, in your employment at the agency, you have not seen a formal document in which PRD grants or denies in reference to an EFED recommendation?

A. No, I have not seen any one.

Q. So, returning to the substance of EFED's

recommendation as set forth in this document, let's focus for simplicity on one of the remaining five data requirements, even though as we discussed, it applies equally to all of them, correct?

A. Correct.

Q. Let's just follow through the guideline 850.1350, chronic mysid. Mr. Sayres, could you put up Joint Exhibit 67, please? Ms. Wendel, are you familiar with this document?

A. I have seen it, yes.

Q. Do you recall approximately when you would have first reviewed this document?

A. I don't recall seeing it until at least 2020.

Q. And when you recall seeing it in approximately 2020, was that as a result of the PRD BEAN procedure that we discussed previously?

A. Yes.

Q. Mr. Sayres, could you go to page nine of this document, please? Again, this document which is dated 2018, which you believe you first reviewed in 2020, what we're looking at here on the screen, just page nine of Joint Exhibit 67, this is AMVAC's response to EFED's 2014 memorandum, correct?

A. Correct.

Q. And would it be fair to summarize this as AMVAC

agreeing with or accepting the acute and chronic toxicity study and daphnid approach that EFED had suggested in Joint Exhibit 66?

A. You can interpret that, yes.

Q. Is there an alternate interpretation of this document?

A. Just whether additional testing is warranted or not. Just doing the chronic studies, the acute and chronic studies for the daphnid may or may not result in additional data being needed.

Q. Correct. But insofar as the next step that EFED was recommending could be a solution as to this data requirement and to all five of the TPA ecotoxicology requirements still at issue, EFED's proposal, or "solution" was to conduct the acute and chronic TPA daphnid study and, as you say, depending on the results of those studies, a full suite, as it says here, may or may not be subsequently required, correct?

A. Correct. It was a suggestion to use as an example daphnid, acute and chronic. It could have been other species, acute and chronic. Not necessarily only daphnid. It was a suggested proposal to use daphnid. It wasn't the only opinion that could have been completed.

Q. So AMVAC conceivably could have come back and said we want to test acute and chronic for a different

invertebrate?

A. Correct. Mysid or --

Q. And sought EFED or PRD's acceptance of that approach, but what it did here was it accepted the specific suggestion to conduct an acute and chronic toxicity study in daphnids, correct?

A. Correct.

Q. And in fact did submit acute and chronic daphnid data, correct?

A. Correct.

Q. And additionally, beyond simply submitting the results of the studies that were performed, it provided a separate analytical writeup of those results putting them in context of various other TPA ecotox data for DCPA and TPA that were then available, correct?

A. Correct.

Q. Mr. Sayres, could you put petitioner AMVAC's Exhibit 45 up on the screen? Do you recognize this document, Ms. Wendel?

A. Yes.

Q. And this is AMVAC's analytical writeup of the results of both the acute and chronic daphnia data and many other data points that were then available, correct?

A. Correct.

Q. Do you recall approximately when EFED received

the BEAN to review this document?

A. I believe it was close to at the end of December or early January '21.

Q. So relatively close to the submission date?

A. To my understanding.

Q. In December 2020?

A. To my recollection.

Q. So, given that AMVAC was responding to a specific suggestion from EFED to support its original waiver request, wouldn't it be fair to characterize this document as a further justification of AMVAC's initial waiver request?

A. Yes, you could.

Q. But regardless of how it's characterized, you would agree that it provided a discussion of the data that EFED had requested, correct?

A. Correct.

Q. And the scenario that we've been discussing, we've mentioned perhaps a few times now, applied to all five of the remaining TPA ecotox studies?

A. Correct.

Q. Which are five of the nine studies remaining in this matter at issue, correct?

A. Correct.

Q. Do you recall when EFED issued a memorandum

responding to the information in this document?

A. With the NOITS in 2022. It was signed earlier that year.

Q. Mr. Sayres, could you pull up Joint Exhibit 69? Is this the next document in which EFED responds to the prior document PAX 45 that we were just looking at?

A. Yes.

Q. And as you mentioned, it is dated April 19 of 2022?

A. Yes.

Q. And your understanding is that it was provided to AMVAC on the same day that AMVAC received the NOITS, correct?

A. To my knowledge.

Q. You are aware, correct, that the NOITS was dated April 21 of 2022?

A. I don't recall the exact date, but I know it was in April.

Q. Do you recall when EFED completed its scientific analysis of the prior AMVAC document that we were looking at, PAX 45?

A. It was finalized in April '22, but we had been working on it before that.

Q. To your knowledge, was PRD waiting to issue the NOITS until it received this scientific review document

from EFED?

A. I don't know.

Q. Do you recall if PRD requested a specific return date for this analysis at any point?

A. I don't recall.

Q. Now, ultimately, this document did recommend granting several waivers following EFED's review of the daphnia data and other data, correct?

A. Correct.

Q. So those waivers were recommended to be granted, essentially concurrently with the notice of intent to suspend?

A. Correct.

Q. But with respect to the five that we've been discussing, EFED concluded that even in view of the daphnia data, it still believed that it required additional data for risk assessment, correct?

A. Correct.

Q. Was it EFED's belief that it could not conduct a risk assessment at all, or only that it would be forced to make conservative assumptions if it were to do so?

A. Very conservative. Make conservative assumptions.

Q. And so if we look back to EFED's proposal, proposed solution in Joint Exhibit 66, Mr. Sayres, page

seven, please, and if you could zoom in on the second bolded clause, the bottom of the paragraph, the middle of the page; you would agree with me, would you not, that it was not until April 19 of 2022, or perhaps several days later concurrent with the NOITS, that AMVAC learned that it was EFED's conclusion that at least a fuller suite of studies would be required in EFED's view, correct?

A. Correct.

Q. But AMVAC never had any opportunity to conduct those studies whilst not under the threat of suspension, correct?

A. No. It didn't.

Q. Mr. Sayres, if you could turn us back to Joint Exhibit 69, please? So, as we discussed in this EFED document, it recommended granting several waivers and it recommended denying with respect to TPA studies, the five that remained at issue, correct?

A. Correct.

Q. And EFED's hesitation to recommend granting those five waivers was based on EFED's further scientific review of all the literature about TPA that it then had available to it when it was reviewing AMVAC's 2020 document, correct?

A. Correct.

Q. And this document sets forth that rationale,

and some of it is also reproduced in your testimony, correct?

A. Correct.

Q. So, in particular with respect to the mysid -- Mr. Sayres, if you could take us to page nine of 24 of Joint Exhibit 69 -- and I believe this is repeated in your testimony, EFED had concerns based on the lifecycle toxicity study that was available for DCPA which was MRID 49307512, correct?

A. Correct.

Q. And it was based on that that EFED was concerned, even in view of the daphnia data, that there might be excess conservatism in a risk assessment, correct?

A. We were concerned because the mysid were more sensitive than the daphnia.

Q. And with respect to the three fish early life stage studies -- if we could go to page 11 of 24 in Joint Exhibit 69. Eleven of 24. Isn't it true that EFED's hesitation to grant, or recommend granting, a waiver for these three data requirements was grounded on its review of MRID 49307520 and two additional studies from an earlier endocrine disruptor screening program data call-in, correct?

A. Correct. And the missing data from DCPA. We

didn't have that at the time.

Q. For the additional two fish species for DCPA, correct?

A. Correct.

Q. Which has now been submitted?

A. Correct.

Q. And EFED, as you stated, completed its review?

A. Correct.

Q. Of that information? Apart from those two studies that have now been submitted, EFED's hesitance was based on MRID 49307520 and the prior endocrine disruptor studies, correct?

A. Correct.

Q. And finally, with respect to the marine diatom, as was discussed on page eight of your testimony, EFED's hesitance to grant the waiver was based on MRID 49307504, correct?

A. Correct. And then the additional TPA and DCPA study as well that are referenced in my witness statement.

Q. 51499401 and 51499402?

A. Correct.

Q. And those were both additional studies that AMVAC had submitted, correct?

A. Correct. In 2020.

Q. So, returning to the studies that gave EFED pause, isn't it true that MRID 49307512, 49307520 and the endocrine disruptor studies, and MRID 49307507, excuse me, -504 were all submitted by AMVAC in 2014?

A. I couldn't tell you the dates when they were submitted.

Q. Mr. Sayres, could you bring up Joint Exhibit 82, please? Ms. Wendel, do you recognize this document?

A. Yes.

Q. And what is this document?

A. It's the DER for the mysid lifecycle study.

Q. And it states that the study completion date was in January 15 -- on January 15 of 2014, correct?

A. Yes.

Q. And it shows that an initial review performed by CDM Smith/CSS Dynamac joint venture, presumably?

A. I couldn't tell you all of the acronyms, but that sounds familiar.

Q. It indicates that CDM Smith is what's called -- that is, an EPA contractor, correct?

A. That is correct.

Q. And EPA routinely sends out studies that it receives from registrants to such contractors for, would it be fair to characterize that as, an initial review?

A. That is correct. But we provide the final

review.

Q. Right. And then the contractors will return the study to -- did they return it directly to EFED or did they return it to PRD?

A. EFED. It's a contract managed by EFED.

Q. And then an EFED biologist or other appropriate scientists, in this case, you, Ms. Wendel, would perform, you called it final review?

A. That is correct.

Q. And so, in this case it's clear, at least in this document, that this study was provided to EPA at least prior to October 2016, correct?

A. Correct.

Q. Has this document refreshed your recollection as to the initial submittal date of this study?

A. Not necessarily because I've seen -- my experience of study completion dates does not necessarily align with when it's submitted to the agency, as past studies can be referenced that are even older or the completion date is by the lab and then it takes time to go through the registrant's processing and then the EPA's processing and the submission.

Q. Mr. Sayres, could you bring up Joint Exhibit 27, and turn to page two of seven? If you could start by zooming in on the bottom half of that page. We're

talking now about a mysid study. Do you recognize the bottom entry in the chart that we are currently looking at in Joint Exhibit 27, specifically the final entry on page two to refer to a mysid 850.1350 guideline study?

A. Yes.

Q. Mr. Sayres, can you look at the top of this document, page one? This is a transmittal from AMVAC in January 2014, correct?

A. Correct.

Q. And it would appear to reference submittal of a chronic mysid study in early 2014, correct?

A. Correct.

Q. And if we look back at Joint Exhibit 82, it would appear that this study was submitted a few weeks after it was completed in January 2014, correct?

A. Correct.

Q. But then it took two years from January 2014 until October 2016 for EPA's contractor to complete its review, correct?

A. Correct.

Q. Do you recall when this particular DER was returned from CDM Smith to EFED?

A. I don't have a recollection of the exact date that it came back.

Q. Do you recall if it was, generally speaking,

closer to October or November 2016, or closer to December 2021?

A. Possibly around 2016, 2017.

Q. Ms. Wendel, is it typical of both contractor and EFED review times for a study submitted in 2014 to not receive final signature by an EFED reviewer until seven years later?

A. It's not uncommon. It can happen for a variety of reasons, including workload of the contractor, assigned work load in division. A lot of factors can potentially play into it.

Q. You stated that you believe this document was returned from the contractor to AMVAC at some point in 2016 or 2017?

A. Typical practice would be once it's completed from the contractor it's submitted back to EFED.

Q. So, when AMVAC indicated in 2018 that it was proceeding with the Agency’s suggested approach of conducting the acute and chronic daphnia studies, you believe that EFED had in hand the DER, or the draft DER at least from the contractor, on which it would, in 2022, decide not to grant the waiver or recommend granting the waiver, correct?

A. Correct.

Q. And EFED could have at any point after

receiving this study back from the contractor, if it had recognized that concern, informed AMVAC, perhaps through PRD, that submittal of the acute and chronic daphnia studies would in no event, as of that point, result in a recommendation to grant a waiver, correct?

A. Correct.

Q. But EFED did not do that, correct?

A. Not to my knowledge, no. They did not do that.

Q. Are you aware that this DER was not in fact provided to AMVAC until concurrent with the issuance of the NOITS?

A. When DER returns to the registrant, I don't know when those are finalized. You know, we completed our review in '21, the end of 2021 and submitted the information back to PRD when we logged out the DERs in January, I think.

Q. Turning to the fish studies, you stated that MRID 49307520 was the basis, along with some earlier endocrine disruptor studies, for EFED's ultimate recommendation not to grant the waiver even in view of the daphnia data, correct?

A. Correct.

Q. Mr. Sayres, can you pull up Joint Exhibit 51? Ms. Wendel, do you recognize this document?

A. Yes, it's the DER.

Q. For the study with MRID 49307520?
A. That's correct.
Q. And similar to the prior example we looked at, you would expect that this document was back in EFED's hands in 2016 or perhaps 2017, correct?
A. Correct.
Q. And with respect to the final one of the five, the marine diatom, you stated that AMVAC's ultimate recommendation, concurrent with the NOITS, was based on MRID 49307504, correct?
A. Correct.
Q. Mr. Sayres, do you have access to the documents from the regulations docket, and specifically the one ending in 0027? Give me a moment. Let me see if that's been separately entered into evidence. Since we can't, you have access to the Internet? Let's have some fun with regulations.gov.
If you could navigate to regulations.gov, please, Mr. Sayres. And in the search box type in the alphanumeric beginning EPA HQ, which I believe you had in a copy of my cross-exam, but it is EPA for the record. EPA-HQ-OPP-2011-0374-0027. For the record, those must be short dashes or else regulations.gov does not recognize them. Ms. Wendel, do you recognize this document?
A. Yes.

Q. And this is the DER for the third and final MRID that we were discussing, correct?

A. Correct.

Q. In this case, slightly different. The lab appears to have gotten this back to EFED at some point after 2020, correct?

A. Correct.

Q. And EFED's review was completed roughly the same point at the end of 2021, correct?

A. Correct.

Q. And are you aware that this document was not provided to AMVAC until concurrently with the NOITS?

A. Correct.

Q. So, in each of the three cases that we've just discussed which encompassed all five of the remaining TPA ecotoxicology data requirements, the ultimate recommendation not to grant them was based on data which had been provided to EPA in early 2014, correct?

A. Correct.

Q. But regardless of when this data was submitted when EFED reviewed it, you would agree with me that AMVAC did provide the acute and chronic data that EFED suggested in its memorandum that has been dated March 2014, correct?

A. Correct.

Q. I want to turn now to the sixth and final data requirement that remains at issue from your testimony that's enumerated as number 12. It's the Leptocheirus data requirement. For this study AMVAC initially indicated that it would develop new data, correct?

A. Correct.

Q. And would you agree with me generally that AMVAC only requested a waiver after its contract laboratory was experiencing severe difficulties running the study, correct?

A. Yes. Correct.

Q. And those difficulties were not specific to AMVAC's at the time, correct?

A. Correct.

Q. In your testimony at page nine you discuss AMVAC's status updates and you characterize it as AMVAC noted that it was still developing the methodology, correct?

A. Excuse me. What part of the page?

Q. Page nine of your testimony.

A. Uh-huh.

Q. The final paragraph that begins on that page about halfway down there is a discussion of AMVAC's initial efforts to provide the data that had been requested by the DCI. And you characterize it on several

occasions that AMVAC was working on developing methodology, correct?

A. Correct.

Q. In actuality, AMVAC had retained Smithers Viscient, a contract laboratory to conduct the study, correct?

A. To my knowledge, based on the submissions that are discussed here through Smithers.

Q. By which you mean that certain of the updates that EFED received were perhaps on Smithers' letterhead and had been authored by Smithers?

A. That's correct.

Q. Smithers is a highly capable and highly regarded contract laboratory, are they not?

A. To my knowledge. Yes, we receive multiple studies conducted from their laboratory.

Q. And it was only after encountering these difficulties that AMVAC submitted a waiver request for the first time in March 2016, correct?

A. I couldn't speculate why AMVAC switched from protocol to a waiver request but the path that was taken in 2016 was the submission of the waiver request.

Q. And you testified that EFED recommended denying this request in June 2016, correct?

A. Correct.

Q. And on the bottom of page nine of your testimony, the next document that you refer to is a statement from AMVAC in December 2020, correct?

A. Correct.

Q. Mr. Sayres, could you bring up Joint Exhibit 76, please. Ms. Wendel, do you recall seeing this document in the past?

A. No.

Q. Take a moment and read through it and then we'll discuss it. The title of this -- this is a transmittal letter, correct?

A. Correct.

Q. That we're currently looking at. This is page one of Joint Exhibit 76?

A. That is correct.

Q. And the study title is response to EPA's memorandum of June 27, 2016, from EFED. Is that the June 2016 recommendation to deny AMVAC's waiver request?

A. That's correct.

Q. Which, for the record, has been identified as Joint Exhibit 74 in this proceeding. Mr. Sayres, if you could flip ahead from the transmittal page to the next page, please. Do you recall seeing this document previously?

A. Yes. But not until later in 2016.

Q. Do you recall approximately when you first saw this document?

A. Around 2020, in December.

Q. Do you recall why you did not see this document until December 2020?

A. No.

Q. Your testimony completely omits this document, correct? It doesn't mention that you saw in 2016 or 2020 or at all, correct?

A. Correct.

Q. But your testimony is that you did receive it in December 2020?

A. I think I may have received this document. I know on our response to waiver request document we discussed one of the leptocheirus waiver request submissions from 2016 and I can't recall if it was this one or the first one.

Q. Well, this project number at the bottom of the screen currently is identified as AMVAC report 100-AQU-031, correct?

A. Correct.

Q. Mr. Sayres, if you could bring up Joint Exhibit 73, please. Do you recognize this document?

A. Yes.

Q. Is this the AMVAC waiver request to which EFED

issued a recommendation in June 2016?

A. Yes.

Q. Which you discuss at the bottom of page nine of your testimony, correct?

A. Correct.

Q. And this document is identified as AMVAC report number 100-AQU-028. So, it appears the reports were proceeding sequentially, correct, and the later in time report was identified as 31, correct?

A. Correct.

Q. Mr. Sayres, could you put up Joint Exhibit 69, please? This is EFED's final recommendation that was issued concurrent with the NOITS, correct?

A. Correct.

Q. And at the bottom of this first page it references some specific documents that EFED was considering when it issued this report, correct?

A. Correct.

Q. And the second of the two identifies AMVAC project number 100-AQU-028, correct?

A. Correct.

Q. Isn't it true that the subsequent report provided in November 2016 is not referenced in this document at all?

A. No. It does not appear to be.

Q. If you would like to take a moment and flip through the document and confirm that that report is referenced in this document, you may do so. Let Mr. Sayres know if you would like to see a different page.

A. Could you go down to the leptocheirus section, please?

Q. Just keep going. We'll get there. It's the green title near the bottom of the page. There we go. I think there's some further bibliography also at the end of this document.

A. Uh-huh. Would you like to take a look at the bibliography?

A. Yes, quickly, look at the bibliography.

Q. It should be the final two pages. It would be the third from the bottom here is the 100-AQU-028?

A. Uh-huh.

Q. So, isn't it true that EFED's final recommendations in this matter does not reference AMVAC's November 2016 waiver request?

A. Correct. Just the first one.

Q. You testified that you recalled seeing the subsequent waiver request in 2020, correct?

A. Possibly. Based on the reference here I may not have. I could have gotten them confused because they both said 2016.

Q. But you will agree with me, won't you, that this document appears to respond to only one of those two documents, correct?

A. Correct.

Q. Do you recall if there was any specific discussion in this document of AMVAC's rationale that's set forth in the November 2016 document, notwithstanding the document that's not cited?

A. I couldn't possibly predict either way whether it's referenced or what is contained in the second waiver request, if it's how different than the first waiver request.

Q. So, you don't recall as you sit here today the substance of the second waiver request?

A. No, I don't recall. No.

Q. Did you recall the substance of the second waiver request when you were preparing the testimony?

A. No, I don't recall.

Q. You testified at the beginning of your cross examination that you had reviewed certain agency documents but that they were limited to those referenced in your testimony, correct?

A. Correct.

Q. So, you did not review AMVAC's November 2016 waiver request when you were preparing your testimony,

correct?

A. Correct.

Q. Ms. Wendel, on page three of your testimony you refer to a document, an EPA document dated October 16 of 2020 as the data delay letter, isn't that correct?

A. Correct.

Q. And you say there AMVAC satisfied 20 of the 40 outstanding DCI requirements by providing acceptable data or through EPA waiving the requirement, correct?

A. Correct.

Q. In that sentence you are not using the nomenclature that we have been -- that we had discussed and it is was used in the balance of your report in which tests on the technical and the degradate and tests on multiple species are identified as separate data requirements, are you?

A. The data delay letter was created from PRD so that total may be different than --

Q. So, that account is in some way tied to the data delay letter itself rather than your own --

A. Correct.

Q. -- accounting of --

A. Correct.

Q. -- data requirements? Mr. Sayres, could you pull up Joint Exhibit 21, please? Ms. Wendel, do you

recognize this document?

