UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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; J&D Produce; Ratto Bros., Inc.; and Huntington Farms, Petitioners.	)	**Docket No. FIFRA-HQ-2022-0002**

PETITIONER AMVAC CHEMICAL CORPORATION'S
POST-HEARING BRIEF

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INTRODUCTION

On April 28, 2022, Respondent Office of Pesticide Programs ("OPP") published a Notice of Intent to Suspend ("NOITS") a DCPA technical registration belonging to AMVAC Chemical Corporation ("AMVAC") and thereafter moved for an Accelerated Decision based on a narrow and erroneous interpretation of 7 U.S.C. § 136a(c)(2)(B)(iv) (the "Suspension Provision"). OPP's argument was that a registrant can be suspended solely for not submitting data deemed acceptable by OPP by the initial deadline set in a Data Call-In ("DCI"). This legal theory was rejected by the Environmental Appeals Board ("EAB"). Decision and Remand Order, EAB Docket ("Dkt.") 11 (Sept. 28, 2022) ("Remand Order").

In addition to OPP's initial legal theory having been rejected, several facts that OPP suggested were the basis of and/or motivation for the NOITS have now changed. OPP's most prominent explanation for issuing the NOITS was that OPP was unable to move forward with its human health risk assessment because it needed additional data on thyroid effects.[1] Notably, this assertion was a complete reversal of its prior statement to AMVAC in October of 2020: that OPP could and would proceed with that assessment. Joint Exhibit ("JX") 21 p. 1 of 6. OPP had not revealed its reversal to AMVAC during the intervening year and a half.

The study OPP belatedly asserted that it could not proceed without – the Comparative Thyroid Assay ("CTA Study") – was near completion at the time of the NOITS, and it was submitted in June of 2022 – just as AMVAC had consistently told OPP was the schedule since August of 2021.[2] The CTA Study was novel and complex – requiring a significant number of preliminary studies and protocol development, which took eight years to complete, during which time AMVAC worked closely with OPP and OPP's received regular updates on progress and

[1] Joint Exhibit ("JX") 1 p. 1 of 29; JX 2 p. 2 of 5.
[2] Petitioner AMVAC's Exhibit ("PAX") 95, Jonynas Statement ¶¶ 134-144.

expected submission dates.[3] This was part of the ongoing dialog AMVAC was having with OPP in connection with the DCI. Eight months after issuing the NOITS, OPP determined, in December of 2022, that AMVAC had satisfied the CTA Study data requirement. Respondent's Status Report and Joint Stipulations, Dkt. 44 ¶ 10 (Dec. 23, 2022). OPP's Team Leader, Ms. Bloom, admitted during testimony at the hearing that, with the CTA data in hand, OPP intends to proceed with its risk assessments. Hearing Transcript ("TX") 242:11-18. A second fact that OPP alluded to in an apparent attempt to justify the NOITS was the existence of an October 2022 statutory deadline for registration review. But this deadline was extended by Congress to October 2026, and the EAB confirmed that the deadline was irrelevant to the statutory inquiry anyway, as AMVAC had urged.

Finally, the number of data requirements that OPP continues to assert as basis for the NOITS has been more than halved since the issuance of the NOITS: from 20 data requirements (out of a total of 74 in the DCI)[4] to nine at the time of post-hearing briefing.[5] All the remaining data requirements on which OPP seeks suspension are ones for which AMVAC sought waivers during the course of the DCI. Studies addressing the remaining nine are well underway, and study reports are scheduled for submission later this Fall.[6] None of the studies currently underway are necessary for OPP to move forward with the risk assessment process as OPP stated it would do in October of 2020. TX 242:11-18.

Despite all the foregoing developments, OPP nevertheless pushes on to suspend

[3] *See generally*, PAX 95, Jonynas Statement ¶¶ 9-147.
[4] PAX 93, McMahon Statement, Ex. B, p. 15 of 15; JX 2 p. 3 of 5.
[5] *See* Respondent's Status Reports at Dkt. 44 (deeming CTA Study data requirement satisfied and indicating that OPP would no longer pursue suspension in connection with six others) and 53 (stating that OPP would no longer pursue suspension in connection with four others).
[6] PAX 93, McMahon Statement Ex. B, ¶¶ 37-42.

AMVAC's technical registration – without supplementing any of its witnesses' direct testimony after its initial legal theory was rejected – for no apparent reason other than OPP's counterfactual and ahistorical assertion that the scientific dialogue regarding waivers between AMVAC and OPP was not appropriate. The record well establishes, as discussed in Section I.A., that iterative discussions of the type here were standard in DCI responses, and that a registrant would interpret a first recommendation to deny from the Environmental Fate and Effects Division ("EFED") as perhaps the end of the first round of dialog, but not the end of the discussion. The lack of a clear communication from OPP's Pesticide Reevaluation Division ("PRD") to AMVAC stating that PRD would entertain no further discussion of waivers – something PRD could have communicated with a quick email at any point during the DCI – is glaring against the backdrop of PRD and EFED's continued *participation* in that discussion, even up to the time of the NOITS at which EFED recommended that several additional waivers be granted..

Also, as discussed in Section I.B., OPP also represented to AMVAC in October of 2020 that OPP could and would proceed with risk assessment, using conservative assumptions where it lacked data. This was exactly what AMVAC had urged it to do. The appropriateness of AMVAC's conduct in continuing to wait for decisions on waivers must be judged in view of its reasonable belief that OPP was moving forward to complete the risk assessments as OPP had stated it would do. AMVAC nonetheless provided additional support for its waiver requests after this statement from OPP, even though OPP appeared to be ready to act based on the essential premise of AMVAC's waiver requests. In view of these facts, all OPP might fall back on is essentially a *res ipsa* argument – *i.e.*, look how long the DCI took, there must be inappropriate conduct in there somewhere. But any argument along those lines is negated both by the substance of AMVAC's waiver requests, and by observing the tremendous amount of

delay introduced into the process by OPP's own lapses in reviewing and transmitting documents to AMVAC. AMVAC's waiver requests, and OPP's delays in connection with each of the three groups of data requirements still at issue, are discussed in detail in Section I.C.

OPP now pivots to a new legal position on the Suspension Provision that involves creation of a new set of rules. Neither AMVAC, nor any other registrant, could possibly have been aware of these rules, even as general principles, prior to OPP's Prehearing Brief in this matter. OPP's new proposed rule is that the deadline for submitting data is deemed to be extended one-time from the date a first "denial" of a waiver request is transmitted to the registrant, for a duration equal to the original "Time Frame" listed in the DCI for the data requirement at issue. OPP posits that a registration may validly be suspended if this once-extended time frame lapses, regardless of other appropriate steps a registrant may have taken. OPP Prehearing Brief ("OPP Ph'g Br."), Dkt. 48 at 3 n.1, 5 (Jan. 6, 2023). This proposed position is a completely novel theory: unknown to registrants throughout the course of the DCI program; wholly unsupported by OPP's witnesses; and at odds with the course of conduct between OPP and AMVAC during the DCI.

In rejecting OPP's initial legal theory for issuing the NOITS, the EAB clarified that whether a registrant failed to "take appropriate steps" "within the time required by the Administrator" can only be determined based on a facts-and-circumstances inquiry into the course of conduct between OPP and the registrant (and the typical practices of DCIs at the time). Remand Order at 790.[7] OPP's new legal position is wholly inconsistent with this standard

[7] AMVAC briefed the meaning of the phrases "failed to take appropriate steps to secure the data required" and "within the time required by the Administrator," as used in the Suspension Provision, in Sections II and III of its Prehearing Brief, Dkt. 52, and incorporates that briefing by reference here.

because it turns on mechanical timing rules, not he inquiry required by the EAB. OPP's shifting position on the basis for the NOITS raises larger concerns about what standard it was even applying when it issued the NOITS and whether its NOITS-in-search-of-a-legal theory can stand.

This proceeding is not the appropriate vehicle for OPP to announce a new, retroactive policy for evaluating registrants' responses to DCIs, or to attempt to improve the overall administration of its DCI program. If OPP wishes to redefine how it operates its DCI program, it may apprise the registrant community by appropriate means of the relevant changes. But it cannot succeed in what it seeks to do here – apply its new legal position retroactively in this proceeding to impose a draconian suspension remedy on AMVAC that would jeopardize growers' access to a vital crop protection product. AMVAC refers the Presiding Officer to the brief of the Grower Petitioners for a more fulsome discussion of the impacts that an interruption in DCPA supply would have on growers and domestic agriculture more broadly.In short, there is no question that AMVAC acted appropriately and reasonably in view of the course of conduct established by OPP for this DCI and others during the same time frame. AMVAC was – at all times – conducting and submitting required studies, supporting waivers, and engaged in what it understood to be, and what in fact was, an ordinary and typical scientific dialog with OPP.

Section I of this brief discusses the evidence adduced at the hearing. Sections I.A. and I.B. discuss the evidence related to the course of conduct of the DCI generally. Section I.C. discusses the nine remaining data requirements at issue (in three groups) and explains why the evidence supports the conclusion that AMVAC took appropriate steps at all times. Section II discusses why OPP's newly proposed legal theory is incorrect. Section III discusses why, in the event of a suspension, a limited component of OPP's proposed existing stocks order is inconsistent with FIFRA in light of the facts presented in this case.

I. PROPOSED FINDINGS BASED ON EVIDENCE AT HEARING

As discussed below, the course of conduct of this DCI, which has been typical of other DCIs during the relevant time frame, was that there was an ongoing scientific dialog between AMVAC and OPP with no clear "time required" by which AMVAC had to submit data. The evidence relating to the course of conduct of this DCI (discussed in Sections I.A. and I.B. immediately below) supports the conclusion that the steps taken by AMVAC have been appropriate throughout its response to the DCI. Those steps are discussed in detail with respect to the few remaining data requirements at issue in Section I.C.

