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 REPLY BRIEF

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I. INTRODUCTION

Respondent Office of Pesticide Programs' Post-Hearing Brief, Docket ("Dkt.") 63 (Apr. 7, 2023) ("OPP Post-Hr'g Br.") is most notable for what it does not say.

First, OPP does not defend or even refer to the mechanical "one waiver denial" timing theory advanced in its Pre-Hearing Brief. OPP appears to continue to advance, however, the idea that AMVAC should have immediately capitulated and abandoned any attempt to further justify its waiver requests after being informed of the Environmental Fate and Effects Division's ("EFED's") initial recommendations to deny a waiver. There was no testimony at the hearing supporting the existence of such a requirement.

Second, while OPP repeatedly asserts that it has established that AMVAC failed to take appropriate steps within the "time required," OPP never specifies, for any data requirement, when that "time required" ended. *See* OPP Post-Hr'g Br. Section II.A. OPP ignores the concession, by OPP's Team Leader Bloom, that the initial deadlines set forth in *this* Data Call-In ("DCI") were "meaningless" for purposes of judging AMVAC's compliance with the "appropriate steps" standard of 7 U.S.C. § 136(a)(c)(2)(B)(iv) (the "Suspension Provision").[1]

Third, OPP never asserts, or cites evidence to prove, that any document issued in response to an AMVAC waiver request came from an Agency official who, at the relevant time, possessed delegated legal authority to deny waiver requests. This failure is fatal to the establishment of OPP's *prima facie* case. OPP's position, by implication, is that AMVAC's *interpretation* of an EFED recommendation as a denial can cure the Agency's wholesale failure to exercise properly delegated authority. Or, put another way, OPP requires the Presiding

[1] Hearing Transcript ("TX") 210:20-212:3 (Ms. Bloom asserting that the original DCI time frames were "meaningless" for purposes of crafting a new "statement of position" by which AMVAC's conduct might now be judged).

Officer to find that a registrant's lack of contemporaneous knowledge of OPP's internal, non-public delegation structure relieves OPP of the requirement to follow it. It would be remarkable if OPP could validly suspend a registration (premised entirely on alleged improper responses to waiver denials) without establishing that OPP ever actually lawfully denied any waiver requests.

Rather than analysis concerning how AMVAC's conduct was inappropriate in view of a defined legal theory, OPP's Post-Hr'g Br. offers only three things. First, it provides OPP's views on other actions AMVAC *could* have taken that OPP would have deemed acceptable. This boils down to an argument that AMVAC could have abandoned its requests for waivers but did not. But OPP thus sidesteps the essential inquiry: whether what AMVAC *actually did* was inappropriate in the context of what it had been hearing from OPP throughout the DCI such that, under the statutory standard, the draconian remedy of registration suspension is justified. Second, OPP engages in unpersuasive attacks on the credibility of AMVAC's witnesses, in particular AMVAC's expert witness (and the sole expert witness who testified at the hearing), Mr. Gur. Court Exhibit ("CE") 4, Joint Status Report; TX 391:14-392:13 (OPP stipulating to Mr. Gur's expertise).

Third, OPP offers an erroneous analysis of the existing stocks issue. OPP incorrectly asserts that the Environmental Appeals Board ("EAB") endorsed the Presiding Officer's prior conclusion and OPP's 1991 statement of policy on existing stocks. The EAB did neither. Decision and Remand Order, EAB Dkt. 11 at 770, 795 (Sept. 28, 2022) ("Remand Order"). OPP's analysis is based on its own policy statement, Respondent OPP's Exhibit ("RX") 24,[2] which is owed no deference and which is inconsistent with FIFRA if it is to be interpreted as

[2] Existing Stocks of Pesticide Products, Statement of Policy, 56 Fed. Reg. 29,362 (June 26, 1991).

OPP now urges, *i.e.*, to require an examination of market effects in connection with cancellations and suspensions for imminent hazard, but not for suspensions under the Suspension Provision.

The Presiding Officer should reject OPP's *post-hoc* rationalizations for the NOITS. Instead, the Presiding Officer should hold that no suspension is appropriate where, as here, the record demonstrates that: (1) AMVAC and OPP engaged in a scientific dialog, in the course of which AMVAC advanced meritorious justifications for its waiver requests and OPP considered further justifications for waivers, granting some even concurrent with the NOITS; (2) OPP was responsible for major delays in the process; (3) OPP failed to re-establish any deadlines for AMVAC to take any specific action after OPP's own delays had rendered the initial DCI timeframes meaningless; (4) in OPP's final communication concerning the data requirements remaining at issue before OPP went dark for eighteen months and then re-emerged with the NOITS, OPP represented to AMVAC that OPP *would proceed* with risk assessments using conservative assumptions as AMVAC had advocated in its waiver requests; and (5) OPP's stated basis for the NOITS – *inability to proceed* even with conservative assumptions – had never been shared with AMVAC before issuance of the NOITS, was directly in conflict with its statement eighteen months prior, and in any event is no longer valid as AMVAC has submitted (and EPA has accepted) the data OPP belatedly asserted it needed to proceed.

II. ARGUMENT

OPP's assertions in Sections II.A.1. through II.A.9. of its Post-Hr'g Br. concerning the data requirements still at issue in this case are misleading, rebutted, and/or irrelevant when considered under the correct legal standard as discussed in Section II.A.1. through II.A.4. of this Reply brief, below. This brief then addresses, in turn: (1) how it is fatal to OPP's case that OPP has failed even to allege, much less prove, which (if any) of the waiver response documents were issued with appropriate delegated authority (Section II.B.); (2) why OPP's attacks on AMVAC's witnesses' credibility fail (Section II.C.); and (3) the flaws in OPP's existing stocks argument (Section II.D.).

A. OPP's Arguments on Individual Groups of Data Requirements Do Not Provide a Basis for Suspension

This section addresses OPP's arguments concerning AMVAC's actions regarding the several categories of data requirements still at issue, in the order they were examined by OPP in its Post-Hr'g Br. OPP's arguments fail when considered in the context of the chronology of the DCI, the course of conduct engaged in by EPA and AMVAC, and OPP's typical practices.

Each sub-section below first discusses how an examination of AMVAC's actions in view of the chronology of events and communications relevant to each category overcomes OPP's suggestion that the only reasonable course was for AMVAC to immediately abandon its waiver requests after receiving the first indication that EFED was recommending denial. Sections II.A.1. (on the *Leptocheirus* data requirement) and II.A.3. (on the Guideline 835.4200 and Guideline 835.4440 data requirements) then additionally provide a point-by-point rebuttal of certain other assertions made by OPP in its Post-Hr'g Br. Section II.A.3. also contains a sub-section that addresses OPP's implicit argument that AMVAC had ulterior motives for advocating for the use of conservative assumptions.

1. *DCPA Leptocheirus*

OPP's argument concerning the chronic *Leptocheirus* data requirement does not overcome the showing that AMVAC's conduct was appropriate. OPP suggests that if AMVAC had started either the chronic *Leptocheirus* or the alternate 850.1740 study "at any of several points following OPP's 2017 denial," it could have timely submitted data – presumably meaning, OPP does not say, before April 2022. OPP Post-Hr'g Br. at 3. But AMVAC's conduct following each relevant communication must be judged on the basis of what OPP had communicated at that time, and whether AMVAC's response was reasonable in view of OPP's communications. This analysis quickly reveals that AMVAC's conduct in continuing to attempt to (using OPP's word from its Post-Hr'g Br. at 3) "bolster," its waiver request was appropriate.