A. I don't know if I've seen this document per my transmission to EFED work.

Q. The subject of this document, Joint Exhibit 21, is "notification of outstanding data requirements in anticipated registration review schedule for DCPA," correct?

A. Correct.

Q. You stated that you reviewed the documents referenced in your testimony when you were preparing it, correct?

A. Correct.

Q. Is the document that was previously on the screen --

JUDGE BIRO: Which exhibit are we waiting for now?

BY MR. ROSS:

Q. Is the document that is now on the screen the document that you understand to be the October 16, 2020, data delay letter?

A. Can we scroll down, please. One more page. Yes. Yes, that's correct.

Q. Do you recall if PRD consulted with EFED when it was preparing this letter?

A. I believe so.

Q. Do you recall the subject of the consultation between PRD and EFED when PRD was preparing this letter?

A. My understanding was to -- I believe we confirmed the status of documents that were in review or if, based on our latest information, if they were still outstanding.

Q. Do you recall if EFED -- sorry, if PRD consulted with EFED concerning the substance of the first portion of the letter?

A. Not to my recollection. I just remember seeing this table. I don't know about the top part of the document.

Q. To your recollection -- is it -- any consultation was limited to confirming the status of various submissions and reviews and EFED recommendations in response as of October 16, 2020, correct?

A. Correct.

Q. But you have reviewed the substance of the communication on the first and second page in connection with your testimony, correct?

A. Correct.

Q. And Mr. Sayres, if you could take us to the first page. If you look at the final portion of the first paragraph here it reads, "the agency will rely on data available at the time when risk assessments are

being developed. Where the agency is lacking data conservative assumptions may be used in their place to complete the risk assessments," correct?

A. Correct.

Q. Is that a fair statement of the state of EFED's ability to complete the risk assessment at this time?

A. We would have to use conservative assumptions. That is correct. No additional data was submitted.

Q. And so, this letter does not say that if no additional data were submitted EFED would be incapable of performing risk assessments, correct?

A. Correct.

Q. And it does not inform AMVAC the risk assessment will be delayed if no further data is submitted, correct?

A. That is correct, based on what's written here.

Q. In fact, it states that EFED or EPA expects to complete the draft risk assessment in June 2021, correct?

A. That's what it states.

Q. And that statement was not qualified on AMVAC's submission of any data?

A. I have no knowledge of that.

Q. And AMVAC had pending waiver requests at the time, correct, as we've just been discussing, right?

A. That's correct.

Q. Now, a draft risk assessment was not completed in June 2021, was it?
A. No.
Q. Has a draft risk assessment for ecological affects and environmental fate yet been completed?
A. Not completed, no.
Q. And your testimony is that EFED could complete a conservative risk assessment just as PRD indicated that it could in this letter; correct?
A. That's correct.
Q. So, there was no point at which EFED realized that a statement in this letter was inaccurate; correct?
A. Correct.
Q. So, the fact that the draft risk assessment was not completed in June of 2021 has nothing to do with the fact that AMVAC continued to wait for the responses to its waiver request; correct?
A. Correct. To my knowledge I can't postulate, but to my knowledge.
Q. To the best of your knowledge, the fact that a draft risk assessment was not completed in June of 2021, has nothing to do with the fact that AMVAC continued to wait for responses to its waiver request in some instances; correct?
A. Correct.

MR. ROSS: No further questions, Your Honor. If I could consult with my co-counsel for a moment and see if they agree with my assertion.

JUDGE BIRO: Oh, of course. Yes.

MR. ROSS: No further questions, Your Honor.

JUDGE BIRO: Thank you, Mr. Ross. Mr. Pittman?

REDIRECT EXAMINTION

BY MR. PITTMAN:

Q. Ms. Wendel, are you familiar with any registration review cases in which multiple waiver requests were submitted for the same data requirement?

A. Yes. I have had that experience with one of my chemicals where multiple data waiver requests were submitted and denied.

Q. And what was the chemical?

A. Nicarbazin.

Q. About how many studies at issue in that case had multiple waiver requests submitted?

A. There was one study and it was an avian reproduction.

Q. Are you aware or can you recall the reason that a second waiver request was submitted?

A. The waiver request was submitted for nicarbazin is a -- well, it's for reproduction to control the

production of eggs and there was postulation that a guideline avian reproduction was not needed multiple times.

Q. Thank you. With respect to a special study 1072, I believe we were referring to as the Leptocheirus study earlier.

A. Uh-huh.

Q. Are you aware of approximately how many of that type of study on that species had been completed in other registration review cases?

A. My understanding, I'm aware of about 16 studies that have been completed successfully either acceptable or supplemental for use within our risk assessment since 2017. There could be more than that, but there is at least 16 studies.

Q. And you said since about 2017, correct?

A. Correct.

Q. Do you recall which laboratories submitted these studies successfully?

A. Both Smithers Laboratory as well as Eurofins which is now known as EAG, or vice versa. It used to be called Wildlife International, but at least two contract labs have successfully completed the study.

Q. Do you by any chance recall when the earliest examples of I guess Smithers completed a version of this

study was submitted to EFED?

A. 2017.

Q. So, that Smithers was the first one to submit one and this was in about 2017?

A. I think they were very similar in timeframe. They were both able to do successful studies.

MR. PITTMAN: No further questions, Your Honor.

JUDGE BIRO: Any recross?

MR. ROSS: Yes, Your Honor.

RECROSS EXAMINATION

BY MR. ROSS:

Q. Mr. Sayres, can you pull up Joint Exhibit 22, please? And go to the second page. The largest two paragraphs there, if you could zoom in. Ms. Wendel, do you recognize this document?

A. Yes.

Q. Is it accurate to characterize this as a statement by AMVAC concerning the back and forth over the performance of the leptocheirus data requirement?

A. That is correct. Yes.

Q. And it says in the second paragraph, "AMVAC has chosen to await specific DCI requirements for the acute study or will wait for confirmation that the chronic study guideline has been validated." The receipt of the studies from Smithers and Eurofins that you just

testified to, would you characterize that as evidence that a chronic study guideline had been validated?

A. I am not aware of what classifies as a guideline being validated, but it's a non-guideline special study that utilizes other EPA methods that after consultation with protocol the lab was able to successfully complete the studies. There were highlighted issues that were discussed and talked about, that since 2017 and onward they've been able to successfully complete studies.

Q. So, EPA became aware, you testified in 2017, that it was receiving studies that it believed were useful for risk assessment, correct?

A. Correct.

Q. Would that be broadly equated to the concept of the study being validated?

A. Again, I don't know what the definition of a validated guideline. It's a special study.

Q. To your knowledge, did anyone from EFED or PRD ever inform AMVAC that other chronic leptocheirus studies had been received, that the agency had deemed useful for its assessment?

A. I know I have a statement, or I believe I have a statement, in the '22 waiver response that states that other studies have been successfully completed.

Q. And that was the response that was issued concurrently with the NOITS, correct?

A. That is correct.

MR. ROSS: No further questions.

JUDGE BIRO: Ms. Rose, are you with us? Okay. Do you have any questions?

MS. ROSE: I do not.

JUDGE BIRO: Do you want to reserve the right to recall Ms. Wendel? At a later time? Do you want to reserve the right to recall Ms. Wendel?

MR. PITTMAN: Yes, specifically with respect to any possible witness rebuttal testimony.

JUDGE BIRO: Okay. Thank you, Ms. Wendel. You remain under the sequestration order, so don't discuss your testimony with anyone.

THE WITNESS: I'm sorry. I can't hear you.

JUDGE BIRO: Sorry. There is a possibility you will come back and testify again, so you remain under the sequestration order.

THE WITNESS: Okay.

JUDGE BIRO: Don't discuss your testimony with anybody.

THE WITNESS: Understood.

JUDGE BIRO: Okay. Thanks.

THE WITNESS: Thank you.

JUDGE BIRO: Please step down. It's 11:47. Would you like to break for lunch? Yes? Mr. Pittman? Okay. I think we agreed to one hour. So, can we come back by one? Okay. Thank you. We will stand in recess until one.

MR. PITTMAN: Thank you, Your Honor.

(Whereupon, at 11:48 a.m. a lunch recess was taken)

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

(1:01 p.m.)

JUDGE BIRO: Good afternoon. Please be seated. Are there any preliminary matters before we begin again? No? Okay. Would the agency like to call its second witness?

MR. PITTMAN: Good afternoon, Mr. Wente. Would you please state your name and current title for the record?

JUDGE BIRO: Wait. We haven't sworn the witness in.

MR. PITTMAN: Oh, sorry. My apologies.

JUDGE BIRO: Mr. Reporter, could you please swear in the witness.

(Whereupon,

STEPHEN WENTE,

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

JUDGE BIRO: All right. Please begin.

DIRECT EXAMINATION

BY MR. PITTMAN:

Q. Good afternoon. Could you please state your name and your current title for the record?

A. My name is Steve Wente and my title is Senior Scientist in the Ecological Risk Branch number two in the Office of Pesticide Programs of US EPA.

Q. Can you pull up -- Mr. Wente, are you able to see the document that's in front of you?
A. Yes, I do.
Q. Do you recognize this document?
A. I do.
Q. How do you recognize it?
A. It's a statement that I prepared for this hearing.
Q. Is it a true and accurate copy?
A. Yes.
MR. PITTMAN: Your Honor, I would move that the witness statement of Stephen Wente be admitted into the record as RX-26.
JUDGE BIRO: Mr. Ross, is there any objection?
MR. PITTMAN: No objection, Your Honor.
JUDGE BIRO: Ms. Rose, is there any objection?
MS. ROSE: No, objection, Your Honor.
JUDGE BIRO: So, no objection, RX26 is admitted into the record.
(Exhibit RX-26 is admitted)
BY MR. PITTMAN:
Q. Would you like to ask we have an electronic copy to follow along with or do you want to handle that?
MR. ROSS: I think we'll be able to see what is brought up. It should be all right.

MR. PITTMAN: All right. Thank you.

CROSS EXAMINATION

BY MR. ROSS:

Q. Good afternoon, is it Dr. Wente?

A. Yes, officially it is Dr. Wente, but Steve is fine.

Q. We'll meet in the middle with Mr. Wente. How about that?

A. That's fine.

Q. All right. Do you happen to have a copy of your written testimony available to you to refer to during this cross examination?

A. Let me minimize the screen and --

Q. Okay. If you would prefer not to have to refer back and forth, we can instead, to the extent that I reference a specific portion of your testimony, I can ask my colleague to actually cause that to come up on the screen if you would prefer.

A. That might be a better way of doing it just so I am not trying to figure out where you are at.

Q. All right. We will try that approach. I apologize. I got a bit ahead of myself. My name is Hume Ross. I'm an attorney with Wiley Rein. We represent AMVAC Chemical Corporation in its request for hearing of the notice of intent to suspend DCPA. As an introductory

matter, Mr. Wente, you are aware that this proceeding examines whether AMVAC met or failed to meet a particular statutory standard laid out in FIFRA, correct?

A. Yes. Whether or not those studies were submitted or not.

Q. Is your understanding of that statutory standard to be, essentially, whether or not the studies were submitted by the deadline in the DCI?

A. Potentially it's "were they submitted in a timely fashion"? So, in other words, it's not -- it's not unheard of for somebody to go beyond the timeline established in the DCI if there are some extenuating circumstances, but other than that typically soon after.

Q. When you say typically soon after, are you referring to specific other notices of intent to suspend that you have worked with in which such notices were issued soon after the passage of the original DCI deadline?

A. So, I am -- so I'm in one of the science branches so essentially I won't say it's like a factory but it's -- things come in to us for us to work on and unless there is, you know, definite reasons for us to go ahead and be involved in timing of things so occasionally we will end up with something that has to be done by a certain deadline and so you're more aware of the

timeline, but essentially actions, or in other words if you were to submit a document or AMVAC were to submit a document to me, essentially the registration division RD, or the pesticide reevaluation division PRD, would submit something to us and tell us to go ahead and do it at that time.

So, it's -- when I say typically it just means that I assume that there's some schedule that people are keeping to.

Q. And with respect to the statutory standard, your written testimony that Mr. Pittman referred you to is your personal factual testimony concerning the history of some interactions on documents concerning DCPA between EFED and PRD and between PRD and the registrant, correct?

A. Yeah. So, I've looked at some of those documents, or I've looked through all those documents at one time or another and seen them and to the best of my ability, you know, put the proper dates in order and that kind of thing in my statement. If you're asking have I, you know, seen those documents come in and that kind of thing, no, because we're in the science division and we don't receive the documents.

If you're asking whether I was actually in the branch that had DCPA for the entire history of this, no, I became a senior scientist I want to say about five

years ago, so I would have missed out on some of the early back and forth. So, I was -- previously I would have been in a different branch, so I wouldn't have had -- I wouldn't have paid attention to this chemical at that time.

But since being in the branch and being a senior scientist, I have to review things that go in and out and so, yes, a lot of the documents that were more recent, I reviewed those and then, like I said, I looked at the old documents.

Q. When approximately did you transition into the current branch which entails responsibility for DCPA?

A. I want to say it was 2017, 2018, somewhere in there. It would be on my witness statement in the resume at the end. I believe that was accurate -- if you need more accuracy.

Q. Sure. So, whenever you transferred into your current role that could also be when you began the involvement with the branch that was associated with DCPA, correct?

A. That's correct.

Q. And returning to the statutory standard, the testimony in your written statement does not provide your opinion as to the meaning of that standard, does it?

A. Not that I'm -- no, not in any sense that I

would think of.

Q. And your factual testimony is not directed to AMVAC's compliance or noncompliance with that statutory standard, correct?

A. So, my only responsibility in the science division is to say whether the studies that do come in, whether or not they are acceptable and whether they meet our guidelines, whether that study was conducted in a way that we could actually use that data for risk assessment. Other than that, we recommend to PRD that, you know, either a waiver, if they submit a waiver instead of a study, whether that waiver would be accepted or whether that waiver should be denied.

Q. So, to confirm, there is no place in your written statement where I can look and find the opinion of Stephen Wente as to whether or not AMVAC complied with the statutory standard in FIFRA, correct?

A. So, it wouldn't -- no --

Q. Regardless of whether it would be expected to find it in your statement, can you confirm that I would not find it in your statement?

A. I don't believe what you're looking for is in my statement.

Q. In page one of your statement you say that it is based upon your personal knowledge and the records of

respondent. Can you elaborate what records you consulted, if any, beyond the documents referenced in this statement when you were preparing for this statement?

A. So, you're asking essentially what other documents I would have been looking at in our branch in order to, you know, judge whether this makes sense or not. Is that kind of the gist?

Q. Yes. When you were asked to prepare this statement, you presumably consulted a set of documents to do so. I'm asking if you can recall any of them that are not also specifically cited at some point within your statement?

A. So, there's a -- there's a drinking water assessment being prepared for DCPA. Sometimes senior scientists -- I'm kind of overseeing the science parts of that to make sure that that is working out and that the drinking water assessment is being prepared.

So, from doing that I would have -- or I looked back at a lot of the individual studies that have been submitted historically so I have some idea of, you know, what was the -- what data have been submitted and what data have not been submitted and occasionally we have studies that have been submitted that have been, you know, been unreliable and I go back and review those to

see whether there's anything that can be pulled out of them.

I look back at previous assessments to see whether, you know -- how people have assessed the chemical in previous assessments. So, I would be aware of a lot of documents that the science branches have produced. I would not be so aware of things that PRD has gone back and forth with the -- for the registrant.

Q. Mr. Wente, on page three of your written testimony, just below Roman II concerning the series 835 transformation water study -- transformation water and soil studies you state, quote, as laid out in respondent's June 13, 2022, motion for accelerated decision -- decision and the supporting memorandum, additional data on transformation in water and soil studies were necessary for EPA to complete registration review, correct?

A. Yeah.

Q. And as you began to state earlier, EFED is a science branch that supports the pesticide reevaluation division or PRD, correct?

A. Correct.

Q. And it is ultimately PRD which completes registration review based in part on scientific reviews provided to PRD by EFED, correct?

A. Yes. The only thing I would change in that statement is that "PRD produces the decision." So, in other words, I'm not sure exactly what you mean by complete registration review as far as, you know, what actually does that, but usually it's the decision document that's made and that's produced solely by PRD.

Solely by PRD. They write it and then the other parts of the -- the other divisions within the Office of Pesticides review it. So, they will prepare a decision and then they'll send it past us to make sure that they have captured what we had said correctly.

Q. So, it is PRD that issues the decision document, as you say. Not EFED, correct?

A. Yes. It's actually signed by their director in the Pesticide Re-evaluation Division.

Q. So, it's ultimately PRD, is it not, that decides what data is or is not necessary to complete registration review specifically, correct?

A. Yeah. So, we recommend to PRD. We do not make the decision on that. That is -- well, so in other words, if we're talking about, like, was the data acceptable, do we need data, is the question I think you're probably trying to get at.

Q. No, I'm not. I'm very specifically trying to get at the question of the determination of whether data

is necessary for, in this case, PRD to complete registration review as is stated on page three of your testimony?

A. So, for them to come to a decision that would be a risk management decision and they're the ones that make the decision whether to call in new data and they're the ones that make the final decision whether the chemical should be registered or whether there's any mitigations.

Q. So, PRD could determine. They could issue a decision document in a registration review case, notwithstanding the absence of certain data that was called in prior to DCI, correct?

A. They could make the decision that essentially, they don't believe it is needed and so when -- that definitely happens -- if they don't believe that the chemical rises to be such a risk issue then they could go ahead and say, no, we've got enough information.

At this point we don't think that the registrant needs to send you another study for us to be able to make a determination that this chemical was either -- you know, that we can make our safety finding or not make -- or be assured that they're not going to make a safety finding for this chemical.

Q. So, as far as your personal, factual testimony

about what data is or is not necessary for PRD to complete registration reviews specifically, that would be a determination made by someone in the PRD and not someone in EFED, correct?

A. I'm sorry. Can you repeat that, just the first part of it?

Q. The determination -- I believe you just stated -- a determination of what data is necessary to produce a registration review decision or complete registration review is a determination made by personnel in the PRD, correct?

A. So, they would make the final determination. We would -- obviously they would listen to us, but sometimes they don't -- so they're not a science division, so we'll have, you know, science issues that maybe they'll come across in our memos and we'll have meetings to go ahead and explain to them why, you know, we think that they really do need that data and what uncertainties are in our assessment, but in the final analysis, yes, it's their decision.

They're the ones that are going to say -- we're not going to contact the registrant. They're going to contact the registrant and either ask for it or not ask for it. And make the decision at the end whether or not -- would make the decision on the registrant review case.

Q. So, if you are providing testimony in your personal capacity as an employee of EFED, you cannot provide testimony directly to the question of whether or not a particular study is necessary to complete registration review, correct?

A. So, I think if what you're asking is do we make the decision, no, but do we have input on it then I think it would be yes. But I don't know how that works out in the legal world.

Q. The prior part of the sentence states that you essentially cite for your conclusion that additional data on transformation and water and soil studies were necessary. You refer back to that and you say that is as laid out in respondent's June 13, 2022, motion for accelerated decision, correct?

A. Yeah.

Q. Are you relying on OPP's June 13, 2022, motion for accelerated decision for the conclusion that additional data were needed to complete registration review?

A. So, I mean there were a whole series of meetings that discussed this in considerable depth. So, if you're asking is it just specifically because of that one document, no, it's not just due to that one document.

Q. Well, Mr. Wente, if you could focus on my

specific question which is your statement in your testimony that additional data on transformation and soil and water studies were necessary to complete registration review, are you basing that statement on information you obtained from OPP's legal memorandum filed in this matter in June 2022?

A. I was aware of it long before then. So, I believe the sentence just says that that's essentially the way that it's laid out in the motion for accelerated decision is something that I agree with essentially based upon many, many meetings I went to on DCPA before that as well as I read through that motion for accelerated decision and I agree with the way it was summarized I guess is what you would say.

Q. The many, many meetings that you went through, can you tell us the chronology of these meetings that you're referring to?

A. You don't want specific dates. I assume you just want to know what -- are you looking for just a general description of what meetings we went through to get to this point?

Q. Generally, it sounds as though that you're testifying that there was a series of meetings on the general question of whether or not there was sufficient data. And again, per your testimony, to complete

registration review and --

A. Yes.

Q. -- and I'm asking you generally, when did those meetings begin?

A. Oh, I would have to look back in my records to see exactly, but I would -- you know, for a general answer I would say at least a year before the motion for accelerated decision was put out and probably a little bit longer than that.

Q. Probably longer than a year prior to the motion or a year prior to the notice of intent to suspend?

A. Probably -- probably a year before the notice of intent to suspend.

Q. Was when these meetings began?

A. So, as a senior scientist I get pulled into some meetings and some of the early meetings there is no science question. It's just kind of organizational, things like that. So, I would miss some of the original meeting, or some of the early meetings, but as it became more of an issue that we were going to have a tough time trying to come up with documents for DCPA and also at the time when they were denying the last set of waivers, then I would have been pulled into the meetings at that time.

