

In The Matter Of:

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

*Vol. 1
January 24, 2023*



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

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

The above-entitled matter came on for virtual hearing pursuant to notice before the HONORABLE SUSAN BIRO, Administrative Law Judge, at the Environmental Protection Agency East Building, 1201 Constitution Avenue, NW, Room 1152, Washington, D.C., on Tuesday , January 24, 2023, at 9:00 a.m.

1 APPEARANCES:

2 On behalf of the Agency:

3 FORREST PITTMAN, ESQ.

4 ERIN KOCH, ESQ.

5 Pesticides and Toxic Substances Law Office

6 Office of the General Counsel

7 U.S. Environmental Protection Agency

8 Mail Code 2310A

9 1200 Pennsylvania Avenue, NW

10 Washington, D.C. 20460

11 pittman.forrest@epa.gov

12 On behalf of the Petitioner (Grower-Shipper Association
13 of Central California; J&D Produce; Ratto Bros, Inc.; and
14 Huntington Farms):

15 CRISTEN S. ROSE, ESQ.

16 Haynes Boone

17 800 17th Street NW

18 Washington, D.C. 20006

19 cristen.rose@haynesboone.com

20

21 On behalf of the Petitioner (AMVAC Chemical Corp.):

22 DAVID B. WEINBERG, ESQ

23 Wiley Rein

24 (202) 719-7102

25 dweinberg@wiley.law

1 APPEARANCES: (Continued)

2
3 On behalf of the Petitioner (AMVAC Chemical Corp.):

4 HUME M. ROSS, ESQ.

5 Wiley Rein

6 (202) 719-7296

7 hross@wiley.law

8
9 MARK SWEET, ESQ.

10 (202) 719-4649

11 msweet@wiley.law

12
13 TRACY HEINZMAN, ESQ.

14 (202) 719-7106

15 theinzman@wiley.law

16

17

18

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P R O C E E D I N G S

(9:01 a.m.)

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2
3 JUDGE BIRO: Good morning. I'm Susan Biro,
4 Chief Administrative Law Judge for the Environmental
5 Protection Agency. Counsel for the petitioner, can you
6 please identify yourself for the record?

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

10 JUDGE BIRO: Good morning.

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

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

19 JUDGE BIRO: Agency?

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

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

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

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

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

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

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

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

6 MR. WEINBERG: Your Honor, if I may?

7 JUDGE BIRO: Yes.

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

11 JUDGE BIRO: No. No, of course --

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

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

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

1 this hearing while we continue to have an ongoing
2 pandemic.

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

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

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

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

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

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

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

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

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

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

25 JUDGE BIRO: Yeah. Let's just do opening

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

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

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

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

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

13 MS. ROSE: I can hear you.

14 JUDGE BIRO: We can.

15 MR. WEINBERG: Yes. Yes.

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

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

25 MR. WEINBERG: No, Your Honor.

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

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

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

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

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

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

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

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

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

1 AMVAC's conduct was broadly typical of other registrants.

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

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

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

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

1 informing a registrant that that data is actually needed.

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

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

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

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

1 for AMVAC to comply with the DCI. Thank you.

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

4 MR. WEINBERG: Thank you, Your Honor.

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

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

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

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

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

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

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

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

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

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

4 Initially, though, I want to say that there's
5 various ways to quantify the amounts of studies, and you
6 may already have a question about how many studies are
7 issued here versus how many guidelines, or some different
8 numbers that have been tossed around in various briefs.

9 Do we have the opportunity to put up that chart?

10 (Referring to McMahon Ex. B).

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

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

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

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

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

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

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

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

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

1 by changing the label on the product.

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

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

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

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

6 Now, interestingly, during the pendency of the
7 preceding years, EPA personnel, scientific personnel have
8 been quite open to talking with the company's scientific
9 personnel. Talking may be the wrong word.

10 Communicating. These days so much communication is by
11 email rather than talk. I have to be more careful.

12 But, for example, for five of the nine studies
13 still at issue, EFED, the Environmental Fate Division of
14 the EPA had suggested to AMVAC's people that they follow
15 a particular limited test approach to avoid having to do
16 all of those studies. And, AMVAC did that and submitted
17 the data from that effort to EPA in August 2020.

18 Submitted the data in August, a report on what that data
19 said in December 2020. But EPA only informed AMVAC
20 essentially simultaneously with the publication of the
21 notice of intent to suspend that, based on the work that
22 had been done, it believed further tests had to be done.

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

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

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

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

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

25 And some of those were even at issue

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

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

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

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

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

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

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

25 Now there are a number of other things that are

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

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

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

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

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

1 you for allowing me to appear remotely. I represent the
2 Growers Association of Central California, J&D Produce,
3 Ratto Brothers and Huntington Farms. The Grower's
4 Association is a regional trade association founded in
5 1930 based in California Salinas Valley.

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

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

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

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

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

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

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

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

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

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

18 MR. PITTMAN: Thank you, Your Honor. I have a
19 list that Mr. Ross provided, if I get the numbers wrong
20 here. Pursuant to stipulations I would -- I guess I'll
21 move these in in chunks, if that's the easiest way to do
22 it, so I would move that joint exhibits 1 through 48 and
23 50 through 92 to be admitted to the record.

24 MR. WEINBERG: No objection.

25 JUDGE BIRO: Okay. Joint Exhibits one through

1 48 and 50 through 92 are admitted into the record.

2 (Joint [Exhibit 1](#) through 48 and 50 to 92 are
3 admitted)

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

7 JUDGE BIRO: Is there any objection.

8 MR. ROSS: No objection.

9 JUDGE BIRO: Okay.

10 MS. ROSE: No objection.

11 JUDGE BIRO: Sorry, Ms. Rose. I'm so sorry.
12 Please feel free to speak up any time I forget to include
13 you because you're not physically here and I really
14 apologize. Respondent's exhibits one through 12, 17 to
15 18 and 24 are admitted into the record without objection.

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

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

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

23 MR. ROSS: No objection, Your Honor.

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

1 MS. ROSE: No objections.

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

6 (Petition AMVAC Exhibits 1 through 43, 45, 47, 49,
7 51, 78 through 82 and 91 and 92 are admitted)

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

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

16 MS. ROSE: No objection.

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

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

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

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

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

6 MR. PITTMAN: Okay.

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

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

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

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

25 MS. ROSE: No. No, Your Honor.

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

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

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

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

21 JUDGE BIRO: Are you continuing without
22 objection?

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

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

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

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

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

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

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

18 JUDGE BIRO: Okay. So why don't we take a 10
19 minute break. I'm not exactly sure what time it is now.
20 9:44. So we could come back at 10. Okay. We will stand
21 in recess until 10 o'clock. Thank you.

22 (Off the record)

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

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

5 (Whereupon,

6 CHRISTINA WENDEL,
7 having been first duly sworn, was called as a witness
8 herein and testified as follows:)

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

11 DIRECT EXAMINATION

12 BY MR. PITTMAN:

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

15 A. Christina Wendel, biologist.

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

19 A. Yes.

20 Q. How do you recognize it?

21 A. I was the author of the document.

22 Q. So, what is it?

23 A. Oh, sorry.

24 Q. What is the document?

25 A. The document is my witness statement.

1 Q. Is it a true and accurate copy?

2 A. That's correct, yes.

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

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

9 MR. ROSS: No, Your Honor.

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

12 MS. ROSE: No, Your Honor.

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

16 MR. PITTMAN: I suppose this would become RX-
17 25, if we're going to designate it such.

18 JUDGE BIRO: Respondent [Exhibit 25](#) did you
19 say?

20 MR. PITTMAN: 25. Yes.

21 JUDGE BIRO: Okay. Respondent [Exhibit 25](#) is
22 admitted into the record.

23 (Respondent [Exhibit 25](#) is admitted)

24 JUDGE BIRO: Please proceed.

25 MS. ROSE: Thank you.

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

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

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

6 MR. ROSS: May I proceed?

7 CROSS EXAMINATION

8 BY MR. ROSS:

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

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

19 A. Yes.

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

24 A. To the best of my knowledge, yes.

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

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

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

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

7 A. That is correct, yes.

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

11 A. That is correct. Yes.

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

17 A. That's correct, no.

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

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

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

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

8 A. That's correct, yes.

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

11 A. That's correct.

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

16 A. Correct.

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

20 A. Correct.

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

25 A. Correct.

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

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

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

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

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

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

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

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

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

4 A. That's correct.

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

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

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

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

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

23 A. Possibly, yes.

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

1 is requested or required to provide a response within?

2 A. Sometimes. And sometimes it's renegotiated.

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

7 A. Correct.

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

11 A. That's correct, from my understanding.

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

14 A. I don't know that information.

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

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

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

1 request, and scientific study, correct?

2 A. Correct.

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

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

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

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

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

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

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

21 A. It's my understanding.

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

25 A. Correct.

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

4 A. Correct.

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

10 A. Yes.

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

15 A. That's correct.

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

19 A. That's correct.

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

24 A. Yes.

25 Q. And when did you become aware of that?

1 A. Less than a month ago.

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

6 A. No. I was not, no.

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

10 A. Not to specific details, no.

11 Q. You said not to specific details.

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

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

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

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

23 A. That's correct.

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

1 ecotox studies, correct?

2 A. Correct.

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

5 A. I remain assigned to the chemical.

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

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

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

13 A. I don't know either way.

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

21 A. Correct.

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

25 A. Correct.

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

3 A. That's correct.

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

7 A. Correct.

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

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

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

15 A. Response to comments for the mysid study.

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

18 A. They have been completed.

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

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

25 Q. Has EFED taken any steps to communicate this

1 conclusion to PRD?

2 A. Yes. We informed them.

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

5 A. I have no knowledge of that.

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

9 A. Correct.

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

13 A. Probably, yes.

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

17 A. Correct.

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

22 A. Correct.

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

1 A. Correct.

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

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

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

11 A. Correct. And it cannot be refined.

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

17 A. Correct.

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

21 A. Correct.

22 Q. At several points in your testimony, and I'm
23 speaking now about the five TPA ecotox studies, you
24 referred to waiver requests submitted by AMVAC in 2013,
25 2014 and 2020. Examples of this, if you would like to

1 take a brief review, are on page three of your testimony
2 near the bottom. There is a parenthetical first at 2013,
3 2014, 2020, and at the top of page six, the same
4 reference; isn't that, right?

5 A. Correct.

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

9 A. Correct.

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

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

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

21 A. Yes, to my understanding.

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

24 A. To my knowledge, yes.

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

1 response to the DCI, correct?

2 A. Correct.

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

5 A. Vaguely, yes.

6 Q. Can you describe the nature of that document?

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

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

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

13 Q. Mr. Sayres, could you bring up Joint Exhibit
14 67, please? And Ms. Wendel, if you would like to -- when
15 one of these documents is shown, if you would like to see
16 a different portion of it, just let us know and we can
17 scroll around. But the document apparently up on the
18 screen states that it is a waiver request in support of
19 the dacthal registration review provided in response to
20 the agency's memorandum dated March 21, 2014, received
21 March 17 of 2017, correct?

22 A. Correct. That's what it states.

23 Q. Is it possible that this is the document that
24 you referred to several times in your testimony as the
25 2014 document?

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

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

7 A. That's correct.

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

10 A. Correct.

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

14 A. Only the leptochirus responses from 2016.

15 Q. But with respect to the five TPA ecotox
16 documents, waiver requests, rather, you don't recall a
17 2014 waiver request?

18 A. Just our response.

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

22 A. Correct.

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

1 section as, quote, the agency's memorandum dated March
2 21, 2014?

3 A. Correct. Correct, yes.

4 Q. And this document continues, "received on March
5 17 of 2017." As you sit here today, are you aware that
6 EFED's March 21, 2014, response was not provided to AMVAC
7 until March 2017?

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

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

12 A. Correct.

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

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

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

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

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

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

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

14 Q. Gotcha. When approximately would that
15 procedure change?

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

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

20 A. It's been a number of years.

21 Q. Was it near the beginning of this DCI?

22 A. No. It was after 2014, but I believe before
23 2016, but I'm not 100 percent sure on the dates for the
24 transition.

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

1 [Exhibit 5](#), please. Ms. Wendel, this is what we have been
2 referring to as the initial waiver request from 2013.

3 A. Okay.

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

8 A. Correct.

9 Q. And Mr. Sayres, if you could bring up Joint
10 [Exhibit 66](#), please? Do you recognize this document, Ms.
11 Wendel?

12 A. Yes.

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

15 A. Correct.

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

19 A. Correct.

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

24 A. Correct.

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

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

6 A. Correct.

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

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

14 A. Correct.

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

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

1 required, correct?

2 A. Correct.

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

5 A. Correct.

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

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

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

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

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

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

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

24 A. No, I have not seen any one.

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

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

5 A. Correct.

6 Q. Let's just follow through the guideline
7 850.1350, chronic mysid. Mr. Sayres, could you put up
8 Joint [Exhibit 67](#), please? Ms. Wendel, are you familiar
9 with this document?

10 A. I have seen it, yes.

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

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

14 Q. And when you recall seeing it in approximately
15 2020, was that as a result of the PRD BEAN procedure that
16 we discussed previously?

17 A. Yes.

18 Q. Mr. Sayres, could you go to page nine of this
19 document, please? Again, this document which is dated
20 2018, which you believe you first reviewed in 2020, what
21 we're looking at here on the screen, just page nine of
22 Joint [Exhibit 67](#), this is AMVAC's response to EFED's 2014
23 memorandum, correct?

24 A. Correct.

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

1 agreeing with or accepting the acute and chronic toxicity
2 study and daphnid approach that EFED had suggested in
3 Joint [Exhibit 66](#)?

4 A. You can interpret that, yes.

5 Q. Is there an alternate interpretation of this
6 document?

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

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

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

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

1 invertebrate?

2 A. Correct. Mysid or --

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

7 A. Correct.

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

10 A. Correct.

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

16 A. Correct.

17 Q. Mr. Sayres, could you put petitioner AMVAC's
18 [Exhibit 45](#) up on the screen? Do you recognize this
19 document, Ms. Wendel?

20 A. Yes.

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

24 A. Correct.

25 Q. Do you recall approximately when EFED received

1 the BEAN to review this document?

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

4 Q. So relatively close to the submission date?

5 A. To my understanding.

6 Q. In December 2020?

7 A. To my recollection.

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

13 A. Yes, you could.

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

17 A. Correct.

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

21 A. Correct.

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

24 A. Correct.

25 Q. Do you recall when EFED issued a memorandum

1 responding to the information in this document?

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

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

7 A. Yes.

8 Q. And as you mentioned, it is dated April 19 of
9 2022?

10 A. Yes.

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

14 A. To my knowledge.

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

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

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

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

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

1 from EFED?

2 A. I don't know.

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

5 A. I don't recall.

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

9 A. Correct.

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

13 A. Correct.

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

18 A. Correct.

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

22 A. Very conservative. Make conservative
23 assumptions.

24 Q. And so if we look back to EFED's proposal,
25 proposed solution in Joint [Exhibit 66](#), Mr. Sayres, page

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

8 A. Correct.

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

12 A. No. It didn't.

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

18 A. Correct.

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

24 A. Correct.

25 Q. And this document sets forth that rationale,

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

3 A. Correct.

4 Q. So, in particular with respect to the mysid --
5 Mr. Sayres, if you could take us to page nine of 24 of
6 Joint [Exhibit 69](#) -- and I believe this is repeated in
7 your testimony, EFED had concerns based on the lifecycle
8 toxicity study that was available for DCPA which was MRID
9 49307512, correct?

10 A. Correct.

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

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

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

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

1 didn't have that at the time.

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

4 A. Correct.

5 Q. Which has now been submitted?

6 A. Correct.

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

8 A. Correct.

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

13 A. Correct.

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

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

21 Q. 51499401 and 51499402?

22 A. Correct.

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

25 A. Correct. In 2020.

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

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

7 Q. Mr. Sayres, could you bring up Joint Exhibit
8 82, please? Ms. Wendel, do you recognize this document?

9 A. Yes.

10 Q. And what is this document?

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

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

14 A. Yes.

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

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

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

21 A. That is correct.

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

25 A. That is correct. But we provide the final

1 review.

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

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

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

9 A. That is correct.

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

13 A. Correct.

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

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

23 Q. Mr. Sayres, could you bring up Joint Exhibit
24 27, and turn to page two of seven? If you could start by
25 zooming in on the bottom half of that page. We're

1 talking now about a mysid study. Do you recognize the
2 bottom entry in the chart that we are currently looking
3 at in Joint [Exhibit 27](#), specifically the final entry on
4 page two to refer to a mysid 850.1350 guideline study?

5 A. Yes.

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

9 A. Correct.

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

12 A. Correct.

13 Q. And if we look back at Joint [Exhibit 82](#), it
14 would appear that this study was submitted a few weeks
15 after it was completed in January 2014, correct?

16 A. Correct.

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

20 A. Correct.

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

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

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

1 closer to October or November 2016, or closer to December
2 2021?

3 A. Possibly around 2016, 2017.

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

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

12 Q. You stated that you believe this document was
13 returned from the contractor to AMVAC at some point in
14 2016 or 2017?

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

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

24 A. Correct.

25 Q. And EFED could have at any point after

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

6 A. Correct.

7 Q. But EFED did not do that, correct?

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

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

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

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

22 A. Correct.

23 Q. Mr. Sayres, can you pull up Joint [Exhibit 51](#)?
24 Ms. Wendel, do you recognize this document?

25 A. Yes, it's the DER.

1 Q. For the study with MRID 49307520?

2 A. That's correct.

3 Q. And similar to the prior example we looked at,
4 you would expect that this document was back in EFED's
5 hands in 2016 or perhaps 2017, correct?