The first point to examine was when AMVAC received Joint Exhibit ("JX") 74 (EFED's initial recommendation to deny, which also offered the additional path of the 850.1740 acute study) in July, 2016. Shortly thereafter, AMVAC supplied an expanded technical justification for the waiver of the chronic study (JX 76) which also responded to OPP's proposal for the acute study as an intermediate step. AMVAC Post-Hr'g Br. at 20 n.16 (discussing ways in which JX 76 provided additional information beyond JX 73). *In the seven-plus years since, OPP has never responded to JX 76. Id.*, Section I.C.2.b. It was not referenced in the NOITS or in OPP's testimony in support of the NOITS. *Id.* AMVAC acted appropriately by providing an expanded technical response and responding to EFED's proposal for the acute study (in JX 76) and then waiting for a further response from OPP.

OPP's next communication, in October, 2020 (JX 21), ignored JX 76 entirely. In JX 21, OPP also made no mention of other successful chronic studies it now asserts had occurred, and instead reiterated the suggestion to try the acute study as a first step, *cf.* JX 21 p. 6 of 6. That suggestion, of course, was premised from the start on the existence of difficulties with the

chronic study. JX 74 p. 2 of 3. In response, AMVAC (in JX 22) reasonably requested that the acute study be added to the DCI, which would be a simple administrative task for OPP, and which would protect AMVAC's rights in generated data under FIFRA. AMVAC Post-Hr'g Br. at 22. AMVAC also reasonably requested that EPA advise it if the *Leptocheirus* guideline was validated. *Id.* at 23.

These were both reasonable requests, particularly as OPP had stated in JX 21 (to which JX 22 was responding) that OPP would proceed to perform a risk assessment with conservative assumptions *exactly as AMVAC had urged in its waiver requests*. JX 21 p. 1 of 6 (stating conservative assumptions will be used); JX 76 p. 6 of 17 (urging exactly that approach). It was therefore reasonable for AMVAC to await either: (1) a response to either of its reasonable proposals in JX 22; or (2) the results of the risk assessment OPP had stated would soon be completed (by June of 2021). JX 21 p. 1 of 6.

The record reveals that, based on OPP's typical practices, AMVAC would have been expecting to risk, at most, a determination by OPP that label amendments would be required – not a NOITS. Petitioner AMVAC Exhibit ("PAX") 97, Gur Statement ¶¶ 41, 48; TX 400:7-24 (Gur). Even EPA's witness testified that OPP's practice is to sometimes (time allowing) accept data *after* a risk assessment if the risk assessment is not acceptable to a registrant. 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.]").[3] OPP

[3] AMVAC is not arguing here that registrants have a right, after risk assessments are completed, to submit more data or to have OPP act on it. AMVAC is observing that OPP's course of conduct was, as confirmed by Ms. Bloom, to sometimes *permit* more data to be submitted. This confirms AMVAC's contention that the NOITS was an unprecedented modification of OPP's practices, and that AMVAC's decision to wait for the risk assessments promised in JX 21 was in accord with the typical course of conduct of DCIs if a registrant was comfortable with OPP proceeding with conservative assumptions.

has not disputed that it is unprecedented for OPP to tell a registrant that it could proceed with a risk assessment only to later assert the opposite for the first time and on the same day it issues a NOITS. PAX 94, Freedlander Statement ¶ 117; PAX 97, Gur Statement ¶ 73.

OPP's Post-Hr'g Br. raises several additional points on the chronic *Leptocheirus* study that: (1) are inconsistent with OPP's other arguments; (2) are misleading; and/or (3) lack any basis in the record:

- In its legal argument, OPP characterizes its suggestion to perform the acute 850.1740 study as an option for AMVAC to "bolster its waiver requests." OPP Post-Hr'g Br. at 3. This is a concession by OPP that an ongoing scientific dialog was underway, as AMVAC has asserted, and that OPP's attempt to characterize AMVAC as having made "multiple" requests is an artificial attempt to make AMVAC's conduct appear to be at odds with typical practice. *See generally* AMVAC Post-Hr'g Br. at 6-9. OPP itself is inconsistent as to whether it is alleging AMVAC submitted multiple waivers ("a future waiver request") or was attempting to "bolster" its prior waivers. *Compare* OPP Post-Hr'g Br. at 2 *with id.* at 3. This also undermines OPP's attempt to discredit Mr. Gur's testimony as discussed further in Section II.C., below.
- OPP asserts that AMVAC chose not to proceed "based on [its] assertion that the lack of this data 'would not delay [OPP's] conclusions'," quoting Dr. McMahon. OPP Post-Hr'g Br. at 2. Insofar as OPP is trying to suggest this was the sole rationale for AMVAC's position, OPP's assertion is misleading. AMVAC's rationale is amply described in prior briefing, AMVAC Post-Hr'g Br. at 18-24. Dr. McMahon's statement is consistent with the broader concept that AMVAC

believed (and stated) that OPP could and should proceed with conservative assumptions.

- The record contains no support for OPP's assertion that the chronic *Leptocheirus* study could have been completed in a year and a half. OPP Post-Hr'g Br. at 3. OPP does not even assert at what point in time this was supposedly true. OPP cites in support of this statement only a portion of Dr. McMahon's testimony in which she is discussing completion of ecotoxicology studies as a general matter, not completion of a chronic *Leptocheirus* study. AMVAC Post-Hr'g Br. at 23-24; TX 299:14-301:11.[4]
- OPP twice refers to the alternate study suggested by OPP as being less "onerous." OPP Post-Hr'g Br. at 2, 3. AMVAC has never asserted it should not have to conduct the chronic *Leptocheirus*, or any study, based on its onerousness (or any other term relating to burden). AMVAC's reason for requesting a waiver was that the chronic *Leptocheirus* could not be reliably performed at the time and other existing data permitted the use of conservative assumptions in place of the data. AMVAC Post-Hr'g Br. at 23-24.
- OPP asserts that there was "no obligation" for OPP to inform AMVAC that no further waiver requests would be considered. OPP Post-Hr'g Br. at 3. OPP's citations for this statement are its own Prehearing Brief (with no further citation),

[4] Dr. McMahon was answering questions about the duration of "ecotoxicology studies on [*e.g.*,] sheepshead minnows[.]" TX 299:14-16, 22-23. Within this discussion, Dr. McMahon used the acute "10-day" *Leptocheirus*, not the 28-day chronic study, as an example of an ecotoxicology study. TX 300:8-11. The challenges with the chronic study related to control organism survival and reproduction, and implicate more than the difference between a 10 and 28 day "in-life" phase. TX 357:3-9.

the Opening Statement of its counsel at the hearing, and a *cf.* citation to AMVAC's Pre-Hr'g Br. at 2 (in which AMVAC asserts "OPP could have easily, at any time, told AMVAC that no further waiver requests would be considered. But it did not."). OPP is perhaps attempting to argue that, because there is no express regulatory requirement that OPP so inform AMVAC, AMVAC should have interpreted a recommendation by a science division that a waiver should not be granted to have ended the discussion. The record establishes that registrants do not understand such a communication from EFED to prohibit further attempts by a registrant to "bolster" the waiver. *E.g.*, PAX 97, Gur Statement ¶ 39-49. *See also* Section II.C., below (explaining why OPP's attempt to impeach Mr. Gur's credibility in connection with this statement fails).