Q. Mr. Wente, are you aware that the last set of waivers were denied concurrently with the issuance of the

NOITS?

A. I know that -- I know that it was sent to AMVAC at the same time for the very last one but I believe I was actually -- I'm not sure about this, but I believe I was actually involved earlier than that, so if there were previous -- well, no, it may have been actually that AMVAC was notified that it actually -- got involved with that earlier.

So, it may have been actually that last set of, you know, waiver denials. I do recall that one of the -- oh, I know why I'm thinking this was actually further than that. There was a response to comments document that went out before. That's why I'm thinking it's much earlier than the email. The notice to suspend. I'm sorry. You need to explain.

Q. I'm considering my next question. Give me a moment.

A. Okay.

Q. And so, at some point in the year proceeding the issuance of the NOITS, a view was reached that, and I want to be very specific here, is that either PRD could not complete risk assessment -- sorry. PRD could not complete registration review or EFED could not complete risk assessment?

Let's start with which it was. Was it a

determination that PRD could not complete registration review or that EFED could not complete risk assessment?

A. I believe it was that EFED could not complete the risk -- let me put it this way. HED, the human health -- the health effects division could not complete their draft -- their draft human health risk assessment because of the missing CTA data is my understanding of that.

That's not data that I review or anything like that, but we do provide the drinking water assessment that goes into determining exposure values for HED to use in their human health assessment. So, because they couldn't perform a human health risk assessment due to that missing study. That meant that essentially it kind of made it so that we couldn't get what we were supposed to get done, either.

So, you can kind of say that EFED -- EFED really wasn't able -- so the difficulty in the EFED portion is that essentially there was data missing in terms of figuring out both the exposure in the water, not just from the human health risk assessment but also the ecological risk assessment.

Additionally, there were end points that were missing. So, when you try and figure out risk, they're actually talking about comparing the exposure to the end

points and essentially, we didn't have it either. So, it was essentially numerically you could have assumed a number or stuck it in there and run through and made a number, but essentially it would have been based on two numbers that were completely uncertain and so it wouldn't have made any sense. It wouldn't have been of value I guess is what I'm trying to say.

Q. Let's pick that apart. The two numbers -- your testimony -- your written testimony in this matter goes to only one of them, correct, the exposure. In other words, the environmental fate parameters, correct?

A. Yes.

Q. And the issue with respect to completion of a human health risk assessment was that you were experiencing uncertainty in both the exposure and a toxicity end point with respect to human health, correct?

A. So, yes. It's kind of the same way on the ecological assessment side, so both the -- there was a problem with the end point for the ecological organisms. There is a problem with the end point for the human health risk assessment, but then there was a problem with trying to calculate the exposure for either one. So, in other words, missing studies is what I mean by problem.

Q. The catalyst though for the NOITS I believe you mentioned was the inability to complete the human health

risk assessment, correct?

A. Well, that's typically the most serious problem, so just a little bit of explanation.

Q. Would you characterize it as the catalyst for the issuance of the NOITS?

MR. PITTMAN: Your Honor, I would like to object, this is well beyond the scope of Mr. Wente's testimony.

JUDGE BIRO: If you can answer the direct questions. I mean you can ask a leading question, maybe we could narrow it down a little bit.

MR. PITTMAN: Yes, Your Honor.

BY MR. ROSS:

Q. Let me actually return specifically to this determination, putting aside the specifics of it you testified that the determination was made at some point in the year before the issuance of the NOITS, correct?

A. Yes. Sometime within that year.

Q. But to your knowledge no one within OPP, either EFED or PRD, ever contacted AMVAC to inform them that an issue had been identified and that unless specific studies were submitted some division would be unable to complete a scientific review that it had been working on, correct?

A. So, I'm not --

Q. Are you aware of any contact during that year preceding the NOITS from anyone in EPA to AMVAC stating we have discovered that we are unable to complete a scientific risk assessment?

A. I am unaware of anybody making contact but I don't know whether they did or not.

Q. Let's talk specifically for a bit about the outstanding environmental data requirements that are the subject of your testimony. In the past, EPA assumed that TPA, the breakdown product of DCPA which is the degradate that remained at issue, correct --

A. Yes.

Q. -- is stable in the environment, correct?

A. Yes. EPA has made that assumption before.

Q. And it has used that assumption to complete a risk assessment, correct?

A. So, yes. The one I'm thinking of is a California red legged frog assessment.

Q. And in fact, in the context of completing that risk assessment, isn't it true that EFED observed that the studies then available showed that, and I'll quote from the document, that no degradation of TPA was observed indicating that the assumed stability may not be overly conservative?

A. So, the way you would judge the stability of

TPA would be to see how it behaved later in the study. So, in other words, TPA is not formed until later in the study. The problem was the study ended about that same time -- I should correct that. The DCPA studies that we had ended about the same time that TPA was actually forming and should have been degrading if it was going to degrade. So, we didn't have very much evidence either way.

So, if it is stated as I believe just mentioned that we didn't have any evidence that it was degrading. We didn't have any evidence, but we also didn't have any evidence that it would not degrade.

Q. Mr. Sayres, could you pull up petitioner AMVAC Exhibit 80 at page 79 of 176, please? Mr. Wente, do you recognize this to be a page from the red legged frog assessment that you previously referenced?

A. It's very small. Is it possible to make it bigger?

Q. Yeah, Mr. Sayres, if you could --

A. There it is.

Q. This particular table is not germane but down below there is the discussion that I was referring to about halfway down beginning data are only available from studies where DCPA did degrade and then in both of these studies no degradation of TPA was observed indicating

that the assumed stability may not be overly conservative?

A. Yes.

Q. It seems to be based, would it not, on observation of TPA that had degraded from DCPA but degraded no further, correct?

A. Yes, but that's where the study ends and that's kind of the problem is we don't know what happened to much of any degree what happened after TPA formed.

Q. But something prompted the author of this document to indicate that they assumed stability may not be overly conservative, correct?

A. Yes. So, it could be that TPA is absolutely stable or -- and I believe the author of this particular document would probably agree with the idea that well, it could actually be not stable but, you know, something that's actually pretty long-lived.

Q. And assuming stability, full stability in the absence of test results showing degradation is consistent with EFED guidance for model inputs, correct?

A. So, there is actually a document called the input parameter guidance. I'm not sure that it actually specifies it. It's really more of a -- it's really more of a, I want to say, I guess that when we -- if a registrant doesn't provide data we would go ahead and say

we can -- it's kind of a carrot and a stick thing.

So, if you give us the data we'll use your half-life. That would be much better for your chemical in terms of the risk assessment. If you don't give us the data then we say that we can assume -- we'll assume stability which is kind of saying that bad things are going to happen with your chemical because it's not going to do very well in a risk assessment, and in fact in this risk assessment the chemical exceeded the end points or the levels of concern and essentially it's saying that -- essentially the results of this particular document say that DCPA is likely to adversely affect the California red legged frog which is an endangered species. So, by making conservative estimates, yeah, it exceeded.

Q. Correct. But PRD and other appropriate EPA branches were able to take the results of this EFED risk assessment and take appropriate mitigation steps, correct, even in view of the conclusion that there was the potential for affects to this particular species, right?

A. Well, so this is an endangered species document and I'm not sure that PRD actually had much to do with that. It's really dependent on the US Fish and Wildlife service. So, in other words they're supposed to determine whether that creates -- whether our action of

registering DCPA would threaten the continued existence of the California red legged frog.

I'm kind of -- I'm not sure that PRD actually has much to do with these endangered species assessment, at least not at this time. They may have more something to do with it now.

Q. But an appropriate government agency was able to take this risk assessment and proceed to implement whatever mitigation steps it felt was necessary in view of this risk assessment, correct?

A. Not really. This is the problem with -- there's been an ongoing problem with Endangered Species Act compliance for the agency and we did a lot of these assessments. I did a lot of these assessments and I don't believe that they actually just -- whole handedly the US Fish and Wildlife service said that they just were not useful to them and were not able to use our analysis provided in these documents.

I would defer to Christine Wendel, would be able to tell you much better than I could on that but, no, there were -- as far as my knowledge, these did not actually result in actual mitigations implemented by the EPA or on the labels of the chemicals for -- DCPA.

Q. But to your knowledge, the professed inability of the Fish and Wildlife Service to use the document was

unrelated to conservative assumptions with respect to the persistence of TPA, correct? If anything, the conservative assumption would have alerted them that they needed to take additional steps to ensure its conservation which they then decided they were unable to take for whatever reason, correct?

A. I wouldn't characterize it that way, but that's probably -- that's probably close enough to the situation. I don't think that they ever even noticed -- I don't think they got to the point where they said, you know, oh, there is an overly conservative assumption made here.

Yeah, I don't think they actually went through the document with any great review at all. But I don't think that would have held them back from -- you know, I think having a conservative assumption is not something that would have particularly caused problems for the Fish and Wildlife Service.

Q. So, coming back to within -- within the walls of OPP and specifically EFED's assessment of the three data requirements remaining at issue here, if we take a look, Mr. Sayres, at Joint Exhibit 77, first page to begin with. Mr. Wente, are you familiar with this document?

A. Blurry right now. Is there some way to make it

a little bit bigger? That's good. Yeah, I'm familiar with this document.

Q. And this document, the subject, the second enumerated purpose of this is response to registrant's data waiver request for environmental studies with TPA, correct?

A. Yeah.

Q. And Mr. Sayres, if you could turn to the third page of this document. It addresses one of the three currently outstanding studies. The anaerobic soil metabolism study and then in the final paragraph it says since EFED has designated TPA as stable for both aerobic and anaerobic soil metabolism study AMVAC -- EFED accepts AMVAC's proposal for a new study to verify the finding for the anaerobic soil metabolism, correct? Before you get confused, which ultimately did happen, AMVAC did submit that study and it's no longer outstanding, correct?

A. The aerobic soil metabolism study is not outstanding. That was submitted. The anaerobic soil metabolism is the one that's not submitted.

Q. Correct. So, the paragraph continues that EFED does not believe the results of the aerobic soil metabolism study can be applied to TPA, therefore EFED believes the reliable anaerobic soil metabolism is needed

for risk assessment but will assume stability in the absence of the study, correct?

A. Yeah, that's kind of boilerplate, but it's not expressed the exact way that we usually say it, but that's close enough. We assume stability if we don't have a study for it.

Q. And this does not even explicitly contain even a recommendation from EFED to PRD, does it?

A. I believe that historically EFED, in a sense cavalierly said, don't you know, told PRD, you know, don't recommend the study or don't -- don't ask for the study or do ask for the study. It at some point became a problem that, you know, EFED was not -- it became understood that EFED was not supposed to be telling PRD what to do.

It was supposed to be recommending to PRD what to do and so I just recall that -- and I think this occurs periodically where people get confused and forget to add the "recommend" word in there so it just came out that, yes, you should recommend or shouldn't tell PRD what to do.

Q. But EFED and PRD's turf contest would not necessarily be known to a registrant reading this, correct?

A. I think -- I think very few registrants are

actually aware of the back and forth within the EPA a lot of times.

Q. And so, it's conceivable that in the various formulations of the EFED's documents, with "recommendations" somewhere higher, this would be somewhat a bit more ambiguous in that it did not even purport to be a recommendation to PRD, correct? It simply states EFED's belief but that it will assume stability in the absence of the study, correct?

A. Yeah.

Q. Now, this document that we're looking at was dated in 2017, correct?

A. We would have to go back up to the front and look at the that to verify that. So, that would have been before I was there or before I was in that branch.

Q. In your testimony at page five -- Mr. Sayres, if you could pull this up -- beginning on the fifth line under Roman III on February 7, 2017, it refers to the issuance of this document and then it says after receiving no response from AMVAC EPA notified AMVAC in the October 16, 2020, data delay letter that this DCI data requirement remained outstanding, correct?

A. That's my understanding. Yeah.

Q. That strongly implies, does it not, that AMVAC had the opportunity to respond but did not, correct?

A. Yes, maybe not strongly, but otherwise I agree.
Q. Are you aware that the first time that the EFED memorandum that we were just reviewing was provided to AMVAC was concurrent with the October 16, 2020, delay letter?
A. So, if that's the case then my statement is probably wrong there. So, I do recall that there was some delay in the communications and people had talked about that at different times.
Q. Moving forward through that chronology to discuss the notification to AMVAC. This is still on page 5 of your testimony on the October 16, 2020, delay letter. After that, AMVAC supplied an additional scientific analysis in further support of its waiver request for the environmental fate studies, correct?
A. They provided a waiver request. I didn't really think of it as a scientific evaluation.
Q. Mr. Sayres, could you pull up -- Joint Exhibit 78, please? Are you familiar with this document?
A. I have seen it before.
Q. Do you recall approximately when you might have first seen it?
A. Probably I assumed in the preparation of the -- what do you call it, the suspension document.
Q. Which per your prior testimony could not have

been more than a year prior to the issuance of the NOITS, correct?

A. Something like that, yeah.

Q. So, is it your testimony that this document was provided to you in the context of preparing a notice of intention to suspend against AMVAC?

A. It would have been that or this may have been the document that was actually being -- so, yes, it would have been in preparation of the waiver request. So, I'm sorry, during the preparation of the waiver response.

Q. The question --

A. In other words, I might have seen it at that time or I might have seen it at the -- is prior to the suspension, somewhere between there.

Q. But you characterized or -- you resist my characterization of this as a scientific analysis, correct?

A. Yes. So, yes. That would be correct.

Q. Mr. Sayres, could you scroll down through to the index first? This is a 15 page document that refers to prior responses from EFED, correct?

A. Yes, I assume so.

Q. And it has a lengthy bibliography at the end?

A. It does.

Q. But go back to the index, Mr. Sayres. In

section 3 in particular it provides an assessment of scientific literature on the anaerobic metabolism of chlorobenzoates and phthalates in environment? Are you aware if AMVAC had previously provided this comparative -- a comparative analysis of these particular compounds in the environment?

A. I am aware that they refer to these particular compounds in comparison to the chemical, yes.

Q. And EFED provided a response to this document in its ultimate recommendation to continue denying these waivers that was issued concurrently with the NOITS, correct?

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

Q. EFED did review this document and discuss it in the EFED memorandum concerning the remaining three environmental fate data requirements that was issued at the same time as the NOITS, correct?

A. We would have considered it, yes.

Q. And that would have been the first time that AMVAC would have received any response to this document, correct?

A. If your characterization earlier of the lag in providing the information to AMVAC, that's correct then, yes, that probably would have been the first one.

Q. And is it your understanding of this document

that AMVAC was agreeing that the assumption of stability could be appropriate in connection with the DCPA? Or TPA rather. I'm sorry.

A. What happens in most of these responses, most of the time AMVAC has characterized this, as I said, is if it would be appropriate for EPA to go ahead and assume stability and that's exactly what's being presented here -- it says that EFED should do that but in reality, and I'm paraphrasing, in reality, the chemical would break down, but it breaks down after a lag phase and therefore it wouldn't be measurable in OPP's study design.

Q. That AMVAC is urging waiver of the data requirements with the knowledge that that would lead to EFED being -- EFED using the most conservative assumption possible, correct?

A. They are encouraging it at one point and then they're saying that even though you should make that assumption it would be wrong essentially -- they're arguing that essentially it will break down at some point. Therefore, whatever you assume, if you assumed stability then obviously, you're wrong because what they're saying right here is it degrades. So, on one hand they're saying yes, assuming stability is perfectly fine and then that's the thing you should do and on the other hand they're saying essentially, they're hedging

their bets and saying, but in reality, it's going to break down and so the number that you use is not going to be correct, or the stability assumption is not going to be correct.

Q. But for purposes of risk assessment, the stability assumption would be made, correct?

A. Well, so you can calculate a number doing that but the question is always going to be what is the uncertainty in those numbers and so essentially -- and just in fact like some of the other earlier testimony I gave, you're looking at uncertainty in the exposure number and you're looking at uncertainty in the -- end point that we're comparing it to and essentially it's meaningless because of the uncertainty in the assumptions in other words you have -- you're assuming stability --

Q. Let's constrain ourselves to the three fate requirements that are discussed in your testimony and that is the one side of the equation. With respect to the persistence side of the equation, the expectation is that in the absence of data, full stability will be assumed, correct? Let me put this another way. Does AMVAC suggest an alternate value for the half-life in this document?

A. No, they do not.

Q. And so, the only possible effect of the grant

of a waiver request in this case, with respect to the upcoming risk assessment would be that full stability would be assumed, correct -- unless EFED were to, on its own, make up one and say, we'll use this value for the half-life?

A. So, what we have tried to do that I guess is what I'm trying to -- we have tried to figure out is there any degradation observed for TPA. So, we don't believe that it's actually stable. So, AMVAC has argued that the Agency should-- assume stability but it's not actually stable -- and we actually have indicated, I think in a couple of documents, that we believe that may be true, that it's not stable.

Q. So, as between EFED and AMVAC in the scenario that you've just described, it is AMVAC arguing for the more conservative assumption and EFED believing that perhaps a study might show hypothetically that there is degradation in these studies?

A. If the Agency or EFED is concerned that there would be too much uncertainty in the risk assessment for it to be of value.

Q. But any uncertainty - the only question would be how excessively conservative the risk assessment was, correct? There would be no concern that the risk assessment would be insufficiently conservative?

A. So, it would be essentially that the chemical failed assessment -- is the issue. So, in other words, it's kind of preordained that if you go ahead and say, we'll assume stability and -- it gets kind of complicated -- but if you assume stability in the water body that the EPA uses for their ecological risk assessment and you assume stability for the -- both the aquatic metabolism studies, essentially the chemical was going to build up continuously over time, and so essentially, it's kind a preordained conclusion that their chemical is going to fail. So, we prepare risk assessment making, you know, making conservative assumptions, knowing the chemical is going to fail and we would be right back at that same place where it would be like, well, do we believe those numbers. Do we need a study to go ahead and tell us what, you know, what those numbers are going to show. It's not so much that -- the study could actually come back and say, yes, it is stable but the question is -- what's the uncertainty in the assumption. So, in other words, nobody's going to believe it until you've got a study that backs it up is the way that I would say it.

Q. Well, that gets us into a related issue to the question of whether an assumption of stability is substantively correct. There is a related question of whether a laboratory study under the 835 series

guidelines would be expected to show degradation of TPA even if it does in fact degrade in the environment, correct?

A. So, what AMVAC is arguing is that there would be a lag time when you -- if you were to go ahead and do that TPA study -- and I shouldn't put words in AMVAC's mouth -- but my understanding of what AMVAC is arguing is that the study duration would not be long enough to actually get past that lag phase. So, what you would see is that it would appear that the chemical was actually stable and then it would start breaking down after the study was over is what is likely AMVAC's argument.

Q. And the degradation that you understand AMVAC to be arguing would occur is microbial in nature, correct?

A. That's what they are arguing and that would be my understanding. That would be my assumption, too.

Q. That there might be microbes in that field, so to speak, that would acclimate and be able to break down TPA over a longer time horizon?

A. That is what AMVAC -- that is my understanding of what AMVAC is arguing, yes.

Q. But we would not see that fact in the laboratory study that is closed off from the environment, correct?

A. That's what they are arguing, yes. That's my understanding of what they are arguing.

Q. So, for the first time in EFED's memorandum issued concurrent with the NOITS, EFED acknowledged that, and I quote, "longer than standard duration might be needed to measure degradation of TPA," correct?

A. So, I actually, you know, wrote that in there or edited that into the document. It's essentially -- I'll explain it this way. In the OPP guidelines it says studies, and I'm paraphrasing here, but the studies should not typically be more than 120 days, and it says similarly for the -- so that would apply to the anaerobic soil metabolism and it says studies should not typically be longer than 100 days for aerobic and anaerobic aquatic metabolism studies, but the actual guidelines actually allows you to go beyond that and actually mentioned at least for the soil metabolism studies says it could be six months or a year within the duratioin -- a lot of people assume that 120 days is, you know, that's where we should stop. EFED has a lot of studies that have gone on six months to a year and they appear to be perfectly good studies, and so that phrase is supposed to say don't stop at one hundred days. You know, go ahead and do the longer duration. So, that was the intent at least.

Q. And the document issued at the same time as the

NOITS was the first time, as you just stated, that EFED had explicitly referenced the potential to extend the study out longer in the case of DCPA, correct? You said the general understanding of registrants that study under these guidelines may only last 100 or 120 days, but that they can be run longer, correct?

A. Yes, but that's in the OPP guidelines. It says that. A lot of people don't -- they read over it and they don't see that, I think is the issue. So, what you're saying, though, is true is that that was the first time that anybody had actually put that phrase into a document regarding DCPA to AMVAC as far as I know.

Q. And on page 4 of your testimony-- Mr. Sayres, could you bring that up? In the italics in several spots, if we could focus on perhaps the second one, you reference the OPP, the guidelines, the 835 series guideline, and this is the language that you are referring to that you say sometimes folks skip over that. There's kind of the standard, but you can go longer if you need. So, down below where it says when necessary to characterize the decline of the test substance studies can be continued for longer periods, correct?