6 A. Correct.

7 Q. And with respect to the final one of the five,
8 the marine diatom, you stated that AMVAC's ultimate
9 recommendation, concurrent with the NOITS, was based on
10 MRID 49307504, correct?

11 A. Correct.

12 Q. Mr. Sayres, do you have access to the documents
13 from the regulations docket, and specifically the one
14 ending in 0027? Give me a moment. Let me see if that's
15 been separately entered into evidence. Since we can't,
16 you have access to the Internet? Let's have some fun
17 with regulations.gov.

18 If you could navigate to regulations.gov,
19 please, Mr. Sayres. And in the search box type in the
20 alphanumeric beginning EPA HQ, which I believe you had in
21 a copy of my cross-exam, but it is EPA for the record.
22 EPA-HQ-OPP-2011-0374-0027. For the record, those must be
23 short dashes or else regulations.gov does not recognize
24 them. Ms. Wendel, do you recognize this document?

25 A. Yes.

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

3 A. Correct.

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

7 A. Correct.

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

10 A. Correct.

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

13 A. Correct.

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

19 A. Correct.

20 Q. But regardless of when this data was submitted
21 when EFED reviewed it, you would agree with me that AMVAC
22 did provide the acute and chronic data that EFED
23 suggested in its memorandum that has been dated March
24 2014, correct?

25 A. Correct.

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

6 A. Correct.

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

11 A. Yes. Correct.

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

14 A. Correct.

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

19 A. Excuse me. What part of the page?

20 Q. Page nine of your testimony.

21 A. Uh-huh.

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

1 occasions that AMVAC was working on developing
2 methodology, correct?

3 A. Correct.

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

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

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

12 A. That's correct.

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

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

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

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

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

25 A. Correct.

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

4 A. Correct.

5 Q. Mr. Sayres, could you bring up Joint Exhibit
6 76, please. Ms. Wendel, do you recall seeing this
7 document in the past?

8 A. No.

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

12 A. Correct.

13 Q. That we're currently looking at. This is page
14 one of Joint [Exhibit 76](#)?

15 A. That is correct.

16 Q. And the study title is response to EPA's
17 memorandum of June 27, 2016, from EFED. Is that the June
18 2016 recommendation to deny AMVAC's waiver request?

19 A. That's correct.

20 Q. Which, for the record, has been identified as
21 Joint [Exhibit 74](#) in this proceeding. Mr. Sayres, if you
22 could flip ahead from the transmittal page to the next
23 page, please. Do you recall seeing this document
24 previously?

25 A. Yes. But not until later in 2016.

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

3 A. Around 2020, in December.

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

6 A. No.

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

10 A. Correct.

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

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

18 Q. Well, this project number at the bottom of the
19 screen currently is identified as AMVAC report 100-AQU-
20 031, correct?

21 A. Correct.

22 Q. Mr. Sayres, if you could bring up Joint Exhibit
23 73, please. Do you recognize this document?

24 A. Yes.

25 Q. Is this the AMVAC waiver request to which EFED

1 issued a recommendation in June 2016?

2 A. Yes.

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

5 A. Correct.

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

10 A. Correct.

11 Q. Mr. Sayres, could you put up Joint [Exhibit 69](#),
12 please? This is EFED's final recommendation that was
13 issued concurrent with the NOITS, correct?

14 A. Correct.

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

18 A. Correct.

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

21 A. Correct.

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

25 A. No. It does not appear to be.

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

5 A. Could you go down to the leptochairus section,
6 please?

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

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

13 A. Yes, quickly, look at the bibliography.

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

16 A. Uh-huh.

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

20 A. Correct. Just the first one.

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

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

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

4 A. Correct.

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

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

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

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

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

18 A. No, I don't recall.

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

23 A. Correct.

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

1 correct?

2 A. Correct.

3 Q. Ms. Wendel, on page three of your testimony you
4 refer to a document, an EPA document dated October 16 of
5 2020 as the data delay letter, isn't that correct?

6 A. Correct.

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

10 A. Correct.

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

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

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

21 A. Correct.

22 Q. -- accounting of --

23 A. Correct.

24 Q. -- data requirements? Mr. Sayres, could you
25 pull up Joint [Exhibit 21](#), please? Ms. Wendel, do you

1 recognize this document?

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

4 Q. The subject of this document, Joint [Exhibit 21](#),
5 is "notification of outstanding data requirements in
6 anticipated registration review schedule for DCPA,"
7 correct?

8 A. Correct.

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

12 A. Correct.

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

15 JUDGE BIRO: Which exhibit are we waiting for
16 now?

17 BY MR. ROSS:

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

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

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

25 A. I believe so.

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

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

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

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

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

17 A. Correct.

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

21 A. Correct.

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

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

4 A. Correct.

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

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

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

12 A. Correct.

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

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

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

19 A. That's what it states.

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

22 A. I have no knowledge of that.

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

25 A. That's correct.

1 Q. Now, a draft risk assessment was not completed
2 in June 2021, was it?

3 A. No.

4 Q. Has a draft risk assessment for ecological
5 affects and environmental fate yet been completed?

6 A. Not completed, no.

7 Q. And your testimony is that EFED could complete
8 a conservative risk assessment just as PRD indicated that
9 it could in this letter; correct?

10 A. That's correct.

11 Q. So, there was no point at which EFED realized
12 that a statement in this letter was inaccurate; correct?

13 A. Correct.

14 Q. So, the fact that the draft risk assessment was
15 not completed in June of 2021 has nothing to do with the
16 fact that AMVAC continued to wait for the responses to
17 its waiver request; correct?

18 A. Correct. To my knowledge I can't postulate,
19 but to my knowledge.

20 Q. To the best of your knowledge, the fact that a
21 draft risk assessment was not completed in June of 2021,
22 has nothing to do with the fact that AMVAC continued to
23 wait for responses to its waiver request in some
24 instances; correct?

25 A. Correct.

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

4 JUDGE BIRO: Oh, of course. Yes.

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

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

8 REDIRECT EXAMINATION

9 BY MR. PITTMAN:

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

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

16 Q. And what was the chemical?

17 A. Nicarbazin.

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

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

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

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

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

4 Q. Thank you. With respect to a special study
5 1072, I believe we were referring to as the Leptocheirus
6 study earlier.

7 A. Uh-huh.

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

11 A. My understanding, I'm aware of about 16 studies
12 that have been completed successfully either acceptable
13 or supplemental for use within our risk assessment since
14 2017. There could be more than that, but there is at
15 least 16 studies.

16 Q. And you said since about 2017, correct?

17 A. Correct.

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

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

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

1 study was submitted to EFED?

2 A. 2017.

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

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

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

8 JUDGE BIRO: Any recross?

9 MR. ROSS: Yes, Your Honor.

10 RECCROSS EXAMINATION

11 BY MR. ROSS:

12 Q. Mr. Sayres, can you pull up Joint [Exhibit 22](#),
13 please? And go to the second page. The largest two
14 paragraphs there, if you could zoom in. Ms. Wendel, do
15 you recognize this document?

16 A. Yes.

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

20 A. That is correct. Yes.

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

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

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

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

14 A. Correct.

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

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

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

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

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

3 A. That is correct.

4 MR. ROSS: No further questions.

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

7 MS. ROSE: I do not.

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

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

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

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

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

20 THE WITNESS: Okay.

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

23 THE WITNESS: Understood.

24 JUDGE BIRO: Okay. Thanks.

25 THE WITNESS: Thank you.

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

6 MR. PITTMAN: Thank you, Your Honor.
7 (Whereupon, at 11:48 a.m. a lunch recess was taken)

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

1 (1:01 p.m.)

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

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

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

11 MR. PITTMAN: Oh, sorry. My apologies.

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

14 (Whereupon,

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

18 JUDGE BIRO: All right. Please begin.

19 DIRECT EXAMINATION

20 BY MR. PITTMAN:

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

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

1 Q. Can you pull up -- Mr. Wente, are you able to
2 see the document that's in front of you?

3 A. Yes, I do.

4 Q. Do you recognize this document?

5 A. I do.

6 Q. How do you recognize it?

7 A. It's a statement that I prepared for this
8 hearing.

9 Q. Is it a true and accurate copy?

10 A. Yes.

11 MR. PITTMAN: Your Honor, I would move that the
12 witness statement of Stephen Wente be admitted into the
13 record as RX-26.

14 JUDGE BIRO: Mr. Ross, is there any objection?

15 MR. PITTMAN: No objection, Your Honor.

16 JUDGE BIRO: Ms. Rose, is there any objection?

17 MS. ROSE: No, objection, Your Honor.

18 JUDGE BIRO: So, no objection, RX26 is
19 admitted into the record.

20 (Exhibit RX-26 is admitted)

21 BY MR. PITTMAN:

22 Q. Would you like to ask we have an electronic
23 copy to follow along with or do you want to handle that?

24 MR. ROSS: I think we'll be able to see what is
25 brought up. It should be all right.

1 MR. PITTMAN: All right. Thank you.

2 CROSS EXAMINATION

3 BY MR. ROSS:

4 Q. Good afternoon, is it Dr. Wente?

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

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

9 A. That's fine.

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

13 A. Let me minimize the screen and --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 A. That's correct.

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

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

1 would think of.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 A. Yeah.

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

22 A. Correct.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 A. Yeah.

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

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

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

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

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

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

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

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

1 registration review and --

2 A. Yes.

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

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

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

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

14 Q. Was when these meetings began?

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

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

1 NOITS?

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

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

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

18 A. Okay.

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

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

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

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

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

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

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

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

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

12 A. Yes.

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

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

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

1 risk assessment, correct?

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

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

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

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

12 MR. PITTMAN: Yes, Your Honor.

13 BY MR. ROSS:

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

18 A. Yes. Sometime within that year.

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

25 A. So, I'm not --

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

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

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

12 A. Yes.

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

14 A. Yes. EPA has made that assumption before.

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

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

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

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

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

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

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

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

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

20 A. There it is.

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

1 that the assumed stability may not be overly
2 conservative?

3 A. Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 A. Yeah.

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

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

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

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

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

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

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

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

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

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

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

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

10 A. Yeah.

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

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

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

23 A. That's my understanding. Yeah.

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

1 A. Yes, maybe not strongly, but otherwise I agree.

2 Q. Are you aware that the first time that the EFED
3 memorandum that we were just reviewing was provided to
4 AMVAC was concurrent with the October 16, 2020, delay
5 letter?

6 A. So, if that's the case then my statement is
7 probably wrong there. So, I do recall that there was
8 some delay in the communications and people had talked
9 about that at different times.

10 Q. Moving forward through that chronology to
11 discuss the notification to AMVAC. This is still on page
12 5 of your testimony on the October 16, 2020, delay
13 letter. After that, AMVAC supplied an additional
14 scientific analysis in further support of its waiver
15 request for the environmental fate studies, correct?

16 A. They provided a waiver request. I didn't
17 really think of it as a scientific evaluation.

18 Q. Mr. Sayres, could you pull up -- Joint Exhibit
19 78, please? Are you familiar with this document?

20 A. I have seen it before.

21 Q. Do you recall approximately when you might have
22 first seen it?

23 A. Probably I assumed in the preparation of the --
24 what do you call it, the suspension document.

25 Q. Which per your prior testimony could not have

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

3 A. Something like that, yeah.

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

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

11 Q. The question --

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

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

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

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

22 A. Yes, I assume so.

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

24 A. It does.

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

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

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

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

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

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

18 A. We would have considered it, yes.

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

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

25 Q. And is it your understanding of this document

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

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

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

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

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

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

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

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

24 A. No, they do not.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 A. Yes.

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

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

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

9 A. Yeah.

10 Q. And Mr. Sayres, if you could go to page 17 of
11 19, please, to the citation, the J9 citation. That's the
12 line -- nine just above there, SETAC 1995. The reference
13 to J9 is the citation for this document, correct?

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

17 Q. Are you familiar with this 1995 SETAC
18 publication?

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

1 be -- a study should not last longer than 120 days. In
2 the SETAC guidelines that always has it should not last
3 longer than 120 days. Or for the aerobic -- or aquatic
4 metabolism studies says it should not last longer than
5 100 days. So, EPA made a conscious decision to not use
6 that same text and actually added in the "not normally,"
7 you know, modifier or whatever they call that to indicate
8 that you could go longer than.

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

12 A. That's correct.

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

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

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

1 A. No, I was not.

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

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

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

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

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

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

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

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

1 had something to do with duration.

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

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

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

11 JUDGE BIRO: Okay. Overruled.

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

13 JUDGE BIRO: Go ahead.

14 BY MR ROSS:

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

19 A. Yes. I think.

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

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

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

1 quote, but the quote from the 835 series guideline that
2 you reference in your testimony and's with "(e.g., 6 to
3 12 months)" that we're seeing here on the screen,
4 correct?

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

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

12 A. Yes.

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

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

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

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

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

13 Q. And that would appear to be --

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

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

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

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

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

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

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

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

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

21 A. Yes.

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

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

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

6 Q. Are you aware that the EFED document dated
7 March 21, 2014, was not provided to AMVAC until March
8 2017?

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

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

23 A. Yes, that's correct.

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

1 correct?

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

7 Q. Correct. Yes.

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

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

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

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

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

23 Q. And in Joint [Exhibit 79](#), which was issued --
24 this is the EFED memorandum issued concurrent with the
25 NOITS, Mr. Sayres, if you could pull up Joint [Exhibit 79](#)

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

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

9 MR. ROSS: No further questions, your honor.

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

13 MS. ROSE: I do not Your Honor.

14 REDIRECT EXAMINATION

15 BY MR. PITTMAN:

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

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

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

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

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

10 MR. PITTMAN: No further questions.

11 MR. ROSS: No further recross, Your Honor.

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

14 MS. ROSE: No, Your Honor.

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

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

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

25 THE WITNESS: Yes. So, through Friday, I

1 believe, is the end of the hearing?

2 JUDGE BIRO: I'm sorry?

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

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

9 THE WITNESS: Okay.

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

14 THE WITNESS: Okay.

15 JUDGE BIRO: Okay. Thank you for your
16 testimony.

17 THE WITNESS: Okay. Thank you.

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

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

24 JUDGE BIRO: Sure. Let's do that.

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

1 break if you like and afterwards --

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

5 (Whereupon, a recess was taken)

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

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

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

12 THE WITNESS: I'm sorry?

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

16 THE WITNESS: Okay.

17 (Whereupon,

18 JILL BLOOM,
19 having been first duly sworn, was called as a witness
20 herein and testified as follows:)

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

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

24 JUDGE BIRO: Okay.

25 THE WITNESS: Thank you.

1 DIRECT EXAMINATION

2 BY MR. PITTMAN:

3 Q. Good afternoon, Ms. Bloom.

4 A. Hi.

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

7 A. My name and what?

8 Q. Current title?

9 A. Oh, this is Jill. -- I'm Jill Bloom and my
10 title is lead environmental protection specialist.11 Q. I just provided you with what has been marked
12 as the witness statement of Jill Bloom.

13 A. Uh-huh.

14 Q. Do you recognize this document?

15 A. I sure do.

16 Q. How do you recognize it?

17 A. I drafted it and signed it.

18 Q. And so, this is a true and accurate copy?

19 A. It looks to be.

20 Q. I move that the witness statement of Jill Bloom
21 be admitted into the record as Rx 27.

22 JUDGE BIRO: Is there any objection?

23 MR. PITTMAN: No objection.

24 MR. WEINBERG: No objection, Your Honor.

25 JUDGE BIRO: Ms. Rose, do you have any

1 objection?

2 MR. ROSS: No objection, but if the witness
3 could move the microphone closer to her when she speaks
4 that would be helpful. Thank you.

5 JUDGE BIRO: Okay. So, without objection, Rx
6 27 is admitted into the record.

7 (Exhibit Rx 27 was admitted)

8 JUDGE BIRO: Mr. Weinberg?

9 MR. WEINBERG: Yes, ma'am. I'm just looking at
10 my copy of the testimony. I will be right with you,
11 ma'am.

12 JUDGE BIRO: If you can't find it, I would be
13 happy to give you mine.

14 CROSS EXAMINATION

15 BY MR. WEINBERG:

16 Q. Okay. Good afternoon, Ms. Bloom. How are you?

17 A. I'm fine. How are you.

18 Q. I think we've met before, but it's nice to see
19 you again.

20 A. Thank you.

21 Q. My job here as counsel for AMVAC Chemical
22 Corporation is to ask you a number of questions raised by
23 your direct testimony in this proceeding. If you ever
24 don't understand a question or require clarification,
25 please let me know. This is, for better or worse, not

1 like your TV program Perry Mason or anything of that
2 sort. We're just trying to draw out the facts.

3 A. I will just state that I'm a little hard of
4 hearing so if you could speak up, that would be helpful.

5 Q. I'd like to start out with an understanding, if
6 we could, of your role. You describe yourself in your
7 testimony as a lead environmental protection specialist.
8 Could you tell me what it means to be a lead
9 environmental protection specialist?

10 A. So, what a lead environmental specialist is in
11 my case is a team leader who assists chemical review
12 managers in all of the functions of their job.

13 Q. And is that the same as a chemical review
14 manager?

15 A. In PRD, the chemical review managers would be
16 the people I was advising and helping.

17 Q. I'm sorry. In your C.V., you were I think --

18 A. I'm a team leader. The people the next level
19 down are chemical review managers or CRMs.

20 Q. Okay.

21 A. I was a CRM before I was a team leader.

22 Q. And in the first page of your testimony you
23 indicate that you held other leadership positions in the
24 risk management and implementation branch over the years.
25 You didn't really say much about what those were in your

1 biography, included as an attached -- the resume attached
2 to your testimony was a little incomplete. Could you
3 tell us a little bit more about what the leader positions
4 are you played at EPA?