2. *Guideline 835.4300, TPA Aerobic Aquatic Metabolism*

AMVAC refers the Presiding Officer to its discussion of why its conduct in connection with the TPA Guideline 835.4300 does not warrant suspension in its Post-Hr'g Br. at 30-31. OPP ignores, in its Post-Hr'g Br., the fact that EFED *formally concurred* with the basis of the waiver requested for this study. AMVAC Post-Hr'g Br. at 31 (noting that "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[.]").

OPP attempts to minimize the import of testimony from its witness Dr. Wente that confirmed that OPP understood the basis of AMVAC's waiver request. OPP attempts to recast Dr. Wente's testimony as "merely noting that JX 22 mentioned a previous DCPA study." OPP Post-Hr'g Br. at 4. But Dr. Wente's testimony confirmed more than that – he agreed that JX 22 "was asking EFED to take note of a DCPA guideline 835.4300 study[.]" TX 136:24-137:22.

Dr. Wente also confirmed that the only DCPA guideline 835.4300 study submitted by AMVAC during the DCI was MRID 49307515. And, as shown in a document signed by Dr. Wente himself, EFED used that study to derive a stable half-life for TPA for aerobic aquatic metabolism. JX 79 p. 5 of 12, n.2. Taken together, these points establish that EFED understood the basis for AMVAC's waiver request and ultimately determined it was reasonable.

3. *Guidelines 835.4200 and 835.4400, TPA Anaerobic Aquatic and Soil Metabolism*

As to these guidelines, OPP again asserts that AMVAC failed to secure this data "within the time required" by the Administrator, but again does not say what that time was.

For the 835.4200 TPA data requirement, OPP has not explained why its own theory renders the NOITS premature. *See* OPP's Pre-Hr'g Br., Dkt. 48 at 3 n.1 (Jan. 6, 2023) ("OPP Pre-Hr'g Br.") (" . . . 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."); *id.* at 5 (suggesting AMVAC should have completed a study within the initial DCI time frame after initial waiver denial). OPP stipulates it provided *no response* to AMVAC's timely submitted waiver request for the 835.4200 TPA data requirement until October 16, 2020. CE 1, Joint Stipulated Facts ¶ 48. Adding the initial 24-month time frame to this study, *see* JX 4 p. 28 of 46, from the date of OPP's first response, yields October 2022. That is six months *after* the April, 2022, NOITS.[5]

For the 835.4400 data requirement, AMVAC received one response prior to October of 2020 (*i.e.,* JX 66, in March, 2017). AMVAC responded appropriately to this communication: it

[5] This is even ignoring OPP's suggestion simultaneous with the NOITS that "a longer-than-standard study duration might be needed to quantify the potential anaerobic metabolism of TPA." JX 79 p. 4 of 12.

provided additional support for its contention that "it is reasonable to assume full stability of TPA under anaerobic aquatic metabolism conditions with the expectation that a short-lived laboratory study would demonstrate no evidence of any degradation." JX 67 p. 14 of 29. At that time, OPP was still reviewing MRID 00114651 (in connection with the 835.4200 data requirement) and AMVAC's request for a waiver of a hydrolysis study for TPA (guideline 835.2120). Data on the behavior of TPA in anaerobic *soils* (*i.e.,* MRID 00114651) and the assumption that TPA's breakdown would not be accelerated by water (*i.e*., it was stable to hydrolysis) were important elements of AMVAC's waiver request for TPA in anaerobic aquatic environments. Given that OPP was, at the time AMVAC submitted JX 67, still evaluating both these points (OPP's response would not come until October, 2020, in JX 77, on both), it was reasonable for AMVAC to clarify its fundamental point pending the conclusion of that review, as a response to JX 66, as it did in JX 67.

Finally, as with the chronic *Leptocheirus* data requirements, AMVAC's course of action after receipt of JX 21 in October, 2020, was reasonable (putting aside that the NOITS would be premature as to both if JX 21 was the point in time at which AMVAC should have initiated studies) because JX 21 communicated that OPP would proceed with conservative assumptions. This was exactly what AMVAC had urged OPP to do in its waiver requests. JX 67 p. 14 of 29 (835.4400); JX 78 p. 5 of 14 (providing an expanded justification for 835.4200 and 835.4400 waivers after receipt of JX 21, *see also* AMVAC Post-Hr'g Br. at 27).

OPP's Discussion of "Conservative Assumptions"

OPP "maintains" that the importance of its own statements to AMVAC that OPP would proceed using conservative assumptions "is [a question that is] legal in nature[.]" OPP Post-Hr'g Br. at 5. AMVAC agrees that OPP's statements in this regard are highly relevant to the outcome,

as argued in this Reply and in its Post-Hr'g Br. Section I.B. Just by "maintaining" this, OPP displays the cracks in its *de facto* legal theory that immediate abandonment of waiver requests after a first recommended denial was AMVAC's only proper course. AMVAC discusses OPP's statements in this regard in this section concerning the Guideline 835.4200 and 835.4400 data requirements because it is in the corresponding section of OPP's Post-Hr'g Br. that OPP attempts to distract from its own statements that it would proceed with conservative assumptions – which contribute strongly to a finding that AMVAC acted appropriately – by advancing theories concerning AMVAC's allegedly improper "beliefs" in connection with use of conservative assumptions. OPP Post-Hr'g Br. at 5. It is worth pausing to reflect on how far OPP's discursion into AMVAC's "beliefs" strays from any coherent legal theory, let alone any of OPP's previously suggested ones.

OPP proceeds with a metaphoric suggestion that AMVAC had some subjective motivation to, in OPP's words, "have its cake and eat it too[.]" OPP Post-Hr'g Br. at 6. By this, OPP appears to mean that AMVAC thought it could support the use of a conservative assumption without suffering any consequences, *i.e.*, registration review would conclude without any undesirable-to-AMVAC label mitigations being required. OPP's implicit argument is that even if AMVAC's waiver requests were well-supported, AMVAC's nonetheless was not taking appropriate steps because it was trying to avoid generating data and thought that its registration might not be adversely affected even if the data was not generated. OPP has not produced a shred of evidence to suggest that AMVAC had any sort of improper motive. And in any event, OPP has produced no evidence that registrants "ought" to expect their registrations to be adversely affected whenever they submit a waiver request.

OPP's support for the existence of improper motivation for waiver requests consists of

three purportedly inconsistent statements from Dr. Freedlander. OPP Post-Hr'g Br. at 5-6.[6] Dr. Freedlander's statements that OPP cites, summarized in footnote 6 below, are in no way inconsistent – they simply address different elements of Dr. Freedlander's thinking, *i.e.*, he understood that there *could* be an adverse result, but did not think that there *would* be.[7]

OPP first suggests that AMVAC perhaps hoped that OPP would extrapolate from the results of a study in European soils (which OPP accepted as "supplemental," in satisfaction of the DCI's TPA Guideline 835.4100 (aerobic soil) data requirement), *see* JX 21 p. 3 of 6. This study showed degradation of TPA, but had been conducted in potentially acclimated European soils, which is not permitted by OPP's test guideline. There would be nothing improper about OPP nonetheless relying on this data it OPP felt it was reasonable to do so. But AMVAC never advocated that OPP should rely on it. OPP attempts to bury the fact that AMVAC never advocated for this outcome by acknowledging this in a footnote. OPP Post-Hr'g Br. at 6 n.5.