A. Yes.

Q. And then there is a citation to paragraph J9 of this guideline.

A. So, that refers to someplace further. It's actually page 11. I kind of had a real hard time following the chain on the kind of thing but, yes. Where those words came from on page 11.

Q. Mr. Sayres, can you bring up PAX 82, please, page 13. And if you could give us the "test duration" paragraph. So, this is the source of your quote, correct?

A. Yeah.

Q. And Mr. Sayres, if you could go to page 17 of 19, please, to the citation, the J9 citation. That's the line -- nine just above there, SETAC 1995. The reference to J9 is the citation for this document, correct?

A. Actually, this is the first time that I've understood the footnotes in this document, but that makes sense to me.

Q. Are you familiar with this 1995 SETAC publication?

A. So, it's -- we were just provided with a copy of it yesterday. I read through this portion and I can testify that, you know, it says something different than our guidelines say regarding the amount of time or essentially -- essentially, they look very similar but instead of saying normally or -- I'm sorry, paraphrasing here again, typically would not -- or typically it should

be -- a study should not last longer than 120 days. In the SETAC guidelines that always has it should not last longer than 120 days. Or for the aerobic -- or aquatic metabolism studies says it should not last longer than 100 days. So, EPA made a conscious decision to not use that same text and actually added in the "not normally," you know, modifier or whatever they call that to indicate that you could go longer than.

Q. You just stated that until yesterday or the day before you had never actually reviewed the SETAC 1995 publication, correct?

A. That's correct.

Q. And you stated that it is - in some particular - different than the 835 series guidelines that we were talking about, correct?

A. Yeah. It's different, but the language is so similar. It's essentially that I believe that the language we have was probably pulled from this or vice versa but there were differences made between the two. So, somebody - the SETAC publication doesn't go much beyond 120 days, but OPP guidelines do want you to go beyond 120 days, or 100 days depending on which studies.

Q. Were you personally involved in any of the discussions that resulted in the 835 series guidelines reading differently than the SETAC guideline?

A. No, I was not.

Q. So, you have no personal knowledge of why there may be a distinction between the two guidelines?

A. I could speculate from it. I have an idea but I don't, you know, if you don't need it, that's fine.

Q. If your counsel wants it, he can get it. Mr. Sayres, if we could go back to petitioner AMVAC's exhibit, same Exhibit 82 back to page 13 and back to the test duration paragraph. So, you stated that there was a distinction between the 835 series guideline and the SETAC guideline, correct?

A. Yeah. I doubt the SETAC was understood to be called a guideline. It's a -- if there is a difference between the two.

Q. It appears to me that the 835 series guideline cites that SETAC guideline, does it not?

A. Yes. Right. Probably the SETAC guideline is probably older.

Q. And it cites it specifically for its discussion of how long studies can be continued?

A. Well, it cites the guideline, the current one. It cites the document but it doesn't say necessarily what it is that it is citing about, but the fact that it appears after the 6 to 12 months indicates that it has something to do with that, I would assume, or at least it

had something to do with duration.

Q. Mr. Sayres, can you bring up the full version of the PAX 85? This is the SETAC guideline.

MR. PITTMAN: I would object to that. It's admittedly beyond the scope of this testimony. Mr. Wente has expressed that he is not familiar with this document.

MR. ROSS: This document is directly cited in the relevant guideline. I believe we should be -- he's also already testified to knowledge of distinctions between the two.

JUDGE BIRO: Okay. Overruled.

MR. ROSS: Could you pull up to a full version.

JUDGE BIRO: Go ahead.

BY MR ROSS:

Q. Mr. Sayres, do you have the full version, the additional pages? Can you go to page 12 of 56, please? Mr. Wente, is this the document that you said that you'd reviewed for the first time a day or two ago?

A. Yes. I think.

Q. Do you recall if you reviewed this provision here, duration and sampling?

A. Yes. Yes. I remember because I was struck by the fact that it says not to exceed 120 days whereas ours says something different.

Q. And so, your quote -- or rather, not your

quote, but the quote from the 835 series guideline that you reference in your testimony and's with "(e.g., 6 to 12 months)" that we're seeing here on the screen, correct?

A. Oh, that actually does appear in this one. That's surprising to me. I didn't realize that.

Q. And the immediate subsequent sentence reads "in the light of the reduced microbial activity of soil following long periods of incubation in the laboratory, the results of tests conducted over periods longer than four months should be interpreted with caution," correct?

A. Yes.

Q. So, SETAC is not saying that you cannot extend these tests longer. It's just saying that because there is potentially a difference in the microbial activity of field soil versus laboratory soil it may be necessary to view skeptically studies that exceed four months, correct?

A. So, in the OPP guidelines I believe there is actually an additional suggestion or it essentially tells you to go ahead and take additional measurements of microbial biomass if you conduct a longer test. In other words it says that instead of just at the beginning and the end, and I think it suggests that at multiple points throughout. That's my recollection. I know that there's

something about additional biomass but I can't -- or biomass measurements but I can't tell you exactly what that language is.

Q. Now, as we discussed earlier with respect to TPA it is specifically the question of whether or not microbial degradation will occur at some future point. It is essential as to whether or not a lab study would show you the effect that you're looking for, correct?

A. So, if you didn't -- if the microbial activity of the soil, you know, stopped or diminished greatly then, no, you wouldn't be able to see the degradation of TPA anymore.

Q. And that would appear to be --

A. Or any of the other chemicals that are still degrading.

Q. And that would appear to be precisely the outcome that this additional language in the SETAC guideline is cautioning against, correct?

A. That's what this is cautioning against and that's what the additional requests for microbial biomass is trying to ensure. So, in other words, if you saw that the biomass went away, which is kind of what this one is suggesting or it's greatly diminished then you would have to -- or you would know that that longer duration or at least the part that -- at least in those time points

later on when the microbial biomass had diminished then you would know that you should interpret that with caution or potentially throw it out.

Q. Turning back to EFED's memorandum issued concurrent with the NOITS, again, that was the first time that a longer than standard study of any type was explicitly mentioned by EFED, correct?

A. Yes. But that said -- it's in the guidelines that's available to everybody at any time, back to, you know, whenever it was written.

Q. Let’s turn for a moment to the outstanding aerobic aquatic data requirement, the 835.4300 study. On Page 6 of your testimony you state that EPA denied an AMVAC waiver request in a document dated March 21, 2014, correct?

A. On March 21, 2014, denied a data waiver request. Yeah.

Q. This was the date of an EFED memorandum that recommended that PRD not approve the waiver request, correct?

A. Yes.

Q. Are you aware of any separate PRD document dated March 21, 2014, that denied AMVAC’s data waiver request?

A. I would never see any PRD documents. Well,

it's rare that I would see one -- all the PRD the decision documents. Those get reviewed by us. Typically, something like this would not come back to me. And I'll just -- just to be clear, I wouldn't have been in the branch at that time.

Q. Are you aware that the EFED document dated March 21, 2014, was not provided to AMVAC until March 2017?

A. I get the documents confused, but I am aware of that -- I am aware that some of the documents were delayed or were not provided to AMVAC right way, but I'm not -- I only know that because I've heard it in some of the meetings about this and I think it's actually mentioned in either the EPA motion for accelerated decision, or in respondent's documents or motions to the court.

Q. Farther down on page 6 of your testimony you referred to a December 17, 2020 document from AMVAC that disputed EPA's reasons for denying data waiver request but did not submit the required data or provide any new or additional evidence supporting its data waiver request, correct?

A. Yes, that's correct.

Q. But AMVAC did in fact supply a new DCPA guideline 835.4300 study during the course of the DCI,

correct?

A. So, we -- so this is aerobic aquatic metabolism. We received an aerobic soil metabolism study for TPA but I don't recall the -- so, is this -- are you saying that they submitted a study for aerobic aquatic metabolism for DCPA?

Q. Correct. Yes.

A. Okay. I'm not sure exactly when that was provided to us. But I assume that the date you're talking about is correct.

Q. But for the response in December 17 of 2020, you characterized AMVAC as not providing any new or additional evidence. It was urging EPA to consider the separate DCPA 835.4300 study, correct? Which EFED ultimately declined, at least did not respond to that specific invitation, correct?

A. I'm sorry. Can you please repeat that again?

Q. The waiver request that was submitted in December 17 of 2020, was asking EFED to take note of a DCPA guideline 835.4300 study, correct? Which was the basis for a waiver of the TPA study?

A. I do believe what you're saying is correct.

Q. And in Joint Exhibit 79, which was issued -- this is the EFED memorandum issued concurrent with the NOITS, Mr. Sayres, if you could pull up Joint Exhibit 79

at page 5 of 12. And scroll down to the bottom and look at footnote 2. Footnote 2 indicates that EFED ultimately was able to derive a stable half-life based on the DCPA guideline 835.4300 study, correct?

A. So, that's what it says there. I do not -- yeah, to be more specific, when you have to look at things, but I would relate it to what it says there. Oh, aerobic aquatic metabolism. Okay.

MR. ROSS: No further questions, your honor.

JUDGE BIRO: Before you begin, Mr. Pittman, let me see if -- Ms. Rose, do you have any questions you wish to ask?

MS. ROSE: I do not Your Honor.

REDIRECT EXAMINATION

BY MR. PITTMAN:

Q. Good afternoon, Mr. Wente. Just a few quick questions here. When we are evaluating the studies submitted -- I'm sorry, when OPP is evaluating the studies submitted, are they evaluating them against the guidelines that OPP publishes?

A. Yes, but I would say we’re also evaluating the studies against the other studies that are submitted to make sure that things are consistent and make sense.

Q. Does OPP evaluate all of the studies submitted against all possible referenced guidance documents that

are referred to or cited in the guidelines adopted by OCSPP?

A. No. It's essentially, you know, the US EPA, you know, goes by their guidelines. You know, if you want to register a pesticide in the United States you want to go ahead and use the other OPP guidelines and there is no place that I'm aware of that SETAC has any jurisdiction. So, it's not really germane to go back to the other ones, to the other references.

MR. PITTMAN: No further questions.

MR. ROSS: No further recross, Your Honor.

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

MS. ROSE: No, Your Honor.

JUDGE BIRO: Do want the opportunity to reserve the right to recall Dr. Wente?

MR. ROSS: Yes, Your Honor, the same with Ms. Wendel.

JUDGE BIRO: Okay. So, Dr. Wente, we're going to release you, but you remain under the requirements to not discuss your testimony with anybody who would be a witness in this proceeding or really anybody else who might have any interest in this proceeding. Do you understand?

THE WITNESS: Yes. So, through Friday, I

believe, is the end of the hearing?

JUDGE BIRO: I'm sorry?

THE WITNESS: Through Friday is the end of the hearing so I don't talk to anybody until the hearing -- until I'm told that the hearing is over, right?

JUDGE BIRO: Yes. Until you hear from the counsel for the agency who tells you the hearing is concluded. Okay?

THE WITNESS: Okay.

JUDGE BIRO: I don't know what's going to happen on Friday. Somebody might not be available and we continue at a later date. So, until you hear otherwise, just don't say anything.

THE WITNESS: Okay.

JUDGE BIRO: Okay. Thank you for your testimony.

THE WITNESS: Okay. Thank you.

JUDGE BIRO: It's 2:35. Can we take a 10 minute break?

MR. ROSS: Yes. That's agreeable, Your Honor. I know there is at least one Exhibit that I referred to it during the course of the cross that we would like entered into evidence. We can do it now or --

JUDGE BIRO: Sure. Let's do that.

MR. ROSS: -- We can look into that over the

break if you like and afterwards --

JUDGE BIRO: Oh, fine. Okay. That's fine. Maybe you can agree on that. That would be great. So, we have a standing recess until quarter till two.

(Whereupon, a recess was taken)

JUDGE BIRO: Okay. Please be seated. Okay, Mr. Pittman, would you like to call your next witness?

MR. PITTMAN: Thank you, Your Honor. Respondent would call Ms. Jill Bloom.

JUDGE BIRO: Ms. Bloom, if you would just stand by the witness chair.

THE WITNESS: I'm sorry?

JUDGE BIRO: If you could just stand there, raise your right hand, the court reporter will swear you in.

THE WITNESS: Okay.

(Whereupon,

JILL BLOOM,

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

JUDGE BIRO: Please be seated. Do you have water? Would you like water?

THE WITNESS: Actually, I just -- thank you.

JUDGE BIRO: Okay.

THE WITNESS: Thank you.

DIRECT EXAMINATION

BY MR. PITTMAN:

Q. Good afternoon, Ms. Bloom.

A. Hi.

Q. Would you please state your name and current title for the record?

A. My name and what?

Q. Current title?

A. Oh, this is Jill. -- I'm Jill Bloom and my title is lead environmental protection specialist.

Q. I just provided you with what has been marked as the witness statement of Jill Bloom.

A. Uh-huh.

Q. Do you recognize this document?

A. I sure do.

Q. How do you recognize it?

A. I drafted it and signed it.

Q. And so, this is a true and accurate copy?

A. It looks to be.

Q. I move that the witness statement of Jill Bloom be admitted into the record as Rx 27.

JUDGE BIRO: Is there any objection?

MR. PITTMAN: No objection.

MR. WEINBERG: No objection, Your Honor.

JUDGE BIRO: Ms. Rose, do you have any

objection?

MR. ROSS: No objection, but if the witness could move the microphone closer to her when she speaks that would be helpful. Thank you.

JUDGE BIRO: Okay. So, without objection, Rx 27 is admitted into the record.

(Exhibit Rx 27 was admitted)

JUDGE BIRO: Mr. Weinberg?

MR. WEINBERG: Yes, ma'am. I'm just looking at my copy of the testimony. I will be right with you, ma'am.

JUDGE BIRO: If you can't find it, I would be happy to give you mine.

CROSS EXAMINATION

BY MR. WEINBERG:

Q. Okay. Good afternoon, Ms. Bloom. How are you?

A. I'm fine. How are you.

Q. I think we've met before, but it's nice to see you again.

A. Thank you.

Q. My job here as counsel for AMVAC Chemical Corporation is to ask you a number of questions raised by your direct testimony in this proceeding. If you ever don't understand a question or require clarification, please let me know. This is, for better or worse, not

like your TV program Perry Mason or anything of that sort. We're just trying to draw out the facts.

A. I will just state that I'm a little hard of hearing so if you could speak up, that would be helpful.

Q. I'd like to start out with an understanding, if we could, of your role. You describe yourself in your testimony as a lead environmental protection specialist. Could you tell me what it means to be a lead environmental protection specialist?

A. So, what a lead environmental specialist is in my case is a team leader who assists chemical review managers in all of the functions of their job.

Q. And is that the same as a chemical review manager?

A. In PRD, the chemical review managers would be the people I was advising and helping.

Q. I'm sorry. In your C.V., you were I think --

A. I'm a team leader. The people the next level down are chemical review managers or CRMs.

Q. Okay.

A. I was a CRM before I was a team leader.

Q. And in the first page of your testimony you indicate that you held other leadership positions in the risk management and implementation branch over the years. You didn't really say much about what those were in your

biography, included as an attached -- the resume attached to your testimony was a little incomplete. Could you tell us a little bit more about what the leader positions are you played at EPA?

A. So, when I was in RMIB5 I was always a lead environmental protection specialist. For part of that time -- for that part of that time I was acting in that position and then for the last nine years, I forget how many years, I've been a team leader. Before that I was a chemical review manager in a couple of branches.

Q. And what generally speaking is the role of a team leader, or more specifically, your role as a team leader?

A. Right. So, I'm kind of positioned between the branch chief and the chemical review manager. Typically, a team leader will work with chemical review managers on specific projects. It might be the TL for somebody on one case and not for another case, but the job of the TL is to assist the CRM in getting work done that needs to be done; providing advice, counsel, editing et cetera.

Q. And excuse me, that role in the hierarchy of the EPA is below the level of a branch chief; is that correct?

A. It is.

Q. And the branch chief is below the level of a

division director --

A. Correct.

Q. -- for OPP, correct?

Could you pull up 13, please? It's RX-13. I'm sorry. This is a document that we were provided by EPA in discovery in this case. Are you familiar with this document?

A. Yes.

Q. And there is a companion piece. If we could pull up RX-14 as well just so we can get the -- which is also what I would describe as a process explanation; is that a fair statement?

A. This is for -- yes.

Q. And would you -- you explain what is the role of these documents, these two documents?

A. So, it provides general guidance for the chemical review manager of the steps of registration review including responsibilities for bringing about certain milestones, holding team meetings, talking to registrants, all aspects of the role of the chemical review manager.

Q. And this would be the guidance from the -- for the team lead as to how to proceed and others as to how to proceed in the context of the Data Call-In and re-registration; is that correct?

A. Yeah, and it's targeted more to the CRM, but it applies to team leaders as well.

Q. Uh-huh. So, if I look at RX-14 a minute, just to be clear, and page 1, there is a reference to the CRM and being responsible for creating the DCI in Prism. That's right under stage IV there. Was that a role that you were in at the time that DCI was issued?

A. So, when the DCI was issued, I was the chemical review manager and I think that predated this guidance, but it was similar.

Q. Okay. Were you in that role for the DCPA Data Call-In?

A. So, just about the time -- I believe -- I think the Data Call-In was completed before I went to go to be a team leader and so consequently it was issued after I went to be a team later but, yeah, but I was -- until that point, I was involved in the development of the Data Call-In.

Q. Uh-huh. Okay. And then if we look at RX-14, there was also a reference to the chemical review manager there as well in terms of the roles of the chemical review manager and he would be in that position. That would be the position you were also in, currently involved in, although over the last 10 years you may have had slightly different positions, as I understand?

A. I'm not sure what your question is.

Q. Sure. Let me restate it. Let me restate it. For the purposes of this Registration Review Guidance, do you see how "issuance to decision" that is Exhibit 14, the first line identifies the activities to be a guidance for the chemical review manager and that's the role that you played currently, or you may not have played it at the very beginning of the process of the DCI which is the subject of this case?

A. So, I was a chemical review manager for the development of the DCI and just about at the time it was issued. After that I was the team leader in a different branch.

Q. Okay. On the second page of Exhibit 14, Respondents Exhibit 14. Excuse me, I have a cold that I caught from my granddaughter and that's the problem with having children that go to preschool. In RX 14, there is reference to OMB having to approve studies before DCI can go out to registrants. Do you see that?

A. Yes. So, that changed a little bit. Originally, we had to justify all of the studies and send the information to OMB, but then they were looking at the same studies over and over again which were very basic studies, so we sort of limited it from a sort of -- we limited it after a while to special studies, or unusual

requirements.

Q. And how was that changed?

A. How was that changed how?

Q. No. How was that changed? We asked for all of them was a -- documents that provided guidance for the -- for this is what we got?

A. Yeah, I don't know that that would be documented anywhere.

Q. Okay.

A. It could have been requested by OMB, but I'm not sure.

Q. You currently do less with OMB?

A. I'm sorry?

Q. The CRMs and team leaders currently do less review with OMB when there are Data Call-Ins?

A. If there's providing justifications only for a subset of the studies in the DCI. I guess that would be true.

Q. And in the middle of the page and the first bullet under “registrant submits 90-day responses” it indicates that the 90 day response on the second line will generally indicate whether the registrant will be conducting a study, requesting a waiver, or rather that they have made an offer of pay. So, that's the first response that you get from a registrant as to how they

are going to respond, correct?

A. Yeah. That's not all the options but that's summary of probably the more frequent ones.

Q. Okay. And then just going down a little bit further to the bullet point that says the registrant produces and submits data. The first bullet, the second sentence says the CRM should be in contact with registrants in the months prior to the date of submission due date to ensure that the data submission will be on schedule, or why it may be too late, be delayed. Do you see that sentence?

A. Uh-huh.

Q. So, the person in your role, the team leader, in your role would be responsible for having undertaken that responsibility?

A. No. That would be the chemical review manager's responsibility, but essentially, they meet their responsibilities --

Q. Well, let's try to be more specific than with regard to this particular DCI. Who had the responsibility at your branch for undertaking this responsibility?

A. So, after the DCI was issued, shortly after, I went to a different division -- not a different division -- a different branch and the chemicals stayed in the

original branch and went to other people and I wasn't involved.

Q. So, who would have been -- while you were not at this branch, who would have been the CRM? Do you recall?

A. So, there were a number of changes over time. I looked in my records. I believe that Meg Hathaway was the first one and Matt Manupella was also one. Sue Bartow was one and there was some correspondence managed by Tom Myers who was a team leader in that branch at the time.

Q. And then when you came back to the branch and responsibilities for the DCPA DCI?

A. So, I didn't come back to that branch. I went to another branch and then eventually the responsibility for that chemical came back to our branch and --

Q. Well, when you became responsible, when it was transferred to the branch in which you had moved -- let me back up, my understanding is that they transferred the responsibility to a new branch and you were at that new branch and you --

A. Yes, I was the team leader.

Q. Correct. So, would you have been playing the role of a CRM at that point as the team leader?

A. So, the first correspondence that I had that I

looked at shows that there was a lag between the time I made it to the branch and a CRM was assigned and I would have been, but I didn't find any correspondence to that, you know, for myself at that time.