5 A. So, when I was in RMIB5 I was always a lead
6 environmental protection specialist. For part of that
7 time -- for that part of that time I was acting in that
8 position and then for the last nine years, I forget how
9 many years, I've been a team leader. Before that I was a
10 chemical review manager in a couple of branches.

11 Q. And what generally speaking is the role of a
12 team leader, or more specifically, your role as a team
13 leader?

14 A. Right. So, I'm kind of positioned between the
15 branch chief and the chemical review manager. Typically,
16 a team leader will work with chemical review managers on
17 specific projects. It might be the TL for somebody on
18 one case and not for another case, but the job of the TL
19 is to assist the CRM in getting work done that needs to
20 be done; providing advice, counsel, editing et cetera.

21 Q. And excuse me, that role in the hierarchy of
22 the EPA is below the level of a branch chief; is that
23 correct?

24 A. It is.

25 Q. And the branch chief is below the level of a

1 division director --

2 A. Correct.

3 Q. -- for OPP, correct?

4 Could you pull up 13, please? It's RX-13. I'm
5 sorry. This is a document that we were provided by EPA
6 in discovery in this case. Are you familiar with this
7 document?

8 A. Yes.

9 Q. And there is a companion piece. If we could
10 pull up RX-14 as well just so we can get the -- which is
11 also what I would describe as a process explanation; is
12 that a fair statement?

13 A. This is for -- yes.

14 Q. And would you -- you explain what is the role
15 of these documents, these two documents?

16 A. So, it provides general guidance for the
17 chemical review manager of the steps of registration
18 review including responsibilities for bringing about
19 certain milestones, holding team meetings, talking to
20 registrants, all aspects of the role of the chemical
21 review manager.

22 Q. And this would be the guidance from the -- for
23 the team lead as to how to proceed and others as to how
24 to proceed in the context of the Data Call-In and re-
25 registration; is that correct?

1 A. Yeah, and it's targeted more to the CRM, but it
2 applies to team leaders as well.

3 Q. Uh-huh. So, if I look at RX-14 a minute, just
4 to be clear, and page 1, there is a reference to the CRM
5 and being responsible for creating the DCI in Prism.
6 That's right under stage IV there. Was that a role that
7 you were in at the time that DCI was issued?

8 A. So, when the DCI was issued, I was the chemical
9 review manager and I think that predated this guidance,
10 but it was similar.

11 Q. Okay. Were you in that role for the DCPA Data
12 Call-In?

13 A. So, just about the time -- I believe -- I think
14 the Data Call-In was completed before I went to go to be
15 a team leader and so consequently it was issued after I
16 went to be a team later but, yeah, but I was -- until
17 that point, I was involved in the development of the Data
18 Call-In.

19 Q. Uh-huh. Okay. And then if we look at RX-14,
20 there was also a reference to the chemical review manager
21 there as well in terms of the roles of the chemical
22 review manager and he would be in that position. That
23 would be the position you were also in, currently
24 involved in, although over the last 10 years you may have
25 had slightly different positions, as I understand?

1 A. I'm not sure what your question is.

2 Q. Sure. Let me restate it. Let me restate it.
3 For the purposes of this Registration Review Guidance, do
4 you see how "issuance to decision" that is [Exhibit 14](#),
5 the first line identifies the activities to be a guidance
6 for the chemical review manager and that's the role that
7 you played currently, or you may not have played it at
8 the very beginning of the process of the DCI which is the
9 subject of this case?

10 A. So, I was a chemical review manager for the
11 development of the DCI and just about at the time it was
12 issued. After that I was the team leader in a different
13 branch.

14 Q. Okay. On the second page of [Exhibit 14](#),
15 Respondents [Exhibit 14](#). Excuse me, I have a cold that I
16 caught from my granddaughter and that's the problem with
17 having children that go to preschool. In RX 14, there is
18 reference to OMB having to approve studies before DCI can
19 go out to registrants. Do you see that?

20 A. Yes. So, that changed a little bit.
21 Originally, we had to justify all of the studies and send
22 the information to OMB, but then they were looking at the
23 same studies over and over again which were very basic
24 studies, so we sort of limited it from a sort of -- we
25 limited it after a while to special studies, or unusual

1 requirements.

2 Q. And how was that changed?

3 A. How was that changed how?

4 Q. No. How was that changed? We asked for all of
5 them was a -- documents that provided guidance for the --
6 for this is what we got?

7 A. Yeah, I don't know that that would be
8 documented anywhere.

9 Q. Okay.

10 A. It could have been requested by OMB, but I'm
11 not sure.

12 Q. You currently do less with OMB?

13 A. I'm sorry?

14 Q. The CRMs and team leaders currently do less
15 review with OMB when there are Data Call-Ins?

16 A. If there's providing justifications only for a
17 subset of the studies in the DCI. I guess that would be
18 true.

19 Q. And in the middle of the page and the first
20 bullet under "registrant submits 90-day responses" it
21 indicates that the 90 day response on the second line
22 will generally indicate whether the registrant will be
23 conducting a study, requesting a waiver, or rather that
24 they have made an offer of pay. So, that's the first
25 response that you get from a registrant as to how they

1 are going to respond, correct?

2 A. Yeah. That's not all the options but that's
3 summary of probably the more frequent ones.

4 Q. Okay. And then just going down a little bit
5 further to the bullet point that says the registrant
6 produces and submits data. The first bullet, the second
7 sentence says the CRM should be in contact with
8 registrants in the months prior to the date of submission
9 due date to ensure that the data submission will be on
10 schedule, or why it may be too late, be delayed. Do you
11 see that sentence?

12 A. Uh-huh.

13 Q. So, the person in your role, the team leader,
14 in your role would be responsible for having undertaken
15 that responsibility?

16 A. No. That would be the chemical review
17 manager's responsibility, but essentially, they meet
18 their responsibilities --

19 Q. Well, let's try to be more specific than with
20 regard to this particular DCI. Who had the
21 responsibility at your branch for undertaking this
22 responsibility?

23 A. So, after the DCI was issued, shortly after, I
24 went to a different division -- not a different division
25 -- a different branch and the chemicals stayed in the

1 original branch and went to other people and I wasn't
2 involved.

3 Q. So, who would have been -- while you were not
4 at this branch, who would have been the CRM? Do you
5 recall?

6 A. So, there were a number of changes over time.
7 I looked in my records. I believe that Meg Hathaway was
8 the first one and Matt Manupella was also one. Sue
9 Bartow was one and there was some correspondence managed
10 by Tom Myers who was a team leader in that branch at the
11 time.

12 Q. And then when you came back to the branch and
13 responsibilities for the DCPA DCI?

14 A. So, I didn't come back to that branch. I went
15 to another branch and then eventually the responsibility
16 for that chemical came back to our branch and --

17 Q. Well, when you became responsible, when it was
18 transferred to the branch in which you had moved -- let
19 me back up, my understanding is that they transferred the
20 responsibility to a new branch and you were at that new
21 branch and you --

22 A. Yes, I was the team leader.

23 Q. Correct. So, would you have been playing the
24 role of a CRM at that point as the team leader?

25 A. So, the first correspondence that I had that I

1 looked at shows that there was a lag between the time I
2 made it to the branch and a CRM was assigned and I would
3 have been, but I didn't find any correspondence to that,
4 you know, for myself at that time.

5 Q. Well, with regard to this DCI that we're
6 talking about here today, at the time that you took over
7 that responsibility, and when was the time approximately?

8 A. I think it was -- I'm getting the year wrong.
9 I think it was December 2014.

10 Q. Okay.

11 A. And then a CRM was assigned in January 2015, as
12 I recall.

13 Q. Okay. So, in terms of the responsibility for
14 being in contact with registrants in the months prior to
15 the data submission due date in the DCI, was that your
16 responsibility or was that the responsibility of the
17 person who reported to you?

18 A. That would have been -- okay, so before I
19 changed branches it would have been a person that wasn't
20 reporting to me.

21 Q. I'm talking about when you were there, when you
22 came back and 2014, I believe you testified?

23 A. Right. I would have been -- the CRM would
24 ultimately have been responsible and I would have been
25 guiding that person.

1 Q. I'm sorry. I misunderstood you.

2 A. The CRM would have been ultimately responsible,
3 but I was guiding that person.

4 Q. Okay. So, there was somebody that reported to
5 you?

6 A. Yes.

7 Q. Now, let me just move down to some specific
8 questions about the testimony that has been submitted
9 and, excuse me. Did you write the first draft of this
10 testimony?

11 A. I think so. I don't really recall, but I think
12 so.

13 Q. Okay. Do you recall whether it was prepared
14 before or after the motion -- there had been a decision
15 made to file a motion for accelerated decision?

16 A. Gosh, I don't remember. Sorry.

17 Q. Well, it does make reference to endorsing the
18 facts that are in that motion. Does that clarify your
19 recollection at all?

20 A. Yeah, so that probably -- I mean that seems
21 about right. So, we had to -- we had to prepare the
22 statements when we thought there was going to be a
23 hearing before the ALJ. That's right.

24 Q. And were you consulted by counsel on the
25 question of whether -- let me be clear. I'm not asking

1 what your counsel told you. I'm just asking for the --
2 were you consulted by counsel as counsel prepared the
3 motion for accelerated decision?

4 A. I was.

5 Q. Okay. And did they run every fact that they
6 were going to assert in that document past you?

7 A. I'm sorry. Could you please repeat that?

8 Q. Sure. Did counsel run every fact that is
9 asserted in that document past you for confirmation?

10 A. As I recall, I was one of the people who was
11 asked to comment on that draft. So, I read the whole
12 thing several times.

13 Q. Okay. So, if I understand it, you put together
14 a first draft of the testimony and what were you asked to
15 do in that first draft? Somebody must have told you we
16 need some testimony about something. What was it that
17 they told you to do?

18 A. So, I think I was asked about my role and I
19 think I was asked about the history of correspondence
20 with the EPA on the DCPA DCI. Yeah, that pretty much
21 sums it up.

22 Q. Well, did anyone other than yourself in your
23 branch other than counsel have a role in preparation of
24 the testimony?

25 A. I believe that we all reviewed each other's

1 work.

2 Q. I'm sorry. Could you explain what we all means
3 in that sentence?

4 A. So, the written statements were prepared and a
5 group of us who were involved as potential witnesses
6 reviewed the other people's --

7 Q. And who would be in that group?

8 A. So, you've met two of them today, Christina
9 Wendel and Steve Wente.

10 Q. And was there anyone else?

11 A. In the other witnesses? You

12 Q. No, any other person?

13 A. Yes, there was a whole group of us. I mean up
14 my management chain, OD, yeah.

15 Q. And do you remember the names of any of the
16 other individuals?

17 A. That reviewed the statement?

18 Q. That reviewed the draft or the drafts as you
19 were preparing your testimony?

20 A. Right. Well, it would have been Forrest, it
21 would have been my branch chief, Cathryn Britton. I
22 believe it probably involved my division director Ms.
23 Reaves and then the folks that we talked about from
24 EFED Christina and Steve.

25 Q. Uh-huh.

1 A. There were other statements, too, but I guess
2 they have fallen by the wayside. So, there were other
3 people too in science divisions.

4 Q. Can you state on page 2 of your testimony --
5 and that's just quoted as you probably remember it. As
6 laid out in Respondents June 2013 memorandum, motion for
7 accelerated decision, and then the supporting memorandum,
8 AMVAC failed to take appropriate steps to secure the data
9 required in the DCI deadlines set out for the review.

10 Are you with me?

11 A. Yes. I'm following. Did you have a question
12 about that statement?

13 Q. What did you understand the word appropriate
14 steps -- the words appropriate steps to mean.

15 MR. PITTMAN: Objection. Calls for legal
16 conclusions.

17 MR. WEINBERG: No, it did not.

18 JUDGE BIRO: She can answer what she was
19 thinking when she --

20 MR. WEINGBERG:

21 Q. I'm asking what your understanding was?

22 A. The appropriate steps?

23 Q. Yes.

24 A. Yeah. So, it would be a commitment to fulfill
25 data requirements or another appropriate response, a

1 waiver request or submitting data that already existed or
2 something like that, and following through until we got
3 the data.

4 Q. And when you say that as laid out in the motion
5 or the supporting memorandum, AMVAC failed to take
6 appropriate steps. Were you testifying in support of
7 their brief's factual conclusion in that motion or
8 memorandum?

9 A. Can I testify as to what? I'm sorry?

10 Q. In support -- are you swearing to the truth of
11 every factual statement in the motion and memorandum?

12 A. Yes.

13 Q. Okay. All right. Now, would I be correct in
14 understanding that you are not trying to opine as to the
15 legal meaning of the appropriate steps or any of the
16 legal conclusions of the memorandum?

17 A. I'm not sure what that line would be between
18 legal and of those --

19 Q. Why not?

20 A. I take appropriate steps to have to do with
21 getting the data, right, and then there are other
22 interpretations of what those appropriate steps are, and
23 I've read them and they seem consistent with what I
24 understand.

25 Q. Well, you do believe that the statutory mandate

1 to take appropriate steps, close quote, is what grants
2 you the authority to make judgments as to whether they
3 have been made, didn't you?

4 A. I guess. Yeah. Not myself alone, but yeah.

5 Q. I'm sorry?

6 A. Not myself alone, I guess.

7 Q. No. Of course not. As you recall, in your
8 testimony, you testified that AMVAC's responses were much
9 longer than others. I think you use the phrase dilatory
10 and abnormal in testimony. Do recall that?

11 A. Yes.

12 Q. What do you understand the word dilatory to
13 mean?

14 A. Causing delay.

15 Q. I'm sorry?

16 A. Causing a delay, repeatedly --

17 Q. You understand that the -- do you know the
18 dictionary definition of what dilatory is?

19 A. I probably do, but I don't know.

20 Q. If you would just put up that picture and go at
21 the one sentence that matters. This is the Oxford
22 English, concise Oxford English dictionary. I've chosen
23 because I happen to have it in my desk. I did not do a
24 full on of all possible definitions. Do you see that
25 definition?

1 A. Yes, I do.

2 Q. And is it an accurate definition of what you
3 meant by the word dilatory?

4 A. So, I see definition one and two and that two
5 goes to intent and I don't know what the intent was, so I
6 would say the definition one "slow to act" would be what
7 I meant.

8 Q. So, could you just repeat what you said. I'm
9 sorry. When you look it that way, I don't hear you very
10 well.

11 A. Oh, I'm sorry. What I said is definition
12 number one is "slow to act" would be what I meant because
13 the second one talks about intent and I don't know what
14 the intent was.

15 Q. Okay. Now, let me turn to another aspect of
16 your testimony. You repeatedly -- a rather let me just
17 ask it a couple of -- yes. On page 3 of your testimony,
18 you say that it is common for registrants to submit
19 comments on preliminary work plans?

20 A. Yeah, I would say that's true.

21 Q. How many preliminary work plans have been put
22 out for comment under your supervision?

23 A. So, it would be around 50. I've been involved
24 in about 50 registration reviews and I might have come
25 into some after the preliminary work plan was published,

1 so around 50.

2 Q. Around 50?

3 A. Yeah.

4 Q. And when you say common, what do you understand
5 that to mean?

6 A. So, covers the preliminary -- well, we
7 published the availability of the preliminary work plan
8 in the Federal Register and we opened a comment period.
9 And comments are submitted to the public docket and
10 typically I would say more times than not a registrant --
11 people will comment on the data requirement part of the
12 preliminary work plan and other things. Yeah, including
13 the registrant.

14 Q. And how often do those comments result in
15 changes in the study requirements --

16 A. I would say pretty frequently.

17 Q. Again, can you help me understand briefly what
18 we have -- you said more than half of the comments you
19 received -- more than half of the preliminary plans you
20 have received comments. So, it's some fraction of that,
21 more than half. What was your estimate be a fraction?

22 A. I'm sorry. I'm not understanding your
23 question.

24 Q. Okay. Sure. You just testified that once the
25 agency publishes preliminary work plans for comments, you

1 think you typically get comments back on the data
2 requirements about half the time. I believe that's what
3 you said.

4 A. That would be a good, round ballpark figure.
5 Perhaps more than that.

6 Q. And of that half, what percentage of that half
7 do you believe result in changes to the work plan?

8 A. If I had to give you a ballpark figure?

9 Q. Well, ma'am, you're the one who testified
10 commonly and I'm just trying to understand what it means.

11 A. Right. So, if I had to put a number on how
12 often the data requirements change because of comments on
13 the preliminary work plan, I'd say maybe 25 percent of
14 the time.

15 Q. 25 percent of the 50 percent or the 25 percent
16 of all work plans that were ever put out for comment?

17 A. 25 percent of 50 percent. I'm not sure. I
18 feel uncomfortable making a guess of that percent.

19 Q. It's not a trick question. I'm just trying to
20 --

21 A. No, I know.

22 Q. -- Just make sure we get the number clear. If
23 there were comments from 100 people, you would expect
24 that there might be 25 of those that would result in
25 changes. Is that --

1 A. Oh, no, that's not what I meant.

2 Q. Okay.

3 A. I meant in any individual case, probably about
4 -- you know, that's an estimate of how the data
5 requirements would change. Not how many people commented
6 on it.

7 Q. I understand it, but let me restate it myself.
8 I'm assuming you've got 100 comments, what percentage of
9 those comments do you believe resulted in changes in the
10 data requirements?