A. OPP Followed its Typical Approach of Scientific Discussion

The course of performance of this DCI amply establishes that OPP was engaged in an ongoing dialog with AMVAC in connection with this DCI. Within this course of conduct, OPP documents which stated that they were EFED "recommendations" to deny a waiver were part of an ongoing discussion rather than indications that OPP as a whole, or EFED or PRD specifically, would not engage in further dialog and review of additional information. This is evidenced by the timeline of the documents themselves and the fact that OPP continued reviewing and responding to additional information provided by AMVAC. Much of OPP's cross examination focused on whether an AMVAC employee understood that an EFED document recommending that PRD deny a waiver request was an indication from the Agency that a waiver was not being granted in that document. *E.g.*, TX 265:14-19 (McMahon/environmental fate); TX 317:10-14 (Freedlander/*Leptocheirus*). These inquiries miss the point. Under the correct course-of-conduct analysis, it is not important if an AMVAC employee should have or did understand a particular document to be a "denial," or an EFED recommendation that PRD deny: what is important, in view of the typical course of conduct established at the hearing, is whether or not a document

would have alerted AMVAC that any further scientific dialog was being foreclosed.

While the focus of the hearing was on AMVAC's actions with respect to the few data requirements still at issue, evidence from AMVAC's witness statements and the record concerning studies that are no longer at issue is also relevant to examining the broader course of conduct of the DCI. This broader course of conduct is, in turn, relevant to the appropriate steps inquiry for the remaining data requirements.

Specifically, the existence of the ongoing dialog (and the arbitrariness of the NOITS timing) is demonstrated by the fact that EFED recommended granting seven waivers concurrently with the NOITS in the very same documents in which it recommended denying those remaining at issue. JX 69 p. 2 of 24 (recommending grant of six waivers) and JX 79 pp. 6-7 of 12 (recommending grant of one). All of these data requirements were subject to discussions very similar – in some cases *identical* – to discussions in connection with data requirements OPP still asserts as a basis for suspension. Of the six waivers recommended to be granted in JX 69, all but one (the final bullet on JX 69 p. 2 of 24) were the topic of *the same* waiver support documents and responses relevant to the TPA Ecotoxicology studies still at issue (discussed in Section I.C.1, below).[8] The waiver recommended to be granted in JX 79 followed a timeline very similar to those ultimately recommended for denial and discussed in Section I.C.3, below.[9]

The only thing distinguishing the seven waivers recommended for grant in these

[8] In short, JX 5 (initial request and support); JX 66 (initial recommendation not to grant with *Daphnia* proposal); JX 67 (AMVAC response/acceptance of *Daphnia* proposal); PAX 91 (submittal of chronic *Daphnia* data in August 2020); JX 21 (reference to recommendation to deny in EFED correspondence predating submittal of *Daphnia* data); JX 22, PAX 45 (AMVAC response); JX 69 (EFED split decision on waivers concurrent with NOITS).

[9] In short, JX 5 (a request to waive or cite existing data); JX 66 (initial EFED recommendation to deny); JX 67 (additional information submitted); JX 21 (reference to recommendation to deny in JX 66 without mention of JX 67); JX 22 (additional supporting data submitted in December of 2020 by AMVAC with a report (AMVAC Report No. 100-REV-047, MRID No. 51398101)).

examples from those recommended for denial is whether EFED concurred, as a scientific matter, with AMVAC's assertion that the data would not be useful for risk assessment. *See generally*, Sections I.C.1 and I.C.2, below; JX 69 at p. 6-16 of 24; JX 79. AMVAC does not dispute that OPP has the final say on whether or not a waiver is granted. TX 346:9-19. But whether a waiver is granted is not dispositive of whether the request for a waiver, and the support provided for it, were meritorious and constituted appropriate steps. A registrant can (and AMVAC submits it did here) fully comply with the "appropriate steps" standard even if a waiver request is ultimately denied by OPP. An OPP denial of a waiver (be it an EFED recommendation or PRD's action on that recommendation) does not render the prior conversation inappropriate.

OPP and AMVAC's actions regarding data requirements in the DCI, other than those still at issue, are also critical in establishing another key element of the course of conduct of this DCI: that extension requests were not required. AMVAC submitted an extension request early on in the conduct of this DCI, in connection with a data requirement that OPP has abandoned as a basis for suspension and to which no response was ever received. JX 53. The evidence at the hearing also supported that it was typical for OPP not to require formal extension requests. Petitioner AMVAC Exhibit ("PAX") 97, Gur Statement ¶¶ 33-38. OPP provided no contrary testimony in witness statements or at the hearing. The frequent correspondence in connection with the CTA Study – also no longer at issue – also supports that there was no expectation of formal extension requests. PAX 95, Jonynas Statement ¶¶ 31, 32, 57, 82, 105, 134 (n.3).

PRD could have advised AMVAC at any time that, in view of a recommendation from EFED, it was finally denying a waiver and would entertain no further attempts to justify one. But PRD **never** did. TX 56:6-9, 21-24 (Ms. Wendel confirming that PRD determines whether to grant waivers, but she has never seen such a document); TX 102:12-20 (Dr. Wente discussing

that PRD makes the final determination and sometimes disagrees with EFED as to the necessity of data). PRD was not even obligated to pass along AMVAC's further waiver justifications to EFED and/or HED for review. TX 40:5-23 (Ms. Wendel indicating that PRD could "elect not to forward [registrant submissions] to EFED because no action was required on them[.]"). Thus, if PRD wished to end the discussion, it need not even have sought concurrence from EFED to do so. TX 117:9-15 (Dr. Wente testifying that EFED has historically "cavalierly" told PRD whether to require a study or not but that it "at some point became a problem that, you know, EFED was not – it became understood that EFED was not supposed to be telling PRD what to do.").

AMVAC provided written fact and expert testimony that a scientific dialog of the nature that occurred here is typical, PAX 97, Gur Statement ¶¶ 48-49, and that the only part of this matter that is "unprecedented [is] for [OPP] to issue a NOITS at the same time that it provides EFED's conclusions regarding certain waivers as occurred here[.]" PAX 94, Freedlander Statement ¶ 117; *see also* TX 305:10-16; 410:6-20 (discussing iterative nature of process). OPP provided no testimony supporting that it directly advised, or in any way indicated to AMVAC, that it was breaking from its typical practices in connection with this DCI. To the contrary, as discussed in the next section, OPP explicitly (and unreservedly) stated that it would proceed to perform risk assessments with the data that it had. This was also a typical step that contributed to AMVAC's understanding that it was engaged in an ongoing scientific dialog with OPP that would continue after the risk assessments were complete.

OPP took other actions which further confirmed and defined the scientific dialog relevant to three categories of remaining data requirements discussed in Sections I.C.1, 2, and 3, below. To avoid duplication, those actions are discussed primarily in the corresponding sections below.

B. AMVAC Reasonably Expected OPP to Complete Promised Risk Assessments Before Making Final Decisions on Waivers

The propriety of AMVAC's conduct in continuing to wait for decisions on waivers after October of 2020 can only be properly judged in view of OPP's statement to AMVAC in October of 2020 that OPP was working to complete the risk assessments and would use conservative assumptions – just as AMVAC had urged it to do. As discussed in the following sections, OPP informed AMVAC in October of 2020 that it was proceeding with risk assessments with the then-available data and would complete those risk assessments in June of 2021. JX 21 p. 1 of 6. AMVAC thus reasonably would have expected OPP to conduct these assessments, after which OPP would reach final decisions on pending waivers, consistent with typical OPP practice. Testimony at the hearing confirmed that OPP subsequently became concerned that it could not complete a human health risk assessment until after AMVAC submitted additional CTA data. But instead of notifying AMVAC of this, OPP began preparing the NOITS in which it would first reveal its updated assertion. This was a fundamental departure from the approach OPP communicated in JX 21, and from OPP's typical practice. The fact that OPP made an abrupt about face (without telling the registrant prior to the NOITS) does not create or further an inference that AMVAC's conduct was inappropriate.

1. *OPP Clearly Stated That It Could and Would Conduct Risk Assessments Even Absent Additional Data in October 2020*

OPP's statement to AMVAC in October 2020 was short, clear, and unqualified. OPP stated that it "expects to complete the draft risk assessments in June 2021." JX 21 p. 1 of 6. Although OPP noted that there was outstanding data at the time, OPP stated that it would "rely upon data available at the time when the risk assessments are being developed [and w]here the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments." *Id.* At the hearing, Ms. Wendel confirmed that this was an accurate statement of EFED's ability to complete the risk assessments as of October 2020, TX 82:22-83:8. No

testimony was provided that would suggest AMVAC would have had a reason to question – in October 2020, or at any point until after the NOITS was issued – whether OPP was proceeding with a risk assessment while certain ecotoxicology and environmental fate data requirement waivers remained pending.

Moreover, unrebutted testimony established that it was typical OPP practice to do this, TX 327:12-16 (Freedlander), and that OPP did not need or expect AMVAC's concurrence regarding the use of conservative assumptions to proceed. TX 232:7-17 (Bloom); TX 411:18-22 (Gur). Ms. Bloom also corroborated Mr. Gur's testimony that often "data requirement[s] [are] driven by the results of a risk assessment," provided that the Agency can complete an initial assessment using conservative assumptions, and that the Agency might refine its analysis based on later-submitted data. PAX 97, Gur Statement ¶¶ 41, 48; TX 400:7-24 (Gur); TX 239:12-240:8 (Bloom: "If it's a matter of months or maybe even a year, we might be willing to hold off to get [additional] data [after publication of a post-risk assessment interim decision.]"). Mr. Gur testified that he would not have expected OPP to act further on waivers before publishing a risk assessment based on the facts of this matter. TX 445:24-447:5.