Second, OPP conjectures that AMVAC was trying to set OPP up by having it proceed with conservative assumptions, thus introducing a scientific weakness into OPP's eventual conclusions that AMVAC could exploit if OPP later proposed mitigation that AMVAC did not wish to implement. OPP Post-Hr'g Br. at 7 ("possibly with the intent of . . . ."). This is pure

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[6] Dr. Freedlander first explained that AMVAC understood that the use of conservative assumptions could result in the agency "going" in a "direction" that the Agency was "warning" AMVAC of. TX 326:14-17. He did, as OPP asserts, confirm that there was no specific communication in which AMVAC confirmed that use of conservative assumptions would be "acceptable" to AMVAC, TX 329:8-22, though there are many communications in which AMVAC advocates an assumption of stability. *E.g.*, JX 67. And finally, he noted that he did not think the use of conservative assumptions would work against AMVAC's "best interest." TX 341:19-24.

[7] It also bears repeating that believing that TPA would in fact degrade in field conditions, *see* AMVAC Post-Hr'g Br. at 29 n.22, but not in a laboratory study, was a reasonable position to hold in view of the data available. AMVAC could reasonably believe both things to be true without being inconsistent. And AMVAC would not know how, if at all, EFED would take into account evidence of real-world degradation until after a risk assessment was published.

conjecture without record support.

A third alternative, not stated by OPP, is that the assumption of stability might not lead to any label mitigations to which AMVAC objected. OPP might make other assumptions, based on leaching, off-site transport, or other monitoring data, to establish expected environmental concentrations that, in connection with ecotoxicity endpoints, would not require mitigation AMVAC would oppose. The very nature of a waiver request is a belief that OPP can, even absent certain data, proceed with risk assessments and registration review based on other data in its possession. OPP's entire conjectural discursion into AMVAC's subjective motivations for certain waiver requests is misguided and cannot overcome the fact that those communications were appropriate and well supported.

Several additional points raised by OPP in its section on the Guideline 835.4200 and Guideline 835.4400 data requirements merit a response:

- At hearing, AMVAC demonstrated that EPA's witness Dr. Wente was unaware of a cautionary statement in a guidance document (PAX 85) from the Society of Environmental Toxicology and Chemistry ("SETAC") that is directly cited in the relevant section of OPP's own test guideline. AMVAC Post-Hr'g Br. at 28-29. This cautionary statement explains why it is problematic to extend the duration of the guideline study, particularly for a substance whose breakdown is mediated by microbes (which Dr. Wente confirmed is the relevant method of breakdown here).[8] This cautionary statement explains why AMVAC did not earlier suggest extending the duration of the study as OPP later would in a document signed by Dr. Wente, JX 79. OPP attempts to minimize this testimony as merely

[8] TX 126:13-17.

establishing that EPA "did not choose" to incorporate this cautionary statement into its Guideline. OPP's statement is incorrect. EPA did incorporate the cautionary statement, by use of a footnote to the SETAC document within the relevant section of its own Guideline. AMVAC Post-Hr'g Br. at 28-29. Dr. Wente testified that he was not involved in the drafting of the Guideline and so had no personal knowledge of the rationale for any distinctions. TX 131:2-6.

- Likewise, OPP points to Dr. Wente's speculation that biomass measurements in the OPP Guideline are intended to address or, in the words of OPP's brief, "control for any negative consequences resulting from the longer timeline." OPP Post-Hr'g Br. at 8. But "control[ling] for" potential elimination of microbial populations, or the inability of those microbial populations to break down the test substance, would not be addressed through biomass measurements, as AMVAC has previously explained. AMVAC Post-Hr'g Br. at 29.

4. *The TPA Ecotoxicology Data Requirements*

OPP's Post-Hr'g Br. arguments concerning the five remaining TPA Ecotoxicology data requirements are all directed at straw men, not at AMVAC's actual arguments. OPP has completely failed to confront the central issue regarding these five data requirements: (1) that EFED suggested AMVAC follow a particular testing strategy after which OPP would further review the broader group of waiver requests; (2) that AMVAC did what EFED suggested; and (3) that OPP proposed to suspend AMVAC's registration at the same time it provided the promised further review. *See* AMVAC Post-Hr'g Br. Section I.C.1.

Instead of addressing its own course of conduct,[9] OPP attempts to make AMVAC's acceptance of EFED's suggestion to submit the *Daphnia* data sound nefarious. OPP now says that "AMVAC attempted to demonstrate that, in lieu of submitting a number of required studies on the other species listed above, the company chose to submit two studies conducted with the species *Daphnia magna*" as if this were a delaying tactic. OPP Post-Hr'g Br. at 8. In fact, however, AMVAC was responding to the suggestion from EFED, made in JX 66 p. 7 of 9.

OPP also suggests that AMVAC's argument as to the propriety of its actions on these studies is based on three "faulty assumptions." OPP Post-Hr'g Br. at 8. But these alleged "faulty assumptions" are, as discussed immediately below, either not faulty, or are not assumptions (or arguments) made by AMVAC.

OPP first asserts that "AMVAC assumed that OPP suggested a more-limited testing strategy of only *daphnia* studies in its first denial of these data requirements, provided to AMVAC in 2017." *Id.* AMVAC did not "assume" this – this is *exactly* what EFED suggested. TX 57:20-59:10; JX 66 p. 7 of 9.[10]

OPP then seeks to refute an argument AMVAC *has never made*: that "OPP . . . indicated that it would waive these data requirements if AMVAC only submitted the more limited data."

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[9] In its Post-Hr'g Br. at 8 n.7, OPP asks the Presiding Officer to excuse OPP delays because AMVAC did not "inform OPP via email" that it had submitted certain documents through the system OPP had set up to receive them. But what OPP seems to be arguing for – an obligation on registrants to pester OPP to confirm OPP's own internal processes were functioning properly – goes beyond an obligation to take "appropriate steps" and any reasonable reading of the term. Mr. Gur's testimony, cited by OPP in the footnote, was not that individual registrants "usually" take proactive steps to address shortcomings of OPP's systems, as OPP suggests, but that industry as a whole (*i.e.*, the CropLife registration committee) had worked with OPP on "ensuring better training and ensuring consistency." TX 444:6-15.

[10] "[O]ne possible solution is conducting a limited set of toxicity tests initially for TPA (for example, an acute and chronic toxicity study in daphnids); and depending on the results of these initial studies, a full suite of studies may or may not be subsequently required."

OPP Post-Hr'g Br. at 8. AMVAC has never argued that OPP was agreeing in advance to waive any data requirement. AMVAC is arguing that OPP created an expected course of conduct whereby, as plainly stated in JX 66, OPP would review the *Daphnia* data and, "depending on the results of these initial studies," determine whether "a full suite of studies," *i.e.*, the other studies in this category now remaining at issue, were required. *See* JX 66 p. 7 of 9. The suggestion is plain – AMVAC could *defer commencing* of the non-*Daphnia* studies subject to OPP's review of the *Daphnia* data. OPP's review of the *Daphnia* data was issued concurrently with the NOITS, JX 69, leaving no time for AMVAC to take any further action. This clearly contravenes the course EFED had suggested and violates OPP's own "basic tenets of fairness" test. *See* OPP Pre-Hr'g Br. at 3 n.1. The NOITS was thus premature and invalid as to the studies in this group.