11 A. If you are talking about 100 comments over a
12 number of preliminary work plans?

13 Q. No, I'm talking about a single workplan.

14 A. Oh, I don't think very many. First of all, we
15 hardly ever get 100 comments and those comments are more
16 than likely to come from the registrant. Yeah. So, I
17 would say I was more willing to say that whenever a PWP
18 comes out and the data requirements change, that's maybe
19 25 percent.

20 Q. Okay. Okay. Now, in your testimony you make
21 frequent reference to actions taken by EPA. In some
22 cases, you make reference taken by a particular branch of
23 the EPA, but not in all. You are aware, are you not,
24 that the statute, different statutes assign
25 responsibilities to the Administrator of EPA?

1 A. Yes.

2 Q. And the Administrator of the EPA then issues
3 documents referred to as delegations?

4 A. Yeah, that's typical, I think.

5 Q. That's a common practice, right? And that is -
6 - someone casually looked at your testimony that says EPA
7 did something, one might not be able to identify from the
8 statement who it was that actually took the particular
9 action; isn't that correct?

10 A. Yes, I would say that is probably true but it's
11 almost always within my division. I can't think of a
12 case where it's not actually.

13 Q. Now, are you aware that in this case AMVAC
14 asked for copies of all documents memorializing
15 delegations of authority to grant or request -- to grant
16 or deny waiver requests in connection with the DCPA DCI -
17 - that grants any authority to any person in or within
18 the EPA below the level of the administrator that are now
19 in force or were in force at any time after the issuance
20 of the DCI?

21 A. Yes, I'm aware.

22 Q. Okay. Now, EPA did in fact produce a number of
23 documents; isn't that correct? And are you generally
24 familiar with those documents?

25 A. Very generally.

1 Q. Are you generally familiar with the format that
2 those documents -- the form that those documents take?

3 A. Yes.

4 Q. Okay. Let me show you one that has been
5 identified as PAX 71.

6 MR. PITTMAN: Your Honor, objection. Scope.
7 This is not part of the sworn testimony.

8 MR. WEINBERG: I believe it is necessarily part
9 of her testimony. She's just testified that the phrase,
10 the word EPA as used in her testimony is imprecise and
11 from the perspective of this matter that is quite an
12 important issue, I think we need to understand who she is
13 talking about making certain decisions, and that's why
14 I'm going to clear this up, Your Honor.

15 JUDGE BIRO: I think it is beyond her direct
16 and I don't think there's any dispute about these
17 delegations, that it did not go down to EFED. That's not
18 in dispute.

19 MR. WEINBERG: Your Honor, with due respect, we
20 think they didn't go down to levels above EFED and that's
21 why we want to go into this. I was not aware that
22 plaintiffs were prepared in this -- pardon me, not
23 plaintiffs -- the government was prepared to stipulate or
24 concede that EFED hadn't been delegated, but I do believe
25 that there is reason to believe that no one below

1 division director had --

2 JUDGE BIRO: Don't these documents all speak
3 for themselves? Don't they say what they say? Either
4 there is a delegation or there isn't. What difference
5 does it make what she knows or doesn't know? You know,
6 that's a legal determination, isn't it?

7 MR. WEINBERG: Well ultimately it is a legal
8 determination. But we believe, Your Honor, that there is
9 sufficient complexity here. We were provided by counsel
10 in that discovery request a number of documents and
11 several pages, at least two pages of explanation as to
12 how they all fit together, which is by no means clear
13 from the face of the documents. It is our impression
14 that EPA has no intention of clarifying that matter
15 through testimony, so we thought it would be useful to
16 get clarified on this cross-examination that issue. Now,
17 admittedly the documents are going to be in the record.
18 I believe they have been stipulated to, I am I correct?

19 MR. PITTMAN: No, that's not correct.

20 MR. WEINBERG: Okay. Well, if the government
21 is prepared to stipulate, they are in the production and
22 in the record, and we can -- or recognition as an
23 official government document, that would eliminate me
24 from doing this. I agree with you on that, but to date
25 they have not been prepared to do either of those things.

1 JUDGE BIRO: Okay. So, tell me who you think
2 the documents reflect the authority to grant or deny
3 waivers?

4 MR. WEINBERG: I think until very recently,
5 under any characterization of the documents, the
6 authority to grant waivers did not go below the division
7 director role. And I think that all of the waiver
8 decisions and activities -- most of those that we are
9 talking about in this case were never approved at the
10 division director level.

11 JUDGE BIRO: And that is -- in that division
12 would be OCSPP or OPP? What is the division we are
13 talking about?

14 MR. PITTMAN: OPP.

15 JUDGE BIRO: OPP?

16 MR. PITTMAN: OPP.

17 MR. WEINBERG: OPP. Yes. I'm sorry. That's
18 why I started that.

19 JUDGE BIRO: Okay. And is there a dispute
20 about that issue in terms of what shows up in the
21 document?

22 MR. PITTMAN: Your Honor, it's our position
23 that we laid it out in our response to AMVAC's initial
24 request for these delegations and documents. I believe
25 they're pointing to the 5-38 delegations, but I have not

1 yet looked at the 5-1-B delegation and its sub-delegation
2 they provided to me, which I do believe delegates that
3 authority down to the team lead level, if I'm correct.
4 But I would have to confirm about the team lead level.

5 JUDGE BIRO: Okay. So, that's just two
6 different documents we are arguing over which control.
7 So, what are you going to get out of her on that issue?

8 MR. WEINBERG: I was frankly going to try to
9 lay the groundwork for moving to get these documents
10 introduced, because I didn't have agreement with opposing
11 counsel that that could happen.

12 MR. PITTMAN: Can I clarify? So, we did
13 stipulate to the entry of these. I misspoke earlier. I
14 did not stipulate to allowing for these generally on
15 cross. I specifically made that reservation, that they
16 also heard today.

17 JUDGE BIRO: Okay. Could we agreed to let in
18 these two delegation documents?

19 MR. PITTMAN: Yes, Your Honor.

20 JUDGE BIRO: Okay. Let's admit them. What's
21 the exhibit number?

22 MR. ROSS: The totality of the delegation
23 documents that were either received in response to our
24 FOIA request or provided directly by OPP counsel are the
25 range of petitioner AMVAC's exhibits from PAX 63 to PAX

1 77.

2 JUDGE BIRO: So, these are RX 63 to 77?

3 MR. PITTMAN: PAX.

4 JUDGE BIRO: Oh, PAX. Okay. Okay. Is there
5 any objection, Ms. Rose? Do you have any objections?

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

7 JUDGE BIRO: So, were going to admit into the
8 record this set of documents on the issue of delegation.
9 PAX 63 to 77; is that correct, gentlemen?

10 MR. WEINBERG: That is correct.

11 MR. PITTMAN: Yes, Your Honor.

12 (PAX-63 through 77 admitted)

13 JUDGE BIRO: Okay. Can we move on to another
14 topic?

15 MR. WEINBERG: Yes.

16 JUDGE BIRO: Because I don't think that's
17 exactly what we are here for.

18 MR. WEINBERG: Yes, ma'am. Mr. Sayres, could
19 you please pull up JX 65?

20 BY MR. WEINBERG:

21 Q. Is this the preliminary work plan that you had
22 previously testified about?

23 A. No, it's the problem formulation. The
24 preliminary work plan is based primarily on the
25 formulation from EFED and the scoping document from HED,

1 primarily.

2 Q. Thank you. Could we go to page 25? So, what
3 purpose does this document serve?

4 A. This is the scientists advising us in this case
5 what they know about the chemical already, what data they
6 think we need and what assessments they think we need to
7 do.

8 Q. Okay. And we do look at page 25, please? With
9 regard to the ecological effects data on TPA that the DCI
10 might need, does it say there for future assessments, in
11 the absence of toxicity data for the degradate TPA, EFED
12 will make highly conservative assumptions when evaluating
13 the toxicity of TPA?

14 A. I don't see that in the text that is in front
15 of me, no. Oh, it's there. It's the --

16 Q. It's the last line, yeah.

17 A. Yes.

18 Q. It does say that?

19 A. Uh-huh.

20 Q. Is that correct?

21 A. Yes.

22 Q. And do you have any reason to believe that the
23 authors of this email did not -- pardon me, on this
24 memorandum, did not intend that to be accurate?

25 A. No. I think that's what they believed, yeah.

1 Q. Okay. And then you would pull up JX 21,
2 please? This is what has been referred to I think
3 already as the October 2020 data review letter that was
4 sent out notifying AMVAC that the agency intended to move
5 forward with registration at --

6 A. My shorthand was the data delay letter.

7 Q. I'm sorry?

8 A. My shorthand for this is the data delay letter.

9 Q. Data delay letter?

10 A. Yeah.

11 Q. All right. And does that letter also state
12 that the safety factors, the assumptions could include
13 among other things adding additional safety factors to
14 account for uncertainties?

15 A. Can you show me the text?

16 Q. Sure.

17 A. Part of the first page? Oh, the date of -- the
18 agency will rely upon data available at the time where
19 the agency is lacking data, conservative assumptions may
20 be used in their place. Is that what you mean?

21 Q. Yes. It's the last sentence in the first
22 paragraph.

23 A. Uh-huh.

24 Q. And this was in fact signed by the then acting
25 division director who is now the division director, I

1 believe.

2 A. Elissa Reaves, yeah. Was in it the same --

3 Q. All right. Yes.

4 A. Yeah, there you go.

5 Q. So, that made the same point, did it not?

6 A. The same point that you are asking about in the
7 problem formulation?

8 Q. Yes.

9 A. Yeah, I would say.

10 Q. But you also testified at page 7 of your
11 testimony that the agency almost always requires the
12 submission of -- excuse me, the submission of necessary
13 data. Do you see that sentence in your testimony?

14 A. Yes. Most registration reviews include that
15 data, for the purpose.

16 Q. What does the word "necessary" in that sentence
17 mean?

18 A. Data that are needed to perform a sound risk
19 assessment.

20 Q. Data that are necessary for a sound risk
21 assessment? Thank you. Do you know when EPA concludes -
22 - you are aware, I believe, that the agency ultimately
23 informed AMVAC that it could not make a risk assessment -
24 - could not actually make a risk assessment with the
25 available data?

1 A. Yes.

2 Q. Making assumptions?

3 A. Yes.

4 Q. Do you know when EPA reached that decision?

5 A. I believe it was in April 2022.

6 Q. April 2022?

7 A. I believe so. It was after we received the
8 preliminary CTA when we saw the results of that.

9 Q. Uh-huh. Okay. And you then characterized the
10 situation at that time, and it's on the prior page where
11 the characterization occurs as there being an abnormally
12 high ratio of non-submission and waiver request on
13 AMVAC's part. Do recall that testimony?

14 A. Yes. Yes. I did say that.

15 Q. How many of the other 50 DCIs which you have
16 worked on had involved suites of testing on both the
17 active ingredient of the product and the degradates of
18 that?

19 A. I'm sorry? Can you say that again?

20 Q. Could you say what percentage. What percentage
21 of the DCIs which you were involved over the years
22 require a full suite of testing on both the active
23 ingredient and the degradate that this one required?

24 A. So, I don't know the full suite. I know that
25 the DCI requires occasionally, frequently, required data

1 on the metabolites and degradates as well.

2 Q. I'm sorry. I didn't hear the last part.
3 Frequently? I'm not asking you to say in a different. I
4 just didn't get it.

5 A. I'm just trying to figure out how to
6 characterize that -- there are DCIs that do that and say
7 they're not the usual, but it certainly happens enough to
8 not be an anomaly.

9 Q. And when you made this statement in your
10 testimony, were you simply relying on your memory as you
11 are today?

12 A. I'm sorry. Say it again, please?

13 Q. When you made the statement in your testimony,
14 were you relying on your memory as you are today?

15 A. Yes. Yeah.

16 Q. You hadn't done a count to see?

17 A. I had counted the number of registration
18 reviews I was involved in. I didn't do a count on this
19 level, no.

20 Q. No, but the word that you used was abnormally -
21 -

22 A. There.

23 Q. -- and I am simply trying to understand the
24 basis of what was your experience --

25 A. Yes.

1 Q. -- And not on having really taken a look and
2 counted up and seen, right?

3 A. I didn't take a count, no. It's my memory. My
4 experience and memory.

5 Q. Now, with regard to the particular DCI that we
6 are dealing with here, when the DCI went out, you were
7 not in your current role. You were not involved in
8 immediate determinations of what would enter the DCI, as
9 I understand it?

10 A. So, I think all of the work was done but the
11 actual mailing occurred after I left, yes.

12 Q. I'm sorry. Were you involved in all of the
13 work?

14 A. Before that? Yes. Starting in 2011.

15 Q. Okay. The issuance -- the issuance of the DCI?

16 A. No, I was not on board. I was not in that
17 position --

18 Q. I'm sorry. That's what I understood you to
19 say, right.

20 A. Right. And very shortly after that.

21 Q. Right. So, the preparation of activities under
22 those two documents that we reviewed at the beginning,
23 that is the exhibits 13 and 14, if you would pull up 13,
24 please. I just want to make sure you know what I'm
25 talking about. Those were being done at that point in

1 time by somebody other than you, correct?

2 A. At that point in time what?

3 A. That responsibilities here involving the
4 issuance in the DCI, the DCPA DCI were being implemented
5 by someone other than you?

6 A. After issuance, yes. I mean until I got back
7 to the project.

8 Q. Up to issuance? Up to issuance?

9 A. Pretty much, yes.

10 Q. Okay. And so there was a -- underneath stage
11 IV there on this document, pardon me, on page 1 of this
12 document it indicates that the CRM was responsible for
13 creating the DCI in Prism, as well as the DCI
14 justification cost estimate; is that correct?

15 A. Yes.

16 Q. To your files show what the cost estimate was
17 at the time of the DCI?

18 A. It would be in my files. I haven't looked at
19 it, and so I can't tell you.

20 Q. You're not familiar with it, I take it?

21 A. I am familiar with it, but I don't know the
22 number that well.

23 Q. Let me ask you, you don't -- that's why I
24 appreciate your clarification. You don't know the number
25 that was used by EPA to justify issuance of this DCI?

1 A. The number? The dollar amount?

2 Q. Yes, that dollar amount?

3 A. We included it in the justification and no, I
4 don't know the price.

5 Q. Okay. It now, there is a reference down here
6 in the bottom of page 3 of this document to doing things
7 based on BEANs, at the very bottom of page 3, right after
8 where the long bullet says that CRM should be in contact
9 with the registrants in the months prior to that date is
10 submission to make sure this addition is on a time limit.
11 And then it says as data submitters -- data are
12 submitted, CRMs BEAN, B-E-A-N, them to the science
13 divisions --

14 A. Yes.

15 Q. -- Managers to BEAN them?

16 A. BEAN meaning assignment, basically.

17 Q. Yeah. What does that mean?

18 A. I think it comes from counting beans. It's
19 just we conveyed to the science divisions that these data
20 are here and then can be reviewed by at a certain date.

21 Q. Do you set deadlines for the science division?

22 A. They're negotiable, but yes.

23 Q. And does the science division typically meet
24 your deadlines?

25 A. I'm sorry. Say again?

1 Q. Does the science division typically meet the
2 deadlines that you propose?

3 A. Given that they are iterative and we discuss
4 them as time goes on, for the most part, yes.

5 Q. Could you please pull up the PAX 46? Thank
6 you. Are you familiar with this document?

7 A. Yes, I am.

8 Q. And could you just describe its purpose,
9 please?

10 A. So, if we come to a point where we feel we're
11 not getting the data we need and the registrant has not
12 fulfilled their obligations under the DCI, the statute
13 gives us the authority to issue a notice of intent to
14 suspend and this describes the process at least before
15 and during notice to suspend and after, too.

16 Q. So, this is an EPA document, is that right?

17 A. Yes. It's a little outdated, but yes.

18 Q. Well, I'm going to get to that in just a
19 moment. It was provided to us in response to the
20 discovery requests we mentioned earlier, and it appears
21 to relate to the transfer of responsibilities from one
22 part of EPA to another portion. Is that correct, from
23 both O-E-C-A and to OPPTS?

24 A. So, as I understand it, the new delegations
25 were needed because OECA no longer had a role in the

1 suspension process, and then it became OPPT's
2 responsibility.

3 Q. You just indicated a minute ago that you don't
4 think this is still in effect?

5 A. Yes. For example, it talks about certified
6 letter. We do everything by email now. That's just a
7 small example.

8 Q. I'm sorry. But is there a replacement
9 document?

10 A. I don't believe there's a more recent copy, no.

11 Q. Is there any formal document that withdraws
12 this document?

13 A. Not that I'm aware of.

14 Q. Okay. And so, the one thing that you think has
15 changed is the first bullet point per certified letter;
16 is that correct?

17 A. That's one thing. It's probably pretty minor,
18 but yeah.

19 Q. And why has that changed?

20 A. People because we're more adept at using emails
21 so typically instead of sending a certified letter that
22 then comes back with a notice that the registrant
23 received and, we send it via email to the registrant and
24 they can respond to it all electronically.

25 Q. Is it still the CRM who you believe is

1 responsible for this content?

2 A. Yes.

3 Q. On the second page under phase 3 there is a
4 description of what happens when the data is received in
5 response to a DCI where there has been a suspension
6 indicated, or initiated, if I may, and it says in the
7 third bullet that when that data are received by SSRD,
8 the suspension coordinator will send the registrant a
9 letter notifying them that the suspension had been
10 lifted. Do you see that sentence?