2. *OPP's Unspoken Concern That It Could Not Complete Risk Assessments Was Related Solely to Preliminary CTA Results Submitted by AMVAC in 2021*

The hearing revealed that OPP apparently meant what it said in October of 2020 – that it could proceed to conduct risk assessments – but that an intervening event changed OPP's view and that OPP did not disclose this to AMVAC until OPP published the NOITS in April of 2022. As Ms. Bloom confirmed, this intervening event was AMVAC's submittal, in May of 2021, of preliminary data from a CTA range finding study. TX 233:20-24 ("Judge Biro: Right. So, was there something that happened or didn't happen that triggered that re-evaluation? [Ms. Bloom]:

Yes. AMVAC submitted preliminary data."); PAX 95, Jonynas Statement ¶ 124 (regarding submittal of CTA range finding data). Ms. Bloom later reconfirmed that the issue of concern identified in the preliminary CTA data was the only basis on which OPP believed that it could not proceed with risk assessments as it had communicated in October of 2020. TX 242:11-17.[10] Ms. Bloom also confirmed that AMVAC was not notified at any point between October 2020 and April 2022 about OPP's new position that it could not proceed with risk assessment. TX 234:22-235:4; *see also* TX 109:19-110:6 (Dr. Wente unaware of pre-NOITS communication about inability to perform risk assessment).

OPP could easily have informed AMVAC of its newfound concern, but failed to do so. OPP and AMVAC were in frequent contact concerning the CTA study between October of 2020 and April of 2022. *E.g.*, PAX 95, Jonynas Statement ¶¶ 124-141 (discussing conversations related to the CTA study and related data and submissions between May of 2021 and February of 2022). And OPP had analyzed the preliminary results in sufficient detail to enable it to comment on the definitive study protocol in July of 2021. *Id.* ¶ 133; PAX 34. By remaining silent about its concern, OPP deprived AMVAC of any ability to respond. AMVAC's conduct must be judged based on OPP's statements that it would be proceeding with risk assessment, making certain conservative assumptions as necessary, not on the basis of now-identified interim agency conclusions that were directly contrary to what OPP had told AMVAC.

[10] Judge Biro: I think you talked about how the [definitive] CTA has been submitted and so now -- is [OPP] going to be able to go ahead and issue [its] assessment based on that? [Ms. Bloom]: So, we're still missing some data that are important, but for those we'd probably make the conservative assumptions we talked about.

C. AMVAC's Waiver Requests Constituted Appropriate Steps

The EAB confirmed that whether a step was appropriate is a "factual inquiry" and that analysis under the standard "naturally and traditionally includes consideration of all the relevant factors," including course of performance and typicality. Remand Order at 790. Neither the NOITS nor the Federal Register notice publishing the NOITS makes any specific allegations concerning how AMVAC's waiver requests were not appropriate under this standard. The NOITS merely recites when various documents were exchanged. JX 1, Attachment III, pp. 8-29 of 29. The Fed. Reg. notice asserted only that AMVAC had "fail[ed] to submit these data or to take other appropriate steps to secure the required data." JX 2 p. 2 of 5.[11] OPP's witness testimony provides no support for an essential element of OPP's case in view of the EAB's decision: that AMVAC's waiver requests were inappropriate in the context of AMVAC's interactions with OPP on this DCI, against the backdrop of typical DCI practices and "all . . . relevant factors." Remand Order at 790. It bears repeating that waiver requests are explicitly provided for as an option on OPP's own DCI forms, *see* JX 4 at pp. 6, 15, 38 of 46, and they are intended to avoid needless investments of time and energy on the part of both the registrant (in conducting an unneeded study) and OPP (in reviewing one).

OPP's written witness statements (which were not updated following the EAB decision) contain only a single specific assertion as to why one individual AMVAC waiver request (in connection with a single data requirement) was not appropriate in the context of this DCI. *See* Respondent OPP's Exhibit ("RX") 25, Wendel Statement at 3-8 (no specific allegations

[11] An incremental additional detail about OPP's allegations in the Fed. Reg. notice, that certain of AMVAC's 90-day responses were allegedly "inadequate," was later revealed to be an "error resulting from the NOITS form submitted to the Federal Register" and that claim was "not a factual basis for the NOITS." *See* OPP Opp'n to AMVAC Mot. for Add'l Discovery, Dkt. 38 at 2 n.1.

concerning 5 TPA Ecotoxicology studies); *id.* at 9 (none concerning *Leptocheirus*); RX 26, Wente Statement at 5-7 (asserting that in connection with one study only (Guideline 835.4300), an AMVAC submission did not "provide any new or additional evidence")[12]; RX 27, Bloom Statement p. 6 of 10 (not addressing specific waiver requests; asserting only that AMVAC's actions were "abnormally dilatory and repetitive" and that in some cases AMVAC "provided rationales similar" to prior requests or "simply opposed the Agency's denials[.]"). OPP itself disavowed that Ms. Bloom's allegations constitute a factual basis for the NOITS. OPP Opp'n to AMVAC Mot. for Add'l Disc., Dkt. 38 at 19 (Oct. 31, 2022). OPP provided no expert testimony on the issue of appropriateness, or otherwise. OPP's claim appears to boil down to an insistence that, given the overall duration of the DCI response and the fact that AMVAC maintained a consistent position (*i.e.*, that certain waivers were appropriate) throughout a scientific dialog with OPP, impropriety must lurk somewhere. AMVAC asserts that OPP thus failed to establish a prima facie case that AMVAC's actions were inappropriate.

Even if the Presiding Officer were to conclude that OPP's generalized allegations could establish a prima facie case, that case was rebutted by the testimony of AMVAC's fact and expert witnesses, who together explain why AMVAC's actions as to each category of data requirements (and each individual requirement) still at issue were appropriate in the context of the DCI. Sections I.C.1, 2, and 3 below address each group of data requirements in turn.

[12] *See* Section I.C.3.b for a specific discussion of this allegation.

1. *The Five TPA Ecotoxicology Data Requirements*

As of the date of the hearing, this group included the Guideline 850.1400 Fish ELS (for three species), 850.1350 Chronic Mysid, and 850.4500 Algal Toxicity (for the marine diatom only) for DCPA degradate TPA.[13] As discussed in the following sub-sections, the testimony confirmed that AMVAC followed a testing plan explicitly suggested by OPP, the results of which OPP first responded to concurrently with the NOITS. OPP also contributed significantly to the duration of the overall time frame in connection with these data requirements by failing to timely forward certain documents and by waiting more than seven years to advise AMVAC of its analysis of studies submitted by AMVAC in 2014.

a. AMVAC Followed a Plan Laid Out by OPP

The evidence shows that AMVAC undertook a specific limited testing plan suggested by EFED in a document provided to AMVAC in March of 2017 – to conduct acute and chronic studies of *Daphnia magna* – which EFED stated would enable it to reconsider granting waivers for the data requirements in this group. AMVAC was therefore clearly not submitting additional duplicative waivers (in JX 67), it was agreeing to – and did – follow the specific approach suggested by OPP.

AMVAC submitted the final *Daphnia* study prior to receiving the so-called "Data Delay Letter," JX 21, and followed up with a full report and additional analysis shortly thereafter. JX 22, PAX 45 (Dec. 2020). Written factual and expert testimony on this issue was provided in PAX 94, Freedlander Statement ¶¶ 8-44, and PAX 97, Gur Statement ¶¶51-56, respectively. AMVAC's acceptance of EFED's suggestion to provide the *Daphnia* data as a first step was

[13] New 850.4500 Algal Toxicity data (for the marine diatom only) was submitted to OPP on March 17, 2023, after the hearing, and assigned MRID 52122002. OPP has not yet indicated whether it continues to pursue suspension based on this data requirement.

clearly appropriate. The only impropriety with respect to these data requirements came when OPP short-circuited the process it had proposed by issuing the NOITS at the same time it provided its review of the *Daphnia* data.

OPP's testimony at the hearing corroborated the facts presented by AMVAC's witnesses. Ms. Wendel, an EFED Ecological Risk Assessor, confirmed that OPP knew that AMVAC had accepted OPP's suggestion to perform the *Daphnia* studies, only after receipt of which EFED would make a further determination concerning additional data, TX 57:25-58:23, and that EFED's proposal related to all the studies in this category. TX 56:25-57:5; 60:18-21. Ms. Wendel also confirmed that AMVAC submitted the data requested by EFED along with a separate analytical writeup, TX 59:8-16; 60:14-17.[14] Significantly, Ms. Wendel did not assert that there was anything deficient with the data submitted or the write up.

In sum, the hearing testimony confirms that AMVAC was proceeding reasonably along a course **laid out for it by OPP** – a course that OPP deviated from when it issued the NOITS at the same time that it provided its response on the waivers in view of the *Daphnia* data. Moreover, as discussed in the following section, OPP was responsible for substantial amounts of delay in connection with this category of data requirements. This undercuts any basis for a finding that AMVAC acted inappropriately merely because of the overall duration of the DCI as to these data requirements.

[14] Ms. Wendel also confirmed that a document she referred to in her testimony as a 2014 waiver request from AMVAC was in fact an EFED response provided to AMVAC in 2017. TX 51:19-22.

b. EFED's 2022 Recommended Denial Was Based on Data Submitted in 2014

OPP was responsible for substantial delay in connection with the data requirements in this category. After AMVAC timely filed its 90-day response, JX 5, AMVAC was not provided with EFED's internal memo to PRD recommending denial of its waiver requests and proposing the limited testing strategy discussed in the preceding section (JX 66) until March 2017, 47 months later. This delay was all attributable to OPP. Thirty-three (33) months elapsed between the date on the EFED memorandum and the date it was provided to AMVAC by PRD. *See* PAX 94, Freedlander Statement ¶¶ 101; Court Exhibit ("CE") 1, Joint Stipulated Facts ¶ 8;[15] and PAX 94, p. 29 of 33, Freedlander Ex. A (TPA Ecotox timeline). OPP similarly was responsible for the time period between when the *Daphnia* data and associated analysis was submitted (August and Dec. 2020) and when EFED's analysis of the *Daphnia* data was provided, concurrently with the NOITS (April of 2022) – an additional 20 months. *See* PAX 94, p. 29 of 33, Freedlander Ex. A (depicting the relevant timeline); PAX 91 (submission of data in August 2020); JX 88 p. 1 of 15 (DER for MRID 51235101, indicating EFED contractor had completed initial review in January of 2021).