Second, OPP relatedly imagines that AMVAC "assumed that the submission of the *Daphnia* studies—received by EPA in late 2020—created an open-ended period of discussion" in which "the determination of whether certain data requirements are still required is contingent on agreement from the registrant." OPP Post-Hr'g Br. at 8-9. AMVAC witnesses did not say either of these things, and AMVAC has argued neither of them. The record is bereft of any suggestion that AMVAC asserted that EFED's *Daphnia* proposal gave AMVAC some elevated right to determine whether the other data requirements would remain outstanding after the *Daphnia* data was reviewed by EFED.

Third, OPP attributes to AMVAC an argument AMVAC has never made: that "it was reasonable to assume that the DCPA DCI [TPA ecotoxicology] data requirements were waived until receiving notice—concurrently with the NOITS—that the data was still outstanding." *Id.* at 9. AMVAC did not assume that the other TPA ecotox requirements were "waived" with the possibility of being "un-waived" based on the review of the *Daphnia* data. AMVAC did believe,

based on EFED's communication in JX 66, only that it was reasonable to proceed with the *Daphnia* data as a first step, as it did.

OPP also appears to fault AMVAC for submitting, in December, 2020, a survey of available TPA ecotox data. In that document (PAX 45) AMVAC provided a broader discussion of the available data incorporating the *Daphnia* data that EFED had suggested AMVAC gather. OPP Post-Hr'g Br. at 9. This submission was voluntary on AMVAC's part and went beyond the mere data suggested by EFED and attempted to place it in the broader context, thereby expanding on AMVAC's prior waiver requests *in addition* to submitting the requested *Daphnia* data. TX 59:11-24 (Ms. Wendel confirming that PAX 45 "provided a separate analytical writeup of [the *Daphnia* data] putting them in context of various other TPA ecotox data for DCPA and TPA that were then available." OPP's other points, OPP Post-Hr'g Br. at 9-10, relate to the results of the *Daphnia* studies, which affected EFED's ultimate conclusion (revealed concurrently with the NOITS) that it was not recommending granting all of the TPA ecotox waivers in view of the *Daphnia* data. But EFED's eventual conclusion does not change the fact that AMVAC behaved appropriately by obtaining the precise data EFED suggested as a first step and then waiting for EFED's response.

B. OPP's Failure to Allege Properly Delegated Waiver Denials

As discussed in the Introduction, OPP failed to plead or prove that any document issued by OPP at any point during the DCI was a properly authorized denial of an AMVAC waiver request. *See also* AMVAC Post-Hr'g Br. at 36-37. This alone should be a sufficient basis to reject the proposed suspension. Establishing the existence of a properly delegated waiver denial is a necessary, though not sufficient, element of OPP's case that a registration should be suspended under the Suspension Provision. OPP appears to hope the proper delegation issue will

simply go away. Its hope is misplaced.

OPP cannot rely on the fact that the Pesticide Reevaluation Division ("PRD") forwarded certain internal memoranda (from EFED to PRD) to AMVAC. As noted in AMVAC's Post-Hr'g Br. at 36 and asserted by OPP itself in discovery, EFED does not possess the authority to grant or deny waivers. S*ee* AMVAC Mot. for Produc. of Delegation Docs., Dkt. 45 at 1-2 (Jan. 4, 2023); *see also* TX 117:9-15. Merely forwarding a recommendation does not constitute action on that recommendation. AMVAC Post-Hr'g Br. at 37 n.29 (discussing *In re Julie's Limousine & Coachworks, Inc.*, 11 E.A.D. 498 (EAB 2004)). And, *even if it could*, the delegation documents in the record (PAX 63-77) reveal that no potentially relevant authority to grant or deny waivers was delegated below the Division Director level in PRD at all prior to February, 2019, as discussed in more detail below. None of the transmittals to AMVAC prior to JX 21 in October of 2020 came from any person at or above the Division Director level. All transmittals to AMVAC prior to JX 21 (all of which occurred prior to February of 2019) consisted of brief notes from the PRD Chemical Review Manager ("CRM") or team leader simply transmitting the EFED internal memorandum. JX 75 (transmitting JX 74); JX 36 (transmitting JX 66).

There are two potentially relevant delegations which confer authority on OPP personnel to grant or deny waiver requests.[11] The first, Delegation 5-38, relates to authority "to perform the [OPP] functions and responsibilities relative to the periodic review of pesticide registrations [under] [S]ection 3(g) of [FIFRA,]" as amended, and the regulations set forth in 40 C.F.R. 155, Subpart C. PAX 70 p. 1 of 2. It provides that the "authority to grant or deny requests for time extensions or data waivers relating to Data Call-in notices issued in conjunction with registration

[11] Potentially relevant delegation documents were provided to AMVAC in early January. *See* Notice of Withdrawal of Mot. for Produc. of Delegation Docs., Dkt. 51 (Jan. 13, 2023); TX 167:20-168:12 (discussing and admitting delegation documents PAX 63-77).

review may be redelegated [further] to the Branch Chief level or equivalent[.]" *Id.* But the delegation documents in the record, provided to AMVAC in response to a FOIA request and directly by Agency counsel, *see* Dkt. 51, establish that authority under Delegation 5-38 has never been delegated below the Division Director level. *See* PAX 70 (June 17, 2008 Memorandum purporting to delegate authority under 5-38 to the Director of SRRD); PAX 73 (addressing SRRD renaming to PRD but not otherwise modifying delegation). Pursuant to these documents, PRD Division Director Elissa Reaves would have possessed the delegated authority to deny waiver requests, to the extent it exists under Delegation 5-38, at all times since the DCI in this matter was issued.

OPP appears to assert that another delegation, Delegation 5-1-B, is the appropriate, or perhaps a concurrent, source of authority for granting or denying waivers in connection with registration review DCIs. OPP Resp. to AMVAC's Mot. for Produc. of Delegation Docs., Dkt. 50 (Jan. 9, 2023). In contrast to Delegation 5-38, Delegation 5-1-B does not relate to the registration review program. But even if Delegation 5-1-B can be stretched to confer authority to grant or deny waiver requests in connection with this DCI (which AMVAC disputes), the record contains no documentation of delegation below the OPP Division Director level under it until, at the earliest, February, 2019. PAX 72 (redelegations from OPP Div. Dir. to PRD Div. Dir. and to PRD Branch Chiefs). Then the authority was redelegated, in a new document chain, to the team leader level in a series of communications in March and April of 2020. PAX 74-76. As such, the transmittal of JX 74 and JX 66 were not properly authorized under Delegation 5-1-B either, because the documents were transmitted prior to February of 2019 by individuals not possessing delegated authority at the time. JX 75 (July, 2016, transmitting JX 74); JX 36 (March, 2017, transmitting JX 66). It thus is not possible that any waiver request was validly denied until

October of 2020 (JX 21), at the earliest.

AMVAC has explained why OPP has not established, and cannot establish, that JX 21 was a ratification, by Ms. Reaves, of prior waiver requests. AMVAC Post-Hr'g Br. at 37 n.29. But even if it were a properly delegated waiver denial, it was the first one. This alone would be fatal to the NOITS for the chronic *Leptocheirus* and three TPA environmental fate (*i.e.*, the Series 835) data requirements because the DCI set 24-month time frames for completion, JX 4 pp. 28, 32 of 46, would not have expired as of April of 2022 when the NOITS was issued. And it would not establish that the NOITS was timely as to the TPA ecotox studies either because all JX 21 would have ratified related to those was EFED's proposal to conduct the *Daphnia* studies, as discussed in the prior section. The next OPP action on those which could possibly have constituted a denial did not come until concurrent with the NOITS in JX 69.