11 A. Yes.

12 Q. Is that sentence still in effect in your view?

13 A. So, we're no longer SSRD. We're PRD and I
14 don't know that we have a suspension coordinator. I
15 think that would kind of fall --

16 Q. Would you expect the notice to be sent upon the
17 receipt of the data?

18 A. Would we expect that the registrant would be
19 informed the suspension was lifted --

20 A. Yes.

21 Q. -- If they provided the data?

22 A. Yes.

23 Q. Yes. If they provided the data?

24 A. Correct.

25 Q. It would, I take it. Okay. Can we go to PAX 57.

1 Does this document look familiar to you?

2 A. Yes.

3 Q. Is it fair for me to say that it was a press
4 release announcing the initiation of this proceeding?

5 A. I'm sorry. Is it fair to say what?

6 Q. A press release announcing the initiation of
7 the suspension that led to this proceeding?

8 A. I wouldn't say it was a press release. It's an
9 OPP update and typically interested parties have
10 subscriptions to OPP updates. I guess the press could be
11 part of that, yeah.

12 Q. Okay. And you note at the end of the first
13 paragraph -- well, let me back up. Were you involved in
14 the preparation of this document?

15 A. Yes.

16 Q. And did you play a primary role in drafting the
17 document?

18 A. It was a shared role. Probably not primary but
19 a shared role.

20 Q. What do you mean by that?

21 A. So, just because it was going out to outside
22 the agency, it had a high level of reviews. So, I'd
23 looked at it and my branch chief looked at it. My
24 division director looked at it. I think it was probably
25 looked at at that level, too. I don't recall exactly.

1 Q. Okay. At the end of the first paragraph, if
2 you would take a look at that sentence. It says due to
3 the registrants long-standing failure to respond to EPA's
4 request for necessary data, the agency is unable to fully
5 evaluate the risks associated with DCPA. Do you see
6 that?

7 MR. PITTMAN: Objection. Scope. This is not
8 in that testimony.

9 MR. WEINBERG: This is what? I'm sorry?

10 MR. PITTMAN: In this testimony.

11 JUDGE BIRO: It says what it says. Are you
12 asking her to agree that that's what it says?

13 MR. WEINBERG: No. I'm now going to ask her
14 what the basis for that was because she just said she was
15 involved in preparation. That's what she's testified
16 about the initiation of the proceeding.

17 JUDGE BIRO: Okay. Overruled. Go ahead.

18 THE WITNESS: I'm sorry. The question again?

19 BY MR. WEINBERG:

20 Q. Yeah. Look at that last sentence so I don't
21 have to read it again. The last sentence in the first
22 paragraph.

23 A. Uh-huh.

24 Q. Do you know when the agency had previously
25 announced that it was unable to evaluate those risks that

1 it described?

2 A. Announced outside the agency, I don't believe
3 that happened.

4 Q. You don't believe --

5 A. That it was announced before this outside the
6 agency.

7 Q. Okay. And this was the first time the agency
8 announced it?

9 A. So, it was confirmed in the actual notice of
10 intent to suspend which said similar things.

11 Q. So, this was -- this and the letter that it was
12 announcing -- was the first time, correct?

13 A. Yes, the NOITS and supporting documents to that
14 end.

15 Q. Okay. And what was the basis, and to the best
16 of your knowledge, for that conclusion being reached?

17 A. That a number of data requirements had not been
18 satisfied and that we didn't have data or expectations
19 for when they would be satisfied.

20 Q. And who were you relying on for that
21 conclusion?

22 A. Well, it was something I was aware of myself.
23 I mean I wasn't relying on anybody. We all reviewed the
24 case and we all knew what was happening and I was one of
25 those.

1 Q. Well, you're not a risk assessor, are you?

2 A. No, I am not a risk assessor.

3 Q. So, this states that the agency was unable to
4 fully evaluate the risks associated with this product.
5 Who were you relying on for that judgment?

6 A. In particular I mean there were probably many
7 examples, but in particular we felt that we couldn't
8 assess the human health risk associated with DCPA because
9 we know there was -- we suspected there was a very
10 sensitive, meaning low -- high toxicity end point based
11 on preliminary data, so it wasn't definitive data, but it
12 made us question whether or not we were able to apply
13 safety factors and still have a health protective
14 assessment.

15 Q. So, did the sentence in your mind refer to the
16 human health risk?

17 A. So, as I said, there were other issues as well.

18 Q. And who was it that you relied upon for this
19 judgment?

20 A. I don't remember the name of the branch. I'm
21 sorry, but it was my Mike Metzger's branch in HED. I
22 don't know the number.

23 Q. Okay. I only push you on this because you have
24 testified about this and you are obviously reporting on
25 what other people have told you. In this proceeding,

1 that's perfectly acceptable, but we do have to try to
2 understand who it was that was telling you this.

3 A. Uh-huh.

4 Q. On the next page that statement says in the
5 middle of the second paragraph, in the nine years since
6 the requirements were imposed, the agency has reviewed
7 insufficient studies provided by AMVAC. How many studies
8 did the agency reject that AMVAC filed?

9 A. So, it's difficult to count the data
10 requirements because you might have one data requirement,
11 but you're asking for data on a couple of different
12 compounds. For example, DCPA and TPA, how many
13 submissions did we get that we didn't think were on
14 point? 10 to 20 maybe.

15 Q. I'm sorry?

16 A. 10 to 20, maybe.

17 Q. So, when -- I asked the question about how many
18 studies that AMVAC submitted were rejected by EPA.
19 You're saying 20 of the studies that AMVAC submitted in
20 response to this DCI were rejected by EPA?

21 A. I'm estimating 10 to 20.

22 Q. 10 to 20. And what is the basis for that
23 estimate?

24 A. Just my experience a recollection of these
25 submissions that we got that didn't answer questions for

1 us.

2 Q. Okay. And how would you have been informed
3 that this study was rejected?

4 A. So, typically, we put the studies in the review
5 with the science division responsible for that type of
6 risk and they would tell us whether or not the studies
7 gave them the information they needed to perform a risk
8 assessment.

9 Q. And how would you keep a tally of those?

10 A. I didn't keep a tally, no.

11 Q. Well, what was the basis for the numbers?

12 A. It's my knowledge that there were numerous
13 insufficient studies.

14 Q. But you can point to anything to demonstrate
15 the basis of that knowledge?

16 A. Not in this document. In my files, yes.

17 Q. Now, do you know how EPA transmitted to AMVAC
18 its dissatisfaction with those studies that you thought
19 were inaccurate?

20 A. So, we generally convey either our explicit
21 rejection of the studies or the reviews that supported
22 the rejection of those studies.

23 Q. And how would that be conveyed?

24 A. Probably attached documents to an email for the
25 most part.

1 Q. Attach what kind of documents?

2 A. Reviews of the studies that were submitted.

3 Q. Would those be reviewed and performed by
4 outside contractors to EPA?

5 A. No, no, no. That would be our science
6 divisions, EFED and HED.

7 Q. And by whom would the email be sent?

8 A. Typically, by the CRM.

9 Q. By the CRM?

10 A. Uh-huh.

11 Q. Okay. Could I have J -- please? Would you
12 pull up JX-4, please? This is the Data Call-In document
13 itself.

14 A. Uh-huh.

15 Q. And I suspect you are generally familiar with
16 this? Is this a standard EPA form document used for
17 generic data call ins?

18 A. Yes.

19 Q. And it's modified for particular chemicals; is
20 that correct?

21 A. So, there's a section that talks about the
22 actual data requirements and asks the registrant how they
23 want to respond. That's also specific to the call-in.

24 Q. Do you know when this was originally drafted?

25 A. I'm sorry, I don't. This particular one?

1 Q. No, I'm sorry. The form.

2 A. The form, I don't know.

3 Q. Does the fact that it said -- says at the page,
4 top of page 2, in the third line that this is issued
5 under OMB control number 20700174. Does that give us an
6 indication of when the form was prepared?

7 A. I don't know because I'm not familiar with that
8 control number.

9 Q. Okay. And if you would look at the first
10 paragraph under options on page 4, one of those options
11 is to request a data waiver, open-"S"-close paren; is
12 that correct?

13 A. I think so. I think it's towards the bottom.
14 It's not on this page that we are looking at now.

15 Q. I think it's right --

16 A. Oh, I see. But there are a number of options -
17 - there are paragraphs that are a number to explain, yes,
18 but that's --

19 Q. And would you look and see if you would agree
20 with me that that's further discussed the pages 13 to 15
21 of the document?

22 A. If you can show me pictures --

23 Q. That option?

24 A. Yes. I mean that's part of the -- that's for
25 the data waivers.

1 Q. Yeah. And in the request for the data waiver
2 on page 15 under paragraph two -- I'm sorry. I beg your
3 pardon. On the last page of the attachment to the
4 document.

5 A. What is your question about this last page?

6 Q. I'm sorry?

7 A. What is your question about this?

8 Q. Your Honor, I apologize, Your Honor. I think
9 that's all I've got on this here.

10 A. Okay.

11 Q. I would like to turn to RX-16, if we might.
12 This is another document which was given to us by EPA in
13 response to our discovery requests. Can you tell us what
14 this document is?

15 A. So, it used to be weekly. Now they're not as
16 frequent. They're biweekly, what we call office hours
17 when knowledgeable people will share their perspectives
18 for the education of other staff members. I was asked to
19 do this one week because I was a longstanding member of
20 PRD. Not everyone who is in the division now was around
21 when reg review started, but I was.

22 Q. So, this was a presentation you provided on
23 January 11, 2021?

24 A. Yes.

25 Q. And who would be on -- who is the audience for

1 a presentation?

2 A. So, it was via Zoom so I can't tell you
3 exactly, but those presentations are usually attended by
4 CRMs, the TLs and the SRAs which are a senior regulatory
5 advisors. Sometimes there is people from outside PRD,
6 but mostly it's people within PRD.

7 Q. How big of a crowd do you think you had for
8 this one?

9 A. How many?

10 Q. How big of a crowd do you think you had for
11 this one?

12 A. I didn't really do -- I didn't really take note
13 of that. I'm sorry. Like I said, it was Zoom.

14 Q. To the best of your knowledge, is this an
15 accurate recording of what you had to say?

16 A. Yes, I looked at it and I think it is.

17 Q. And so, is it fair to say that what this
18 states, represents to your best understanding of the
19 facts and principles that are set forth in that document?

20 A. Yes.

21 Q. Okay. Thank you very much. One other question
22 about that. It notes in the third paragraph of the
23 second sentence that requests for a waiver can be made
24 for scientific reasons?

25 A. Yes.

1 Q. Are scientific reasons listed as one of the
2 basis for waiver on the DCI form that we just looked at?

3 A. Not in those words, but yes. There is another
4 kind of waiver that doesn't rely so much on scientific
5 reasons as economic.

6 Q. I'm sorry. You think it is identified in the
7 generic data --

8 A. Responding, making your request for waiver,
9 yes.

10 Q. Well, respond to the request for waiver for
11 scientific reasons?

12 A. Like I said, I don't think it uses the word
13 scientific reasons, but yes.

14 Q. But it's widely understood --

15 A. Yes.

16 Q. -- In the industry that that is a basis for a
17 waiver request, isn't it?

18 A. Uh-huh. Uh-huh.

19 Q. Could you answer that --

20 A. Yes. Sorry.

21 Q. Thank you. Okay. In the case of the AMVAC DCI
22 at issue here, did take EPA an unusually long time to
23 respond to any data waiver request?

24 A. Yes. There was an incident where the
25 information wasn't conveyed right away.

1 Q. 66, if I can -- if you would pull up JX-66,
2 please? And JX-6, 66, pardon me, is a memorandum dated
3 March 21, 2014, to you and several others from a long
4 list of submitters?

5 A. Right.

6 Q. What was the purpose of this memo?

7 A. So, we were responding to several waiver
8 requests for data from EFED for DCPA and TPA.

9 Q. And did you review this document before it was
10 prepared?

11 A. No. I don't think so.

12 Q. So, who would, to the best of your knowledge,
13 who would have been the senior employee of EPA's who
14 reviewed this document before was distributed?

15 A. Right. So, the highest ranking person for EFED
16 on here is Brian Anderson. You're talking about before
17 it was finalized? That would have been Brian.

18 Q. Yeah. Yeah. Okay. And who is Brian Anderson?

19 A. He was a branch chief in the Environmental Fate
20 and Effects Division.

21 Q. Okay. And so, he was superior to you on the
22 organization chart; is that correct?

23 A. Well, not within the same organization, but he
24 was a branch chief, yes.

25 Q. Fair enough. Can I get those emails, please?

1 Now, you recall and, in your testimony, you described
2 that AMVAC's responses as being dilatory and unusual and
3 I simply want to summarize a couple of things you said,
4 but was the message that you were trying to display in
5 that testimony that they were being difficult?

6 A. That AMVAC was being difficult?

7 Q. Difficult.

8 A. I don't know that that's the word I used. We
9 reviewed a number of waiver requests, two sets of waiver
10 requests for the same data requirements over time. It
11 didn't seem to add any additional information to it.

12 Q. Now, did you review this?

13 A. The waiver request?

14 Q. What you just referred to as a number of waiver
15 requests for that same --

16 A. Right. So, they would have gone to the science
17 division and then I would have seen that, the science
18 division's report on that.

19 Q. And that judgment as to whether or not those
20 were repetitive, I think that's that phrase used, and
21 didn't raise any new concerns -- that would have been the
22 view of the science division; is that correct?

23 A. I don't think in so many words. I think that
24 would have been my conclusion from reading their reviews.
25 They didn't review things in that context.

1 Q. Well, those explanations dealt with some fairly
2 sophisticated toxicological and environmental fate issues
3 -- didn't they?

4 A. I'm sorry. Your question?

5 Q. Isn't it true that many of those dealt with
6 fairly complex toxicological and environmental fate
7 issues?

8 A. Yes.

9 Q. And you consider yourself sufficiently an
10 expert to make that judgment?

11 A. I think that does --

12 MR. PITTMAN: Objection. We're not trying to
13 determine that --

14 JUDGE BIRO: Sustained.

15 MR. WEINBERG: I'm sorry, your honor.

16 JUDGE BIRO: Sustained. Move on.

17 BY MR. WEINBERG:

18 Q. Would you take a look, please, at AMVAC Exhibit
19 48. Could you put that on the screen? Take a look at
20 that because I want to ask you what if anything you
21 remember about it?

22 A. Yeah, I remember this.

23 Q. Have you had a chance to look at it?

24 A. Yes.

25 Q. Would you agree with me that this is an email

1 string of communications between you and Julie Porter of
2 AMVAC?

3 A. Yes.

4 Q. And do recall this series of communications?

5 A. Do I recall?

6 Q. This series of communications?

7 A. Yes.

8 Q. At the bottom of the first page this indicates
9 that the stub does the bottom of the second page. I'm
10 sorry. This indicates that the string started with the
11 response, the ninety-day response documents that was
12 provided in June and then the second email appears to be
13 an email from Ms. Porter to you from about a month later
14 asking about status of that.

15 A. Yes.

16 Q. Is that correct?

17 A. Uh-huh.

18 Q. And she then on August 7 sent you another email
19 that appears to imply you had responded to the prior
20 email?

21 A. That's correct.

22 Q. And in fact, you ultimately got back to her on
23 August 7, isn't that correct?

24 A. So, on August 7 I said that I had just got --
25 oh, this one? Yes.

1 Q. I'm sorry?

2 A. Yes. I'm reading what you're showing me now.

3 Q. Okay. Would you put up PAX 47 for a minute,
4 please? Would it take a quick look at this one as well,
5 please?

6 A. Uh-huh. This is familiar to me.

7 JUDGE BIRO: This is also PAX 47?

8 MR. WEINBERG: I'm sorry, your honor?

9 JUDGE BIRO: It's also PAX 47? That's the
10 number of the exhibit?

11 MR. WEINBERG: This is, yes, PAX 47.

12 JUDGE BIRO: Yeah.

13 MR. WEINBERG: Yeah. Each one of these emails
14 has a -- I'm going to go through it.

15 JUDGE BIRO: I just want to make sure for the
16 record we got the right number.

17 MR. WEINBERG: I completely understand.

18 BY MR. WEINBERG

19 Q. This is an email exchange in which you were
20 copied, but do you recall this email that was made?

21 A. Yes.

22 Q. And do you have any doubt that -- any reason to
23 believe this is an incomplete statement of what came?

24 A. Do you mean there were emails on the same
25 subject?

1 Q. Were there emails in this chain?

2 A. I'm sorry.

3 Q. Whether there were other emails in this chain?

4 A. I'm going to say I don't know.

5 Q. This gentleman, Matthew Manupella was telling
6 Ms. Porter that there was changing hands at DCPA again.
7 Can you explain what that was?

8 A. So, after I left, that branch that was RMIB2,
9 the chemical stayed with RMIB2 and Matt was one of the
10 CRMs who dealt with it, and subsequently it was sent over
11 to my branch RMIB5 because I had a history with it.

12 Q. And would it be correct to agree to that he was
13 giving you a heads up on this to AMVAC on that change?

14 A. Yes. That was giving Julie an update.

15 Q. Could we go to petitioner AMVAC [Exhibit 49](#),
16 please? And again, if you would take a moment to just
17 look at this string. A little bit longer and I'm sorry,
18 but it's a few pages.

19 A. So, this is more of the same exchange where
20 Matt told Julie that it was changing hands.

21 Q. And your first email in this chain appears to
22 be from Matthew Manupella. What was his role at EPA?
23 This is the same gentleman we just talked about before?

24 A. Right. He was a CRM in RMIB2 and his
25 responsibility -- he had a responsibility for DCPA.

1 Q. And then the next one shows an email was sent
2 to you sending a courtesy copy I take it of material
3 being provided on the sediment studies?

4 A. Yes.

5 Q. And you wrote in your communication that you
6 had been out sick. Julie responded that she hoped that
7 you were feeling well and that went on.