OPP also is responsible for overall delays to the process in the time period keyed as blue in Freedlander Ex. A. As Ms. Wendel confirmed, EFED's ultimate recommendation against granting waivers for these five data requirements rested on information that EFED had had in its possession since 2014. JX 69; TX 64:4-16 (concern regarding 850.1350 Chronic Mysid based on MRID 49307512); TX 64:17-65:1 (concern regarding 850.1400 Fish ELS based on MRID 49307520 and earlier EDSP studies); TX 65:14-25 (concern regarding 850.4500 marine diatom based on MRIDs 49307504, 51499401 and 51499402).

[15] JX 37 is a duplicate of JX 66, JX 38 is a duplicate of JX 32, and JX 39 is a duplicate of JX 74.

MRID 49307512 was initially submitted by AMVAC in 2014. JX 27; TX 68:6-12. Ms. Wendel confirmed that EFED had the DER for MRID 49307512 from their contractor, CDM Smith/CSS Dynamac, in hand by at least February of 2018, when AMVAC communicated its acceptance of EFED's proposal to conduct the *Daphnia* data. TX 69:17-24. But the DER was not reviewed by Ms. Wendel for almost three years (until December of 2021). JX 82. Similar Agency delays are documented by the record as to the other data requirements in this category. *See* JX 51; TX 70:23-71:6 (MRID 49307520, returned to OPP from contractor in 2017 at the latest); DER, Acute Toxicity of DCPA to Algae, EPA-HQ-OPP-2011-0374-0027; TX 72:4-10 (MRID 49307504). Remarkably, Ms. Wendel testified that a seven-year delay in finalization of a study evaluation (DER) by EFED personnel is "not uncommon." TX 69:4-11.

This timeline reveals that EFED already had the information on which it would ultimately rely to recommend against granting the waiver in hand during the entire time AMVAC was executing the *Daphnia* testing strategy suggested to it by OPP in JX 66. EFED (or PRD) could have, but did not, advise AMVAC that the strategy proposed by EFED in JX 66 would no longer potentially lead to a grant of waivers for the studies in this category, based on data submitted in 2014, three or more years before AMVAC ultimately received EFED's conclusions in JX 69 in April of 2022, concurrent with the NOITS. TX 72:14-19.

2. *DCPA Leptocheirus*

This section discusses a single data requirement, identified as SS-1072, for chronic lifecycle testing of *Leptocheirus plumulosus* exposed to DCPA. Written factual and expert testimony on this issue was provided in PAX 94, Freedlander Statement ¶¶ 86-116, and PAX 97, Gur Statement ¶¶ 57-62, respectively. Written testimony from OPP's witness on this data requirement, Ms. Wendel, contained no explanation of why AMVAC's waiver requests or other

actions were not appropriate.

As discussed immediately below, the testimony confirms that AMVAC only sought a waiver after its contract laboratory expended significant effort to finalize a protocol capable of satisfying the data requirement and only after other registrants had experienced the same difficulties running the study. AMVAC then provided a well-supported waiver request and an additional document containing further support for its request shortly after it received EFED's initial recommendation to deny the waiver request. But OPP never reviewed the additional document and omitted it from the NOITS and from the written testimony of its witness, even though the witness admitted having seen it prior to the NOITS as discussed in Section I.C.2.b, below. Finally, as discussed in Section I.C.2.c., below, AMVAC's request that OPP issue a DCI for an alternate study (not identified in the DCI at issue here) proposed by EFED, or inform it when study validation issues were resolved, were also appropriate.

a. AMVAC Acted Appropriately to Conduct the Study and to Support a Waiver

AMVAC initially attempted to conduct the study, and, along with all other registrants at the time, encountered substantial difficulty. PAX 94, Freedlander Statement ¶¶ 89-93. Ms. Wendel agreed that AMVAC only requested a waiver after its contract laboratory experienced severe difficulties running the study, TX 73:7-11, and that those difficulties were not specific to AMVAC. TX 73:12-14. She also agreed that the contract laboratory that AMVAC had retained was capable and highly regarded. TX 74:13-16.

Only after encountering these difficulties did AMVAC file a waiver request in March of 2016. JX 62, transmitting JX 73. The waiver request support document provided a summary of chronic study results for four other sediment dwelling organisms and an assessment of the relative sensitivity of relevant types of invertebrates. JX 73 at 5 of 10. *See also* PAX 97, Gur

Statement ¶ 57 (confirming that JX 73 was a "detailed technical document" which presented scientific arguments of a nature that were "typical bas[e]s on which waivers are granted"). OPP has provided no testimony that this document was in some way deficient, let alone so deficient as to not constitute an appropriate step in the context of a DCI.

OPP responded in a document dated June 27, 2016, JX 74, which AMVAC received on July 18, 2016. JX 75. Shortly thereafter (November of 2016) AMVAC provided a further document, JX 76, in support of its waiver request. JX 76 provided additional technical analyses; it can only be fairly characterized as "repetitive" insofar as it necessarily re-stated portions of AMVAC's overall basis for the waiver request for convenience so that important information would not be dispersed between multiple documents.[16] As discussed in the next section, OPP entirely ignored JX 76 without explanation and omitted any indication of its existence from the NOITS.

b. OPP Failed to Review or Respond to a Key Waiver Support Document

The additional waiver support document discussed in the prior section (JX 76) was not mentioned in the "Explanatory Appendix" (Attachment III) to the NOITS. JX 1 at 25 of 29 (skipping from a reference to JX 74 (July 18, 2016) to a reference to JX 21 (Oct. 16, 2020). This represents a material omission from the NOITS as a procedural matter. But the testimony at the hearing confirmed that OPP did not review JX 76 substantively either and thus any assertion by

[16] PAX 97, Gur Statement ¶ 59 (JX 76 contained "additional technical analyses"); PAX 94, Freedlander Statement ¶¶ 99-100 (JX 76 "necessarily re-stated some information concerning historical chronic toxicity studies" but "provided additional literature information concerning the expectation for DCPA in estuarine sediments and an assessment of the likely effect of toxicity to sediment organisms such as *Leptocheirus*"). JX 76 responded directly to OPP's proposal of the 10-day study as an alternate path (Section 2.0, not present in JX 73), provided a discussion of DCPA's overall chemical and ecotoxicological properties not present in JX 73 (Section 3.0), and included an additional section on relative sensitivity of midges and amphipods (Section 6.3) and case studies (Section 6.4) not found in JX 73. *Compare* JX 73 p. 5 of 10 *with* JX 76 p. 7 of 17.

OPP that AMVAC's conduct in connection with this data requirement was inappropriate cannot stand. There is no mention of JX 76 in JX 69, which sets forth EFED's recommendations on waivers at the time of the NOITS. *See* JX 69 (referring to JX 73, assigned identifier 100/AQU/028 at 1 and 20, but not referring to JX 76, assigned identifier 100/AQU/031). Ms. Wendel confirmed that even though she had seen JX 76 in or around December of 2020, its existence was omitted from her written testimony. TX 75:13-76:13. JX 76 had been received by OPP in November of 2016, the same month it was dated. CE 1, Joint Stipulated Facts ¶ 35. Ms. Wendel recalled that she had been involved in the creation of a "response to [a] waiver request document" but could not recall if it was JX 73 or JX 76. TX 76:11-17. After reviewing EFED's recommendation issued concurrent with the NOITS, JX 69, Ms. Wendel confirmed that it did not reference JX 76 at all and only responds to JX 73. TX 77:22-78:20 (only references JX 73); TX 79:1-3 (JX 69 does not respond to JX 76).

OPP cannot prevail on its claim that AMVAC failed to take appropriate steps in connection with the *Leptocheirus* data requirement, to the extent that the claim is premised on AMVAC's waiver requests being "repetitive" or otherwise deficient, where the evidence from the hearing confirmed that OPP never substantively analyzed or responded to AMVAC's most detailed technical support document submitted in 2016.

c. AMVAC's December 2020 Response Was an Appropriate Step in View of OPP's October 2020 Communication

In December of 2020, in JX 22, in response to OPP's October communication in JX 21, AMVAC informed OPP that it would "await a specific DCI requirement for [an additional] acute study or will wait for confirmation that the chronic study guideline has been validated." JX 22 at 2 of 5. AMVAC's decision to await the expected publication of the risk assessments in June of 2021, per OPP's statements in JX 21, without taking further action on a study, was reasonable as

discussed in Section II.B., above, because OPP had established an expected course of conduct wherein it could (and would) proceed to perform risk assessments, making conservative assumptions, without additional data. AMVAC had proposed precisely this approach in JX 76, which was still under Agency review, to the best of AMVAC's knowledge, at the time AMVAC received JX 21. JX 76 p. 6 of 17 (discussing conservative safety factor); JX 21 p. 6 of 6 (citing only JX 73 and not JX 76 as basis for denial).

It would have been reasonable for AMVAC to await the risk assessments in connection with the *Leptocheirus* study on the basis of OPP's statements in JX 21 alone. But AMVAC did more than wait for the risk assessments – it made two additional proposals to OPP. Ironically, much of OPP's attack on AMVAC's conduct at the hearing focused on AMVAC providing these two alternatives. Both of these proposals were reasonable and constituted appropriate steps, particularly against the backdrop of the Agency's communication that it was able to move forward without additional data at all.

First, AMVAC stated that it would perform an alternate study, a Guideline 850.1740 (spiked whole sediment 10-day acute toxicity test) if OPP issued a formal DCI for it. JX 22 at 2 of 5. This was in response to EFED's indication that conducting the acute study might enable the grant of a waiver, but also might not. JX 21 p. 6 of 6. The request for a formal DCI addition was reasonable and appropriate because creating a formal DCI requirement would have imposed a minor administrative burden on the Agency while substantially reducing AMVAC's risk of a potential later costly arbitration proceeding with a follow-on registrant. TX 322:19-323:16; 348:9-349:4 (Freedlander on importance of formal requirements); TX 420:11-421:14 (testimony by Mr. Gur that a formal DCI requirement is the "gold standard" in FIFRA arbitrations and the existence of one "might even avoid an arbitration").

