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

RESPONDENT'S POST-HEARING BRIEF

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I. INTRODUCTION

Respondent, the United States Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs ("OPP"), pursuant to the Presiding Officer's March 17, 2023 Post-Hearing Scheduling Order and 40 C.F.R. § 164.90(a), respectfully submits this Post-Hearing Brief.

II. ARGUMENT

Both the written record of this matter and the evidence introduced during the hearing demonstrate that Petitioner, AMVAC Chemical Corporation ("AMVAC") failed to take appropriate steps to secure the data required by Generic Data Call-In 078701-1140 ("DCPA DCI") within the time required by the DCPA DCI. For the nine DCPA DCI data requirements discussed below, the record clearly demonstrates that AMVAC failed to take appropriate steps to secure the data even after being informed multiple times by OPP that the data were still outstanding.

Furthermore, the provisions of the April 28, 2022 Notice of Intent to Suspend ("NOITS") concerning existing stocks of AMVAC's DCPA technical product (EPA Registration Number 5481-495) are clearly consistent with FIFRA, as already recognized by both the Presiding Officer and the Environmental Appeals Board ("Board"). Order on Respondent's Motion for Accelerated Decision ("Accelerated Decision") at 31-34 (EPA July 1, 2022); Decision and Remand Order ("Remand") at 27-28 (E.A.B. Sep. 28, 2022) (emphasizing excerpt from OPP's policy on existing stocks).

Accordingly, the Presiding Officer should find that AMVAC failed to take appropriate steps to secure the data required by the DCPA DCI, enter an order suspending AMVAC's DCPA technical product, and uphold the existing stocks provision of the NOITS.

A. Respondent has Established that AMVAC Failed to Take Appropriate Steps to Secure the Data Required by the DCI Within the Time Required

1. Special Study 1072; DCPA Chronic Sediment Toxicity (*leptocheirus*)

There is no dispute that AMVAC failed to submit a DCPA chronic sediment (28-day) toxicity special study as required by the DCPA DCI. Accelerated Decision at 28. The record clearly demonstrates that AMVAC failed to take appropriate steps to secure the DCPA chronic sediment toxicity data required by the DCPA DCI within the time required by the Administrator. OPP twice denied AMVAC's requests to waive this data requirement and both times provided AMVAC with a potentially-less onerous alternative study; AMVAC submitted neither the study required by the DCPA DCI nor the alternative. Respondent adopts the substantial pre-hearing briefing submitted on this data requirement. Respondent's Prehearing Brief at 10-13.

During the hearing, AMVAC's witnesses confirmed that OPP denied AMVAC's waiver requests in 2017 and 2020, that both denials included an offer to consider the results of a Guideline 850.1740 sub-chronic study in the context of a future waiver request, and that this data requirement remains outstanding. Transcript of Proceedings ("Tr.") at 272-78 (McMahon); Tr. at 315-19 (Freedlander). Additionally, live testimony from AMVAC witnesses makes clear that AMVAC affirmatively chose not to proceed with the SS-1072 *leptocheirus* study required by the DCPA DCI, based on the company's assertion that the lack of this data "would not delay [OPP's] conclusions" during registration review. Tr. at 280; *see also* Tr. at 321. This position was taken despite the fact that AMVAC acknowledged the study remained outstanding at all points since issuance of the DCPA DCI. Tr. at 282, 318-19. AMVAC's witnesses unanimously acknowledged, in response to direct questioning from the Presiding Officer, that "EPA has th[e] last word" in determining whether a given study is required. Tr. at 303-04, 346, 410.