8 Can we look at 50, please? Pardon me.
9 Petitioner AMVAC [Exhibit number 50](#)? This is another
10 string in which you were carbon copied. Do you recall
11 this?

12 A. Yeah.

13 Q. And that the bottom -- excuse me. It started
14 at the beginning of the chain. Actually, this second
15 note is an email from you indicating another change in
16 staffing for DCPA; is that correct?

17 A. Well, a CRM had been assigned. I wasn't a CRM,
18 but that was when she was assigned --

19 Q. I'm sorry. That wasn't a change?

20 A. It wasn't a change in branch. It was a
21 designation of a CRM. Prior to that I took over some of
22 the communications, but I wasn't a CRM. So, she's a CRM.

23 Q. So, this was the first time a CRM was assigned?
24 Pardon me, in your branch?

25 A. It sounds like it, yeah. I don't think there

1 was --

2 Q. I'm sorry?

3 A. I don't think there was a previous
4 communication of the specific change to the CRM. I think
5 this was it.

6 Q. And you see this -- move up the page and see
7 that Ms. Porter would write to the woman you had
8 identified, Dr. King. It raises some questions about
9 relating to the Health Effects Division and ultimately
10 this -- is it Ms. King?

11 A. Dr. King.

12 Q. I guess it's Dr. King?

13 A. Yes.

14 Q. Pardon me. Arranges for a meeting to be held
15 so that the experts associated with the particular
16 studies involved would be addressed. Is that fair?

17 A. Yes.

18 Q. Would you pull up [Exhibit number 50](#), please?
19 Again, this is a string of emails in which you were
20 copied at least on several of them.

21 A. I think this is the same one as the last one
22 you showed me.

23 Q. I think it is, actually, now that we look at
24 it. AMVAC 53 -- pardon me, AMVAC [Exhibit 53](#). Will you
25 take a look at this one, please? This is another series

1 of emails. Do you recall this series?

2 A. Yes.

3 Q. And do you have any reason to doubt that this
4 is a complete email chain?

5 A. I don't know if there are more before or after.
6 I'm sorry.

7 Q. It appears that from the first email in the
8 string that Mr. Wood of AMVAC was providing an update to
9 EPA, to Ms. Montague, on May 30.

10 A. Yes.

11 Q. And then on August 14 he was calling to find
12 out when the agency would be responding to that document;
13 is that correct?

14 A. Yes.

15 Q. And can you go to Petitioner AMVAC's Exhibit
16 54, please? This is another string of the emails in
17 which you were copied. I don't think you were the direct
18 recipient of any of them, but does this look familiar to
19 you?

20 A. Yes.

21 Q. All right. And if not first email in this
22 string Mr. -- perhaps it is Dr. Wood, I suppose, is
23 transmitting an email from another AMVAC employee that
24 provided a summary of attachments from the laboratory on
25 the CTA range finding study?

1 A. Yes, but it can't see the whole string. If you
2 could --

3 Q. I'm sorry?

4 A. Yes. Thank you. There you go.

5 Q. I'm sorry?

6 A. So, I couldn't see the whole thing. They took
7 away --

8 Q. Oh, okay.

9 A. -- Now I can see it.

10 Q. Take your time. I'm sorry. I didn't mean to -
11 -

12 A. No problem. No problem. That's what it
13 appears to be, yes.

14 Q. Yeah. And that goes from AMVAC to Jordan Page
15 and one of the things that Mr. Wood asked in his email on
16 the bottom of page one of two is how quickly EPA can
17 provide comments on that material, do you see that?

18 A. He does ask when he can get comments, yes.

19 Q. And then Jordan Page responds above that and
20 could you just read what he had to say? Just read it out
21 loud.

22 A. Good morning, Jon. Is that what you mean, from
23 there?

24 Q. This is good morning, Jon. After good morning,
25 Jon.

1 JUDGE BIRO: I don't need anybody to read it
2 for me.

3 MR. WEINBERG: All right.

4 JUDGE BIRO: I'm really good at reading.

5 MR. WEINBERG: Well, fine. That's fine. Your
6 Honor, I'm happy to -- I'm trying to accelerate just a
7 little more quickly.

8 BY MR. WEINBERG:

9 Q. Does it indicate that it's highly unlikely that
10 they would be able to provide feedback by September 1 and
11 that this potentially will add several months in that
12 data development process?

13 A. So, he is saying that as I recall Jon was
14 asking, you know, they were getting animals I think on
15 September 1st, I think it was, and John was asking will
16 you be able to give us feedback before the animals come
17 due and according to Jordan it looks like it will take
18 several months more because it was a big -- large volume
19 of data.

20 Q. He's saying that we're not going to be able to
21 respond to it. EPA will not be able to respond by that
22 date?

23 A. Highly unlikely he says, yes.

24 Q. But he requests whether there could be a call;
25 is that right?

1 A. Uh-huh.

2 Q. And that request is on the 22nd, first thing in
3 the morning apparently a little later that day AMVAC
4 responded and said we could be available for a call
5 tomorrow or Friday I suspect was Wednesday was the day
6 they were talking about they met, correct?

7 A. Yeah, it must have been a Wednesday, right,
8 because it's a Tuesday email and it says tomorrow.

9 Q. In the can we please go to [Exhibit 52](#), and Your
10 Honor, I understand the tediousness of this but I have to
11 go through two more.

12 MR. PITTMAN: Your Honor, can I object to
13 relevance? These documents all concern the CTA, which
14 OPP has informed AMVAC is now considered satisfied.

15 JUDGE BIRO: Overruled. Go ahead. But I --
16 you know, I don't think that were getting anything --

17 MR. WEINBERG: Let me explain, Your Honor. I
18 believe, and I believe -- and know that when you go back
19 and ask Ms. Bloom -- that many readers of her testimony
20 would read her accusations about the lack of compliance
21 by AMVAC with their obligations under this DCI and their
22 --implicitly their strategy of delay and their refusal to
23 comply in a prompt matter. I believe that's what her
24 testimony intends to say, and we believe it is completely
25 relevant to demonstrate that in fact their communications

1 at all levels of the staff that reported to Ms. Bloom
2 and with Ms. Bloom herself were in fact productive,
3 timely and responsive.

4 JUDGE BIRO: I think that's your argument and I
5 think these exhibits might support your argument, but I
6 don't see you getting any facts out of her that are
7 contested. And that's what we're looking for in this
8 hearing. We're trying to focus on contested facts.

9 MR. WEINBERG: Unfortunately, I needed to be
10 sure I could get these documents in and I need to have
11 her confirm that they were accurate documents because
12 they were documents that we produced.

13 JUDGE BIRO: Okay. So, can we stipulate to
14 this?

15 MR. PITTMAN: Your Honor, we will stipulate to
16 the authenticity of the documents, contesting the
17 admissibility for relevance reasons.

18 JUDGE BIRO: Okay. What are the other two
19 that you're concerned about? Let's stipulate to all of
20 these and get them in.

21 MR. WEINBERG: That's what I'm trying to get
22 done by 5:00 this afternoon, Your Honor.

23 JUDGE BIRO: I don't think so.

24 MR. WEINBERG: I'm sorry?

25 JUDGE BIRO: I don't think so. I think we're

1 going to be here way past five.

2 MR. WEINBERG: No, I don't think so. I think
3 we're actually fairly close.

4 JUDGE BIRO: Okay. What are the exhibits?

5 MR. WEINBERG: Okay. Could you put up the
6 quotation that starts with a reasonable interpretation?

7 MR. PITTMAN: I'm sorry. What to put up?

8 MR. WEINBERG: I'll explain as soon as we put
9 it up. Do you know what I'm talking about?

10 BY MR. WEINBERG:

11 Q. Ms. Bloom, did you review the -- have you seen
12 this sentence before [referring to Respondent's
13 Prehearing Brief at 8]?

14 A. Yes.

15 Q. And where do you think you saw it?

16 A. It was in the Respondents prehearing brief.

17 Q. I'm sorry?

18 A. It was in the Respondents prehearing brief.

19 Q. And were you involved in the preparation of
20 that responsive brief?

21 A. I don't know that I was involved in a
22 preparation, but I did review it.

23 Q. You did review it. So, you were familiar with
24 it?

25 A. Yes.

1 Q. All right. Do you believe that this is a long-
2 standing administration policy of EPA, what it describes
3 here?

4 A. I don't know that I would characterize it that
5 way. This has to do with multiple waiver requests for
6 the same data requirement, which didn't happen that
7 often. So, I wouldn't say it was long-standing, but it
8 didn't give us the data we wanted.

9 Q. Let me ask it a different way. Can you think
10 of any other policy document from EPA that you have ever
11 seen that makes the assertion here?

12 A. Certainly, related statements. I don't know
13 this particular verbatim statement.

14 Q. Now, take a look at paragraph five. I'm sorry,
15 the paragraph on page 5. And if you would look at this,
16 this paragraph, it says "OPP does not regularly specify
17 an appropriate time..." and so forth and EPA thinks you
18 should have to produce the data with the original time
19 frame.

20 A. Well, I think it goes on to say that sometimes
21 the original time frame has been bypassed. So, this
22 doesn't talk about -- It's the period equivalent to, not
23 the exact time.

24 Q. Have you ever seen this statement in any
25 document that EPA has ever published before?

1 A. Not that I -- No, similar statements, but not
2 this one.

3 Q. 21. Now, will you pull up JX 21 again, please.
4 That's the data delay letter. And if you would be kind
5 enough to scroll down to the table and towards the end
6 there and just blow up the middle part of it there so it
7 is legible.

8 Do you recall this letter? This was the one
9 that was sent to explain to AMVAC that there was certain
10 data that was still outstanding; is that correct?

11 A. Well, it's one of them. This is the one that
12 says were going to have to go ahead with registration
13 review if you don't get us the --

14 Q. Great. And that table attached to it, the
15 letter, if I recall correctly, is in fact not dated,
16 although it's been stipulated, to be authentic and this
17 table is attached to it with an October 16, 2020, date on
18 it; isn't that correct?

19 A. Uh-huh.

20 Q. And if I can just pick one of these
21 requirements. That's take right in the middle of the
22 page 835.4300. So, this was prepared in 2020, correct?

23 A. Uh-huh.

24 Q. And in the right-hand column where it has a due
25 date, where it says 1/31/2015, correct?

1 A. Yes.

2 Q. And this was outstanding data, right?

3 A. Yes.

4 Q. And that date is the date that the data was due
5 under the original DCI, was it not?

6 A. Yes. Assuming the registrant received it on 31
7 January, 2013. This was a 24 month study so the due date
8 was the same date in 2015.

9 Q. Thank you. And in fact, that's what's been
10 done on all of the studies on this table where there was
11 data outstanding, the date that was published list and
12 that on the table was the date it was identified in the
13 DCI?

14 A. Can you let me see the rest of the table,
15 please, so I can --

16 Q. I'm sorry. You turned away from the microphone
17 and I had --

18 A. Oh, I'm sorry. I just wanted to see the rest
19 of the table. This is the entirety of the table?

20 Q. This is the table that accompanied the letter.

21 A. Right. I'm looking for one in particular. Oh,
22 it's not here because it was waived. There was only one
23 study that ever got a different due date because the
24 registrant requested an extension, but then the extension
25 became moot.

1 Q. But you agree that the due dates that are
2 listed there are the days from the original DCI, correct?

3 A. Yes.

4 Q. All the lines or the studies were identified as
5 outstanding?

6 A. Yes.

7 Q. And that in fact is not consistent with the
8 quotation that we read a little bit ago of -- about the
9 denial of an initial request, in which the respondent
10 maintained that the DCI respondent should have provided
11 data within a period of equivalent to the original time
12 frame specified with each --

13 MR. PITTMAN: Your Honor, objection. I don't
14 see the relevance of a six month later filed legal
15 pleading to Ms. Bloom's statement from June.

16 JUDGE BIRO: Yeah. Sustained. Go ahead. Go
17 on to something else.

18 BY MR. WEINBERG:

19 Q. Ms. Bloom, are you aware of the policies stated
20 from that document that we read out from a few minutes
21 ago when this table was approved?

22 A. I'm sorry. I don't know which statement you're
23 talking about.

24 Q. Okay. Please put back up that statement from
25 prior page 5. And there is a --

1 MR. PITTMAN: Same objection to relevance.

2 MR. WEINBERG: I'm sorry?

3 MR. PITTMAN: Same objection to relevance.

4 MR. WEINBERG: The objection to relevance,
5 since we're trying to establish, but this is a completely
6 invented policy solely for purposes of this case and not
7 an EPA policy and that in fact when they prepared this
8 letter, of which they are so proud, they in fact didn't
9 follow this policy. Well, left the dates in earlier.
10 They now have come up with policies that they have
11 invented in a reply brief, in a prehearing brief that
12 have no substantiation in any other EPA documentation.

13 JUDGE BIRO: As far as I could tell, I read
14 this as their response to I think the EAB's decision in
15 this matter about setting an appropriate time frame and
16 that was their offer of a suggestion of what would be
17 appropriate.

18 MR. WEINBERG: Well, they historically had
19 never taken that position before, Your Honor, and that's
20 what we want to establish. You will decide what the
21 legal significance is, from my understanding. The
22 factual question is whether this is a newly announced
23 policy, and that's simply what I'm trying to establish.

24 JUDGE BIRO: Well, I'm not sure EPA's
25 prehearing brief constitutes an EPA policy because policy

1 documents have very specific definitions and go through
2 certain procedures and this is not how it's done, but
3 I'll let you ask her whether she's seen anything that
4 similar to that. Although I think she already answered
5 that the question, but go ahead.

6 THE WITNESS: So, the question again, please?
7 I'm sorry.

8 MR. WEINBERG: I think at this point, Your
9 Honor, the question was whether you were aware of the
10 policies stated in the quotation that is on the board
11 that is one that starts "OPP does not regularly specify
12 ..." when the table that was attached to the data delay
13 letter was prepared.

14 THE WITNESS: Your question is this is a policy
15 that I've seen elsewhere?

16 BY MR. WEINBERG:

17 Q. No. No. It was were you aware of this policy at
18 the time the data delay letter was prepared?

19 A. I don't consider it a policy per se.

20 Q. And were you aware of this statement of --

21 JUDGE BIRO: Position. It's a statement of
22 position.

23 MR. WEINBERG: Yes.

24 JUDGE BIRO: Do you agree with that?

25 MR. WEINBERG: In that --

1 THE WITNESS: Yeah, I do agree because it's the
2 same as the original -- the same length as the original
3 requirement time period. So, we wouldn't expect them to
4 do it any faster.

5 MR. WEINBERG: So, it should be the whole same
6 length to be --

7 A. Period equivalent to the original time.

8 Q. The original time or the length of time?

9 A. Period equivalent. I think that's the length
10 of time.

11 Q. Well, if one says the length of time. The time
12 was approximately three years, if I recall correctly.

13 A. So, some data requirements were one, two, and
14 then three years.

15 Q. And you were providing somebody notice of a
16 denial in 2020. I'm assuming that would be the case.
17 Would you add three years on to that or would you go back
18 to three years after when the data call-in was issued?

19 A. Oh, no, you could relate it back to the DCI.
20 Some of those time frames expired so they would be
21 meaningless.

22 Q. Why would it be meaningless?

23 A. Well, it's something -- if we're talking about
24 something in 2020 and the deadline was in 2015, that's
25 meaningless. But the DCI provided two years for the

1 submission of that data. So, what this says is we give
2 you another -- you know, generally speaking they should
3 have provided the data within the next two years.

4 Q. And do you believe that's what this table says?

5 A. The table says?

6 Q. That table that --

7 A. No, that the table doesn't reflect that. There
8 are no -- these are the original due dates. There were -
9 - there was one request for an extension that I don't
10 believe is here because that became moot. So, these are
11 the original dates. There was never a request to extend
12 the dates. This was our being reasonable that, okay, now
13 we told you definitively. We really need these data. We
14 expect it will take you a year or two, or whatever to
15 develop those data and that's what they should have --
16 that's when they should have given us data. They should
17 have been able to give us data.

18 Q. Your Honor, I have one other series of brief
19 questions and then will be done.

20 Q. In the testimony that you submitted in June in
21 the earlier testimony I believe from you and maybe from
22 someone else, but you said in your testimony that the EPA
23 was unable to assess DCPA's risk to man and the
24 environment due to AMVAC's failure to submit the
25 necessary data. That was on page 7 of your --

1 A. Yes, but that's not in this document.

2 Q. I'm sorry?

3 A. That's a different set of documents altogether.
4 That was the document that was the information that was
5 conveyed to him when --

6 Q. Yes. That is a very different document. I'm
7 going back to your testimony. I'm going back to page 7
8 of your testimony.

9 A. Seven. Okay.

10 Q. Where we started?

11 A. And what phrase is it that you're concerned
12 about?

13 Q. The phrase is that you said that the EPA is not
14 able to assess DCPAs risk to man and the environment due
15 to AMVAC's failure to submit necessary data?

16 A. I don't think that's in this document. That
17 was a determination that was made subsequently.

18 Q. Well, I may have written the wrong page down in
19 my notes, but I'll go and check it.

20 A. I mean not this document. Not my testimony,
21 but the table you showed me, for example. If it says
22 that here I would like to see where.

23 Q. It's up on the board now. They'll help you
24 find it. Was the wrong about the page number?

25 A. And what page is this?

1 Q. It's on page 7 of your testimony.

2 A. Oh, I see it. Yep. You're right.

3 Q. Right? Now, as of today AMVAC has submitted
4 all the data that's pertinent to human risk, correct?

5 A. The data requirements that were responsive to
6 toxicology for the -- well, none of this is toxicology.
7 For the human health risk assessment, yeah, they provided
8 data that was required.