Second, AMVAC stated that it would begin the chronic *Leptocheirus* study if OPP "confirm[ed] that the chronic study guideline has been validated." JX 22 p. 2 of 5. Ms. Wendel testified at the hearing that she did not understand the concept of "validation" as referenced by AMVAC in JX 22. TX 87:21-88:18. AMVAC would not reasonably have expected OPP to not understand the reference to validation. Mr. Gur explained the industry understanding of the term in his written testimony. PAX 97, Gur Statement ¶ 18. *See also* TX 320:1-321:14 (Dr. Freedlander explaining concept on cross-examination). OPP was clearly aware that there had been "challenges some laboratories have experienced running the chronic sediment toxicity test with *L. plumulosus*." JX 74 p. 2 of 3, as referenced in JX 21 p. 6 of 6. JX 22 therefore reasonably communicated to OPP that if OPP felt these challenges had been resolved, OPP could advise AMVAC of that and AMVAC would proceed with the chronic study. OPP did not do so, however, until concurrent with the NOITS. JX 69 pp. 18-19 of 24 (asserting only that several studies had been submitted and deemed to be acceptable for use in risk assessment and that this should "limit the previously identified issues" with the testing). This confirms that OPP was aware that what AMVAC was asking for in JX 74 was confirmation that OPP had deemed other chronic *Leptocheirus* studies acceptable.[17]

AMVAC's request that OPP provide this information also was reasonable in view of separate testimony establishing that AMVAC would not have been able to timely access OPP data evaluations ("DERs") for other studies, either because there was a substantial lag in issuance of the DERs, TX 69:4-11 (seven year lag not uncommon), or because they would not be timely posted to any publicly accessible database. TX 229:12-23 (public docket uploads are

[17] For either the first or second proposal discussed above, OPP could have informed AMVAC that they were rejected at any point between December of 2020 and April of 2020, but did not.

manual and not contemporaneous); TX 437:2-19 (public docket for DCPA not updated for seven years prior to NOITS).[18]

Even if AMVAC had learned between December of 2020 and April of 2022 that limited success had been achieved with the chronic studies, it still would have been reasonable to wait for the risk assessments in view of the pendency of JX 76 and the Agency's statement in JX 21 that it would complete risk assessments using conservative assumptions – this was the precise conclusion AMVAC had urged. *E.g.*, JX 76 p. 6 of 17.

3. *TPA Environmental Fate*

This group includes three environmental fate metabolism studies for DCPA degradate TPA: Guideline 835.4200 (anaerobic soil); 835.4300 (aerobic aquatic); and 835.4400 (anaerobic aquatic). A fourth environmental fate metabolism data requirement for TPA, 835.4100 (aerobic soil), was also included in the DCI, but was deemed satisfied in 2020 based on a study submitted by AMVAC in 2014. JX 21 p. 3 of 6; TX 370:2-373:6 (Dr. Freedlander discussing submittal and acceptance of MRID 49307516). Written testimony concerning these data requirements appears in PAX 94, Freedlander Statement ¶¶ 8-32 and in PAX 97, Gur Statement ¶¶ 63-65. As with the other groups of studies, OPP's witnesses largely did not testify that there was anything inappropriate concerning AMVAC's waiver requests.[19]

All three of these studies seek to quantify the rate at which the test substance degrades in

[18] Dr. Freedlander testified that he understood that the issues with the chronic study were persisting because he was aware the Agency included the acute as an alternative on later DCIs. TX 357:10-21. He additionally testified that he was aware that recent changes in the source of the organisms for testing may have introduced additional issues. TX 357:4-6.

[19] The sole exception is in regard to the 835.4300 data requirement. *See* RX 26, Wente Statement at 6 (AMVAC December 2020 response did not "provide any new or additional evidence . . . ."). Facts explaining why Dr. Wente's assertion is incorrect and inapposite to the issue of whether appropriate steps were taken are set forth in Section I.C.3.a., below.

various environments. For all three of these data requirements, AMVAC asserted that, based on OPP's test guidelines, the requested studies would not show degradation and as such, for purposes of its risk assessment, OPP should assume that TPA is stable, *i.e.*, does not degrade over any time horizon.[20] AMVAC also noted that the Agency had assumed TPA to be stable in prior assessments and had characterized that assumption as not "overly conservative."[21]

Using conservative assumptions where fate data was not available, without issuance of a NOITS, is a standard practice for OPP. TX 113:1-8 ("it's kind of a carrot and a stick thing. So, if you give us the data we'll use your half-life. That would be much better for your chemical in terms of the risk assessment. If you don't give us the data then we say that we can assume – we'll assume stability which is kind of saying that bad things are going to happen with your chemical because it's not going to do very well in a risk assessment[.]") And OPP, as discussed in Section I.B., explicitly said in JX 21 it could and would proceed with risk assessment in this case absent additional data. It was therefore reasonable for AMVAC to await the results of that risk assessment without further action, particularly as AMVAC was urging OPP to use the most conservative assumption possible, *i.e.*, stability. TX 122:12-20 (Dr. Wente agreeing AMVAC was suggesting full stability be assumed for risk assessment, even if TPA might not be fully stable in real-world conditions); TX 373:1-6 (Dr. Freedlander confirming that AMVAC never advocated that the Agency use the half-lives calculated in the 835.4100 European study for its risk assessment in absence of additional data).

AMVAC reasonably expected that, if the risk assessment showed exposures of concern

[20] JX 5 p. 21 of 26 (discussing insusceptibility of TPA to hydrolytic and photolytic degradation and further noting that "there is clear evidence within the [DCPA] aerobic soil and anaerobic soil metabolism studies that TPA is quite stable over the duration of the guideline studies").
[21] TX 112:10-17 (Dr. Wente agreeing that there was a basis for the Agency authors of PAX 80 to conclude that an assumption of stability was not "overly conservative").

based on the conservative assumptions, that would then be the catalyst for a discussion with OPP about the need for higher-tier studies, such as a field bioaccumulation study or otherwise. TX 413:11-414:3 (Gur on use of bioaccumulation studies in this circumstance); TX 333:3-8 (Dr. Freedlander on expectations for further engagement after risk assessment and lack of fit of data required in DCI). But there is no debate that these studies were not requested by the DCI and therefor are not at issue in this proceeding.

a. AMVAC Provided Substantial Support for its Waiver Requests

The history of AMVAC's submissions with respect to the 835.4200 and 835.4400 TPA data requirements also demonstrates that AMVAC took appropriate steps to support its waiver requests. AMVAC's waiver request for the 835.4300 was also meritorious and well-supported, but is discussed separately in the following section because the relevant correspondence is different.

For the 835.4200 TPA requirement, AMVAC initially indicated it was "Citing [an] Existing Study," specifically "Anaerobic Soil Metabolism of Dacthal", Duane, W. C. (MRID 114651). JX 5 pp. 19-21 of 26. This was a DCPA anaerobic soil metabolism that OPP had already accepted in satisfaction of the Guideline Requirement for DCPA (*i.e.,* it had been submitted prior to the DCI, and a Guideline 835.4200 study for DCPA was not required by the DCI). AMVAC explained that DCPA studies demonstrated that TPA was stable over the study duration because the TPA which formed during the DCPA study was not observed to further degrade. *Id.*; TX 333:9-16.

OPP did not provide AMVAC with a response to AMVAC's contention concerning the TPA 835.4200 guideline requirement, as set forth in JX 5, for <u>more than seven years</u>. *See* JX 77 (dated February of 2017, replying to AMVAC's April 2013 submission, and not provided to AMVAC until October of 2020, CE 1, Joint Stipulated Facts ¶ 48); TX 118:16-119:7 (Dr. Wente

conceding his statement wrongly implied AMVAC should have responded to JX 77 before the date AMVAC had received it). JX 77 stated that "EFED does not believe that the results [of MRID 114651] can be applied to TPA; therefore, EFED believes that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment, but will assume stability in the absence of a study." JX 77 does not even state EFED's *recommendation* that PRD should or should not deem the data requirement satisfied and this is the only document in which an Agency position on the 835.4200 data requirement was communicated earlier than at the same time as the NOITS (JX 79).

For the 835.4400 TPA requirement, AMVAC initially requested a waiver in April of 2013. JX 5. AMVAC did not receive an initial response (JX 66) until March of 2017, almost four years later. CE 1, Joint Stipulated Facts ¶ 8. AMVAC then supplied additional information in February of 2018, *see* JX 67 p. 14 of 29, but OPP never responded to that submission. Instead, the next communication AMVAC received that even mentioned the 835.4400 data requirement came thirty-two months later. JX 21 (Oct. 2020); CE 1 ¶ 47. JX 21 did not cite JX 67.

After receiving JX 21, AMVAC supplied more information relevant to the 835.4200 and 835.400 data requirements in the form of a substantive additional report on the anaerobic degradation of TPA, JX 78 (Dec. 2020), which provided a more detailed analysis of prior data, and a new analysis of other studies relevant to the anaerobic metabolism of chlorobenzoates and phthalates in the environment. Reference to the documents themselves confirms that this information had not been provided to OPP previously, *compare* JX 5 *with* JX 78, and so cannot fairly be characterized as "repetitive." AMVAC supplied this additional information notwithstanding the fact that it already had in hand OPP's statements in JX 21 that OPP would proceed with risk assessment by making conservative assumptions.