Respondent also notes that, according to testimony from McMahon, the entire SS-1072 *leptocheirus* study could have been completed in no more than a year and a half. Tr. at 301-02.[1] Notwithstanding AMVAC's contested testimony[2] that performance of the study was so difficult or the anticipated results so problematic that AMVAC did not feel the data would be useful to EPA, it is clear that AMVAC could have easily submitted a *leptocheirus* study within a relatively short time after either OPP waiver denial. As Respondent previously briefed the Presiding Officer, there is no obligation for OPP to inform AMVAC that further waiver requests would not be considered. Respondent's Prehearing Brief at 5, Tr. at 14; *cf.* AMVAC Prehearing Brief at 2. Had AMVAC—at any of several points following OPP's 2017 denial of the request to waive SS-1072—accepted OPP's determination that the study was still required, it could have submitted data responsive to the DCPA DCI or at least taken OPP's suggested strategy of bolstering its waiver requests by conducting the less-onerous 850.1740 study. However, despite AMVAC's witnesses understanding that OPP has the final say in whether a given data requirement should be waived or remain outstanding, the record and testimony presented to the Presiding Officer clearly demonstrate that AMVAC simply did not agree with that basic principle and acted accordingly. The question before the Presiding Officer is not whether a given study will return data that OPP—or more pointedly, AMVAC—considers satisfactory; the question is whether AMVAC took appropriate steps to submit data responsive to the DCPA DCI that OPP determined was necessary on multiple occasions when denying the company's successive waiver

[1] During the hearing, AMVAC witness McMahon testified to the approximate cost of performing various studies. Tr. 298-99. Respondent notes that OPP does consider testing costs when initiating a DCI, both through submitting the DCI to the U.S. Office of Management and Budget for approval and in publishing the anticipated data requirements in the Federal Register for public comment. Motion for Accelerated Decision ("MAD") at 5-6, n.3.

[2] *Compare* Tr. at 275-77, 351, 356-58 (discussing alleged problems in *leptocheirus* data submitted in a single prior example) *with* Tr. at 86-88 (Wendel testifying that at least 16 "successful" *leptocheirus* studies had been submitted to OPP since 2017, including studies performed by the same lab AMVAC ultimately contracted to perform the 850.1740 study).

requests. The factual and legal bases demonstrating that AMVAC failed to take appropriate steps to submit data responsive to SS-1072 are not presently—and have never been—genuinely disputed.

2. Guideline 835.4300, TPA Aerobic Aquatic Metabolism

As with the *leptocheirus* study discussed above, the necessary factual and legal bases demonstrating that AMVAC failed to take appropriate steps to submit data responsive to the DCPA DCI have never been at issue with respect to the 835.4300 TPA study. Respondent adopts its prior briefing to the Presiding Officer. Respondent's Prehearing Brief at 13-16. In summary, AMVAC indicated to OPP that it would submit a responsive study, but never did so. *Id.* at 13; *see also* PAX 94 at 10-12 (Freedlander acknowledging that AMVAC never indicated an intent to submit a second waiver request, and that OPP believed AMVAC would submit a new responsive study). AMVAC neither contested the factual or legal basis of Respondent's case in prehearing briefs, nor adduced any testimony during the hearing concerning the same. *Cf.* Tr. at 135-38 (cross-examination testimony from OPP witness Stephen Wente merely noting that JX 22 mentioned a previous DCPA study). AMVAC's entire argument with respect to this data requirement apparently hinges on an oblique December 2020 reference to previously-submitted DCPA data as a reason why AMVAC believed the TPA data was not required. Tr. at 137-38; JX 22 at 1. Putting aside the question of whether OPP should have reasonably understood this reference as a separate waiver request, even accepting AMVAC's argument would mean that the company was just re-asserting the same—previously denied—rationale for waiver of this data requirement. Respondent's Prehearing Brief at 14. Regardless of whether AMVAC made a "clerical error" in suggesting that it would submit a responsive study, or simply re-iterated its disagreement with OPP's waiver denials, neither version of events would constitute appropriate steps to secure the data required by the DCPA DCI.

3. Guideline 835.4200, TPA Anaerobic Soil Metabolism
4. Guideline 835.4400, TPA Anaerobic Aquatic Metabolism

As with the other individual DCPA DCI data requirements discussed above, Respondent adopts its prior briefing. Respondent's Prehearing Brief at 21-23. The record clearly demonstrates that AMVAC failed to take appropriate steps to secure these two data requirements of the DCPA DCI within the time required by the Administrator. There is no dispute that AMVAC failed to submit these studies required by the DCPA DCI. AMVAC requested successive waivers for these studies in 2013 (denied by OPP in 2017 and 2020) and 2020 (denied by OPP in 2022). JX 77, JX 37, JX 22, JX 78, JX 79. As explained in the parties' prehearing briefs and in testimony during the hearing, the central dispute with respect to these data requirements concerns the effect, if any, of OPP's statements about "conservative assumptions." Respondent maintains that question is legal in nature and has been appropriately briefed by the parties. Respondent's Prehearing Brief at 21-23.