C. OPP's Unfounded Attacks on AMVAC Witness Credibility

OPP devotes the largest section of its Post-Hr'g Br., at 10-14, to impugning the credibility of AMVAC's witnesses and, in particular, its expert witness Mr. Gur. OPP's attacks fall flat when the actual content of the pertinent testimony is examined. In many cases, the testimony is in fact consistent with testimony from OPP's witnesses. This case is nothing like the *Smith Farm* case cited by OPP, which simply stands for the unremarkable proposition that the EAB "generally defers" to an ALJ who heard live testimony from witnesses, provided that the ALJ makes a well-supported credibility determination.[12]

[12] The evidence supporting the credibility determination in *Smith Farm* bears no resemblance to the testimony in this case, even skewed as OPP presents it. In *Smith Farm*, a first expert discounted by the ALJ testified in conflict with an expert report he co-authored, and attempted to explain the conflict by stating that his team "had committed [them]selves to the prose in the report." *In re Smith Farm Enterprises, LLC*, 15 E.A.D. 222, 256 (EAB 2011). He was also found to have "limited knowledge" of the physical site at issue. *Id*. A second expert had relied

Somewhat remarkably, OPP did not update its Verified Written Witness statements at all after its initial legal theory-of-the-case was rejected by the EAB. The EAB's decision provided substantial guidance as to the issues on which the hearing should focus. AMVAC's witnesses *did* take the opportunity to review and update their statements given the additional time available and the tighter and more directed focus (in terms of the number of data requirements) of the hearing on remand, as the Presiding Officer explicitly authorized.[13]

OPP tries to make something out of nothing based on this fact. For example, OPP notes that, in several instances, the initial written testimony submitted by an AMVAC witness referred generally to waivers being "denied," while the revised testimony referred to the fact that the same documents were EFED recommendations to PRD to deny a waiver. There is no inconsistency. It can be true both that a document was understood to be a waiver denial at the time (as Dr. Freedlander testified on the stand, and as the initial draft of his witness statement stated) and was also, on its face, merely an EFED recommendation that PRD deny a waiver as the statements were updated to note. Dr. Freedlander simply updated his testimony from being directed at what he understood at the time (*i.e.*, that JX 66 had the practical effect of "denying" AMVAC's waiver request) to referencing the uncontested terms of the document itself (*e.g.*, JX 66 p. 7 of 9 ("EFED recommends that PRD denies request to defer the data collection . . . .")). Dr. Freedlander then truthfully testified concerning his understanding of JX 66. TX 312:1-313:10. OPP strains in vain to paint this modification as evidence of two "competing" versions of the facts. OPP Post-Hr'g Br. at 11.

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on a sampling methodology he himself conceded could introduce bias. The Owner of the property in question resorted to stating "I don't recall" when asked critical questions. *Id.* at 257.

[13] The Presiding Officer's Hearing and Schedule Order Following Remand, Dkt. 30 at 2 (Oct. 3, 2022), stated that the parties may "freely amend [their] witness list[s], narrative summaries of expected testimony, documents, or exhibits" in advance of the re-calendared hearing.

OPP's fails to comprehend that AMVAC's lack of delegated authority argument – an independent basis to declare the NOITS unlawful and/or premature – does not turn on how its own witnesses perceived a particular document. AMVAC argues both that Dr. Freedlander (and the rest of the AMVAC team) responded appropriately based on their understanding of the various documents (be it a "denial" or a "recommendation") and that the NOITS cannot stand because OPP wholly failed to issue properly delegated waiver denials.

OPP also states that Mr. Gur's attestation that he decided to change his statement "strains credulity." *Id.* But OPP does not explain why this is so. Mr. Gur testified that he was "asked [for the hearing on remand] to focus on only nine studies [instead of 20] and, therefore, [he] could read much more carefully all the documents." TX 398:24-399:23. Mr. Gur also confirmed to OPP counsel, "I don't think the facts have changed." TX 399:1. The documents say what they say – they were EFED recommendations to PRD, *see, e.g.*, JX 66, 74, 69, 79 – and AMVAC's witnesses truthfully testified that they nonetheless understood at the time the documents were received that they were evidence that a waiver was not then being granted.

OPP also attempts to discredit Mr. Gur by suggesting that his estimates of average DCI duration are generally longer than those of other witnesses. OPP Post-Hr'g Br. at 12. The core of this attempt is Mr. Gur's statement that it is "very rare to see a DCI finalized in 3 years." TX 434:12-16.[14] But Mr. Gur also put this into context: a "very simple DCI that has very simple and narrow requirements, and probably standard studies" could be completed within three years, not one as complex as the DCPA DCI. *Id.* OPP attempts to contrast Mr. Gur's assertion that it is rare to see a DCI "finalized" in three years with statements from OPP witnesses Bloom and

[14] "Yeah, I think 3 years is a -- is a very -- should be only a very simple DCI that has very simple and narrow requirements, and probably standard studies, very standard. I think it's very rare to see a DCI finalized in 3 years."

Wendel, but even OPP admits the manner in which the witnesses were discussing the timing was not apples-to-apples, *see* OPP Post-Hr'g Br. at 12 n.10 (conceding that Bloom and Wendel's time frames did not include EPA's review of data and *speculating* that three years would still be the low end even if this was added). Thus, when there is an apples-to-apples comparison (even crediting the speculation in OPP's footnote 10) all that comparison shows is that Mr. Gur was saying that DCIs are rarely completed faster than what Ms. Bloom and Ms. Wendel suggested would be the low end of the range. The testimony is therefore consistent.

OPP suggests that Mr. Gur's statement that "the Agency's typical practice [is to] consider multiple waiver requests as to the same data requirement," PAX 97, Gur Statement ¶ 66, is an outlier. To do so, OPP selectively quotes from Dr. McMahon's statement at TX 301-02. But Dr. McMahon was describing how she conceives of the process followed, not disputing that scientific dialog (whether denominated as multiple waivers or not) is typically entertained. TX 302:3-7 ("So official waivers, you know, doing one and then doing another, I usually see those more as a discussion, a technical discussion where you come to an agreement, as opposed to you do a waiver, then you do a waiver, then you do a waiver."). This is fully consistent with Mr. Gur's statement; both describe an iterative process with the Agency. Dr. McMahon was clear that the "conversation" model of waiver discussion was how she understood the discussions *in this case*. TX 301:22-25 ("So you can elaborate on, many times, your position. *And I think that's what's here* is that a position is being taken and then you, you work towards, does the EPA agree with your position.") (emphasis added). Dr. McMahon's testimony therefore confirms Mr. Gur's testimony in this regard.

Furthermore, Ms. Bloom's testimony that "multiple waiver requests for the same data requirement . . . didn't happen that often", TX 205:5-7, also does not discredit Mr. Gur's

assertion that when there are multiple requests, whether denominated as multiple waivers, or an iterative "conversation," the Agency will typically consider the additional requests. Mr. Gur's testimony also has the virtue of being consistent with OPP's practice in this very matter, in which OPP evaluated and even granted waivers, for which AMVAC had provided expanded justifications, throughout the course of the DCI and even up to the time of the NOITS as it did in JX 69 and JX 79.