Q. Well, with regard to this DCI that we're talking about here today, at the time that you took over that responsibility, and when was the time approximately?

A. I think it was -- I'm getting the year wrong. I think it was December 2014.

Q. Okay.

A. And then a CRM was assigned in January 2015, as I recall.

Q. Okay. So, in terms of the responsibility for being in contact with registrants in the months prior to the data submission due date in the DCI, was that your responsibility or was that the responsibility of the person who reported to you?

A. That would have been -- okay, so before I changed branches it would have been a person that wasn't reporting to me.

Q. I'm talking about when you were there, when you came back and 2014, I believe you testified?

A. Right. I would have been -- the CRM would ultimately have been responsible and I would have been guiding that person.

Q. I'm sorry. I misunderstood you.
A. The CRM would have been ultimately responsible, but I was guiding that person.
Q. Okay. So, there was somebody that reported to you?
A. Yes.
Q. Now, let me just move down to some specific questions about the testimony that has been submitted and, excuse me. Did you write the first draft of this testimony?
A. I think so. I don't really recall, but I think so.
Q. Okay. Do you recall whether it was prepared before or after the motion -- there had been a decision made to file a motion for accelerated decision?
A. Gosh, I don't remember. Sorry.
Q. Well, it does make reference to endorsing the facts that are in that motion. Does that clarify your recollection at all?
A. Yeah, so that probably -- I mean that seems about right. So, we had to -- we had to prepare the statements when we thought there was going to be a hearing before the ALJ. That's right.
Q. And were you consulted by counsel on the question of whether -- let me be clear. I'm not asking

what your counsel told you. I'm just asking for the -- were you consulted by counsel as counsel prepared the motion for accelerated decision?

A. I was.

Q. Okay. And did they run every fact that they were going to assert in that document past you?

A. I'm sorry. Could you please repeat that?

Q. Sure. Did counsel run every fact that is asserted in that document past you for confirmation?

A. As I recall, I was one of the people who was asked to comment on that draft. So, I read the whole thing several times.

Q. Okay. So, if I understand it, you put together a first draft of the testimony and what were you asked to do in that first draft? Somebody must have told you we need some testimony about something. What was it that they told you to do?

A. So, I think I was asked about my role and I think I was asked about the history of correspondence with the EPA on the DCPA DCI. Yeah, that pretty much sums it up.

Q. Well, did anyone other than yourself in your branch other than counsel have a role in preparation of the testimony?

A. I believe that we all reviewed each other's

work.

Q. I'm sorry. Could you explain what we all means in that sentence?

A. So, the written statements were prepared and a group of us who were involved as potential witnesses reviewed the other people's --

Q. And who would be in that group?

A. So, you've met two of them today, Christina Wendel and Steve Wente.

Q. And was there anyone else?

A. In the other witnesses? You

Q. No, any other person?

A. Yes, there was a whole group of us. I mean up my management chain, OD, yeah.

Q. And do you remember the names of any of the other individuals?

A. That reviewed the statement?

Q. That reviewed the draft or the drafts as you were preparing your testimony?

A. Right. Well, it would have been Forrest, it would have been my branch chief, Cathryn Britton. I believe it probably involved my division director Ms. Reaves and then the folks that we talked about from EFED Christina and Steve.

Q. Uh-huh.

A. There were other statements, too, but I guess they have fallen by the wayside. So, there were other people too in science divisions.

Q. Can you state on page 2 of your testimony -- and that's just quoted as you probably remember it. As laid out in Respondents June 2013 memorandum, motion for accelerated decision, and then the supporting memorandum, AMVAC failed to take appropriate steps to secure the data required in the DCI deadlines set out for the review. Are you with me?

A. Yes. I'm following. Did you have a question about that statement?

Q. What did you understand the word appropriate steps -- the words appropriate steps to mean.

MR. PITTMAN: Objection. Calls for legal conclusions.

MR. WEINBERG: No, it did not.

JUDGE BIRO: She can answer what she was thinking when she --

MR. WEINGBERG:

Q. I'm asking what your understanding was?

A. The appropriate steps?

Q. Yes.

A. Yeah. So, it would be a commitment to fulfill data requirements or another appropriate response, a

waiver request or submitting data that already existed or something like that, and following through until we got the data.

Q. And when you say that as laid out in the motion or the supporting memorandum, AMVAC failed to take appropriate steps. Were you testifying in support of their brief's factual conclusion in that motion or memorandum?

A. Can I testify as to what? I'm sorry?

Q. In support -- are you swearing to the truth of every factual statement in the motion and memorandum?

A. Yes.

Q. Okay. All right. Now, would I be correct in understanding that you are not trying to opine as to the legal meaning of the appropriate steps or any of the legal conclusions of the memorandum?

A. I'm not sure what that line would be between legal and of those --

Q. Why not?

A. I take appropriate steps to have to do with getting the data, right, and then there are other interpretations of what those appropriate steps are, and I've read them and they seem consistent with what I understand.

Q. Well, you do believe that the statutory mandate

to take appropriate steps, close quote, is what grants you the authority to make judgments as to whether they have been made, didn't you?

A. I guess. Yeah. Not myself alone, but yeah.

Q. I'm sorry?

A. Not myself alone, I guess.

Q. No. Of course not. As you recall, in your testimony, you testified that AMVAC's responses were much longer than others. I think you use the phrase dilatory and abnormal in testimony. Do recall that?

A. Yes.

Q. What do you understand the word dilatory to mean?

A. Causing delay.

Q. I'm sorry?

A. Causing a delay, repeatedly --

Q. You understand that the -- do you know the dictionary definition of what dilatory is?

A. I probably do, but I don't know.

Q. If you would just put up that picture and go at the one sentence that matters. This is the Oxford English, concise Oxford English dictionary. I've chosen because I happen to have it in my desk. I did not do a full on of all possible definitions. Do you see that definition?

A. Yes, I do.

Q. And is it and accurate definition of what you meant by the word dilatory?

A. So, I see definition one and two and that two goes to intent and I don't know what the intent was, so I would say the definition one "slow to act" would be what I meant.

Q. So, could you just repeat what you said. I'm sorry. When you look it that way, I don't hear you very well.

A. Oh, I'm sorry. What I said is definition number one is "slow to act" would be what I meant because the second one talks about intent and I don't know what the intent was.

Q. Okay. Now, let me turn to another aspect of your testimony. You repeatedly -- a rather let me just ask it a couple of -- yes. On page 3 of your testimony, you say that it is common for registrants to submit comments on preliminary work plans?

A. Yeah, I would say that's true.

Q. How many preliminary work plans have been put out for comment under your supervision?

A. So, it would be around 50. I've been involved in about 50 registration reviews and I might have come into some after the preliminary work plan was published,

so around 50.

Q. Around 50?

A. Yeah.

Q. And when you say common, what do you understand that to mean?

A. So, covers the preliminary -- well, we published the availability of the preliminary work plan in the Federal Register and we opened a comment period. And comments are submitted to the public docket and typically I would say more times than not a registrant -- people will comment on the data requirement part of the preliminary work plan and other things. Yeah, including the registrant.

Q. And how often do those comments result in changes in the study requirements --

A. I would say pretty frequently.

Q. Again, can you help me understand briefly what we have -- you said more than half of the comments you received -- more than half of the preliminary plans you have received comments. So, it's some fraction of that, more than half. What was your estimate be a fraction?

A. I'm sorry. I'm not understanding your question.

Q. Okay. Sure. You just testified that once the agency publishes preliminary work plans for comments, you

think you typically get comments back on the data requirements about half the time. I believe that's what you said.

A. That would be a good, round ballpark figure. Perhaps more than that.

Q. And of that half, what percentage of that half do you believe result in changes to the work plan?

A. If I had to give you a ballpark figure?

Q. Well, ma'am, you're the one who testified commonly and I'm just trying to understand what it means.

A. Right. So, if I had to put a number on how often the data requirements change because of comments on the preliminary work plan, I'd say maybe 25 percent of the time.

Q. 25 percent of the 50 percent or the 25 percent of all work plans that were ever put out for comment?

A. 25 percent of 50 percent. I'm not sure. I feel uncomfortable making a guess of that percent.

Q. It's not a trick question. I'm just trying to --

A. No, I know.

Q. -- Just make sure we get the number clear. If there were comments from 100 people, you would expect that there might be 25 of those that would result in changes. Is that --

A. Oh, no, that's not what I meant.
Q. Okay.
A. I meant in any individual case, probably about -- you know, that's an estimate of how the data requirements would change. Not how many people commented on it.
Q. I understand it, but let me restate it myself. I'm assuming you've got 100 comments, what percentage of those comments do you believe resulted in changes in the data requirements?
A. If you are talking about 100 comments over a number of preliminary work plans?
Q. No, I'm talking about a single workplan.
A. Oh, I don't think very many. First of all, we hardly ever get 100 comments and those comments are more than likely to come from the registrant. Yeah. So, I would say I was more willing to say that whenever a PWP comes out and the data requirements change, that's maybe 25 percent.
Q. Okay. Okay. Now, in your testimony you make frequent reference to actions taken by EPA. In some cases, you make reference taken by a particular branch of the EPA, but not in all. You are aware, are you not, that the statute, different statutes assign responsibilities to the Administrator of EPA?

A. Yes.

Q. And the Administrator of the EPA then issues documents referred to as delegations?

A. Yeah, that's typical, I think.

Q. That's a common practice, right? And that is -- someone casually looked at your testimony that says EPA did something, one might not be able to identify from the statement who it was that actually took the particular action; isn't that correct?

A. Yes, I would say that is probably true but it's almost always within my division. I can't think of a case where it's not actually.

Q. Now, are you aware that in this case AMVAC asked for copies of all documents memorializing delegations of authority to grant or request -- to grant or deny waiver requests in connection with the DCPA DCI -- that grants any authority to any person in or within the EPA below the level of the administrator that are now in force or were in force at any time after the issuance of the DCI?

A. Yes, I'm aware.

Q. Okay. Now, EPA did in fact produce a number of documents; isn't that correct? And are you generally familiar with those documents?

A. Very generally.

Q. Are you generally familiar with the format that those documents -- the form that those documents take?

A. Yes.

Q. Okay. Let me show you one that has been identified as PAX 71.

MR. PITTMAN: Your Honor, objection. Scope. This is not part of the sworn testimony.

MR. WEINBERG: I believe it is necessarily part of her testimony. She's just testified that the phrase, the word EPA as used in her testimony is imprecise and from the perspective of this matter that is quite an important issue, I think we need to understand who she is talking about making certain decisions, and that's why I'm going to clear this up, Your Honor.

JUDGE BIRO: I think it is beyond her direct and I don't think there's any dispute about these delegations, that it did not go down to EFED. That's not in dispute.

MR. WEINBERG: Your Honor, with due respect, we think they didn't go down to levels above EFED and that's why we want to go into this. I was not aware that plaintiffs were prepared in this -- pardon me, not plaintiffs -- the government was prepared to stipulate or concede that EFED hadn’t been delegated, but I do believe that there is reason to believe that no one below

division director had --

JUDGE BIRO: Don't these documents all speak for themselves? Don't they say what they say? Either there is a delegation or there isn't. What difference does it make what she knows or doesn't know? You know, that's a legal determination, isn't it?

MR. WEINBERG: Well ultimately it is a legal determination. But we believe, Your Honor, that there is sufficient complexity here. We were provided by counsel in that discovery request a number of documents and several pages, at least two pages of explanation as to how they all fit together, which is by no means clear from the face of the documents. It is our impression that EPA has no intention of clarifying that matter through testimony, so we thought it would be useful to get clarified on this cross-examination that issue. Now, admittedly the documents are going to be in the record. I believe they have been stipulated to, I am I correct?

MR. PITTMAN: No, that's not correct.

MR. WEINBERG: Okay. Well, if the government is prepared to stipulate, they are in the production and in the record, and we can -- or recognition as an official government document, that would eliminate me from doing this. I agree with you on that, but to date they have not been prepared to do either of those things.

JUDGE BIRO: Okay. So, tell me who you think the documents reflect the authority to grant or deny waivers?

MR. WEINBERG: I think until very recently, under any characterization of the documents, the authority to grant waivers did not go below the division director role. And I think that all of the waiver decisions and activities -- most of those that we are talking about in this case were never approved at the division director level.

JUDGE BIRO: And that is -- in that division would be OCSPP or OPP? What is the division we are talking about?

MR. PITTMAN: OPP.

JUDGE BIRO: OPP?

MR. PITTMAN: OPP.

MR. WEINBERG: OPP. Yes. I'm sorry. That's why I started that.

JUDGE BIRO: Okay. And is there a dispute about that issue in terms of what shows up in the document?

MR. PITTMAN: Your Honor, it's our position that we laid it out in our response to AMVAC's initial request for these delegations and documents. I believe they're pointing to the 5-38 delegations, but I have not

yet looked at the 5-1-B delegation and its sub-delegation they provided to me, which I do believe delegates that authority down to the team lead level, if I'm correct. But I would have to confirm about the team lead level.

JUDGE BIRO: Okay. So, that's just two different documents we are arguing over which control. So, what are you going to get out of her on that issue?

MR. WEINBERG: I was frankly going to try to lay the groundwork for moving to get these documents introduced, because I didn't have agreement with opposing counsel that that could happen.

MR. PITTMAN: Can I clarify? So, we did stipulate to the entry of these. I misspoke earlier. I did not stipulate to allowing for these generally on cross. I specifically made that reservation, that they also heard today.

JUDGE BIRO: Okay. Could we agreed to let in these two delegation documents?

MR. PITTMAN: Yes, Your Honor.

JUDGE BIRO: Okay. Let's admit them. What's the exhibit number?

MR. ROSS: The totality of the delegation documents that were either received in response to our FOIA request or provided directly by OPP counsel are the range of petitioner AMVAC's exhibits from PAX 63 to PAX

77.

JUDGE BIRO: So, these are RX 63 to 77?

MR. PITTMAN: PAX.

JUDGE BIRO: Oh, PAX. Okay. Okay. Is there any objection, Ms. Rose? Do you have any objections?

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

JUDGE BIRO: So, were going to admit into the record this set of documents on the issue of delegation. PAX 63 to 77; is that correct, gentlemen?

MR. WEINBERG: That is correct.

MR. PITTMAN: Yes, Your Honor.

(PAX-63 through 77 admitted)

JUDGE BIRO: Okay. Can we move on to another topic?

MR. WEINBERG: Yes.

JUDGE BIRO: Because I don't think that's exactly what we are here for.

MR. WEINBERG: Yes, ma'am. Mr. Sayres, could you please pull up JX 65?

BY MR. WEINBERG:

Q. Is this the preliminary work plan that you had previously testified about?

A. No, it's the problem formulation. The preliminary work plan is based primarily on the formulation from EFED and the scoping document from HED,

primarily.

Q. Thank you. Could we go to page 25? So, what purpose does this document serve?

A. This is the scientists advising us in this case what they know about the chemical already, what data they think we need and what assessments they think we need to do.

Q. Okay. And we do look at page 25, please? With regard to the ecological effects data on TPA that the DCI might need, does it say there for future assessments, in the absence of toxicity data for the degradate TPA, EFED will make highly conservative assumptions when evaluating the toxicity of TPA?

A. I don't see that in the text that is in front of me, no. Oh, it's there. It's the --

Q. It's the last line, yeah.

A. Yes.

Q. It does say that?

A. Uh-huh.

Q. Is that correct?

A. Yes.

Q. And do you have any reason to believe that the authors of this email did not -- pardon me, on this memorandum, did not intend that to be accurate?

A. No. I think that's what they believed, yeah.

Q. Okay. And then you would pull up JX 21, please? This is what has been referred to I think already as the October 2020 data review letter that was sent out notifying AMVAC that the agency intended to move forward with registration at --

A. My shorthand was the data delay letter.

Q. I'm sorry?

A. My shorthand for this is the data delay letter.

Q. Data delay letter?

A. Yeah.

Q. All right. And does that letter also state that the safety factors, the assumptions could include among other things adding additional safety factors to account for uncertainties?

A. Can you show me the text?

Q. Sure.

A. Part of the first page? Oh, the date of -- the agency will rely upon data available at the time where the agency is lacking data, conservative assumptions may be used in their place. Is that what you mean?

Q. Yes. It's the last sentence in the first paragraph.

A. Uh-huh.

Q. And this was in fact signed by the then acting division director who is now the division director, I

believe.

A. Elissa Reaves, yeah. Was in it the same --

Q. All right. Yes.

A. Yeah, there you go.

Q. So, that made the same point, did it not?

A. The same point that you are asking about in the problem formulation?

Q. Yes.

A. Yeah, I would say.

Q. But you also testified at page 7 of your testimony that the agency almost always requires the submission of -- excuse me, the submission of necessary data. Do you see that sentence in your testimony?

A. Yes. Most registration reviews include that data, for the purpose.

Q. What does the word "necessary" in that sentence mean?

A. Data that are needed to perform a sound risk assessment.

Q. Data that are necessary for a sound risk assessment? Thank you. Do you know when EPA concludes -- you are aware, I believe, that the agency ultimately informed AMVAC that it could not make a risk assessment -- could not actually make a risk assessment with the available data?

A. Yes.
Q. Making assumptions?
A. Yes.
Q. Do you know when EPA reached that decision?
A. I believe it was in April 2022.
Q. April 2022?
A. I believe so. It was after we received the preliminary CTA when we saw the results of that.
Q. Uh-huh. Okay. And you then characterized the situation at that time, and it's on the prior page where the characterization occurs as there being an abnormally high ratio of non-submission and waiver request on AMVAC's part. Do recall that testimony?
A. Yes. Yes. I did say that.
Q. How many of the other 50 DCIs which you have worked on had involved suites of testing on both the active ingredient of the product and the degradates of that?
A. I'm sorry? Can you say that again?
Q. Could you say what percentage. What percentage of the DCIs which you were involved over the years require a full suite of testing on both the active ingredient and the degradate that this one required?
A. So, I don't know the full suite. I know that the DCI requires occasionally, frequently, required data

on the metabolites and degradates as well.

Q. I'm sorry. I didn't hear the last part. Frequently? I'm not asking you to say in a different. I just didn't get it.

A. I'm just trying to figure out how to characterize that -- there are DCIs that do that and say they're not the usual, but it certainly happens enough to not be an anomaly.

Q. And when you made this statement in your testimony, were you simply relying on your memory as you are today?

A. I'm sorry. Say it again, please?

Q. When you made the statement in your testimony, were you relying on your memory as you are today?

A. Yes. Yeah.

Q. You hadn't done a count to see?

A. I had counted the number of registration reviews I was involved in. I didn't do a count on this level, no.

Q. No, but the word that you used was abnormally --

A. There.

Q. -- and I am simply trying to understand the basis of what was your experience --

A. Yes.

Q. -- And not on having really taken a look and counted up and seen, right?

A. I didn't take a count, no. It's my memory. My experience and memory.

Q. Now, with regard to the particular DCI that we are dealing with here, when the DCI went out, you were not in your current role. You were not involved in immediate determinations of what would enter the DCI, as I understand it?

A. So, I think all of the work was done but the actual mailing occurred after I left, yes.

Q. I'm sorry. Were you involved in all of the work?

A. Before that? Yes. Starting in 2011.

Q. Okay. The issuance -- the issuance of the DCI?

A. No, I was not on board. I was not in that position --

Q. I'm sorry. That's what I understood you to say, right.

A. Right. And very shortly after that.

Q. Right. So, the preparation of activities under those two documents that we reviewed at the beginning, that is the exhibits 13 and 14, if you would pull up 13, please. I just want to make sure you know what I'm talking about. Those were being done at that point in

time by somebody other than you, correct?
A. At that point in time what?
A. That responsibilities here involving the issuance in the DCI, the DCPA DCI were being implemented by someone other than you?
A. After issuance, yes. I mean until I got back to the project.
Q. Up to issuance? Up to issuance?
A. Pretty much, yes.
Q. Okay. And so there was a -- underneath stage IV there on this document, pardon me, on page 1 of this document it indicates that the CRM was responsible for creating the DCI in Prism, as well as the DCI justification cost estimate; is that correct?
A. Yes.
Q. To your files show what the cost estimate was at the time of the DCI?
A. It would be in my files. I haven't looked at it, and so I can’t tell you.
Q. You're not familiar with it, I take it?
A. I am familiar with it, but I don't know the number that well.
Q. Let me ask you, you don't -- that's why I appreciate your clarification. You don't know the number that was used by EPA to justify issuance of this DCI?