In its pre-hearing brief, AMVAC stated:

> [W]ith respect to conducting a risk assessment, the evidence will show that AMVAC was urging EFED to make worst case assumptions for purposes of risk assessment, *i.e.*, that TPA should be assumed to be "stable" – to not degrade – under each of the relevant conditions for purposes of risk assessment. OPP stated that it could and would do this.

AMVAC Prehearing Brief at 15; *see also* JX 78.[3] However, testimony from AMVAC witnesses during the hearing paints a substantially different picture of the company's beliefs and communications. *Compare* Tr. at 325-28 (Freedlander's belief that "it was appropriate" for OPP to move forward with registration review using conservative assumptions, even if that resulted in onerous label changes or cancellation of the DCPA product), *with* Tr. at 341 (Freedlander stating

[3] Notwithstanding the discussion during the hearing as to whether JX 78 constituted a "scientific analysis" or contained different reasoning to support AMVAC's subsequent waiver requests for the 850.4200 and 850.4400 data requirements, the document is an example of AMVAC arguing both that TPA would build up in the environment but also that TPA would actually degrade. JX 78 at 4, 12; Tr. 119-23 (Wente: "[AMVAC is] encouraging [use of the most conservative assumptions in JX 78] at one point and then they're saying that even though you should make that assumption it would be wrong essentially.").

that he did not believe OPP's conservative assumptions would "work against AMVAC's best interest"); *see also* Tr. at 329 (Freedlander: AMVAC never indicated that OPP's use of conservative assumptions concerning TPA stability would be acceptable to the company). Testimony from AMVAC witnesses Freedlander and Gur demonstrate that AMVAC sought to have its cake and eat it too with respect to the question of whether TPA was stable in the environment. The company understood that the data available to OPP showed TPA to be stable from degradation, which would necessarily lead to OPP making assumptions of very high TPA environmental concentrations in the absence of the Guideline Series 835 TPA data required by the DCPA DCI, and likely lead to severe mitigations being necessary to address the resulting estimated levels of exposure. *Id.*; *see also* Tr. at 341-45.[4] However, AMVAC witness testimony suggests that AMVAC also expected OPP would not ultimately make conservative assumptions, based on a single older, non OCSPP Guideline-compliant, study[5] that showed TPA would eventually break down in some soils.[6] Tr. at 360-68 (Freedlander); Tr. 401-02, 412-16, 421-22 (Gur). Thus, despite OPP's inclusion of TPA degradation data requirements in the DCPA DCI—which would either confirm that TPA is stable or provide a usable degradation curve if run for a

[4] During the hearing, counsel for AMVAC called attention to a footnote in JX 79, wherein OPP "characterized [TPA] as stable to [ ] aerobic aquatic metabolism." Tr. 137-38 (citing JX 79 at 5, n.2 (emphasis added)). Respondent notes that this discussion is not relevant to OPP's ability to "derive a stable half-life" for the anaerobic degradation of TPA, which is at issue in the two DCPA DCI data requirements discussed in this section and at the hearing, for which OPP specifically stated in the same document that the characterization of stability was "due to the lack of supporting data." JX 79 at 5.

[5] *See* Tr. at 370-73. Respondent notes that, despite the non-compliant study forming the basis of AMVAC's belief that TPA would eventually degrade, the company did not advocate that OPP use the non-compliant study to calculate a degradation half-life for TPA. Tr. at 373. AMVAC at no point describes how this data would allow OPP to characterize TPA as anything other than stable.

[6] Respondent notes that AMVAC's expectation was not reasonable, as the company was aware that OPP was considering environmental monitoring data showing high TPA concentrations in groundwater, consistent with assumptions that TPA did not degrade. Tr. at 344-45; *see also* JX 65 at 22-24 (2011 Preliminary Problem Formulation for Ecological Risk Assessment of DCPA, noting sampling and monitoring data show persistence of TPA at high concentrations years after DCPA application).

long enough time period—AMVAC declined to provide the required data while at the same time arguing that OPP should not make assumptions of TPA's stability, possibly with the intent of attacking any such reliance on conservative assumptions as unjustified. *See* Tr. at 121-25 (Wente: "nobody is going to believe [that TPA is stable] until you've got a study that backs it up"). The company was not "urging" OPP's use of conservative assumptions and did not anticipate any serious mitigations to result from the lack of data.