9 Q. And that's why the only studies about which EPA
10 is pursuing suspension at this point are the nine studies
11 for, eight of which that go to TPA, and one of which goes
12 to DCPA?

13 A. From the environmental standpoint, yes.

14 Q. Right? Now, the reason that you were concerned
15 about that inability was that at the time your testimony
16 was prepared in June of last year. The deadline for
17 completing registration review was October 1 of last
18 year; isn't that correct?

19 A. So, we did want to -- your question again? I'm
20 sorry?

21 Q. Isn't it true that at the time you prepared
22 this testimony the deadline for registration review set
23 by the statute was October 1, 2022?

24 A. Yes.

25 Q. And are you aware that Congress has amended

1 that deadline, legislation --

2 A. Yes.

3 Q. -- that was passed --

4 A. Yes.

5 Q. -- In December?

6 A. Yes.

7 Q. And then extended I believe four years --

8 A. 2026.

9 Q. Right. So, that pressure for the need to be
10 able to do the human health risk assessment and, for that
11 matter, the environmental risk assessment is no longer in
12 place in EPA; isn't that correct?

13 A. I don't see it that way. We had identified
14 potential risk concerns and we wanted to sort them out.
15 I do want to add one thing about the environmental data.
16 Some of those relate to the human health risk assessment
17 because of the drinking water. So, it's not just
18 ecological effects. It can also be information through
19 the drinking water assessment that's part of the dietary
20 assessment. That's part of the human health risk
21 assessment.

22 Q. Okay. Do you know what the schedule is for the
23 production of the studies that are still outstanding?

24 A. So, AMVAC has given us -- I don't know them
25 offhand, but the AMVAC has given us a list, yes.

1 Q. And it's roughly between a year and two years
2 for the total studies; is that correct?

3 A. Right. I think the only study that was longer
4 is no longer contested I think the rotational crops was
5 three years, but, yeah, between one and two years.

6 Q. So, to the extent, and I'm not asking you to
7 confirm this, but to the extent that the deadline set for
8 work completing registration review has been extended by
9 Congress, there is less pressure on EPA to complete the
10 registration review; isn't that true?

11 A. I would have to say in this case we had risk
12 concerns, that we feel we need to deal with -- so I can't
13 speak for all of registration review. That's for this
14 one. I'm sorry.

15 Q. Can I have the question read back? I
16 appreciate what you said, but you didn't answer my
17 question.

18 A. Okay. Can you ask it again, please?

19 Q. Well, I mean I can rephrase it, but I would
20 just as soon --

21 JUDGE BIRO: The pressure on EPA has been
22 alleviated by Congress extending the deadline from 2022
23 to 2026, in your opinion?

24 THE WITNESS: I wouldn't describe it that way,
25 no. Uh-uh. That we're able to make the statutory

1 deadline.

2 BY MR. WEINBERG:

3 Q. You do agree that that has happened, that --

4 A. Yes. And I think --

5 Q. And to the extent -- I understand you disagree
6 with it. I don't think this is a very controversial
7 statement, but to the extent that the agency was feeling
8 pressured to get something done by October 1 of 2022, the
9 change in the statute can be read to relieve the
10 pressure?

11 A. Again, that's not the way I would describe it.
12 It does give us more time.

13 Q. Well, you just have to answer my question.

14 A. Okay. So, that's not the way I would describe
15 it.

16 Q. I'm sorry?

17 A. That's not the way I would describe it.

18 Q. So, it's a yes or no question.

19 A. That would have to be no. I'm sorry.

20 Q. Okay. Thank you.

21 MR. WEINBERG: Your Honor, if we could have
22 just one minute.

23 JUDGE BIRO: Of course.

24 MR. WEINBERG: Your Honor, we have no further
25 questions for Ms. Bloom.

1 JUDGE BIRO: Okay. I would like to take a
2 five minute break to get another cup of coffee. So, can
3 we stand in recess just for 10 minutes, I believe until
4 4:50 and come right back.

5 MR. PITTMAN: I have just one follow-up.

6 JUDGE BIRO: Oh, okay. Well, then proceed Mr.
7 Pittman.

8 MR. PITTMAN: Your Honor, should we clarify
9 with Ms. Rose to see if she has any follow-ups that might
10 make a break more preferred now?

11 JUDGE BIRO: Yes. Thank you for reminding me.
12 Ms. Rose, are you still with us?

13 MS. ROSE: I lost the Teams, but I dialed in
14 on the phone. So, I'm trying to get back on the Teams,
15 but I have no questions.

16 JUDGE BIRO: Okay. Thank you.

17 REDIRECT EXAMINATION

18 BY MR. PITTMAN:

19 Q. Good afternoon, Ms. Bloom. I only have one
20 follow-up for you here. So, with respect to the PX-57 I
21 believe in regards to the OPP updates that you testified
22 to some time ago.

23 A. Okay. Yes.

24 Q. Would it be fair to say that your comment
25 concerning 10 to 20 insufficient submissions that you --

1 maybe that was from your recollection. Would it be fair
2 to say that that also included inadequate waiver request?

3 A. It also included waiver requests. I think this
4 statement was just about data that had been submitted.
5 Although some of the waiver requests were accompanied by
6 data. So, it goes to the extent that they were, I would
7 count them, too.

8 MR. PITTMAN: Thank you. No further questions.

9 JUDGE BIRO: Okay. Ms. Rose, do you have any
10 questions?

11 MS. ROSE: I do not. Thank you.

12 JUDGE BIRO: All right. I have a few
13 questions. No, you have to sit and answer my questions.

14 THE WITNESS: Oh, I'm sorry. I misunderstood.
15 I apologize.

16 JUDGE BIRO: No problem.

17 THE WITNESS: I guess that would have been too
18 easy.

19 JUDGE BIRO: I don't think my questions will
20 be any harder. Can you tell me about the agency's
21 electronic filing system, the electronic docket, this
22 pesticide docket management system, this central data
23 exchange, all these references that go in these
24 documents?

25 THE WITNESS: Right. So, there's different

1 things. The CDX that you referred to, the second one you
2 referred to, that's the way that registrants submit data
3 to us, you know, because of COVID and probably predates
4 COVID, but since COVID we didn't accept paper copies
5 anymore. So, we established this portal for submitting
6 data and we would have done it anyway because it's more
7 efficient.

8 JUDGE BIRO: So, did CDX just start in 2020?

9 THE WITNESS: I don't know. I'm sorry. I
10 don't know. It seems like maybe it was longer than that,
11 yeah.

12 JUDGE BIRO: Okay.

13 THE WITNESS: But it definitely gets the data
14 to the people who need to review it quicker than a paper
15 copy.

16 JUDGE BIRO: Okay. So, if I were a registrant
17 and I wanted to submit a study, I upload it into the CDX
18 system?

19 THE WITNESS: Yes.

20 JUDGE BIRO: And it is assigned a number
21 automatically?

22 THE WITNESS: So, yeah, that's a change
23 actually. The registrant needed to have to hear from us
24 what the MRID number was as the accession number, but now
25 the registrants themselves they choose the next number in

1 line.

2 JUDGE BIRO: Okay. And then does it
3 automatically get distributed to where? What's the next
4 step in the process?

5 THE WITNESS: So, the next step is it undergoes
6 a front end screen to make sure that it's legible, that
7 it's got the correct confidentiality statements, just the
8 administrative kind of stuff and that -- yeah.

9 JUDGE BIRO: Who does that?

10 THE WITNESS: Was that?

11 JUDGE BIRO: Who does that?

12 THE WITNESS: So, it used to ITRMD, but we
13 reorganized now it's I think OPS. Is that what it's
14 called?

15 JUDGE BIRO: So, a human being does --

16 THE WITNESS: Human being, yes.

17 JUDGE BIRO: Okay.

18 THE WITNESS: A couple of human beings.

19 JUDGE BIRO: And then what happens?

20 THE WITNESS: So, after that screening happens,
21 if it doesn't hit all of the right marks that group goes
22 back to the registrant and says, oh you are missing page
23 5, or you didn't sign this page. But if everything goes
24 as planned the MRID number is confirmed and then it
25 becomes available to me to share with the people who need

1 to review it.

2 JUDGE BIRO: Okay. What do you mean becomes
3 available to you? Are you get access to it? Do you get
4 an email telling you that it has been submitted?

5 THE WITNESS: Is not always. We get -- usually
6 the registrant will tell us they submitted it, but of
7 course this happens after that.

8 JUDGE BIRO: Wait. They will informally tell
9 you by email that they submitted it?

10 THE WITNESS: Yes. But when it's ready for
11 review we find it in Documentum. I'm not sure that we
12 100 percent of the time get advance notice of that. We
13 just look for the Documentum because we know it's
14 expected. Documentum, I'm sorry is another -- another
15 way of tracking submissions.

16 JUDGE BIRO: Okay. So, you don't get anything
17 that tells you that a registrant has submitted any data
18 automatically?

19 THE WITNESS: I don't think we always do, no.
20 Uh-uh.

21 JUDGE BIRO: Okay. It just goes into like a
22 library of --

23 THE WITNESS: Yes. Definitely looks like a
24 library.

25 JUDGE BIRO: Okay. And then you can look for

1 the data in there in this library of Documentum?

2 THE WITNESS: Yes. It will categorize it by
3 date, and title, and sometimes data requirement, but
4 always the MRID number, the accession number.

5 JUDGE BIRO: Okay. Let's say you go over this
6 data and you think you should go on to the next step.
7 Are you the person who decides where it goes to?

8 THE WITNESS: So, that's pretty well-
9 established and it wouldn't be me. It would be the CRM
10 that's responsible for developing the BEAN. We talked
11 about the BEAN, that tells the science division here this
12 is. Could you please give us your review and this is the
13 date we would like it by.

14 JUDGE BIRO: So, that CRM is a person would
15 look in that Documentum system, see something has been
16 submitted and decide who to send it on to in terms of the
17 science division?

18 THE WITNESS: Yes. Uh-huh.

19 JUDGE BIRO: Okay. And when they send it on
20 to the science division, do they indicate the timeframe
21 for review?

22 THE WITNESS: Yes. We request a particular
23 timeframe, often we renegotiate it.

24 JUDGE BIRO: Okay. So, this CRM is the one
25 who sets that estimated time frame?

1 THE WITNESS: Yeah. Not all by himself. I
2 mean we talk about it.

3 JUDGE BIRO: So, before it goes on to the
4 science division, is there more than the CRM reviewing
5 the data that -- that's submitted?

6 THE WITNESS: So, I don't consider what we do
7 as a review, because it's technical material, but we do
8 look at it so we get a sense of what it is so we can
9 instruct the science division of what we would like to
10 get out of the review.

11 JUDGE BIRO: So, after that bit of a group
12 thing about how maybe what you want to get out of it and
13 what deadlines it should be, it goes on to the science
14 division?

15 THE WITNESS: Yes.

16 JUDGE BIRO: One of the many science divisions
17 that EPA has?

18 THE WITNESS: Yes. And that's another one of
19 our databases that does that.

20 JUDGE BIRO: And which database is that?

21 THE WITNESS: That would be Prism.

22 JUDGE BIRO: Okay. So, the science division,
23 how did they get it from Prism? It goes into Prism
24 system automatically?

25 THE WITNESS: Right. And so, it goes to the

1 group in that division that manages the data submissions
2 and not the actual reviewers, but we will notify the
3 branch chief or somebody equivalent that it's there and
4 they can find it there and the system number. When you
5 BEAN it, you get a BEAN number, and we convey to them
6 what the BEAN number is so they know how to find it.

7 JUDGE BIRO: Okay. So, that CRM would send an
8 email and formally telling the administrative person in
9 the science division that we sent it to your Prism?

10 THE WITNESS: So, we usually copy that person,
11 but we actually tell the reviewers branch or the
12 leadership in that branch or even the individual who is
13 going to do the review that it's there. So, we usually
14 copy those people because they have to be aware of it,
15 too.

16 JUDGE BIRO: Okay. So, then the scientists go
17 in and look at that document?

18 THE WITNESS: Yes.

19 JUDGE BIRO: If they want to evaluate it or
20 send it out for evaluation, do they have to download
21 into a different system?

22 THE WITNESS: I don't know, because we do have
23 contractors that do the screens of data but I'm not sure
24 how the science divisions do that. I would assume it's
25 electronic because those BEANs that I talked to you

1 about, they attach to documents and the document is right
2 there, so it wouldn't be difficult for them to use that
3 and pass it on to the contractor.

4 JUDGE BIRO: Whoever does the review, a
5 contractor or an EPA employee does a scientific review,
6 do they upload their comments about it in to Prism?

7 THE WITNESS: I think primarily they provide us
8 with a memo that gives the review. It should be in
9 Prism, but it is not always there.

10 JUDGE BIRO: So, they might send it to you and
11 formally in the system by email?

12 THE WITNESS: Yeah. I mean when they do that,
13 they close out the BEAN so there it is an official
14 acknowledgment that they did what we asked them to do.

15 JUDGE BIRO: But not necessarily attaching
16 what closed it out?

17 THE WITNESS: The closing out is just saying
18 you completed the BEAN. So, you know, we don't get that.
19 That's between the scientists and the staff that I told
20 you that manages the data submissions.

21 JUDGE BIRO: So, when you say you get it back,
22 that goes to the CRM?

23 THE WITNESS: Is typically just to the CRM, the
24 team leader and the branch chief.

25 JUDGE BIRO: Then what happens?

1 THE WITNESS: So, we'll review it, and in the
2 best case we prepare a transmittal letter that says
3 exactly what we want the registrant to do next. So, for
4 example if the study is unacceptable or if there is some
5 missing data that can upgrade this study, we will pass
6 that on to the registrant and say please provide this
7 material. Or in the case of a waiver request your waiver
8 is denied and gives the reason, or whatever.

9 JUDGE BIRO: And do you send that to them by
10 email or by mail or is it -- how do they know?

11 THE WITNESS: It's typically by email. I think
12 always email now.

13 JUDGE BIRO: Do registrants have access to any
14 of these systems you mentioned, CDX, documentum, or
15 Prism?

16 THE WITNESS: They have access to CDX because
17 that's where they submit data. I don't think they have
18 access to the other two that you mentioned.

19 JUDGE BIRO: Okay. And the response to the
20 data they submit that the science group has done, does
21 that go into CDX at any point?

22 THE WITNESS: No. It doesn't go into CDX.
23 CDX is just the portal for submitting data and getting
24 the routing number for it.

25 JUDGE BIRO: Is there a docket system where

1 everything that's happened in the case is accessible to
2 the registrants?

3 THE WITNESS: So, is there a docket system that
4 everything that the registrant submitted is available?
5 So, the one thing I think was qualifying, is we're
6 supposed to capture those reviews and post them to the
7 docket, the EPA docket. So, that's accessible to
8 everybody.

9 JUDGE BIRO: So, would you post the
10 scientists' evaluation of the studies submitted?

11 THE WITNESS: Yes.

12 JUDGE BIRO: To this EPA docket?

13 THE WITNESS: That's ideally, I can't say it
14 always happens.

15 JUDGE BIRO: And would registrants have access
16 to the EPA docket?

17 THE WITNESS: Yes.

18 JUDGE BIRO: So, in this case, there seem to
19 be some documents that went astray. So, I'm trying to
20 figure out how that works in this system. If the
21 scientist reviewed a study that AMVAC submitted, their
22 review would have gone into EPA dockets. They put it
23 into EPA dockets?

24 THE WITNESS: No. No, no. We put them into
25 the docket.

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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

1 of the passing of the responsibility onto different
2 people that unfortunately misplaced --

3 JUDGE BIRO: Okay. So, it was just that it
4 didn't go out by email. It didn't get uploaded in the
5 docket. They didn't get it. Is that --

6 THE WITNESS: Directly into the docket now but,
7 no, at the time it did not, it was not.

8 JUDGE BIRO: Is there any other system that's
9 in this whole process, any other computer system?

10 THE WITNESS: I mean we have lots of computer
11 systems but relating to the submission and review of the
12 data in PRD, I think that's pretty much it. What we do
13 is we expect the CRM to keep tabs on all of the data; and
14 keep their own records; and we encourage them to save the
15 transmittal memos; and the memos as in as central place,
16 because if they're gone, we can still find them.

17 JUDGE BIRO: Is there any tickler system for
18 that?

19 THE WITNESS: No.

20 JUDGE BIRO: Is there any tickler system for
21 the deadlines that are set on a DCI or any kind of
22 request?

23 THE WITNESS: So, we get automated emails long
24 past their relevance. We get automated notices that
25 something is overdue and I've been getting them for, you

1 know, the time immemorial cases that aren't even relevant
2 anymore but usually what happens is we find they're
3 available and the registrant tells us. I mean, excuse
4 me, when the reviewer tells us and sends it to us and
5 then it's PRD's responsibility to convey that to the
6 registrant.

7 JUDGE BIRO: Okay. So, other than
8 communicating by email, there is no way of the registrant
9 determining what the status of a study they submitted to
10 EPA is?

11 THE WITNESS: Well, they can ask us. We
12 converse all the time.

13 JUDGE BIRO: Right. I mean other than an
14 email to you, there is no way for them independently to
15 determine it. You have to ask somebody at EPA by email,
16 or by phone, or by letter.

17 THE WITNESS: Right. If a review is completed
18 and it doesn't get passed on to the registrant, they
19 wouldn't know. They would have to ask if it was done and
20 then the CRM would have to look and say, oh, it's done
21 and send it to them.

22 JUDGE BIRO: So, is that a common thing that a
23 registrant writes to you and says I submitted this, you
24 know, last year and I still haven't heard anything?