A. The number? The dollar amount?
Q. Yes, that dollar amount?
A. We included it in the justification and no, I don't know the price.
Q. Okay. It now, there is a reference down here in the bottom of page 3 of this document to doing things based on BEANs, at the very bottom of page 3, right after where the long bullet says that CRM should be in contact with the registrants in the months prior to that date is submission to make sure this addition is on a time limit. And then it says as data submitters -- data are submitted, CRMs BEAN, B-E-A-N, them to the science divisions --
A. Yes.
Q. -- Managers to BEAN them?
A. BEAN meaning assignment, basically.
Q. Yeah. What does that mean?
A. I think it comes from counting beans. It's just we conveyed to the science divisions that these data are here and then can be reviewed by at a certain date.
Q. Do you set deadlines for the science division?
A. They’re negotiable, but yes.
Q. And does the science division typically meet your deadlines?
A. I'm sorry. Say again?

Q. Does the science division typically meet the deadlines that you propose?

A. Given that they are iterative and we discuss them as time goes on, for the most part, yes.

Q. Could you please pull up the PAX 46? Thank you. Are you familiar with this document?

A. Yes, I am.

Q. And could you just describe its purpose, please?

A. So, if we come to a point where we feel we're not getting the data we need and the registrant has not fulfilled their obligations under the DCI, the statute gives us the authority to issue a notice of intent to suspend and this describes the process at least before and during notice to suspend and after, too.

Q. So, this is an EPA document, is that right?

A. Yes. It's a little outdated, but yes.

Q. Well, I'm going to get to that in just a moment. It was provided to us in response to the discovery requests we mentioned earlier, and it appears to relate to the transfer of responsibilities from one part of EPA to another portion. Is that correct, from both O-E-C-A and to OPPTS?

A. So, as I understand it, the new delegations were needed because OECA no longer had a role in the

suspension process, and then it became OPPT's responsibility.

Q. You just indicated a minute ago that you don't think this is still in effect?

A. Yes. For example, it talks about certified letter. We do everything by email now. That's just a small example.

Q. I'm sorry. But is there a replacement document?

A. I don't believe there's a more recent copy, no.

Q. Is there any formal document that withdraws this document?

A. Not that I'm aware of.

Q. Okay. And so, the one thing that you think has changed is the first bullet point per certified letter; is that correct?

A. That's one thing. It's probably pretty minor, but yeah.

Q. And why has that changed?

A. People because we're more adept at using emails so typically instead of sending a certified letter that then comes back with a notice that the registrant received and, we send it via email to the registrant and they can respond to it all electronically.

Q. Is it still the CRM who you believe is

responsible for this content?

A. Yes.

Q. On the second page under phase 3 there is a description of what happens when the data is received in response to a DCI where there has been a suspension indicated, or initiated, if I may, and it says in the third bullet that when that data are received by SSRD, the suspension coordinator will send the registrant a letter notifying them that the suspension had been lifted. Do you see that sentence?

A. Yes.

Q. Is that sentence still in effect in your view?

A. So, we're no longer SSRD. We're PRD and I don't know that we have a suspension coordinator. I think that would kind of fall --

Q. Would you expect the notice to be sent upon the receipt of the data?

A. Would we expect that the registrant would be informed the suspension was lifted --

A. Yes.

Q. -- If they provided the data?

A. Yes.

Q. Yes. If they provided the data?

A. Correct.

Q. It would, I take it. Okay. Can we go to PAX 57.

Does this document look familiar to you?

A. Yes.

Q. Is it fair for me to say that it was a press release announcing the initiation of this proceeding?

A. I'm sorry. Is it fair to say what?

Q. A press release announcing the initiation of the suspension that led to this proceeding?

A. I wouldn't say it was a press release. It's an OPP update and typically interested parties have subscriptions to OPP updates. I guess the press could be part of that, yeah.

Q. Okay. And you note at the end of the first paragraph -- well, let me back up. Were you involved in the preparation of this document?

A. Yes.

Q. And did you play a primary role in drafting the document?

A. It was a shared role. Probably not primary but a shared role.

Q. What do you mean by that?

A. So, just because it was going out to outside the agency, it had a high level of reviews. So, I'd looked at it and my branch chief looked at it. My division director looked at it. I think it was probably looked at at that level, too. I don't recall exactly.

Q. Okay. At the end of the first paragraph, if you would take a look at that sentence. It says due to the registrants long-standing failure to respond to EPA's request for necessary data, the agency is unable to fully evaluate the risks associated with DCPA. Do you see that?

MR. PITTMAN: Objection. Scope. This is not in that testimony.

MR. WEINBERG: This is what? I'm sorry?

MR. PITTMAN: In this testimony.

JUDGE BIRO: It says what it says. Are you asking her to agree that that's what it says?

MR. WEINBERG: No. I'm now going to ask her what the basis for that was because she just said she was involved in preparation. That's what she's testified about the initiation of the proceeding.

JUDGE BIRO: Okay. Overruled. Go ahead.

THE WITNESS: I'm sorry. The question again?

BY MR. WEINBERG:

Q. Yeah. Look at that last sentence so I don't have to read it again. The last sentence in the first paragraph.

A. Uh-huh.

Q. Do you know when the agency had previously announced that it was unable to evaluate those risks that

it described?

A. Announced outside the agency, I don't believe that happened.

Q. You don't believe --

A. That it was announced before this outside the agency.

Q. Okay. And this was the first time the agency announced it?

A. So, it was confirmed in the actual notice of intent to suspend which said similar things.

Q. So, this was -- this and the letter that it was announcing -- was the first time, correct?

A. Yes, the NOITS and supporting documents to that end.

Q. Okay. And what was the basis, and to the best of your knowledge, for that conclusion being reached?

A. That a number of data requirements had not been satisfied and that we didn't have data or expectations for when they would be satisfied.

Q. And who were you relying on for that conclusion?

A. Well, it was something I was aware of myself. I mean I wasn't relying on anybody. We all reviewed the case and we all knew what was happening and I was one of those.

Q. Well, you're not a risk assessor, are you?
A. No, I am not a risk assessor.
Q. So, this states that the agency was unable to fully evaluate the risks associated with this product. Who were you relying on for that judgment?
A. In particular I mean there were probably many examples, but in particular we felt that we couldn't assess the human health risk associated with DCPA because we know there was -- we suspected there was a very sensitive, meaning low -- high toxicity end point based on preliminary data, so it wasn't definitive data, but it made us question whether or not we were able to apply safety factors and still have a health protective assessment.
Q. So, did the sentence in your mind refer to the human health risk?
A. So, as I said, there were other issues as well.
Q. And who was it that you relied upon for this judgment?
A. I don't remember the name of the branch. I'm sorry, but it was my Mike Metzger's branch in HED. I don't know the number.
Q. Okay. I only push you on this because you have testified about this and you are obviously reporting on what other people have told you. In this proceeding,

that's perfectly acceptable, but we do have to try to understand who it was that was telling you this.

A. Uh-huh.

Q. On the next page that statement says in the middle of the second paragraph, in the nine years since the requirements were imposed, the agency has reviewed insufficient studies provided by AMVAC. How many studies did the agency reject that AMVAC filed?

A. So, it's difficult to count the data requirements because you might have one data requirement, but you're asking for data on a couple of different compounds. For example, DCPA and TPA, how many submissions did we get that we didn't think were on point? 10 to 20 maybe.

Q. I'm sorry?

A. 10 to 20, maybe.

Q. So, when -- I asked the question about how many studies that AMVAC submitted were rejected by EPA. You're saying 20 of the studies that AMVAC submitted in response to this DCI were rejected by EPA?

A. I'm estimating 10 to 20.

Q. 10 to 20. And what is the basis for that estimate?

A. Just my experience a recollection of these submissions that we got that didn't answer questions for

us.

Q. Okay. And how would you have been informed that this study was rejected?

A. So, typically, we put the studies in the review with the science division responsible for that type of risk and they would tell us whether or not the studies gave them the information they needed to perform a risk assessment.

Q. And how would you keep a tally of those?

A. I didn't keep a tally, no.

Q. Well, what was the basis for the numbers?

A. It's my knowledge that there were numerous insufficient studies.

Q. But you can point to anything to demonstrate the basis of that knowledge?

A. Not in this document. In my files, yes.

Q. Now, do you know how EPA transmitted to AMVAC its dissatisfaction with those studies that you thought were inaccurate?

A. So, we generally convey either our explicit rejection of the studies or the reviews that supported the rejection of those studies.

Q. And how would that be conveyed?

A. Probably attached documents to an email for the most part.

Q. Attach what kind of documents?
A. Reviews of the studies that were submitted.
Q. Would those be reviewed and performed by outside contractors to EPA?
A. No, no, no. That would be our science divisions, EFED and HED.
Q. And by whom would the email be sent?
A. Typically, by the CRM.
Q. By the CRM?
A. Uh-huh.
Q. Okay. Could I have J -- please? Would you pull up JX-4, please? This is the Data Call-In document itself.
A. Uh-huh.
Q. And I suspect you are generally familiar with this? Is this a standard EPA form document used for generic data call ins?
A. Yes.
Q. And it's modified for particular chemicals; is that correct?
A. So, there's a section that talks about the actual data requirements and asks the registrant how they want to respond. That's also specific to the call-in.
Q. Do you know when this was originally drafted?
A. I'm sorry, I don't. This particular one?

Q. No, I'm sorry. The form.
A. The form, I don't know.
Q. Does the fact that it said -- says at the page, top of page 2, in the third line that this is issued under OMB control number 20700174. Does that give us an indication of when the form was prepared?
A. I don't know because I'm not familiar with that control number.
Q. Okay. And if you would look at the first paragraph under options on page 4, one of those options is to request a data waiver, open-"S"-close paren; is that correct?
A. I think so. I think it's towards the bottom. It's not on this page that we are looking at now.
Q. I think it's right --
A. Oh, I see. But there are a number of options -- there are paragraphs that are a number to explain, yes, but that's --
Q. And would you look and see if you would agree with me that that's further discussed the pages 13 to 15 of the document?
A. If you can show me pictures --
Q. That option?
A. Yes. I mean that's part of the -- that's for the data waivers.

Q. Yeah. And in the request for the data waiver on page 15 under paragraph two -- I'm sorry. I beg your pardon. On the last page of the attachment to the document.

A. What is your question about this last page?

Q. I'm sorry?

A. What is your question about this?

Q. Your Honor, I apologize, Your Honor. I think that's all I've got on this here.

A. Okay.

Q. I would like to turn to RX-16, if we might. This is another document which was given to us by EPA in response to our discovery requests. Can you tell us what this document is?

A. So, it used to be weekly. Now they're not as frequent. They're biweekly, what we call office hours when knowledgeable people will share their perspectives for the education of other staff members. I was asked to do this one week because I was a longstanding member of PRD. Not everyone who is in the division now was around when reg review started, but I was.

Q. So, this was a presentation you provided on January 11, 2021?

A. Yes.

Q. And who would be on -- who is the audience for

a presentation?

A. So, it was via Zoom so I can't tell you exactly, but those presentations are usually attended by CRMs, the TLs and the SRAs which are a senior regulatory advisors. Sometimes there is people from outside PRD, but mostly it's people within PRD.

Q. How big of a crowd do you think you had for this one?

A. How many?

Q. How big of a crowd do you think you had for this one?

A. I didn't really do -- I didn't really take note of that. I'm sorry. Like I said, it was Zoom.

Q. To the best of your knowledge, is this an accurate recording of what you had to say?

A. Yes, I looked at it and I think it is.

Q. And so, is it fair to say that what this states, represents to your best understanding of the facts and principles that are set forth in that document?

A. Yes.

Q. Okay. Thank you very much. One other question about that. It notes in the third paragraph of the second sentence that requests for a waiver can be made for scientific reasons?

A. Yes.

Q. Are scientific reasons listed as one of the basis for waiver on the DCI form that we just looked at?

A. Not in those words, but yes. There is another kind of waiver that doesn't rely so much on scientific reasons as economic.

Q. I'm sorry. You think it is identified in the generic data --

A. Responding, making your request for waiver, yes.

Q. Well, respond to the request for waiver for scientific reasons?

A. Like I said, I don't think it uses the word scientific reasons, but yes.

Q. But it's widely understood --

A. Yes.

Q. -- In the industry that that is a basis for a waiver request, isn't it?

A. Uh-huh. Uh-huh.

Q. Could you answer that --

A. Yes. Sorry.

Q. Thank you. Okay. In the case of the AMVAC DCI at issue here, did take EPA an unusually long time to respond to any data waiver request?

A. Yes. There was an incident where the information wasn't conveyed right away.

Q. 66, if I can -- if you would pull up JX-66, please? And JX-6, 66, pardon me, is a memorandum dated March 21, 2014, to you and several others from a long list of submitters?

A. Right.

Q. What was the purpose of this memo?

A. So, we were responding to several waiver requests for data from EFED for DCPA and TPA.

Q. And did you review this document before it was prepared?

A. No. I don't think so.

Q. So, who would, to the best of your knowledge, who would have been the senior employee of EPA's who reviewed this document before was distributed?

A. Right. So, the highest ranking person for EFED on here is Brian Anderson. You're talking about before it was finalized? That would have been Brian.

Q. Yeah. Yeah. Okay. And who is Brian Anderson?

A. He was a branch chief in the Environmental Fate and Effects Division.

Q. Okay. And so, he was superior to you on the organization chart; is that correct?

A. Well, not within the same organization, but he was a branch chief, yes.

Q. Fair enough. Can I get those emails, please?

Now, you recall and, in your testimony, you described that AMVAC's responses as being dilatory and unusual and I simply want to summarize a couple of things you said, but was the message that you were trying to display in that testimony that they were being difficult?

A. That AMVAC was being difficult?

Q. Difficult.

A. I don't know that that's the word I used. We reviewed a number of waiver requests, two sets of waiver requests for the same data requirements over time. It didn't seem to add any additional information to it.

Q. Now, did you review this?

A. The waiver request?

Q. What you just referred to as a number of waiver requests for that same --

A. Right. So, they would have gone to the science division and then I would have seen that, the science division's report on that.

Q. And that judgment as to whether or not those were repetitive, I think that's that phrase used, and didn't raise any new concerns -- that would have been the view of the science division; is that correct?

A. I don't think in so many words. I think that would have been my conclusion from reading their reviews. They didn't review things in that context.

Q. Well, those explanations dealt with some fairly sophisticated toxicological and environmental fate issues -- didn't they?

A. I'm sorry. Your question?

Q. Isn't it true that many of those dealt with fairly complex toxicological and environmental fate issues?

A. Yes.

Q. And you consider yourself sufficiently an expert to make that judgment?

A. I think that does --

MR. PITTMAN: Objection. We're not trying to determine that --

JUDGE BIRO: Sustained.

MR. WEINBERG: I'm sorry, your honor.

JUDGE BIRO: Sustained. Move on.

BY MR. WEINBERG:

Q. Would you take a look, please, at AMVAC Exhibit 48. Could you put that on the screen? Take a look at that because I want to ask you what if anything you remember about it?

A. Yeah, I remember this.

Q. Have you had a chance to look at it?

A. Yes.

Q. Would you agree with me that this is an email

string of communications between you and Julie Porter of AMVAC?

A. Yes.

Q. And do recall this series of communications?

A. Do I recall?

Q. This series of communications?

A. Yes.

Q. At the bottom of the first page this indicates that the stub does the bottom of the second page. I'm sorry. This indicates that the string started with the response, the ninety-day response documents that was provided in June and then the second email appears to be an email from Ms. Porter to you from about a month later asking about status of that.

A. Yes.

Q. Is that correct?

A. Uh-huh.

Q. And she then on August 7 sent you another email that appears to imply you had responded to the prior email?

A. That's correct.

Q. And in fact, you ultimately got back to her on August 7, isn't that correct?

A. So, on August 7 I said that I had just got -- oh, this one? Yes.

Q. I'm sorry?
A. Yes. I'm reading what you're showing me now.
Q. Okay. Would you put up PAX 47 for a minute, please? Would it take a quick look at this one as well, please?
A. Uh-huh. This is familiar to me.
JUDGE BIRO: This is also PAX 47?
MR. WEINBERG: I'm sorry, your honor?
JUDGE BIRO: It's also PAX 47? That's the number of the exhibit?
MR. WEINBERG: This is, yes, PAX 47.
JUDGE BIRO: Yeah.
MR. WEINBERG: Yeah. Each one of these emails has a -- I'm going to go through it.
JUDGE BIRO: I just want to make sure for the record we got the right number.
MR. WEINBERG: I completely understand.
BY MR. WEINBERG
Q. This is an email exchange in which you were copied, but do you recall this email that was made?
A. Yes.
Q. And do you have any doubt that -- any reason to believe this is an incomplete statement of what came?
A. Do you mean there were emails on the same subject?

Q. Were there emails in this chain?
A. I'm sorry.
Q. Whether there were other emails in this chain?
A. I'm going to say I don't know.
Q. This gentleman, Matthew Manupella was telling Ms. Porter that there was changing hands at DCPA again. Can you explain what that was?
A. So, after I left, that branch that was RMIB2, the chemical stayed with RMIB2 and Matt was one of the CRMs who dealt with it, and subsequently it was sent over to my branch RMIB5 because I had a history with it.
Q. And would it be correct to agree to that he was giving you a heads up on this to AMVAC on that change?
A. Yes. That was giving Julie an update.
Q. Could we go to petitioner AMVAC Exhibit 49, please? And again, if you would take a moment to just look at this string. A little bit longer and I'm sorry, but it's a few pages.
A. So, this is more of the same exchange where Matt told Julie that it was changing hands.
Q. And your first email in this chain appears to be from Matthew Manupella. What was his role at EPA? This is the same gentleman we just talked about before?
A. Right. He was a CRM in RMIB2 and his responsibility -- he had a responsibility for DCPA.

Q. And then the next one shows an email was sent to you sending a courtesy copy I take it of material being provided on the sediment studies?

A. Yes.

Q. And you wrote in your communication that you had been out sick. Julie responded that she hoped that you were feeling well and that went on.

Can we look at 50, please? Pardon me. Petitioner AMVAC Exhibit number 50? This is another string in which you were carbon copied. Do you recall this?

A. Yeah.

Q. And that the bottom -- excuse me. It started at the beginning of the chain. Actually, this second note is an email from you indicating another change in staffing for DCPA; is that correct?

A. Well, a CRM had been assigned. I wasn't a CRM, but that was when she was assigned --

Q. I'm sorry. That wasn't a change?

A. It wasn't a change in branch. It was a designation of a CRM. Prior to that I took over some of the communications, but I wasn't a CRM. So, she's a CRM.

Q. So, this was the first time a CRM was assigned? Pardon me, in your branch?

A. It sounds like it, yeah. I don't think there

was --

Q. I'm sorry?

A. I don't think there was a previous communication of the specific change to the CRM. I think this was it.

Q. And you see this -- move up the page and see that Ms. Porter would write to the woman you had identified, Dr. King. It raises some questions about relating to the Health Effects Division and ultimately this -- is it Ms. King?

A. Dr. King.

Q. I guess it's Dr. King?

A. Yes.

Q. Pardon me. Arranges for a meeting to be held so that the experts associated with the particular studies involved would be addressed. Is that fair?

A. Yes.

Q. Would you pull up Exhibit number 50, please? Again, this is a string of emails in which you were copied at least on several of them.

A. I think this is the same one as the last one you showed me.

Q. I think it is, actually, now that we look at it. AMVAC 53 -- pardon me, AMVAC Exhibit 53. Will you take a look at this one, please? This is another series

of emails. Do you recall this series?

A. Yes.

Q. And do you have any reason to doubt that this is a complete email chain?

A. I don't know if there are more before or after. I'm sorry.

Q. It appears that from the first email in the string that Mr. Wood of AMVAC was providing an update to EPA, to Ms. Montague, on May 30.

A. Yes.

Q. And then on August 14 he was calling to find out when the agency would be responding to that document; is that correct?

A. Yes.

Q. And can you go to Petitioner AMVAC's Exhibit 54, please? This is another string of the emails in which you were copied. I don't think you were the direct recipient of any of them, but does this look familiar to you?

A. Yes.

Q. All right. And if not first email in this string Mr. -- perhaps it is Dr. Wood, I suppose, is transmitting an email from another AMVAC employee that provided a summary of attachments from the laboratory on the CTA range finding study?

A. Yes, but it can't see the whole string. If you could --

Q. I'm sorry?

A. Yes. Thank you. There you go.

Q. I'm sorry?

A. So, I couldn't see the whole thing. They took away --

Q. Oh, okay.

A. -- Now I can see it.

Q. Take your time. I'm sorry. I didn't mean to --

A. No problem. No problem. That's what it appears to be, yes.

Q. Yeah. And that goes from AMVAC to Jordan Page and one of the things that Mr. Wood asked in his email on the bottom of page one of two is how quickly EPA can provide comments on that material, do you see that?

A. He does ask when he can get comments, yes.

Q. And then Jordan Page responds above that and could you just read what he had to say? Just read it out loud.

A. Good morning, Jon. Is that what you mean, from there?

Q. This is good morning, Jon. After good morning, Jon.

JUDGE BIRO: I don't need anybody to read it for me.