In its briefing, AMVAC also argues that OPP only recently "conceded" that "longer than standard" degradation studies may be necessary to characterize TPA degradation. AMVAC Prehearing Brief at 15. As previously explained in OPP witness Wente's written testimony, the "requirement" for a longer-duration test is not something separately imposed by OPP, but rather is apparent from the text of the Series 835 test guidelines. RX 26 at 4. Under 40 C.F.R. § 158.1300, OPP may require metabolism data. *Id.* Guidelines 835.4200 and 835.4400 provide methods by which a registrant can obtain data likely to satisfy such data requirements, including potential testing modifications that may be necessary depending on the chemistry of the product being tested. *Id.* For example, Guideline 835.4400 provides that "the study should be conducted until the decline of parent and the formation and decline of the degradates are established." PAX 81 at 14; *see also* Tr. at 125-29; PAX 82 at 13. During the hearing, AMVAC's counsel questioned OPP witness Wente concerning a non-EPA document, PAX 85. Tr. at 129-35. While the apparent purpose of this discussion was to demonstrate that PAX 85—cited in Guideline 835.4200—cautioned against running soil metabolism tests for longer than four months, AMVAC succeeded only in demonstrating that EPA did not choose to incorporate that cautionary language into its final guidelines. Tr. at 133. Wente noted that the EPA did not include a caution against longer-duration studies, likely because the EPA Guidelines also include

requirements for measurement of microbial biomass in order to control for any negative consequences resulting from the longer timeline. Tr. at 133-35.

5. **Guideline 850.1350, TPA Aquatic Invertebrate Life-Cycle, Estuarine/Marine Mysid**
6. **Guideline 850.1400, TPA Fish Early Life-Stage (Rainbow Trout)**
7. **Guideline 850.1400, TPA Fish Early Life-Stage (Bluegill Sunfish)**
8. **Guideline 850.1400, TPA Fish Early Life-Stage (Sheepshead Minnow)**
9. **Guideline 850.4500, TPA Algal Toxicity Test, Tier 1/II (Marine Diatom)**

Respondent adopts its prior briefing on these five data requirements. Respondent's Prehearing Brief at 24-26. Through its prehearing brief and witness testimony during the hearing, 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*. AMVAC's Prehearing Brief at 13-14. That argument is premised on several faulty assumptions. First, 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. *See* JX 37 at 7. In both the 2017 denial of AMVAC's waiver request and in the 2020 Data Delay Letter, OPP clearly indicated that data responsive to these requirements were necessary to complete registration review. JX 37, JX 21. OPP never indicated that it would waive these data requirements if AMVAC only submitted the more limited data.

Second, AMVAC assumed that the submission of the *daphnia* studies—received by EPA in late 2020[7]—created an open-ended period of discussion in which OPP and AMVAC would "review those [*daphnia*] results with [OPP] in order to determine whether additional aquatic

[7] Respondent acknowledges that AMVAC submitted the chronic *daphnia* study in 2018, but that an issue with the data-submission system CDX likely resulting in OPP not receiving the studies until late 2020. However, in OPP witness Bloom's unrebutted testimony, registrants will usually also inform OPP via email that a study has been submitted. Tr. at 222. Thus, Respondent asserts that delayed delivery should not be used to justify the timing of AMVAC's actions with respect to this data requirement. *See also* Tr. 441-45 (Gur: industry usually takes proactive steps to address outstanding waiver requests due to "the limitations of [OPP's] current system" of communication).

organism testing is warranted." *See* JX 67 at 10. OPP has not indicated to AMVAC—or any other registrant, for that matter—that the determination of whether certain data requirements are still required is contingent on agreement from the registrant.