AMVAC received no further response until concurrent with the NOITS when OPP conceded for the first time that a "longer-than-standard study duration might be needed to quantify the potential anaerobic metabolism of TPA." JX 79 p. 4 of 12 (835.4200); *id.* p. 6 of 12 (835.4400). This demonstrates that OPP agreed that the normal duration study would not provide useful results. But merely extending the study does not mean that useful data will be generated, and doing so may introduce issues with which the hearing demonstrated that OPP's witness, Dr. Wente, was unfamiliar.

Dr. Wente admitted that he was unfamiliar with a critical cautionary statement about extending test durations appearing in a Society of Environmental Toxicology and Chemistry ("SETAC") publication that had informed OPP's testing guidelines, and with the SETAC publication itself, TX 129:17-20. He had also never realized that the SETAC publication was cited in the OPPTS Guideline in the section relevant to study duration. TX 129:14-15 ("Actually, this is the first time that I've understood the footnotes in this document[.]"). The SETAC publication is cited in a parenthetical to the OPTTS Guideline's statement that "[t]he rate and pathway studies should normally not exceed 120 days (*see* paragraphs (j)(4), (j)(7), (j)(9) of this guideline) because thereafter a decrease of the soil microbial activity with time would be expected in an artificial laboratory system isolated from natural replenishment." PAX 82 p. 13 of 19. The "(j)(9)" is a reference to the SETAC document. *Id*. at 15. The SETAC 1995 Guidance, which predates the Guideline, states (as does the Guideline) that studies may be continued beyond 120 days but, critically, the cited SETAC guidance continues on to clarify that "[i]n the light of the reduced microbial activity of soil, following long periods of incubation in the laboratory, the results of tests conducted over periods longer than [120 days] should be interpreted with caution." PAX 85 p. 12 of 56. This cautionary statement is reasonably read to

be incorporated by reference into OPP's test guideline based on the location of the (j)(9) footnote and helps explain the Guideline's reference to a potentially problematic "decrease of the soil microbial activity" during lab testing.

Dr. Wente proceeded to speculate that initial and final biomass measurements called for in the OPP Guideline might be intended to confirm whether reduced microbial activity was occurring, TX 133:19-135:3. At best, this would provide confirmation that a particular microbial population had not been able to sustain itself in the test environment – it would not address the concerns raised by AMVAC that microbial populations in non-acclimated laboratory soils would be incapable of identifying and "induc[ing] reductive dechlorination and decarboxylation reactions" to break down TPA at all, JX 5 p. 21 of 26, or at least within the duration of a laboratory study as prior studies had suggested.[22]

This fact, together with the evidence provided above concerning the additional non-repetitive information supplied by AMVAC, the fact that OPP stated it would move forward with conservative assumptions, and the extensive delays introduced by OPP into the process, is sufficient to establish that AMVAC took appropriate steps in connection with these three data requirements. The facts also rebut any assertion that AMVAC should have simply run "longer than standard" tests as first suggested in OPP's comments in JX 79 (provided at the same time as the NOITS).

[22] Breakdown of TPA was demonstrated to occur in acclimated soils in a European test. TX 415:1-23 (Mr. Gur explaining concept of soil "acclimation"); TX 413:11-414:3 (Mr. Gur discussing field observations of microbial degradation of nominally "stable" soil); TX 363:24-366:2 (Dr. Freedlander explaining that disparate TPA degradation results in European test likely reflect varying degrees of acclimation). But OPP and European test requirements have a critical distinction; the OPP requirements do not permit testing in acclimated soils, which supported AMVAC's belief that no degradation would be shown in the lab studies.

b. OPP Understood and Ultimately Concurred With the 835.4300 Waiver Request

The 835.4300 environmental fate requirement followed a slightly different path from the other two discussed in the prior section. Instead of being further supported by AMVAC in JX 78 like the other two, AMVAC did not supply additional information following its response in December of 2020. It was appropriate for AMVAC not to provide further information after receiving JX 21 for all the reasons discussed in the prior sections, *i.e.*, JX 21 communicated that OPP would proceed with conservative assumptions exactly as AMVAC had been urging it to do.

But it was additionally reasonable because, in the case of the 835.4300 TPA data requirement, AMVAC believed that it had directed OPP to consider a Guideline 835.4300 study submitted for DCPA to satisfy the requirement for TPA. PAX 94, Freedlander Statement ¶¶ 54-59. This was a reasonable suggestion because DCPA rapidly degrades to TPA, so an environmental fate study that nominally studies DCPA is also probative of the degradation of TPA as it will identify any degradation of TPA that occurs between its formation from DCPA and the end of the study. *Id.* ¶ 59; TX 333:9-20.

Here, AMVAC intended to direct OPP to the pertinent DCPA study in its February 2018 response document, JX 67 p. 15 of 29. However, as explained in Dr. Freedlander's written testimony, PAX 94 ¶¶ 54-63, AMVAC's response apparently did not clearly communicate its intent that OPP review MRID 49307515 and consider whether the 835.4300 TPA data requirement could be waived in view of that study (a DCPA 835.4300 study).

OPP argues in its Prehearing Brief, Dkt. 48 at 16, that, to the extent AMVAC "mislead OPP into believing that the company would submit a responsive study," this would constitute a failure to take an appropriate step. Perhaps if there were evidence that AMVAC *intentionally* misled OPP into so believing to obtain some advantage, that might be the case. But there is no

such evidence, and OPP does not appear to even assert that AMVAC intentionally misled OPP. Dr. Freedlander's unchallenged written testimony establishes that AVMAC intended to direct OPP to the DCPA study, not mislead it into believing an additional study would be conducted. PAX 94, Freedlander Statement ¶ 57.

AMVAC does not concede that a single communication that has the *inadvertent* effect of confusing OPP as to a registrant's position concerning a single data requirement would constitute an independently sufficient basis to determine that a registrant was not taking appropriate steps under the statutory standard. However, because this communication did not in fact mislead OPP or otherwise hamper its work, the Presiding Officer need not reach this issue.

Testimony at the hearing, as well as other documentary evidence, confirms that OPP was not in fact misled, and that it was able to make the connection AMVAC sought to have it make. Dr. Wente agreed that he understood that JX 22 was "asking EFED to take note of a DCPA guideline 835.4300 study . . . [as] the basis for a waiver of the TPA study[.]" TX 137:11-22 ("I do believe what you're saying is correct."). Additionally, as described in PAX 94, Freedlander Statement ¶¶ 62-63, EFED ultimately did use MRID 49307515 to derive a stable half-life for TPA, as shown in note 2 on p. 5 of 12 of JX 79, issued concurrent with the NOITS. This was exactly what AMVAC had urged EFED to do. *See also* TX 137:23-138:8.

Thus, whether EFED was assisted in locating MRID 49307515 and understanding its applicability to deriving a stable half-life for TPA in aerobic aquatic environments in part by AMVAC or not, EFED was not misled and ultimately applied MRID 49307515 exactly as AMVAC intended it to. Absent intent to mislead (not shown or even alleged) an isolated less-than-clear communication of the nature alleged here cannot form the basis for a suspension.

II. OPP'S VAGUE, SHIFTING, AND INCORRECT LEGAL THEORIES

OPP's statement of the basis for the NOITS has continually evolved, even though the NOITS itself has not been updated or re-issued. The NOITS should be declared deficient for its failure to adequately apprise AMVAC, the public, or other registrants of the specific grounds on which OPP is seeking suspension. *See* AMVAC Ph'g Br., Dkt. 52, Section V (Jan. 13, 2023). But even if OPP is permitted to *de facto* amend the NOITS and argue for suspension based on its new "statement of position," TX 210:17-211:4, the record reveals that OPP's new "statement of position" is hopelessly at odds with the course of conduct of the DCI and historical practice.[23] And, as discussed below, for OPP to prevail under its new theory, OPP would need the Presiding Officer to use, as the dates of waiver "denial," the dates that certain EFED documents were provided to AMVAC even though those documents did not reflect an exercise of properly delegated authority to deny waivers.

A. OPP's Prior Legal Theories Have Been Rejected

The NOITS failed to provide anything beyond a recitation of facts and the two suggestions as to further OPP motivation discussed at pp. 1-2, *supra*. The legal theory in the Motion for Accelerated Decision (that all that mattered was the expiration of the initial DCI deadlines) was rejected by the EAB. Now, OPP has suggested in its Prehearing Brief that the "appropriate steps" standard can be evaluated by a never-before-announced or alluded to

[23] Additionally, application of OPP's new "statement of position" is unquestionably a new "statement of position" affecting substantive rights now being enforced without any public notice or consideration of substantial reliance interests engendered by OPP's prior practices is arbitrary on that basis. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015). AMVAC expressly reserves this and other arguments under the Administrative Procedure Act ("APA") for other fora in which they may be directly considered. AVMAC does note that the consideration of "serious reliance interests" discussed in, *e.g., FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) may overlap, in terms of the facts considered, with the examination of the course of performance and typicality of the parties required by the EAB's Remand Order.

mechanical timing formula in which the DCI "time required" clock resets upon a first waiver denial (and only a first waiver denial) such that a registrant is afforded the original DCI Time Frame for the requirement at issue from that point, apparently regardless of the broader course of conduct of the parties. OPP's new theory fares no better than its original one, in view of the EAB's direction concerning the evaluation of the standard. And OPP's constantly shifting explanation for the NOITS raises larger concerns about what standard it was even applying when it issued the NOITS and whether its NOITS-in-search-of-a-legal theory can stand.

The NOITS did not even refer to the statutory standard, except by implication in the section concerning actions AMVAC could take to avoid suspension. JX 1 pp. 3-4 of 29 (*i.e.*, it could "take[] appropriate steps to comply." The NOITS's discussion of why AMVAC was "receiving this Notice," stated merely that AMVAC had "failed to comply with the terms of the Data Call-In (DCI)" and then proceeded to discuss: (1) the always-irrelevant-to-this-proceeding-and-now-superseded October 2022 deadline for registration review;[24] and (2) OPP's previously unspoken professed inability to complete a risk assessment, *see* Section I.B.2. The NOITS fails to specify whether those points were part of the basis for the NOITS or merely for informational purposes. JX 1 p. 1 of 29.