MR. WEINBERG: All right.

JUDGE BIRO: I'm really good at reading.

MR. WEINBERG: Well, fine. That's fine. Your Honor, I'm happy to -- I'm trying to accelerate just a little more quickly.

BY MR. WEINBERG:

Q. Does it indicate that it's highly unlikely that they would be able to provide feedback by September 1 and that this potentially will add several months in that data development process?

A. So, he is saying that as I recall Jon was asking, you know, they were getting animals I think on September 1st, I think it was, and John was asking will you be able to give us feedback before the animals come due and according to Jordan it looks like it will take several months more because it was a big -- large volume of data.

Q. He's saying that we're not going to be able to respond to it. EPA will not be able to respond by that date?

A. Highly unlikely he says, yes.

Q. But he requests whether there could be a call; is that right?

A. Uh-huh.

Q. And that request is on the 22nd, first thing in the morning apparently a little later that day AMVAC responded and said we could be available for a call tomorrow or Friday I suspect was Wednesday was the day they were talking about they met, correct?

A. Yeah, it must have been a Wednesday, right, because it's a Tuesday email and it says tomorrow.

Q. In the can we please go to Exhibit 52, and Your Honor, I understand the tediousness of this but I have to go through two more.

MR. PITTMAN: Your Honor, can I object to relevance? These documents all concern the CTA, which OPP has informed AMVAC is now considered satisfied.

JUDGE BIRO: Overruled. Go ahead. But I -- you know, I don't think that were getting anything --

MR. WEINBERG: Let me explain, Your Honor. I believe, and I believe -- and know that when you go back and ask Ms. Bloom -- that many readers of her testimony would read her accusations about the lack of compliance by AMVAC with their obligations under this DCI and their --implicitly their strategy of delay and their refusal to comply in a prompt matter. I believe that's what her testimony intends to say, and we believe it is completely relevant to demonstrate that in fact their communications

at all levels of the staff that reported to Ms. Bloom and with Ms. Bloom herself were in fact productive, timely and responsive.

JUDGE BIRO: I think that's your argument and I think these exhibits might support your argument, but I don't see you getting any facts out of her that are contested. And that's what we're looking for in this hearing. We're trying to focus on contested facts.

MR. WEINBERG: Unfortunately, I needed to be sure I could get these documents in and I need to have her confirm that they were accurate documents because they were documents that we produced.

JUDGE BIRO: Okay. So, can we stipulate to this?

MR. PITTMAN: Your Honor, we will stipulate to the authenticity of the documents, contesting the admissibility for relevance reasons.

JUDGE BIRO: Okay. What are the other two that you're concerned about? Let’s stipulate to all of these and get them in.

MR. WEINBERG: That's what I'm trying to get done by 5:00 this afternoon, Your Honor.

JUDGE BIRO: I don't think so.

MR. WEINBERG: I'm sorry?

JUDGE BIRO: I don't think so. I think we’re

going to be here way past five.

MR. WEINBERG: No, I don't think so. I think we're actually fairly close.

JUDGE BIRO: Okay. What are the exhibits?

MR. WEINBERG: Okay. Could you put up the quotation that starts with a reasonable interpretation?

MR. PITTMAN: I'm sorry. What to put up?

MR. WEINBERG: I'll explain as soon as we put it up. Do you know what I'm talking about?

BY MR. WEINBERG:

Q. Ms. Bloom, did you review the -- have you seen this sentence before [referring to Respondent's Prehearing Brief at 8]?

A. Yes.

Q. And where do you think you saw it?

A. It was in the Respondents prehearing brief.

Q. I'm sorry?

A. It was in the Respondents prehearing brief.

Q. And were you involved in the preparation of that responsive brief?

A. I don't know that I was involved in a preparation, but I did review it.

Q. You did review it. So, you were familiar with it?

A. Yes.

Q. All right. Do you believe that this is a long-standing administration policy of EPA, what it describes here?

A. I don't know that I would characterize it that way. This has to do with multiple waiver requests for the same data requirement, which didn't happen that often. So, I wouldn't say it was long-standing, but it didn't give us the data we wanted.

Q. Let me ask it a different way. Can you think of any other policy document from EPA that you have ever seen that makes the assertion here?

A. Certainly, related statements. I don't know this particular verbatim statement.

Q. Now, take a look at paragraph five. I'm sorry, the paragraph on page 5. And if you would look at this, this paragraph, it says "OPP does not regularly specify an appropriate time…" and so forth and EPA thinks you should have to produce the data with the original time frame.

A. Well, I think it goes on to say that sometimes the original time frame has been bypassed. So, this doesn't talk about -- It's the period equivalent to, not the exact time.

Q. Have you ever seen this statement in any document that EPA has ever published before?

A. Not that I -- No, similar statements, but not this one.

Q. 21. Now, will you pull up JX 21 again, please. That's the data delay letter. And if you would be kind enough to scroll down to the table and towards the end there and just blow up the middle part of it there so it is legible.

Do you recall this letter? This was the one that was sent to explain to AMVAC that there was certain data that was still outstanding; is that correct?

A. Well, it's one of them. This is the one that says were going to have to go ahead with registration review if you don't get us the --

Q. Great. And that table attached to it, the letter, if I recall correctly, is in fact not dated, although it's been stipulated, to be authentic and this table is attached to it with an October 16, 2020, date on it; isn't that correct?

A. Uh-huh.

Q. And if I can just pick one of these requirements. That's take right in the middle of the page 835.4300. So, this was prepared in 2020, correct?

A. Uh-huh.

Q. And in the right-hand column where it has a due date, where it says 1/31/2015, correct?

A. Yes.
Q. And this was outstanding data, right?
A. Yes.
Q. And that date is the date that the data was due under the original DCI, was it not?
A. Yes. Assuming the registrant received it on 31 January, 2013. This was a 24 month study so the due date was the same date in 2015.
Q. Thank you. And in fact, that's what's been done on all of the studies on this table where there was data outstanding, the date that was published list and that on the table was the date it was identified in the DCI?
A. Can you let me see the rest of the table, please, so I can --
Q. I'm sorry. You turned away from the microphone and I had --
A. Oh, I'm sorry. I just wanted to see the rest of the table. This is the entirety of the table?
Q. This is the table that accompanied the letter.
A. Right. I'm looking for one in particular. Oh, it’s not here because it was waived. There was only one study that ever got a different due date because the registrant requested an extension, but then the extension became moot.

Q. But you agree that the due dates that are listed there are the days from the original DCI, correct?

A. Yes.

Q. All the lines or the studies were identified as outstanding?

A. Yes.

Q. And that in fact is not consistent with the quotation that we read a little bit ago of -- about the denial of an initial request, in which the respondent maintained that the DCI respondent should have provided data within a period of equivalent to the original time frame specified with each --

MR. PITTMAN: Your Honor, objection. I don't see the relevance of a six month later filed legal pleading to Ms. Bloom's statement from June.

JUDGE BIRO: Yeah. Sustained. Go ahead. Go on to something else.

BY MR. WEINBERG:

Q. Ms. Bloom, are you aware of the policies stated from that document that we read out from a few minutes ago when this table was approved?

A. I'm sorry. I don't know which statement you're talking about.

Q. Okay. Please put back up that statement from prior page 5. And there is a --

MR. PITTMAN: Same objection to relevance.
MR. WEINBERG: I'm sorry?
MR. PITTMAN: Same objection to relevance.
MR. WEINBERG: The objection to relevance, since we're trying to establish, but this is a completely invented policy solely for purposes of this case and not an EPA policy and that in fact when they prepared this letter, of which they are so proud, they in fact didn't follow this policy. Well, left the dates in earlier. They now have come up with policies that they have invented in a reply brief, in a prehearing brief that have no substantiation in any other EPA documentation.
JUDGE BIRO: As far as I could tell, I read this as their response to I think the EAB's decision in this matter about setting an appropriate time frame and that was their offer of a suggestion of what would be appropriate.
MR. WEINBERG: Well, they historically had never taken that position before, Your Honor, and that's what we want to establish. You will decide what the legal significance is, from my understanding. The factual question is whether this is a newly announced policy, and that's simply what I'm trying to establish.
JUDGE BIRO: Well, I'm not sure EPA's prehearing brief constitutes an EPA policy because policy

documents have very specific definitions and go through certain procedures and this is not how it's done, but I'll let you ask her whether she's seen anything that similar to that. Although I think she already answered that the question, but go ahead.

THE WITNESS: So, the question again, please? I'm sorry.

MR. WEINBERG: I think at this point, Your Honor, the question was whether you were aware of the policies stated in the quotation that is on the board that is one that starts "OPP does not regularly specify …" when the table that was attached to the data delay letter was prepared.

THE WITNESS: Your question is this is a policy that I've seen elsewhere?

BY MR. WEINBERG:

Q. No. No. It was were you aware of this policy at the time the data delay letter was prepared?

A. I don't consider it a policy per se.

Q. And were you aware of this statement of --

JUDGE BIRO: Position. It's a statement of position.

MR. WEINBERG: Yes.

JUDGE BIRO: Do you agree with that?

MR. WEINBERG: In that --

THE WITNESS: Yeah, I do agree because it's the same as the original -- the same length as the original requirement time period. So, we wouldn't expect them to do it any faster.

MR. WEINBERG: So, it should be the whole same length to be --

A. Period equivalent to the original time.

Q. The original time or the length of time?

A. Period equivalent. I think that's the length of time.

Q. Well, if one says the length of time. The time was approximately three years, if I recall correctly.

A. So, some data requirements were one, two, and then three years.

Q. And you were providing somebody notice of a denial in 2020. I'm assuming that would be the case. Would you add three years on to that or would you go back to three years after when the data call-in was issued?

A. Oh, no, you could relate it back to the DCI. Some of those time frames expired so they would be meaningless.

Q. Why would it be meaningless?

A. Well, it's something -- if we're talking about something in 2020 and the deadline was in 2015, that's meaningless. But the DCI provided two years for the

submission of that data. So, what this says is we give you another -- you know, generally speaking they should have provided the data within the next two years.

Q. And do you believe that's what this table says?

A. The table says?

Q. That table that --

A. No, that the table doesn't reflect that. There are no -- these are the original due dates. There were -- there was one request for an extension that I don't believe is here because that became moot. So, these are the original dates. There was never a request to extend the dates. This was our being reasonable that, okay, now we told you definitively. We really need these data. We expect it will take you a year or two, or whatever to develop those data and that's what they should have -- that's when they should have given us data. They should have been able to give us data.

Q. Your Honor, I have one other series of brief questions and then will be done.

Q. In the testimony that you submitted in June in the earlier testimony I believe from you and maybe from someone else, but you said in your testimony that the EPA was unable to assess DCPA's risk to man and the environment due to AMVAC's failure to submit the necessary data. That was on page 7 of your --

A. Yes, but that's not in this document.
Q. I'm sorry?
A. That's a different set of documents altogether. That was the document that was the information that was conveyed to him when --
Q. Yes. That is a very different document. I'm going back to your testimony. I'm going back to page 7 of your testimony.
A. Seven. Okay.
Q. Where we started?
A. And what phrase is it that you're concerned about?
Q. The phrase is that you said that the EPA is not able to assess DCPAs risk to man and the environment due to AMVAC's failure to submit necessary data?
A. I don't think that's in this document. That was a determination that was made subsequently.
Q. Well, I may have written the wrong page down in my notes, but I'll go and check it.
A. I mean not this document. Not my testimony, but the table you showed me, for example. If it says that here I would like to see where.
Q. It's up on the board now. They'll help you find it. Was the wrong about the page number?
A. And what page is this?

Q. It's on page 7 of your testimony.
A. Oh, I see it. Yep. You're right.
Q. Right? Now, as of today AMVAC has submitted all the data that's pertinent to human risk, correct?
A. The data requirements that were responsive to toxicology for the -- well, none of this is toxicology. For the human health risk assessment, yeah, they provided data that was required.
Q. And that's why the only studies about which EPA is pursuing suspension at this point are the nine studies for, eight of which that go to TPA, and one of which goes to DCPA?
A. From the environmental standpoint, yes.
Q. Right? Now, the reason that you were concerned about that inability was that at the time your testimony was prepared in June of last year. The deadline for completing registration review was October 1 of last year; isn't that correct?
A. So, we did want to -- your question again? I'm sorry?
Q. Isn't it true that at the time you prepared this testimony the deadline for registration review set by the statute was October 1, 2022?
A. Yes.
Q. And are you aware that Congress has amended

that deadline, legislation --

A. Yes.

Q. -- that was passed --

A. Yes.

Q. -- In December?

A. Yes.

Q. And then extended I believe four years --

A. 2026.

Q. Right. So, that pressure for the need to be able to do the human health risk assessment and, for that matter, the environmental risk assessment is no longer in place in EPA; isn't that correct?

A. I don't see it that way. We had identified potential risk concerns and we wanted to sort them out. I do want to add one thing about the environmental data. Some of those relate to the human health risk assessment because of the drinking water. So, it's not just ecological effects. It can also be information through the drinking water assessment that's part of the dietary assessment. That's part of the human health risk assessment.

Q. Okay. Do you know what the schedule is for the production of the studies that are still outstanding?

A. So, AMVAC has given us -- I don't know them offhand, but the AMVAC has given us a list, yes.

Q. And it's roughly between a year and two years for the total studies; is that correct?

A. Right. I think the only study that was longer is no longer contested I think the rotational crops was three years, but, yeah, between one and two years.

Q. So, to the extent, and I'm not asking you to confirm this, but to the extent that the deadline set for work completing registration review has been extended by Congress, there is less pressure on EPA to complete the registration review; isn't that true?

A. I would have to say in this case we had risk concerns, that we feel we need to deal with -- so I can't speak for all of registration review. That's for this one. I'm sorry.

Q. Can I have the question read back? I appreciate what you said, but you didn't answer my question.

A. Okay. Can you ask it again, please?

Q. Well, I mean I can rephrase it, but I would just as soon --

JUDGE BIRO: The pressure on EPA has been alleviated by Congress extending the deadline from 2022 to 2026, in your opinion?

THE WITNESS: I wouldn't describe it that way, no. Uh-uh. That we're able to make the statutory

deadline.
BY MR. WEINBERG:
Q. You do agree that that has happened, that --
A. Yes. And I think --
Q. And to the extent -- I understand you disagree with it. I don't think this is a very controversial statement, but to the extent that the agency was feeling pressured to get something done by October 1 of 2022, the change in the statute can be read to relieve the pressure?
A. Again, that's not the way I would describe it. It does give us more time.
Q. Well, you just have to answer my question.
A. Okay. So, that's not the way I would describe it.
Q. I'm sorry?
A. That's not the way I would describe it.
Q. So, it's a yes or no question.
A. That would have to be no. I'm sorry.
Q. Okay. Thank you.
MR. WEINBERG: Your Honor, if we could have just one minute.
JUDGE BIRO: Of course.
MR. WEINBERG: Your Honor, we have no further questions for Ms. Bloom.

JUDGE BIRO: Okay. I would like to take a five minute break to get another cup of coffee. So, can we stand in recess just for 10 minutes, I believe until 4:50 and come right back.

MR. PITTMAN: I have just one follow-up.

JUDGE BIRO: Oh, okay. Well, then proceed Mr. Pittman.

MR. PITTMAN: Your Honor, should we clarify with Ms. Rose to see if she has any follow-ups that might make a break more preferred now?

JUDGE BIRO: Yes. Thank you for reminding me. Ms. Rose, are you still with us?

MS. ROSE: I lost the Teams, but I dialed in on the phone. So, I'm trying to get back on the Teams, but I have no questions.

JUDGE BIRO: Okay. Thank you.

REDIRECT EXAMINATION

BY MR. PITTMAN:

Q. Good afternoon, Ms. Bloom. I only have one follow-up for you here. So, with respect to the PX-57 I believe in regards to the OPP updates that you testified to some time ago.

A. Okay. Yes.

Q. Would it be fair to say that your comment concerning 10 to 20 insufficient submissions that you --

maybe that was from your recollection. Would it be fair to say that that also included inadequate waiver request?

A. It also included waiver requests. I think this statement was just about data that had been submitted. Although some of the waiver requests were accompanied by data. So, it goes to the extent that they were, I would count them, too.

MR. PITTMAN: Thank you. No further questions.

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

MS. ROSE: I do not. Thank you.

JUDGE BIRO: All right. I have a few questions. No, you have to sit and answer my questions.

THE WITNESS: Oh, I'm sorry. I misunderstood. I apologize.

JUDGE BIRO: No problem.

THE WITNESS: I guess that would have been too easy.

JUDGE BIRO: I don't think my questions will be any harder. Can you tell me about the agency's electronic filing system, the electronic docket, this pesticide docket management system, this central data exchange, all these references that go in these documents?

THE WITNESS: Right. So, there's different

things. The CDX that you referred to, the second one you referred to, that's the way that registrants submit data to us, you know, because of COVID and probably predates COVID, but since COVID we didn't accept paper copies anymore. So, we established this portal for submitting data and we would have done it anyway because it's more efficient.

JUDGE BIRO: So, did CDX just start in 2020?

THE WITNESS: I don't know. I'm sorry. I don't know. It seems like maybe it was longer than that, yeah.

JUDGE BIRO: Okay.

THE WITNESS: But it definitely gets the data to the people who need to review it quicker than a paper copy.

JUDGE BIRO: Okay. So, if I were a registrant and I wanted to submit a study, I upload it into the CDX system?

THE WITNESS: Yes.

JUDGE BIRO: And it is assigned a number automatically?

THE WITNESS: So, yeah, that's a change actually. The registrant needed to have to hear from us what the MRID number was as the accession number, but now the registrants themselves they choose the next number in

line.

JUDGE BIRO: Okay. And then does it automatically get distributed to where? What's the next step in the process?

THE WITNESS: So, the next step is it undergoes a front end screen to make sure that it's legible, that it's got the correct confidentiality statements, just the administrative kind of stuff and that -- yeah.

JUDGE BIRO: Who does that?

THE WITNESS: Was that?

JUDGE BIRO: Who does that?

THE WITNESS: So, it used to ITRMD, but we reorganized now it’s I think OPS. Is that what it's called?

JUDGE BIRO: So, a human being does --

THE WITNESS: Human being, yes.

JUDGE BIRO: Okay.

THE WITNESS: A couple of human beings.

JUDGE BIRO: And then what happens?

THE WITNESS: So, after that screening happens, if it doesn't hit all of the right marks that group goes back to the registrant and says, oh you are missing page 5, or you didn’t sign this page. But if everything goes as planned the MRID number is confirmed and then it becomes available to me to share with the people who need

to review it.

JUDGE BIRO: Okay. What do you mean becomes available to you? Are you get access to it? Do you get an email telling you that it has been submitted?

THE WITNESS: Is not always. We get -- usually the registrant will tell us they submitted it, but of course this happens after that.

JUDGE BIRO: Wait. They will informally tell you by email that they submitted it?

THE WITNESS: Yes. But when it's ready for review we find it in Documentum. I'm not sure that we 100 percent of the time get advance notice of that. We just look for the Documentum because we know it's expected. Documentum, I'm sorry is another -- another way of tracking submissions.

JUDGE BIRO: Okay. So, you don't get anything that tells you that a registrant has submitted any data automatically?

THE WITNESS: I don't think we always do, no. Uh-uh.

JUDGE BIRO: Okay. It just goes into like a library of --

THE WITNESS: Yes. Definitely looks like a library.

JUDGE BIRO: Okay. And then you can look for

the data in there in this library of Documentum?

THE WITNESS: Yes. It will categorize it by date, and title, and sometimes data requirement, but always the MRID number, the accession number.

JUDGE BIRO: Okay. Let's say you go over this data and you think you should go on to the next step. Are you the person who decides where it goes to?

THE WITNESS: So, that's pretty well-established and it wouldn't be me. It would be the CRM that's responsible for developing the BEAN. We talked about the BEAN, that tells the science division here this is. Could you please give us your review and this is the date we would like it by.

JUDGE BIRO: So, that CRM is a person would look in that Documentum system, see something has been submitted and decide who to send it on to in terms of the science division?

THE WITNESS: Yes. Uh-huh.

JUDGE BIRO: Okay. And when they send it on to the science division, do they indicate the timeframe for review?

THE WITNESS: Yes. We request a particular timeframe, often we renegotiate it.

JUDGE BIRO: Okay. So, this CRM is the one who sets that estimated time frame?

THE WITNESS: Yeah. Not all by himself. I mean we talk about it.

JUDGE BIRO: So, before it goes on to the science division, is there more than the CRM reviewing the data that -- that's submitted?

THE WITNESS: So, I don't consider what we do as a review, because it's technical material, but we do look at it so we get a sense of what it is so we can instruct the science division of what we would like to get out of the review.

JUDGE BIRO: So, after that bit of a group thing about how maybe what you want to get out of it and what deadlines it should be, it goes on to the science division?

THE WITNESS: Yes.