And third, AMVAC believed that it was reasonable to assume that the DCPA DCI data requirements were waived until receiving notice—concurrently with the NOITS—that the data was still outstanding. In 2017, OPP declined to grant AMVAC's request to waive these five—and many other—data requirements based on AMVAC's contention that the agency should "perform an ecological risk assessment of the metabolite TPA using the endpoint(s) determined for DCPA." JX 37 at 7. Following OPP's October 2020 Data Delay Letter—which reiterated that the same waivers remained denied—AMVAC submitted a waiver request using the same contention, *i.e.,* "the focus of ecological risk assessments should focus solely on DCPA." PAX 45 at 6. In PAX 45, AMVAC briefly discussed existing studies on the comparative toxicity of DCPA and TPA. *Id.* at 7. One of the *daphnia* studies that AMVAC's case hinges upon in this matter was conducted in 2003, was already previously submitted to OPP during the DCPA DCI, and did not establish a definitive toxicity endpoint for TPA, rather simply finding that both the DCPA and TPA acute toxicity endpoints for *Daphnia* were greater than 0.55mg/L, an exposure substantially lower than tested in the other studies. *Id.* The other studies discussed showed a wide range of toxicity ratios between DCPA and TPA. *Id.* As previously briefed to the Presiding Officer, the fact that OPP *may* move forward with registration review using conservative assumptions as to a chemical's toxicity does not justify AMVAC's failure to submit data that would allow OPP to make an educated estimate of actual toxicity. *See* Respondent's Prehearing Brief at 24-25. OPP clearly required actual data on TPA toxicity, not merely AMVAC's

assertions of its toxicity relative to DCPA, given that TPA was expected to accumulate to very high concentrations that could result in acute and/or chronic toxicity risks. JX 69 at 4-5.

B. Inconsistent Testimony and Comparative Witness Credibility

A primary purpose of the hearing held in this matter was to allow the parties "an opportunity to cross examine the witnesses who provided conflicting statements," and for the Presiding Officer to "evaluate[] the credibility of those witnesses based on live testimony." Remand at 23. The Presiding Official recognized this purpose of evaluating opposing witnesses to resolve disputed issues of material fact. Order on Motions for Additional Discovery at 3 (Nov. 4, 2022). In several instances, the live testimony from AMVAC witnesses is inconsistent with those witnesses' prior statements and with testimony of other AMVAC witnesses. Testimony from its expert witness is also clearly agenda-driven. Such findings would clearly support the Presiding Officer's discounting of that testimony. *In re: Smith Farm Enterprises, LLC*, 15 E.A.D. 222, 2011 WL 946993 at *26-28, (E.A.B. 2011) (upholding an ALJ's "well-supported" credibility determinations based on substantial evidence in the record concerning objectivity and bias).

Live testimony from AMVAC's expert witness, Ephraim Gur, is inconsistent with his own prior written statement and in many key respects with the weight of other evidence before the Presiding Official, including testimony from other AMVAC witnesses. In his June 17, 2022 Verified Written Statement, Gur discusses situations in which "a waiver is denied by EPA." RX 20 at 10-11. However, in his January 9, 2023 Verified Written Statement, Gur included a substantially-identical discussion with one key change: it concerned situations in which "EFED or HED recommends denying a waiver." PAX 97 at 14-15. When confronted with this inconsistency on cross-examination, Gur maintained that the EPA memoranda discussed in RX

20 and PAX 97 only constituted "EFED recommend[ations]," and stated that it was "[his] idea to make changes" in the language. Tr. at 399. While a similar inconsistency appears between AMVAC witness Richard Freedlander's June 17, 2022 and January 9, 2023 written statements, Freedlander acknowledged during live testimony that the memoranda "contain[ed] OPP's denial of AMVAC's waiver requests." *Compare* PAX 94 (January 9, 2023 Verified Written Statement of Richard Freedlander) at 3 ("JX 66 stated that EFED was recommending that PRD deny AMVAC's [waiver request]."), *with* RX 19 (June 17, 2022 Verified Written Statement of Richard Freedlander) at 9-10 ("[JX 66] denied AMVAC's [waiver request]."), *and with* Tr. at 313-14 (acknowledging that JX 66 constituted OPP's denial of AMVAC's waiver requests).