The NOITS "Explanatory Appendix," JX 1 pp. 8-29 of 29, presented only a partial timeline of communications between OPP and AMVAC. And the Federal Register notice of the NOITS's issuance included only a conclusory assertion that AMVAC had "fail[ed] to submit these data or to take other appropriate steps" and repeated assertions concerning an inability to complete risk assessment, JX 2 p. 2 of 5. It did not further explain those assertions.

[24] Remand Order at 786-87 (registration review deadline does not alter appropriate steps analysis); Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 § 711, Registration Review Deadline Extension (extending EPA's deadline for Registration Review until 2026).

OPP's Motion for Accelerated Decision argued that because the initial DCI time frames had come and gone without submittal of data (or in some cases, submittal of data that OPP approved) suspension was appropriate. *See* EPA's Mot. For Accelerated Dec., Dkt. 12 at 44 (June 13, 2022). The EAB, of course, ruled that the statutory standard requires a broader inquiry and does not turn on the limited grounds urged by OPP in its Motion for Accelerated Decision, Dkt. 12. Remand Order at 790. *See also* AMVAC Ph'g Br. Sections II and III concerning the meaning of the key statutory phrases. But OPP never subsequently updated the NOITS nor issued a new Federal Register notice or provided other correspondence to AMVAC. And OPP has not updated the witness testimony it had prepared in support of its initial, now rejected, legal position. As such, its attempts to support its new legal theory discussed in the next section all rely on testimony, and the NOITS and Fed. Reg. notice, that reflect alternate theories of the case.

B. OPP's New Theory is Inconsistent With the Statutory Standard and Past Practice

Having had its initial theory of this case rejected by the EAB, OPP advanced a new legal theory in its Prehearing Brief: that an initial denial of a waiver re-starts the "time required" clock to the original "Time Frame" allowed for the study in the DCI, measured from the date the first denial is communicated to the registrant.[25] This theory has never before been announced, understood to exist, or followed by OPP, *see* PAX 97, Gur Statement ¶¶ 21-32; 48-49; 70-73, and applying it would be inconsistent with the course of conduct and typicality analysis required

[25] OPP Ph'g Br. at 3 n.1 ("basic tenets of fairness may provide registrants with additional time to respond to a data requirement where the timing of OPP's denial of an initial waiver request would leave insufficient time remaining from the original period."); OPP Ph'g Br. at 5 (explaining application of rule to *Leptocheirus* data requirement). *See* also TX 210:8-211:4 (Ms. Bloom asserting that she does not "consider" the method of determining the time required for submittal set forth in OPP Ph'g Br. at 5 to be an OPP "policy per se" but rather a "statement of position" in this case).

by the EAB. The "one waiver denial" theory is incompatible with the statutory standard because it proceeds by ignoring rather than examining the broader course of conduct of the parties. As this DCI shows, there are often several rounds of scientific discussions during a DCI. *E.g.,* JX 66 (EFED suggesting *Daphnia* approach); JX 69, 79 (granting waivers concurrent with NOITS) Mr. Gur provided unrebutted testimony that this was typical, PAX 97, Gur Statement ¶¶48-49. In many cases, a discussion between OPP and a registrant concerning waivers will involve (and here did involve) statements by OPP that it was not yet comfortable granting a waiver. OPP's "one waiver denial" theory can only work if all of these facts and history are ignored.

This new post-hoc justification for the NOITS is also inconsistent with OPP's own internal documents and communications with AMVAC in this case. Testimony at hearing revealed that OPP's internal Standard Operating Procedure ("SOP") concerning registration review instructs CRMs to consider suspension only "[i]f the registrant does not respond to the DCI *or make a good faith effort to comply* with DCI requirements[.]" RX 13 pp. 3-4 of 14 (emphasis added) (using similar terminology in connection with 90-day responses and with development of data); TX 146:16-147:2 (Ms. Bloom confirming that RX 14 and RX 13, which superseded RX 14, are process explanations that tell CRMs and team leaders how to proceed "in the context of the Data Call-In and re-registration)." Whether or not the "good faith" standard referenced in RX 13 and RX 14 is a legally correct legal interpretation of the Suspension Provision, the fact that this reference is as close as OPP has come to articulating a standard in its internal guidance documents further underscores the post-hoc and arbitrary nature of its current legal theory (which is plainly incompatible with a generalized "good faith" principle as

referenced in its internal documents).[26]

Additionally, if OPP had been applying its new theory during this DCI, the "Due Dates" for the data requirements listed in JX 21 should have been updated to reflect application of that theory, but they were not. *Compare* JX 21 (Oct. 2020) p. 6 of 6 (listing *Leptocheirus* deadline as Jan. 2015, the original DCI deadline) *with* OPP Ph'g Br. at 5 (suggesting that JX 74 (received by AMVAC in July of 2016) would have moved *Leptocheirus* deadline to July of 2018, two years after receipt of JX 74). Ms. Bloom's testimony indicated that the deadlines listed in JX 21 might have been updated if OPP had understood them to be changed at the time. TX 207:21-25.

C. Properly Authorized Waiver Denials Were Never Issued

Even if OPP's "one waiver denial" theory had any legitimacy, this NOITS would still be premature and therefore unlawful. This is because, to justify the NOITS under its new theory, OPP is forced to argue that an EFED recommendation (that does not carry the force of law) could serve as the initial waiver denial for purposes of its theory.[27]

OPP does not appear to dispute that only PRD, not EFED, possesses lawfully delegated authority to grant or deny waivers.[28] The record does not contain any document in which a PRD official notified AMVAC that PRD had reviewed EFED's recommendation and was acting on

[26] EPA has not, in any event, alleged bad faith by AMVAC. *See* TX 159:2-159:14 (Ms. Bloom stating that her reference to "dilatory" conduct in her statement was not directed to AMVAC's motives); see also Order on Motions for Additional Discovery, Dkt. 40, at 16 (Nov. 4, 2022) (finding that OPP requests for AMVAC documents did not have "significant probative value" absent "allegations or evidence that AMVAC intentionally sought to disrupt or delay the registration review of DCPA.")

[27] *E.g.*, OPP Ph'g Br. at 5 (urging use of July 2016 transmittal of JX 74 to re-set 24-month clock for the *Leptocheirus* requirement).

[28] There is also no reference to EFED possessing this authority in any delegation document provided to AMVAC. *See* PAX 63-77.

them.[29] This fact alone renders the NOITS premature as to *all of the data requirements still at issue*, because the clock has not yet undergone its hypothetical one-time reset following a first waiver denial having the force of law.

III. THE EXISTING STOCKS PROVISION IS INCONSISTENT WITH FIFRA

OPP's proposed existing stocks provision appears at JX 1, pp. 4-5 of 29.[30] AMVAC does not seek complete reversal of the proposed existing stocks policy, though it appears OPP may have wholly failed to weigh critical considerations relevant to the entire policy that would warrant such relief as discussed in more detail below. AMVAC seeks elimination only of the limited prohibition on AMVAC's use of DCPA Technical in its possession as of the effective date of any suspension to formulate other pesticide products, *i.e.*, DCPA end-use products. OPP has not sought to prohibit or in any way restrict the sale, distribution, or use of DCPA end-use products by AMVAC or any other entity following a suspension. OPP has also specifically clarified that the proposed terms of its existing stocks order would *not* prevent an entity other

[29] OPP suggests that JX 21, transmitted in October 2020, should serve as a backstop for PRD's failure to act on EFED's recommendations. OPP Ph'g Br. at 30. OPP appears to ground this argument on what it alleges AMVAC should have understood from JX 21, not that JX 21 was in fact PRD's endorsement of prior EFED recommendations. AMVAC disputes that JX 21 is evidence PRD exercised its delegated authority an acted on any EFED recommendation. *See In re Julie's Limousine & Coachworks, Inc.*, 11 E.A.D. 498 (EAB 2004) (Agency official's memorandum was not sufficient to confirm that that official had exercised delegated authority where, as with JX 21, the memorandum nowhere so stated and did "not ascribe to anyone responsibility for the analysis or the ultimate determination[.]" Additionally, Ms. Wendel testified that she had reviewed JX 21, TX 82:18-21, but has never "in [her] employment at the agency" seen "a formal document in which PRD grants or denies in reference to an EFED recommendation[.]" TX 56:21-24.

[30] "After the suspension becomes final and effective, [AMVAC], including all supplemental registrants of [DCPA Technical], cannot legally distribute, sell, use (including use to formulate another pesticide product), offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, [DCPA Technical], except for the purpose of disposal . . . Persons other than [AMVAC], may continue to distribute, sell, use, [etc. even after a suspension.]" The same text appears in the Fed. Reg. Notice. JX 2 p. 4 of 5.

than AMVAC from formulating DCPA technical in its possession at the time of suspension into end use products. OPP EAB Response Br., EAB Dkt. 4 at 39 (July 28, 2022). But there is no entity other than AMVAC who might do such formulating however, because AMVAC is the sole registrant of DCPA Technical and its end-use products. PAX 93, McMahon Statement ¶ 14. As a result, growers are likely to suffer significant impacts based on shortages of DCPA end-use products that would not occur if the market structure was different.[31]

OPP paints these assertions as an attempt to erect a rule that "any registrant with a monopoly on a given pesticide product [would be] immune from meaningful suspension." OPP EAB Response Br., EAB Dkt. 4 at 38 (July 28, 2022). Neither AMVAC nor the Grower Petitioners has advanced this argument. The facts related to market structure are presented solely to establish that potential impacts to growers may be more acute here as a result of the market structure and thus warrant attention from OPP and the Presiding Officer in the analysis.

The following sections discuss, in turn: (A) how OPP has itself recognized that consideration of market disruptions is relevant prior to its assertion in this case that they are not; (B) how the submittal of the CTA data, along with statements made at the hearing, confirm that OPP's stated basis for the existing stocks policy no longer exists; and (C) how any residual support for the current existing stocks policy is outweighed by potential market disruption, rendering it inconsistent with FIFRA.