25 THE WITNESS: Yes.

1 JUDGE BIRO: Can you tell me what's happening?

2 THE WITNESS: That's very common.

3 JUDGE BIRO: And you respond to those
4 requests?

5 THE WITNESS: Were supposed to, yes, and we
6 usually do, but not always.

7 JUDGE BIRO: I'm somewhat confused about this
8 issue that EPA was willing to go ahead and use
9 conservative assumptions to make assessments, and the
10 reason I'm confused is because it's not clear to me if
11 they were looking for AMVAC's agreement to go forward to
12 use those conservative assumptions.

13 THE WITNESS: Yeah, I don't believe so. It's -
14 - the conservative assumptions would be made if we didn't
15 get the data and so we told AMVAC that was the case with
16 many of these requirements, but we don't need their
17 agreement to do that.

18 JUDGE BIRO: So, if you were to say tell us
19 whether you agree, or don't agree with what's going
20 ahead, you didn't care what they said?

21 THE WITNESS: Well, they had the data. That
22 was really the only avenue open to us.

23 JUDGE BIRO: Was there any timeframe for this
24 of going forward?

25 THE WITNESS: Timeframe for?

1 JUDGE BIRO: When you told them we could go
2 forward without your data if you don't submit new
3 studies. Did you have any anticipated timeframe for
4 going forward without it.

5 THE WITNESS: No, we were still hoping to get
6 the data, for the most part.

7 MR. ROSS: Your Honor, if I may direct you to
8 Joint [Exhibit 21](#). It does specify that a risk
9 assessment, I believe it's the document that you're
10 referring to, it specifies that the risk assessment would
11 be completed by June 20, 2021, and it does not condition
12 that on the submittal of any particular studies.

13 JUDGE BIRO: Thank you. There were a lot of
14 questions about this issue of, at what point you decided,
15 and when I say you, I mean EPA, OPP decided that it just
16 couldn't just use conservative assessments. That
17 wouldn't be reliable enough.

18 THE WITNESS: In particular relating to the
19 thyroid study, yes.

20 JUDGE BIRO: Right. So, was there something
21 that happened or didn't happen that triggered that re-
22 evaluation?

23 THE WITNESS: Yes. AMVAC submitted preliminary
24 data. The comparative thyroid assay has several steps
25 and one of those steps is you run a study at a wide range

1 of doses, you know, doses of the chemical and then from
2 that you can narrow down what doses you want to explore
3 with a little more resolution in the final study. So,
4 those are range finding studies. So, it took a while and
5 we had a couple of range finding studies, but they
6 weren't adequate but then we got one and we -- yeah, and
7 then we found this was a very unusual effect, a fetal
8 effect. It didn't affect the mother and it was at a very
9 low dose and our science -- our Health Effects Division
10 advised us that they sometimes can have a safety factor,
11 a 10X or something to account for the uncertainty. In
12 this case because it was so unique and so low, they
13 couldn't do that. They didn't feel like that would be
14 defensible just based on that.

15 JUDGE BIRO: Okay. And when did you get that
16 CTA study?

17 THE WITNESS: So, the range finding, I'm sorry,
18 I can't tell. I'm sure it's in some of the documents and
19 that was probably -- it was after the data delay letter;
20 so, after October 2020; and before the notice of intent
21 to suspend went out that HED told us there was no way.

22 JUDGE BIRO: Okay. There was some question on
23 whether AMVAC was notified that that CTA study, or
24 whatever EPA was relying on had changed the situation
25 such that it could no longer use conservative assumptions

1 to do their risk analysis.

2 THE WITNESS: I'm pretty sure that was conveyed
3 with the notice of intent to suspend that they were
4 informed.

5 JUDGE BIRO: In the notice of intent --

6 THE WITNESS: Well, I know -- in the notice, or
7 contemporaneous with it anyway.

8 JUDGE BIRO: Okay. Did you have any
9 understanding about why AMVAC would have been, previous
10 to that, willing to let you go ahead with conservative
11 assumptions?

12 THE WITNESS: Well, on the environmental fate
13 side their contention was that the studies we were asking
14 for wouldn't give us any more information than just
15 making conservative assumptions and that would be about
16 potential exposures to the chemical. In terms of the
17 health effects, I think it's about that same, no. So --

18 JUDGE BIRO: So, your understanding was that
19 AMVAC said you won't get anything more useful out of
20 doing these additional studies and will just spend money.
21 So, just use your conservative assumptions?

22 THE WITNESS: Right. For the environmental
23 fate data, and for some of the ecotox as well.

24 JUDGE BIRO: Did they ever explicitly state
25 that to you, go ahead and use the conservative

1 assumptions, or that was -- you were not going to submit
2 the data so you can go ahead?

3 THE WITNESS: So, I don't know that they ever
4 said go ahead and do that. I don't know who would have
5 responded to that, but they certainly were aware of it.

6 JUDGE BIRO: Okay. You said that AMVAC was
7 dilatory and abnormal in their responses. Can you
8 elaborate a little bit in your own words, what led you to
9 that kind of conclusion?

10 THE WITNESS: Okay. So, it was a -- as DCIs go
11 it was a fairly large one. There were a lot of data
12 requirements and there was testing for both the
13 metabolite and the parent compound. So, depending on how
14 you counted, in any case, there were a lot of data
15 requirements. There were some that AMVAC said they would
16 develop data for and then they didn't. There were many
17 that they requested waivers for. I think the dilatory
18 part of that comes from submitting multiple waiver
19 requests for the same study with little or no additional
20 rationale.

21 JUDGE BIRO: Okay. This DCI was issued in
22 2013, which was coming up, or is about 10 years-time.

23 THE WITNESS: Yeah.

24 JUDGE BIRO: Is that a normal timeframe for
25 DCI to be responding to?

1 THE WITNESS: No, that's pretty long. That's
2 very long.

3 JUDGE BIRO: So, how long are most DCIs
4 responding to?

5 THE WITNESS: So, I would say that, you know,
6 the nature of the data requirements dictates the due
7 dates, right? I don't think there -- I can think of one
8 study that's four years and some that are three years.
9 Most are less than two years, two years or less. So, you
10 know, if everything went as planned if the longest data
11 requirement was in there that took three years you would
12 expect three years after that the DCI was issued that by
13 then you would get the data. And I think your question
14 was does that happen a lot? So, I would say there's
15 always some piece of data that's not adequate. Usually,
16 submitted but not adequate out of any number of data
17 requirements that are levied on a particular registrant.
18 Most of them are not, you know, a death knell for the
19 risk assessment. And so, we often will publish documents
20 with assessments and decisions in them and say, okay, we
21 did this without the data. We don't consider these data
22 to be satisfied, but we made this decision anyway.

23 JUDGE BIRO: What happens if you do that, and
24 you make your conservative assumptions without AMVAC's
25 data and it says it can't be used under these conditions.

1 You narrow the scope of use, maybe you know, in terms of
2 how often it can be used or on what crops, or in any way
3 narrows it. Can AMVAC then come back and provide
4 additional studies. Maybe the studies you requested in
5 the first place and try to get that conclusion
6 reconsidered?

7 THE WITNESS: Yes, that happens.

8 JUDGE BIRO: Okay. So, is that common?

9 THE WITNESS: I don't know how common, but it's
10 not rare.

11 JUDGE BIRO: So, you could go through the
12 whole process of a risk assessment and not really
13 effectively ever close out the process?

14 THE WITNESS: Yes. I mean registration review
15 is a cyclical process. They would go through rounds,
16 every chemical has to be evaluated every 15 years and
17 then the next 15 years it happens again, and then there's
18 more active ingredients by that time, that's why most of
19 our decisions are considered to be interim decisions as
20 opposed to final decisions, because there -- sometimes
21 there are issues that we can't make judgments on.

22 JUDGE BIRO: Let's say you issued on December
23 31 a registration that narrowed, the use of DCPA, and
24 would AMVAC have to wait basically 15 years to get that
25 reevaluated?

1 THE WITNESS: So, after we issue the interim
2 decision, we generally do not open that decision again,
3 but what often happens is before they enter a decision
4 there is a proposed interim decision, and it forecasts
5 what we think we're going to do in terms of registration,
6 such as eliminating uses, or lowering application rates,
7 or people wear protective equipment. So, what will
8 happen is when the registrant finds that those conditions
9 are not satisfactory to them. They will often come in
10 with offers to do more mitigation, or more data to see if
11 they can change the interim decision.

12 JUDGE BIRO: Okay. So, if you had gone ahead
13 and gone with conservative assessments you would have
14 been issued an interim decision, a proposed interim
15 decision, and you would have sent it to AMVAC and it
16 would have had then another chance to go back and
17 potentially say we're not happy. We would like to do
18 these studies now, because what you come up with is not
19 going to work for us.

20 THE WITNESS: Yeah, so that does happen and I
21 should say every step of the way there's a period of
22 public comments that includes the registrant. We usually
23 even tell the registrant that it's out there as opposed
24 to them just looking through our register. And so, as
25 far as what happens between the proposed interim decision

1 and the interim decision, I mean it's a judgment call.
2 If it's going to take five more years to get the data for
3 the decision were going to go ahead and make the interim
4 decision and then consider the data in the next round, or
5 if it's really, really critical, some other avenue, but
6 yeah. If it's a matter of months or maybe even a year,
7 we might be willing to hold off to get that data, those
8 data.

9 JUDGE BIRO: How about if the growers' group,
10 the farmers who buy and use DCPA came in at that point
11 and said -- you say you can't use it on onions anymore
12 and that's where we mostly use it, is that's something
13 that would affect your decision?

14 THE WITNESS: Yes, definitely. Those are part
15 of the public comments we expect to get on the proposed
16 interim decision. And usually testimonial information,
17 like I use this chemical all the time and it's really
18 great, that doesn't matter so much, but if they tell us
19 and can verify that there are no alternatives to that
20 chemical, or this is a really little niche use that has
21 high value, but you wouldn't know about it unless we told
22 you about it, that probably -- yeah, that kind of
23 information is considered. Usage data; how it's used;
24 practices that impact the risk assessment that are
25 specific to a crop that this chemical is used on; those

1 kinds of things all come into play. I mean it can also
2 happen at the risk assessment phase.

3 JUDGE BIRO: Did you receive comments in
4 connection with this DCI in this pending registration
5 evaluation from growers in this process?

6 THE WITNESS: So, nobody responded -- okay, so
7 the comment periods followed the preliminary work plan.
8 Nobody gave us comments on that. The next opportunity
9 for an open comment period would be when we publish the
10 risk assessment, which happens after we get the data and
11 often a user will see the writing on the wall, just
12 without a decision, but with the -- you know, our summary
13 of what the risks are that it's going to impact and he
14 wants us to consider this or that or the other thing.
15 That can come in after the draft risk assessment. It can
16 come in after the proposed interim decision, and yeah, if
17 it's substantive we address it either, you know, decide
18 whether we think it makes a difference, or if it makes a
19 difference, we adjust our decision.

20 JUDGE BIRO: Okay. But in this case, and nine
21 of these grower group organizations or individuals had
22 submitted any comments to EPA challenging anything
23 regarding this registration review?

24 THE WITNESS: So, the last public comment
25 period would have been on the PWP. We didn't get

1 anything, but we have gotten communications from
2 different user groups over time that say we really need
3 this chemical, and we would like to keep it.

4 JUDGE BIRO: Okay. So, outside of a public
5 period to respond, informally they have sent you
6 comments?

7 THE WITNESS: Yes.

8 JUDGE BIRO: And do you take into account
9 their informal comments?

10 THE WITNESS: Yes.

11 JUDGE BIRO: Let's see. I think you talked
12 about how the CTA has been submitted and so now -- is EPA
13 going to be able to go ahead and issue is assessment
14 based on that?

15 THE WITNESS: So, we're still missing some data
16 that are important, but for those we'd probably make the
17 conservative assumptions we talked about. So, we have
18 all of the health information we need. As I indicated
19 before, some of the data that are under the banner of
20 environmental fate actually figure into the human health
21 risk assessment and those would be the cases that we
22 would have to make assumptions about health risk in a
23 chemical is for example.

24 JUDGE BIRO: Okay. I understand that AMVAC
25 has apparently had DCIs about DCPA issued three times

1 previously?

2 THE WITNESS: That's probably correct when we
3 did the registration standard, which would have been
4 before my time. When we did re-registration that was
5 during my time but it wasn't involved in it and now. And
6 then there also would be the endocrine disruptor DCI that
7 most pesticide registrants got.

8 JUDGE BIRO: Okay. Do you have any personal
9 knowledge of those?

10 THE WITNESS: Just what I've read about them.
11 I mean I know what our scientists concluded about the
12 endocrine disruption and the others factored into the
13 decisions that followed them.

14 JUDGE BIRO: I was thinking about the process,
15 how that process went. Do you have any personal
16 knowledge of that?

17 THE WITNESS: I'm sorry. The process of what
18 now?

19 JUDGE BIRO: Of sending out that DCI and AMVAC
20 responding. Did they respond in a more timely way in
21 regard to those in comparison? That's what I'm looking
22 for.

23 THE WITNESS: I can tell you that the DCI that
24 was issued when we did our re-registration eligibility
25 decision, and that was in 1995, contained some of the

1 same data requirements that we repeated that we needed in
2 2013.

3 JUDGE BIRO: And were they done in a timely
4 manner in that case?

5 THE WITNESS: No, some of them are still
6 outstanding, and some of them were outstanding until they
7 responded to this DCI.

8 JUDGE BIRO: So, that DCI was never closed out
9 but a NOITS was never issued in connection with it?

10 THE WITNESS: Right.

11 JUDGE BIRO: And how about on this other
12 dates. I think there were two others. One was in 81 and
13 then there was another one. Do you know?

14 THE WITNESS: The other DCI's?

15 JUDGE BIRO: Yeah.

16 THE WITNESS: You know, I probably knew at one
17 time but I haven't looked at them in a while. So, I
18 don't know. All I know is there were data requirements
19 that weren't satisfied in earlier DCI's that we required
20 again with this DCI, because we still needed it.

21 JUDGE BIRO: Okay. Bear with me one minute.

22 Okay. I don't think I have any more questions
23 to ask at this point. Mr. Pittman, do you have any
24 questions you would like to ask in response to mine?

25 MR. PITTMAN: No, Your Honor.

1 JUDGE BIRO: Okay. Mr. Weinberg, do you have
2 any questions you would like to ask?

3 MR. WEINBERG: Your Honor, I have no questions.
4 I would like to just make one brief comment, and that is,
5 it is very important that you analyze these issues to
6 recognize that there is a substantial difference between
7 the human health issues and the studies in the human
8 health issues and the environmental fate issues; and the
9 assumptions, and the risks, and the decisions that were
10 being made there, what the issues were. We'll talk more
11 about that tomorrow.

12 JUDGE BIRO: You can put it in your brief and
13 I'll read it, you know, as I'm making my decision. Ms.
14 Rose, do you have any questions in response to my
15 questions?

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

17 JUDGE BIRO: Okay. Do you want to reserve the
18 right to call Ms. Bloom again?

19 MR. PITTMAN: Can I have one moment to discuss
20 with counsel?

21 JUDGE BIRO: Oh, of course.

22 MR. PITTMAN: Your Honor, Respondents position
23 would be to release Ms. Bloom at this time.

24 JUDGE BIRO: Lucky you Ms. Bloom.

25 THE WITNESS: Does that mean I'm not needed

1 tomorrow?

2 JUDGE BIRO: You are not going to be called
3 back.

4 THE WITNESS: Okay. But I might be called back
5 later?

6 JUDGE BIRO: No. You're not going to be
7 called back later.

8 THE WITNESS: Oh, okay.

9 JUDGE BIRO: You are released, but you still
10 can't discuss your testimony with anybody who has any
11 connection to this proceeding.

12 Thank you very much. Have a good evening.

13 THE WITNESS: Thank you, Your Honor.

14 JUDGE BIRO: Are there any other exhibits that
15 you want to move into evidence that we discussed in this
16 process?

17 MR. ROSS: There are, Your Honor, but there are
18 probably about ten of them by my account that fall into
19 three categories. Mr. Pittman and I can probably confer
20 and work that out quickly, or we can handle it tomorrow
21 morning if Mr. Pittman is amenable.

22 JUDGE BIRO: Maybe you could just send him an
23 email tonight and you can look it over and get back to
24 it.

25 What time can we start tomorrow? Can we start

1 at 9:00, 8:30, 8? I get here at 6:30, so I am happy to
2 accommodate however early you would like to start.

3 MR. PITTMAN: Your Honor, we would request
4 9:00. Co-counsel lives in Baltimore. It is a little
5 dicey getting in on the MARC early sometimes.

6 JUDGE BIRO: Okay. Let's start at 9:00
7 tomorrow.

8 Thank you very much. We stand in recess.
9 (Whereupon, at 5:19 p.m. the above-entitled matter was
10 recessed to reconvene on Wednesday, January 25, 2023 at
11 9:00 a.m.)

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REPORTER'S CERTIFICATE

BEFORE THE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

IN RE: FIFRA SECTION 3(c)(2)(B) NOTICE OF INTENT TO
SUSPEND DIMETHYL TETRACHLOROTEREPHTHALATE (DCPA)
TECHNICAL REGISTRATION

AMVAC CHEMICAL CORPORATION; GROWER-SHIPPER ASSOCIATION OF
CENTRAL CALIFORNIA; SUNHEAVEN FARMS, LLC, ; J&D PRODUCE;
RATTO BROS, INC.; AND HUNTINGTON FARMS,

Petitioners-Appellants.

DOCKET NUMBER: FIFRA-HQ-2022-0002

Date: January 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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