With respect to this matter—which constituted a substantial portion of AMVAC's litigation effort following remand[8]—Gur's attestation that he alone decided to change his stated understanding of OPP's "denial" of AMVAC waiver requests to one of mere "recommendation" strains credulity. Other than Gur, AMVAC's witnesses agreed during live testimony that the EFED memoranda transmitted to AMVAC by PRD during the course of this matter constituted denials of AMVAC's waiver requests. *Id.*; *see also* Tr. at 271-72 (McMahon statement that JX 37, a 2014 EFED memorandum, constituted a waiver denial). The competing position, that the EFED memoranda constituted only recommendations, first appeared on December 2, 2022, in AMVAC's discovery responses, and was later copied into Gur's and Freedlander's 2023 written statements. AMVAC Response to Requests for Admission at 8; PAX 97 at 14-15; PAX 94 at 3. Respondent urges the Presiding Officer to view Gur's testimony less as a factual examination of

[8] AMVAC devoted substantial energy towards probing the question of whether various EPA subdivisions possessed sufficient delegated authority to deny AMVAC's waiver requests, and in advancing its theory that OPP only belatedly—or never—definitively denied the company's repeated waive requests. *See, e.g.*, AMVAC Response to Requests for Admission at 8, AMVAC Motion for Production of Delegation Documents; Tr. at 116-18, 163-68.

the record and application of his expertise, and more as a carefully-tailored attempt to spin the facts in support of a novel and recent legal strategy.[9]

Gur similarly stands alone in his position on several other matters. With respect to the typical timelines for a registrant to complete a DCI, OPP witness Jill Bloom stated that in most cases OPP expected to receive all data responsive to a DCI within three to four years depending on the nature of the data requirements, with OPP often willing to wait an additional matter of months or a year to obtain data. Tr. at 236-40; *see generally* Tr. at 40-43 (OPP witness Christina Wendel discussing typical timelines for scientific review of registrant-submitted data).[10] AMVAC witness McMahon largely concurred with Bloom, stating that in her experience, completion of registration review DCIs "take somewhere between 3 1/2 to 7 years . . . and 7 years is [ ] starting to get on the long side." Tr. at 290-91. Gur, however, opined that it was "very rare to see a DCI finalized in 3 years," and that multiple unspecified DCI responses he had previously worked on extended "more than 10 years." Tr. at 433-35.

During the hearing, AMVAC witness McMahon and OPP witnesses Wendel and Bloom all noted that it was unusual for a registrant to submit multiple waiver requests for the same data requirement. Tr. at 301-02 (McMahon stating that she engaged in "conversations" with OPP to discuss the need for data, "as opposed to you do a waiver, then you do a waiver, then you do a waiver"); Tr. at 85 (Wendel stating that she was familiar with only a single instance of multiple waiver requests for the same data requirement, which occurred with respect to an avian

[9] Respondent reiterates that all Parties clearly understood the referenced EFED memoranda transmitted to AMVAC by PRD, as denials of waiver requests. Respondent's Prehearing Brief at 29-31. Additionally, all then-outstanding waiver requests were unequivocally denied by the October 2020 data delay letter issued by PRD. *Id.*; JX 21.

[10] Respondent notes that Bloom's estimate of three to four years concerned only registrant submission of data and that, viewed with Wendel's testimony concerning the typical timeline for EFED to review that data, would result in satisfaction of a typical DCI within three to five years. In comparison, testimony from AMVAC witnesses concerned completion of DCIs, including both submission and review. Thus, testimony from Bloom and McMahon is generally confirmatory with respect to this matter.

reproduction study initially required for a chemical intended to reduce egg laying in birds); Tr. at 205 (Bloom stating that "multiple waiver requests for the same data requirement [ ] didn't happen that often"). Only Gur states that OPP's "typical practice" includes entertaining "multiple waiver requests as to the same data requirement." PAX 97 at 19. With respect to this question, which is pivotal to much of AMVAC's challenge to the NOITS, only Gur maintains that it was reasonable for AMVAC to continue submitting waiver requests after OPP's initial denials.