A. Consideration of Market Impacts is Required but Did Not Occur

The statute clearly contemplates consideration of market impacts. Congress created a right for any "person adversely affected" by a NOITS and its existing stocks provisions to obtain

[31] AMVAC incorporates the testimony and post-hearing briefing of the Grower Petitioners with respect to the effects of a shortage of DCPA end-use products.

a hearing, to assess "whether [OPP's] determination with respect to the disposition of existing stocks is consistent with this [FIFRA]." 7 U.S.C. § 136a(c)(2)(B)(iv). If Congress had been concerned solely about a scenario in which a registrant was unwilling or unable to contest a NOITS, it could have permitted hearing requests by other "persons[s] adversely affected" but kept the hearing restricted to whether the absent registrant "failed to take the action that served as the basis" for the NOITS. By both expanding who could seek a hearing and expanding the scope to include the existing stocks provision, Congress clearly contemplated that growers (not just a registrant) might correctly assert that an OPP existing stocks provision was unwarranted in a given case.

As set forth in the Growers brief before the EAB, OPP's own existing stocks policy, RX 24, recognizes that consideration of market impacts is a rational consideration when determining an existing stocks provision. Growers EAB Br., EAB Dkt. 3 at 2-3 (July 21, 2022). As discussed there in more detail, OPP's existing stocks policy provides that in connection with a cancellation action, "unlimited use of existing stocks" is presumed absent "significant risk concerns." RX 24 p. 1 of 8. And even where there are "significant risk concerns," determinations related to existing stocks "will generally require a risk/benefit analysis" that may consider "the social, economic, and environmental benefits associated with [the] distribution, sale, or use exceed the social, economic, and environmental risks" of the cancelled pesticide. *Id.* pp. 2-3 of 8. In the section of the existing stocks policy specific to suspensions other than imminent-hazard suspensions[32] OPP notes that it "does not anticipate generally placing restrictions on the sale, distribution, or use of existing stocks by persons other than the registrant

[32] Imminent hazard suspensions are provided for by a specific section of FIFRA. 7 U.S.C. § 136d(c)(1). EPA is not using its authority under that section in this proceeding.

. . . unless risk concerns were identified." *Id*. p. 6 of 8. It follows that OPP understood FIFRA to require consideration of the same economic risks and benefits in connection with a suspension that it described in connection with cancellations.

OPP has provided no testimony, or other indication, that it has weighed potential market impacts in any way, which is consistent with its assertion that it need not do so. OPP EAB Response Br., EAB Dkt. 4 at 40("the statute and [sic] does not require OPP to weigh market impacts when deciding whether to allow continued use of a suspended product."); *see also* TX 385:16-386:5 (OPP Counsel objecting to introduction of Mr. Ranganath's statement, stating "EPA is not contesting the -- that market effects may occur, but simply that they are not relevant to the scope of this hearing."). It is therefore clear that OPP wholly failed to consider an important aspect of the matter before it when drafting the proposed existing stocks policy, and the ALJ should not credit any post-hoc attempts to make up for this failure.

B. Data Eliminating Alleged Uncertainty Was Submitted in June of 2022

The mere *existence* of uncertainty about an effect cannot support an existing stocks order that is more stringent than what would comport with FIFRA absent that uncertainty. OPP could assert the existence of uncertainty in any case in which it had not yet received data. If OPP has a "significant risk concern" based on data it has received it may assert that, but it has not done so here – in the NOITS it asserted only that it could complete a risk assessment until the final data was received. And EPA has confirmed, as noted in the prior section, that a risk benefit analysis is required even where it does identify "significant risk concerns." OPP's allegation of uncertainty, if it were ever a proper basis for the existing stocks provision, is now out-of-date based on AMVAC's submission of the needed data.

Specifically, OPP asserted that "due to the *lack of data* examining the fetal thyroid

toxicity of DCPA," it could not, in April of 2022, complete a "scientifically robust and defensible human health risk assessment." JX 1 p. 1 of 29 (emphasis added). OPP has not adduced any evidence on the nature of its risk concerns other than the uncertainty concerning whether a standard 10x uncertainty factor would be appropriate pending receipt of the final CTA study. JX 2 p. 2 of 5. And its stated concern – lack of data pending receipt of the final CTA study – was remedied almost a full year ago. PAX 95, Jonynas Statement ¶¶ 143-149 (testimony by Ms. Jonynas that the final CTA data was submitted in June of 2022 and supplemented in August of 2022). OPP stated that the CTA data requirement was fully satisfied, based on its review of the data submitted, on October 21, 2022. OPP Status Report, Dkt. 34 at 2 (Oct. 21, 2022). OPP's concern underlying the existing stocks limitations that there was uncertainty with respect to human health risks has thus been addressed and can no longer serve as a basis for the proposed existing stocks order.

C. The Restriction on Formulation Would Unnecessarily Harm Growers

OPP itself characterizes the relevance of existing stocks provisions, as it relates to the "purpose of FIFRA" as ensuring that "registrants . . . submit necessary data so that risks can be assessed." OPP EAB Response Br., EAB Dkt. 4 at 40-41. This in turn enables OPP to "ensure that the pesticide's continued use will not cause unreasonable adverse effects[.]" *Id.* AMVAC reiterates its arguments that OPP cannot use a suspension proceeding as a de-facto cancellation proceeding if OPP actually harbors a concern (unspoken to AMVAC or anyone else) that use of DCPA would cause an unreasonable adverse effect based on data it has in its possession. FIFRA requires that OPP initiate a cancellation proceeding in that circumstance. *See* AMVAC Notice of Exceptions and Appeal Br., EAB Dkt. 2 at 26-27 (July 21, 2022). Ms. Bloom conceded at hearing that OPP can move forward with risk assessments based on the data it now has. TX

242:11-18. And, as discussed in the prior section, OPP asserted only "uncertainty" in the NOITS and not the existence of any risk concerns and did not adduce any evidence of such concerns at hearing.

As such, the correct inquiry is whether adverse impacts on growers and agriculture from the component of the existing stocks policy that AMVAC is challenging is warranted when those impacts are weighed against OPP's interest in ensuring the completion of the few studies currently underway. PAX 93, McMahon Statement ¶¶ 37-42.[33] This analysis must be performed in view of the fact that OPP confirmed at the hearing that none of the still outstanding studies are required for it to proceed with risk assessment. TX 242:11-17.

The answer to this question is clearly no. AMVAC presented testimony that the remaining data is being generated for all of the still-outstanding data requirements. PAX 93, McMahon Statement ¶¶ 37-42. AMVAC has expended considerable funds to generate this data. TX 298:9-299:21. There is no evidence to suggest, nor could OPP seriously argue that, absent the restriction on formulation of technical in AMVAC's possession at the time of a potential suspension, AMVAC would cease or slow down its data generation. Even if the existing stocks order were modified in the manner that AMVAC and the growers seek, AMVAC would remain subject to prohibitions on obtaining or manufacturing additional technical (and, by extension,

[33] Mr. Ranganath testified that, due to supply chain disruptions, and the fact that AMVAC had only the amount of end use product in inventory as of January 25, 2022, as stated in ¶ 9 of his written statement, TX 385:8-12, it was then-unknown whether AMVAC would be able to "formulate additional EUPs . . . to meet expected grower demand in 2023 and beyond" "[g]iven the uncertainty as to when any possible suspension order may take effect." PAX 96, Ranganath Statement ¶ 12. The harm to the growers is thus the extent to which demand could have been met if technical-stocks-at-the-time-of suspension were permitted to be formulated. Uncertainty in the timing of the hearing and decision process, as well as the supply chain, prevent precise quantification of that harm in advance. AMVAC submits that precise quantification is unnecessary, but will to provide updated testimony by affidavit if the Presiding Officer believes that understanding the precise quantum of impact is necessary to decide this issue.

from formulating end-use-products beyond those it could formulate from whatever technical it had in stock at the time of suspension). Ample incentive to timely complete the remaining studies remains even absent the complained-of portion of the proposed existing stocks policy.

CONCLUSION

For the reasons set forth above, the Presiding Officer should issue an Initial Decision concluding that OPP is not entitled to suspend AMVAC's DCPA Technical registration under the NOITS in connection with any of the nine data requirements that OPP continues to assert provide a basis for such action. In the alternative, the Presiding Officer should issue an Initial Decision concluding that OPP's existing stocks policy proposed in the NOITS is inconsistent with FIFRA in full, or at a minimum in connection with the proposed restriction on formulating existing stocks as discussed in Section III, *supra*.

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Respectfully Submitted,

/s/ Hume M. Ross
David B. Weinberg
Tracy A. Heinzman
Keith A. Matthews
Hume M. Ross
WILEY REIN LLP
2050 M ST NW
Washington, DC 20036
Telephone: (202) 719-7000
dweinberg@wiley.law
theinzman@wiley.law
kmatthews@wiley.law
hross@wiley.law

Counsel for AMVAC Chemical Corp.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Petitioner AMVAC Chemical Corporation's Post-Hearing Brief**, was sent on April 7, 2023, to the following parties in the manner indicated below.

/s/ *Hume M. Ross*
Hume M. Ross

Copy by OALJ E-Filing System to:

Mary Angeles
Headquarters Hearing Clerk
U.S. Environmental Protection Agency
Office of Administrative Law Judges
Ronald Reagan Building, Rm. M1200
1300 Pennsylvania Ave. NW
Washington, DC 20004

Copies by Electronic Mail to:

Forrest Pittman
Erin Koch
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
Mail Code 2310A
1200 Pennsylvania Avenue NW
Washington, DC 20460
Email: pittman.forrest@epa.gov
Email: koch.erin@epa.gov

Counsel for Respondent

Cristen S. Rose
Haynes Boone
800 17th Street NW
Washington, DC 20006
Email: cristen.rose@haynesboone.com

Counsel for Grower Petitioners

Dated April 7, 2023