JUDGE BIRO: One of the many science divisions that EPA has?

THE WITNESS: Yes. And that's another one of our databases that does that.

JUDGE BIRO: And which database is that?

THE WITNESS: That would be Prism.

JUDGE BIRO: Okay. So, the science division, how did they get it from Prism? It goes into Prism system automatically?

THE WITNESS: Right. And so, it goes to the

group in that division that manages the data submissions and not the actual reviewers, but we will notify the branch chief or somebody equivalent that it's there and they can find it there and the system number. When you BEAN it, you get a BEAN number, and we convey to them what the BEAN number is so they know how to find it.

JUDGE BIRO: Okay. So, that CRM would send an email and formally telling the administrative person in the science division that we sent it to your Prism?

THE WITNESS: So, we usually copy that person, but we actually tell the reviewers branch or the leadership in that branch or even the individual who is going to do the review that it's there. So, we usually copy those people because they have to be aware of it, too.

JUDGE BIRO: Okay. So, then the scientists go in and look at that document?

THE WITNESS: Yes.

JUDGE BIRO: If they want to evaluate it or send it out for evaluation, do they have to downloaded into a different system?

THE WITNESS: I don’t know, because we do have contractors that do the screens of data but I'm not sure how the science divisions do that. I would assume it's electronic because those BEANs that I talked to you

about, they attach to documents and the document is right there, so it wouldn't be difficult for them to use that and pass it on to the contractor.

JUDGE BIRO: Whoever does the review, a contractor or an EPA employee does a scientific review, do they upload their comments about it in to Prism?

THE WITNESS: I think primarily they provide us with a memo that gives the review. It should be in Prism, but it is not always there.

JUDGE BIRO: So, they might send it to you and formally in the system by email?

THE WITNESS: Yeah. I mean when they do that, they close out the BEAN so there it is an official acknowledgment that they did what we asked them to do.

JUDGE BIRO: But not necessarily attaching what closed it out?

THE WITNESS: The closing out is just saying you completed the BEAN. So, you know, we don't get that. That's between the scientists and the staff that I told you that manages the data submissions.

JUDGE BIRO: So, when you say you get it back, that goes to the CRM?

THE WITNESS: Is typically just to the CRM, the team leader and the branch chief.

JUDGE BIRO: Then what happens?

THE WITNESS: So, we'll review it, and in the best case we prepare a transmittal letter that says exactly what we want the registrant to do next. So, for example if the study is unacceptable or if there is some missing data that can upgrade this study, we will pass that on to the registrant and say please provide this material. Or in the case of a waiver request your waiver is denied and gives the reason, or whatever.

JUDGE BIRO: And do you send that to them by email or by mail or is it -- how do they know?

THE WITNESS: It's typically by email. I think always email now.

JUDGE BIRO: Do registrants have access to any of these systems you mentioned, CDX, documentum, or Prism?

THE WITNESS: They have access to CDX because that's where they submit data. I don't think they have access to the other two that you mentioned.

JUDGE BIRO: Okay. And the response to the data they submit that the science group has done, does that go into CDX at any point?

THE WITNESS: No. It doesn't go into CDX. CDX is just the portal for submitting data and getting the routing number for it.

JUDGE BIRO: Is there a docket system where

everything that's happened in the case is accessible to the registrants?

THE WITNESS: So, is there a docket system that everything that the registrant submitted is available? So, the one thing I think was qualifying, is we're supposed to capture those reviews and post them to the docket, the EPA docket. So, that's accessible to everybody.

JUDGE BIRO: So, would you post the scientists' evaluation of the studies submitted?

THE WITNESS: Yes.

JUDGE BIRO: To this EPA docket?

THE WITNESS: That's ideally, I can't say it always happens.

JUDGE BIRO: And would registrants have access to the EPA docket?

THE WITNESS: Yes.

JUDGE BIRO: So, in this case, there seem to be some documents that went astray. So, I'm trying to figure out how that works in this system. If the scientist reviewed a study that AMVAC submitted, their review would have gone into EPA dockets. They put it into EPA dockets?

THE WITNESS: No. No, no. We put them into the docket.

JUDGE BIRO: The CRM?

THE WITNESS: Yeah, so they would just email us, basically, or it used to be a paper copy a signed document that says we've reviewed it and this is what we found.

JUDGE BIRO: Is it automatically put into the docket?

THE WITNESS: No. We have to upload to the docket.

JUDGE BIRO: So, somebody has to decide for each individual document to upload? Okay.

THE WITNESS: I mean you can do them in batches, but yes.

JUDGE BIRO: So, if AMVAC didn't get a document in a timely manner, would that be because it wasn’t uploaded into this docket system, or because it wasn’t emailed to them? Could it have been -- maybe I should clarify. I'm trying to figure out if there is a possibility, they didn't get email, but it was in the docket?

THE WITNESS: Probably not.

JUDGE BIRO: Okay.

THE WITNESS: I think the lapses were because

of the passing of the responsibility onto different people that unfortunately misplaced --

JUDGE BIRO: Okay. So, it was just that it didn't go out by email. It didn't get uploaded in the docket. They didn't get it. Is that --

THE WITNESS: Directly into the docket now but, no, at the time it did not, it was not.

JUDGE BIRO: Is there any other system that's in this whole process, any other computer system?

THE WITNESS: I mean we have lots of computer systems but relating to the submission and review of the data in PRD, I think that's pretty much it. What we do is we expect the CRM to keep tabs on all of the data; and keep their own records; and we encourage them to save the transmittal memos; and the memos as in as central place, because if they're gone, we can still find them.

JUDGE BIRO: Is there any tickler system for that?

THE WITNESS: No.

JUDGE BIRO: Is there any tickler system for the deadlines that are set on a DCI or any kind of request?

THE WITNESS: So, we get automated emails long past their relevance. We get automated notices that something is overdue and I've been getting them for, you

know, the time immemorial cases that aren't even relevant anymore but usually what happens is we find they're available and the registrant tells us. I mean, excuse me, when the reviewer tells us and sends it to us and then it's PRD's responsibility to convey that to the registrant.

JUDGE BIRO: Okay. So, other than communicating by email, there is no way of the registrant determining what the status of a study they submitted to EPA is?

THE WITNESS: Well, they can ask us. We converse all the time.

JUDGE BIRO: Right. I mean other than an email to you, there is no way for them independently to determine it. You have to ask somebody at EPA by email, or by phone, or by letter.

THE WITNESS: Right. If a review is completed and it doesn't get passed on to the registrant, they wouldn't know. They would have to ask if it was done and then the CRM would have to look and say, oh, it's done and send it to them.

JUDGE BIRO: So, is that a common thing that a registrant writes to you and says I submitted this, you know, last year and I still haven't heard anything?

THE WITNESS: Yes.

JUDGE BIRO: Can you tell me what's happening?
THE WITNESS: That's very common.
JUDGE BIRO: And you respond to those requests?
THE WITNESS: Were supposed to, yes, and we usually do, but not always.
JUDGE BIRO: I'm somewhat confused about this issue that EPA was willing to go ahead and use conservative assumptions to make assessments, and the reason I'm confused is because it's not clear to me if they were looking for AMVAC's agreement to go forward to use those conservative assumptions.
THE WITNESS: Yeah, I don't believe so. It's -- the conservative assumptions would be made if we didn't get the data and so we told AMVAC that was the case with many of these requirements, but we don't need their agreement to do that.
JUDGE BIRO: So, if you were to say tell us whether you agree, or don't agree with what's going ahead, you didn't care what they said?
THE WITNESS: Well, they had the data. That was really the only avenue open to us.
JUDGE BIRO: Was there any timeframe for this of going forward?
THE WITNESS: Timeframe for?

JUDGE BIRO: When you told them we could go forward without your data if you don't submit new studies. Did you have any anticipated timeframe for going forward without it.

THE WITNESS: No, we were still hoping to get the data, for the most part.

MR. ROSS: Your Honor, if I may direct you to Joint Exhibit 21. It does specify that a risk assessment, I believe it's the document that you're referring to, it specifies that the risk assessment would be completed by June 20, 2021, and it does not condition that on the submittal of any particular studies.

JUDGE BIRO: Thank you. There were a lot of questions about this issue of, at what point you decided, and when I say you, I mean EPA, OPP decided that it just couldn't just use conservative assessments. That wouldn't be reliable enough.

THE WITNESS: In particular relating to the thyroid study, yes.

JUDGE BIRO: Right. So, was there something that happened or didn't happen that triggered that re-evaluation?

THE WITNESS: Yes. AMVAC submitted preliminary data. The comparative thyroid assay has several steps and one of those steps is you run a study at a wide range

of doses, you know, doses of the chemical and then from that you can narrow down what doses you want to explore with a little more resolution in the final study. So, those are range finding studies. So, it took a while and we had a couple of range finding studies, but they weren't adequate but then we got one and we -- yeah, and then we found this was a very unusual effect, a fetal effect. It didn't affect the mother and it was at a very low dose and our science -- our Health Effects Division advised us that they sometimes can have a safety factor, a 10X or something to account for the uncertainty. In this case because it was so unique and so low, they couldn't do that. They didn't feel like that would be defensible just based on that.

JUDGE BIRO: Okay. And when did you get that CTA study?

THE WITNESS: So, the range finding, I'm sorry, I can't tell. I'm sure it's in some of the documents and that was probably -- it was after the data delay letter; so, after October 2020; and before the notice of intent to suspend went out that HED told us there was no way.

JUDGE BIRO: Okay. There was some question on whether AMVAC was notified that that CTA study, or whatever EPA was relying on had changed the situation such that it could no longer use conservative assumptions

to do their risk analysis.

THE WITNESS: I'm pretty sure that was conveyed with the notice of intent to suspend that they were informed.

JUDGE BIRO: In the notice of intent --

THE WITNESS: Well, I know -- in the notice, or contemporaneous with it anyway.

JUDGE BIRO: Okay. Did you have any understanding about why AMVAC would have been, previous to that, willing to let you go ahead with conservative assumptions?

THE WITNESS: Well, on the environmental fate side their contention was that the studies we were asking for wouldn't give us any more information than just making conservative assumptions and that would be about potential exposures to the chemical. In terms of the health effects, I think it's about that same, no. So --

JUDGE BIRO: So, your understanding was that AMVAC said you won't get anything more useful out of doing these additional studies and will just spend money. So, just use your conservative assumptions?

THE WITNESS: Right. For the environmental fate data, and for some of the ecotox as well.

JUDGE BIRO: Did they ever explicitly state that to you, go ahead and use the conservative

assumptions, or that was -- you were not going to submit the data so you can go ahead?

THE WITNESS: So, I don't know that they ever said go ahead and do that. I don't know who would have responded to that, but they certainly were aware of it.

JUDGE BIRO: Okay. You said that AMVAC was dilatory and abnormal in their responses. Can you elaborate a little bit in your own words, what led you to that kind of conclusion?

THE WITNESS: Okay. So, it was a -- as DCIs go it was a fairly large one. There were a lot of data requirements and there was testing for both the metabolite and the parent compound. So, depending on how you counted, in any case, there were a lot of data requirements. There were some that AMVAC said they would develop data for and then they didn't. There were many that they requested waivers for. I think the dilatory part of that comes from submitting multiple waiver requests for the same study with little or no additional rationale.

JUDGE BIRO: Okay. This DCI was issued in 2013, which was coming up, or is about 10 years-time.

THE WITNESS: Yeah.

JUDGE BIRO: Is that a normal timeframe for DCI to be responding to?

THE WITNESS: No, that's pretty long. That's very long.

JUDGE BIRO: So, how long are most DCIs responding to?

THE WITNESS: So, I would say that, you know, the nature of the data requirements dictates the due dates, right? I don't think there -- I can think of one study that's four years and some that are three years. Most are less than two years, two years or less. So, you know, if everything went as planned if the longest data requirement was in there that took three years you would expect three years after that the DCI was issued that by then you would get the data. And I think your question was does that happen a lot? So, I would say there's always some piece of data that's not adequate. Usually, submitted but not adequate out of any number of data requirements that are levied on a particular registrant. Most of them are not, you know, a death knell for the risk assessment. And so, we often will publish documents with assessments and decisions in them and say, okay, we did this without the data. We don't consider these data to be satisfied, but we made this decision anyway.

JUDGE BIRO: What happens if you do that, and you make your conservative assumptions without AMVAC's data and it says it can't be used under these conditions.

You narrow the scope of use, maybe you know, in terms of how often it can be used or on what crops, or in any way narrows it. Can AMVAC then come back and provide additional studies. Maybe the studies you requested in the first place and try to get that conclusion reconsidered?

THE WITNESS: Yes, that happens.

JUDGE BIRO: Okay. So, is that common?

THE WITNESS: I don't know how common, but it's not rare.

JUDGE BIRO: So, you could go through the whole process of a risk assessment and not really effectively ever close out the process?

THE WITNESS: Yes. I mean registration review is a cyclical process. They would go through rounds, every chemical has to be evaluated every 15 years and then the next 15 years it happens again, and then there's more active ingredients by that time, that's why most of our decisions are considered to be interim decisions as opposed to final decisions, because there -- sometimes there are issues that we can't make judgments on.

JUDGE BIRO: Let's say you issued on December 31 a registration that narrowed, the use of DCPA, and would AMVAC have to wait basically 15 years to get that reevaluated?

THE WITNESS: So, after we issue the interim decision, we generally do not open that decision again, but what often happens is before they enter a decision there is a proposed interim decision, and it forecasts what we think we're going to do in terms of registration, such as eliminating uses, or lowering application rates, or people wear protective equipment. So, what will happen is when the registrant finds that those conditions are not satisfactory to them. They will often come in with offers to do more mitigation, or more data to see if they can change the interim decision.

JUDGE BIRO: Okay. So, if you had gone ahead and gone with conservative assessments you would have been issued an interim decision, a proposed interim decision, and you would have sent it to AMVAC and it would have had then another chance to go back and potentially say we're not happy. We would like to do these studies now, because what you come up with is not going to work for us.

THE WITNESS: Yeah, so that does happen and I should say every step of the way there's a period of public comments that includes the registrant. We usually even tell the registrant that it's out there as opposed to them just looking through our register. And so, as far as what happens between the proposed interim decision

and the interim decision, I mean it's a judgment call. If it's going to take five more years to get the data for the decision were going to go ahead and make the interim decision and then consider the data in the next round, or if it's really, really critical, some other avenue, but yeah. If it's a matter of months or maybe even a year, we might be willing to hold off to get that data, those data.

JUDGE BIRO: How about if the growers' group, the farmers who buy and use DCPA came in at that point and said -- you say you can't use it on onions anymore and that's where we mostly use it, is that's something that would affect your decision?

THE WITNESS: Yes, definitely. Those are part of the public comments we expect to get on the proposed interim decision. And usually testimonial information, like I use this chemical all the time and it's really great, that doesn't matter so much, but if they tell us and can verify that there are no alternatives to that chemical, or this is a really little niche use that has high value, but you wouldn't know about it unless we told you about it, that probably -- yeah, that kind of information is considered. Usage data; how it's used; practices that impact the risk assessment that are specific to a crop that this chemical is used on; those

kinds of things all come into play. I mean it can also happen at the risk assessment phase.

JUDGE BIRO: Did you receive comments in connection with this DCI in this pending registration evaluation from growers in this process?

THE WITNESS: So, nobody responded -- okay, so the comment periods followed the preliminary work plan. Nobody gave us comments on that. The next opportunity for an open comment period would be when we publish the risk assessment, which happens after we get the data and often a user will see the writing on the wall, just without a decision, but with the -- you know, our summary of what the risks are that it's going to impact and he wants us to consider this or that or the other thing. That can come in after the draft risk assessment. It can come in after the proposed interim decision, and yeah, if it's substantive we address it either, you know, decide whether we think it makes a difference, or if it makes a difference, we adjust our decision.

JUDGE BIRO: Okay. But in this case, and nine of these grower group organizations or individuals had submitted any comments to EPA challenging anything regarding this registration review?

THE WITNESS: So, the last public comment period would have been on the PWP. We didn't get

anything, but we have gotten communications from different user groups over time that say we really need this chemical, and we would like to keep it.

JUDGE BIRO: Okay. So, outside of a public period to respond, informally they have sent you comments?

THE WITNESS: Yes.

JUDGE BIRO: And do you take into account their informal comments?

THE WITNESS: Yes.

JUDGE BIRO: Let's see. I think you talked about how the CTA has been submitted and so now -- is EPA going to be able to go ahead and issue is assessment based on that?

THE WITNESS: So, we're still missing some data that are important, but for those we'd probably make the conservative assumptions we talked about. So, we have all of the health information we need. As I indicated before, some of the data that are under the banner of environmental fate actually figure into the human health risk assessment and those would be the cases that we would have to make assumptions about health risk in a chemical is for example.

JUDGE BIRO: Okay. I understand that AMVAC has apparently had DCIs about DCPA issued three times

previously?

THE WITNESS: That's probably correct when we did the registration standard, which would have been before my time. When we did re-registration that was during my time but it wasn't involved in it and now. And then there also would be the endocrine disruptor DCI that most pesticide registrants got.

JUDGE BIRO: Okay. Do you have any personal knowledge of those?

THE WITNESS: Just what I've read about them. I mean I know what our scientists concluded about the endocrine disruption and the others factored into the decisions that followed them.

JUDGE BIRO: I was thinking about the process, how that process went. Do you have any personal knowledge of that?

THE WITNESS: I'm sorry. The process of what now?

JUDGE BIRO: Of sending out that DCI and AMVAC responding. Did they respond in a more timely way in regard to those in comparison? That's what I'm looking for.

THE WITNESS: I can tell you that the DCI that was issued when we did our re-registration eligibility decision, and that was in 1995, contained some of the

same data requirements that we repeated that we needed in 2013.

JUDGE BIRO: And were they done in a timely manner in that case?

THE WITNESS: No, some of them are still outstanding, and some of them were outstanding until they responded to this DCI.

JUDGE BIRO: So, that DCI was never closed out but a NOITS was never issued in connection with it?

THE WITNESS: Right.

JUDGE BIRO: And how about on this other dates. I think there were two others. One was in 81 and then there was another one. Do you know?

THE WITNESS: The other DCI's?

JUDGE BIRO: Yeah.

THE WITNESS: You know, I probably knew at one time but I haven't looked at them in a while. So, I don't know. All I know is there were data requirements that weren't satisfied in earlier DCI's that we required again with this DCI, because we still needed it.

JUDGE BIRO: Okay. Bear with me one minute. Okay. I don't think I have any more questions to ask at this point. Mr. Pittman, do you have any questions you would like to ask in response to mine?

MR. PITTMAN: No, Your Honor.

JUDGE BIRO: Okay. Mr. Weinberg, do you have any questions you would like to ask?

MR. WEINBERG: Your Honor, I have no questions. I would like to just make one brief comment, and that is, it is very important that you analyze these issues to recognize that there is a substantial difference between the human health issues and the studies in the human health issues and the environmental fate issues; and the assumptions, and the risks, and the decisions that were being made there, what the issues were. We'll talk more about that tomorrow.

JUDGE BIRO: You can put it in your brief and I'll read it, you know, as I'm making my decision. Ms. Rose, do you have any questions in response to my questions?

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

JUDGE BIRO: Okay. Do you want to reserve the right to call Ms. Bloom again?

MR. PITTMAN: Can I have one moment to discuss with counsel?

JUDGE BIRO: Oh, of course.

MR. PITTMAN: Your Honor, Respondents position would be to release Ms. Bloom at this time.

JUDGE BIRO: Lucky you Ms. Bloom.

THE WITNESS: Does that mean I'm not needed

tomorrow?

JUDGE BIRO: You are not going to be called back.

THE WITNESS: Okay. But I might be called back later?

JUDGE BIRO: No. You're not going to be called back later.

THE WITNESS: Oh, okay.

JUDGE BIRO: You are released, but you still can't discuss your testimony with anybody who has any connection to this proceeding.

Thank you very much. Have a good evening.

THE WITNESS: Thank you, Your Honor.

JUDGE BIRO: Are there any other exhibits that you want to move into evidence that we discussed in this process?

MR. ROSS: There are, Your Honor, but there are probably about ten of them by my account that fall into three categories. Mr. Pittman and I can probably confer and work that out quickly, or we can handle it tomorrow morning if Mr. Pittman is amenable.

JUDGE BIRO: Maybe you could just send him an email tonight and you can look it over and get back to it.

What time can we start tomorrow? Can we start

at 9:00, 8:30, 8? I get here at 6:30, so I am happy to accommodate however early you would like to start.

MR. PITTMAN: Your Honor, we would request 9:00. Co-counsel lives in Baltimore. It is a little dicey getting in on the MARC early sometimes.

JUDGE BIRO: Okay. Let's start at 9:00 tomorrow.

Thank you very much. We stand in recess.

(Whereupon, at 5:19 p.m. the above-entitled matter was recessed to reconvene on Wednesday, January 25, 2023 at 9:00 a.m.)

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 24, 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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