OPP next attempts to discredit Mr. Gur in connection with his testimony concerning the effect of an assumption of stability. This attempt concerns Mr. Gur's written statement that "[i]n JX 69, EPA for the first time presented modeling indicating a concern that assuming stability would lead to a gradual increase in environmental concentrations. EPA had never articulated this concern in the past, even when it stated that it could and would assume stability." PAX 97, Gur Statement ¶ 64. OPP's Post-Hr'g Br. at 13 suggests that the concern was articulated in PAX 80 pp. 79-80 of 176 ("[V]irtually all DCPA measured on day zero in aerobic soil metabolism studies was present as TPA at the end of the study.").

But the statement OPP quotes relates only to why the EFED author of that document thought that the TPA data available at that time suggested an assumption of stability was not "overly conservative." The "DCPA measured on day zero" was in a laboratory study, not in the environment. PAX 80 pp. 79-80 of 176. EFED then proceeded to apply the assumption of stability to two models – GENEEC and PRZM/EXAMs. EFED displayed, in PAX 80 p. 82 of 176, a curve generated by PRZM/EXAMs which showed increasing concentrations, but EFED expressly disregarded this analysis as "not likely to occur in nature."[15] EFED chose instead to

[15] EFED stated in full that, the "PRZM/EXAMS model . . . may result in a very high estimate of EECs because some loss of TPA is expected due to burial of sediment, overflow of the pond

rely on Risk Quotients ("RQs") generated by GENEEC, with which it was able to calculate Peak Estimated Environmental Concentrations ("EECs"). *Id.* at 81. Thus, to the extent the same concern articulated in JX 79 was arguably previously "articulated" in PAX 80, it was expressly rejected by EFED as "not likely to occur in nature." Mr. Gur's statement is therefore accurate, because even if the PRZM/EXAMs model in PAX 80 showed an increasing concentration similar to the chart in JX 79, PAX 80 did not "indicate a concern," as Mr. Gur testified, because OPP had expressly rejected the results of the PRZM/EXAMs model as "not likely to occur in nature" and chosen to rely on GENEEC instead. PAX 80 p. 81 of 176.

A second problem with OPP's attack on Mr. Gur's stability testimony is that OPP mischaracterizes his statement. OPP Post-Hr'g Br. at 13 suggests that Mr. Gur's testimony stands alone for "alleging AMVAC was unaware that OPP might assume an increase in TPA environmental concentration[,]" citing PAX 97 pp. 18-19 of 27. Mr. Gur makes no statements about what AMVAC was or was not aware OPP might assume in his written testimony. His testimony therefore does not "stand alone" in this regard. In his oral testimony, he readily conceded AMVAC *might* have been aware that assuming stability would lead to EECs increasing. TX 401:18-21; 402:11-17.

OPP's last attack on Mr. Gur's credibility comes in n.12 on p. 14 of its Post-Hr'g Br. There, after asserting the other issues with Mr. Gur's testimony are not "exhaustive," OPP offers one more. Following OPP counsel's request for playback by the court reporter, TX 440:1-3, of

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during heavy runoff events, and other processes that would result in dilution (for instance, when fresh rain falls in the pond), flushing of excess chemical and turnover of the water in the pond. Additionally, because of this accumulation the generated EECs do not represent a 1 in 10 year value but a maximum value if TPA were applied every year to the same plot with the same amounts for 30 years with none of the TPA entering the pond being lost. This is illustrated in Figure 3-2, which shows the estimated TPA EECs increase every year in a manner that is not likely to occur in nature." PAX 80 p. 81 of 176.

Mr. Gur's statement responding to a cross-examination question that "in many cases, EPA would probably disregard [comments on work plans]," TX 431:7-13, Mr. Gur confirmed that EPA does, in his expert opinion, sometimes disregard comments that have been submitted on work plans. TX 441:18-24. In response to OPP counsel's assertion at the hearing that Mr. Gur's testimony in this regard was "quite a serious allegation," TX 440:11-14, Mr. Gur clarified that what he specifically meant by "disregard" was that OPP "many times says we received comments from the registrant saying this and this. We heard them. We'll take care of it when we do the risk assessment. It won't address all the specific comments." TX 441:3-6. No evidence from OPP rebuts that testimony.

In n.12 of its Post-Hr'g Br., OPP goes outside the record to find *one single instance* in which OPP modified a DCI in response to a comment filed by a registrant on a Cyflufenamid Preliminary Work Plan. But this reveals only the extent of OPP's misguided attempt to discredit Mr. Gur. OPP witness Ms. Bloom testified that only about half of work plans are commented on in the first place, and she estimated that only between 12.5% and 25% of workplans are modified based on comments.[16] This is fully consistent with Mr. Gur's testimony that, "in many cases," OPP will acknowledge but not directly act on comments. The fact that even OPP's witness stated that work plans are rarely modified in response to comments confirms Mr. Gur's testimony and also supports rejecting any implicit argument by OPP that the common practice of not commenting on work plans should prejudice later waiver requests, particularly where the work plan was, in several key respects, already aligned with the substance of the later waiver requests. TX 338:18-339:2 359:14-360:6.

[16] TX 160:24-161:18 ("25 percent [change] of the 50 percent [commented on]"); TX 162:16-19 ("whenever a [preliminary workplan] comes out and the data requirements change, that's maybe 25 percent.").

Drs. Freedlander and McMahon, and Mr. Gur, as noted in AMVAC's opening statement, TX 19-25, value their relationships with the professionals at OPP and depend in their careers on their relationships with OPP and OPP personnel. They would not sacrifice those relationships in the pursuit of short-term gain in this proceeding. None of their statements provided a basis to question their credibility. OPP's strained attempt to discredit AMVAC's witnesses should be disregarded.

D. Flaws in OPP's Existing Stocks Argument

OPP opens its discussion of the existing stocks issue by asserting again that the EAB "found no issue" with the Presiding Officer's conclusions concerning the existing stocks policy. OPP Post-Hr'g Br. at 14. This is misleading at best. The EAB made clear that "review of the existing stocks determination at this stage is premature." Remand Order at 770 (Syllabus). The Remand Order stated that the Presiding Officer was to, on remand, "first determine whether AMVAC failed to take appropriate steps . . . [and], if the ALJ finds a basis for the suspension, [determine] whether the existing stocks provision of the DCPA NOITS is consistent with FIFRA." Remand Order at 796.

The Remand Order contained directions relevant to the ALJ's consideration on remand, including that no special deference is to be afforded to OPP, Remand Order at 792. It also confirmed that the statutory deadline does not affect the scope of the appropriate steps inquiry, Remand Order at 786. The Presiding Officer's prior Order on the Motion for Accelerated Decision, in its discussion of the existing stocks issue, asserted that one purpose of an existing stocks provision is to give "effect to the statutory deadline for review." Order on Mot. for Accelerated Decision, Dkt. 28 at 34 (July 1, 2022) ("Order on MAD"). Even if the statutory deadline may be considered in connection with the existing stocks inquiry, that deadline has

changed and is now October of 2026.[17]

The factual circumstances have also changed. Dr. McMahon testified, without challenge, that all studies are currently underway. PAX 93, McMahon Statement ¶¶ 37-42. Any interest in "giv[ing] teeth to EPA's ability to enforce FIFRA's data requirements[,]" Order on MAD at 34, applies only to the extent the Presiding Officer believes there is a residual risk that AMVAC would simply cease the ongoing studies absent the existing stocks order as proposed. That risk is not present here.

Additionally, the Presiding Officer previously noted that the coercive effect of the existing stocks policy is appropriate (and Growers' concerns could not be weighed) because "it is impossible to weigh the impact of such disruption against the harm, if any, its cumulative use over time may be causing as determined using current scientific data." *Id.* This assertion was incorrect as a matter of law. OPP necessarily did make a finding that use of DCPA would not cause "unreasonable adverse effects" – which includes an analysis of benefits – when it registered DCPA in the past. *See* AMVAC Request for Hearing and Objections, Dkt. 4, ¶¶ 21, 22 (May 27, 2022); 7 U.S.C. § 136a(a). It cannot be correct that OPP is incapable now – possessing far more data than it did at the conclusion of the 1987, 1992, or 1995 DCIs, the 1998 reregistration, or the 2005 tolerance reassessment – of even considering harm to Growers when it necessarily considered the risks and benefits of DCPA at these points in the past.

To the extent a new concern was created by AMVAC's submittal of preliminary CTA data, that concern has now been addressed by the submittal of the final data. *See* AMVAC Post-Hr'g Br. at 11-12. OPP itself has confirmed that it can and is proceeding with risk assessment.

[17] Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 § 711, Registration Review Deadline Extension (extending OPP's deadline for Registration Review until 2026); TX 214:25-215:9 (OPP witness Bloom confirming she is aware of the extension).

TX 242:11-17. *See also* EPA, Upcoming Registration Review Actions, DCPA,[18] as updated on April 10, 2023,[19] indicating that the "Draft Risk Assessment" for DCPA is expected to be published in FY Q3 (*i.e.*, April – June) 2023. There can be no further concern that weighing is impossible given that OPP has, within the last two weeks, confirmed that a draft risk assessment will soon be published.

OPP's argument that it need not conduct a risk/benefit analysis should be rejected. OPP relies entirely on parsing its own 1991 existing stocks "statement of policy," RX 24 – a document to which the ALJ should afford no deference, *see* Remand Order at 792-93 – to identify a purported distinction between existing stocks policies in connection with FIFRA Section 6 cancellations (which OPP concedes must be informed by a risk/benefit analysis) and existing stocks policies in connection with Suspension Provision suspensions, which OPP asserts do not require such an analysis. OPP Post-Hr'g Br. at 16. Both 7 U.S.C. § 136d(a)(1) (governing existing stocks policies in cancellation actions and suspensions for imminent hazard) and the Suspension Provision, 7 U.S.C. § 136a(c)(2)(B)(iv), refer to an analysis of whether an existing stocks policy is "consistent with" or "not inconsistent with" FIFRA, respectively. There is no statutory basis to argue that one inquiry requires a risk/benefit analysis and the other does not. Finding otherwise would lead to absurd results – for example, that OPP could avoid consideration of market impacts so long as it asserted uncertainty based on lack of data (or even simply in connection with a NOITS where a registrant had ceased operations), but when it initiated a cancellation proceeding based on an actual risk concern, an obligation to consider

[18] EPA, *Upcoming Registration Review Actions*, https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions (updated Apr. 10, 2023).
[19] EPA, *EPA Publishes Updated Registration Review Schedule*, (Apr. 10, 2023) https://www.epa.gov/pesticides/epa-publishes-updated-registration-review-schedule.

market impacts would then arise.

OPP's arguments as to why the "person adversely affected" language does not confirm a Congressional intent to perform a risk/benefit analysis have been addressed by the Growers in their Post-Hr'g Br., Dkt. 61 at 8, 10 (Apr. 7, 2023).

OPP's three additional arguments are inapposite. First, it asserts that the market structure here is not "unique," as has been asserted, because OPP was able to locate several other active ingredients for which there is only one registrant of technical product and end-use-products. OPP Post-Hr'g Br. at 15. OPP's argument is superficial. It is not critical to AMVAC or the Growers' logic that DCPA be *the sole* active ingredient subject to this market structure. There likely are others as OPP suggests. This proves only that in any hypothetical suspension of those, OPP would also have to consider the fact that suspending the technical product would have market impacts that would not occur in the more common scenario of multiple registrants. OPP's only fallback position appears to be its statement that "there is no legal impediment" to a third-party obtaining a registration and thus altering the market structure. OPP Post-Hr'g Br. at 17. That is true, but hardly relevant – OPP has not indicated that this realistically might occur.

OPP finally objects that harms from an exhaustion of DCPA EUPs resulting from the current existing stocks policy are hypothetical in nature. This is not correct. The harm will most assuredly occur at some point if AMVAC's DCPA technical registration is suspended; the only question is how soon. AMVAC presented evidence at the hearing to support that this would likely occur in late 2023 or early 2024. PAX 96, Ranganath Statement ¶ 10. Calculation of the precise date of exhaustion is not possible as a practical matter, given uncertainties in the supply

chain and uncertainty about when a suspension might go into effect. *Id.* ¶ 12.[20] Precise timing evidence would often not be available, given these uncertainties, and thus any meaningful review of OPP's consideration of potential harms to growers would rarely be possible. AMVAC has offered to provide updated figures if the Presiding Officer believes they are necessary, *see* AMVAC Post-Hr'g Br. at 42 n.33. The Presiding Officer, in any event, should not fashion a rule that growers must establish with precision when harm to them would begin. *In re Environmental Defense Fund*, 1 E.A.D. 543 (EAB 1979), cited by OPP in their Post-Hr'g Br. at 18, does not establish such a rule, or even discuss this issue.

The Presiding Officer should initially determine if the proposed existing stocks provisions can stand based on OPP's conceded failure to consider harm to growers. Then, only if necessary, the Presiding Officer should then evaluate whether any punitive/deterrent measures are appropriate (thus warranting potential harms to growers) and then finally (only if needed) assess whether growers should bear additional burden here because there will be no further formulation of technical DCPA after a suspension unless the existing stocks policy is relaxed to permit formulation of technical DCPA that may be in AMVAC's possession at the time a suspension goes into effect.

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[20] It would be an understatement to say that the timing of this matter has been uncertain, given that this Reply is being filed on the one-year anniversary of the NOITS.

III. CONCLUSION

For the reasons set forth above, and in AMVAC's Initial Post-Hearing Brief, 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.

OPP asks for a novel remedy – suspension of a registration where a registrant submitted or otherwise satisfied the vast majority of the data requirements in a DCI, spending millions of dollars in the process – because, in connection with a small subset of the DCI requirements, OPP alleges that the registrant's conduct in making and supporting waiver requests fell below a standard that OPP is hoping the Presiding Officer will delineate fully for the first time in the Order suspending the registrant. If OPP wants to alter its prior practices and promulgate new rules governing DCI responses, it may do so through notice and comment rulemaking. The Presiding Officer should reject OPP's attempt to skirt that process by way of this proceeding.

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Date: April 21, 2023

Respectfully Submitted,

/s/ *Hume M. Ross*

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Petitioner AMVAC Chemical Corporation's Post-Hearing Reply Brief**, was sent on April 21, 2023, to the following parties in the manner indicated below.

/s/ *Hume M. Ross*
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