With respect to the question of whether AMVAC expected that OPP would "assume stability" of TPA,[11] both OPP witness Wente and AMVAC witness Freedlander clearly understood that such an assumption would result in OPP making conservative assumptions in registration review, with the result that DCPA would "not [ ] do very well in a risk assessment." Tr. at 109-13 (Wente) (citing JX 80 at 79); *e.g.* Tr. 325-28 (Freedlander) ("We saw that direction the agency was warning us they were going to take and, and we thought actually it was appropriate to move forward in that way."). Indeed, in a 2009 risk assessment of DCPA—raised by AMVAC's counsel during cross examination of Wente—OPP specifically made the same conservative assumption and explicitly observed that TPA concentrations continued to rise throughout a study. JX 80 at 79-80 ("[V]irtually all DCPA measured on day zero in aerobic soil metabolism studies was present as TPA at the end of the study."); Tr. at 110-15. Here again, Gur's written testimony stands alone, alleging AMVAC was unaware that OPP might assume an increase in TPA environmental concentration. PAX 97 at 18-19. Gur made no such statement in his original written statement. RX 20. During live testimony, when repeatedly asked specifically whether it was reasonable for AMVAC to understand that OPP would assume increasing concentrations of TPA if the Agency assumed TPA was stable in the environment, Gur declined

[11] *Supra* pp. 5-7.

to acknowledge that continued application of DCPA with no degradation of TPA would lead to increasing TPA environmental concentrations. Tr. at 401-07 (Gur conjecture concerning TPA bioconcentration through the food chain, a concept not otherwise discussed in the record), 421-22. Gur's understanding of the circumstances surrounding the DCPA DCI and OPP's registration review process[12] is clearly incomplete, and the Presiding Officer should further discount his written and live testimony given the tight correspondence between his post-2022 testimony and AMVAC's new, post-remand litigation positions, both of which contradict other AMVAC and OPP witness testimony and Gur's own prior written testimony. *Smith Farm Enterprises*, 2011 WL 946993 at *28; *In re: Phoenix Construction Servs., Inc.*, 2004 WL 1658593 at *17 (E.A.B. 2004) (affirming ALJ's decision to rely solely on testimony from more credible witnesses).

C. Existing Stocks Provisions in the NOITS are Consistent with FIFRA and OPP's Longstanding Policy

The Board found no issue with the Presiding Officer's conclusions concerning the existing stocks provisions of the NOITS. Remand at 27-28. The Board recognized the clear statutory authority providing broad discretion to OPP with respect to existing stocks of products suspended under FIFRA Section 3(c)(2)(B)(iv). *Id.* at 27. In quoting OPP's longstanding policy on existing stocks, the Board emphasized that "*the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension*." *Id.* (quoting 56 Fed. Reg. 29362, 29,367 (June 26, 1991)). Absent any contrary indication from the Board or any plausible argument from AMVAC or Grower Petitioners, the Presiding Officer's conclusions

[12] Respondent notes that the above-described instances are not an exhaustive list. *Compare, e.g.*, Tr. at 431, 440-41 (Gur statement that OPP often disregards comments submitted to registration review dockets and will not address specific requests to waive a data requirement) *with* Respondent's Prehearing Brief at 5-6 (citing Cyflufenamid Registration Review Docket, EPA-HQ-OPP-2021-0733-0008, -0009) *and with* Cyflufenamid: Response to Comments on Preliminary Work Plan of Registration Review, EPA-HQ-OPP-2021-0733-0010 (OPP agreeing with registrant comment that certain data would likely not "provide any added value for the risk assessment" and agreeing to use previously-submitted data in risk assessment).

from the Accelerated Decision must stand. Accelerated Decision at 31-34; see also Response Brief of Respondent at 37-41; MAD at 47-51; Respondent's Prehearing Brief at 27-28.

Petitioners Grower-Shipper Association of Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms (collectively "Growers") assert that the existing stocks provisions of the NOITS are "not reasonable, rational or consultative." Tr. at 27. With the exception of the argument that FIFRA Section 3(c)(2)(B) requires consideration of market disruption by virtue of allowing third parties to request a hearing—first raised during the hearing and addressed in more detail below—all of Growers' and AMVAC's (collectively, "Petitioners") arguments concerning existing stocks have been fully briefed previously. *See* Respondent's Prehearing Brief at 27-28, Response Brief of Respondent at 37-41; MAD at 47-51. Respondent briefly recaps the major arguments as follows:

Growers make the unsupported assertion that "a unique market structure in supply and distribution of DCPA" exists. Tr. at 28. As Respondent previously noted, "AMVAC's status as the sole registrant of both the technical and end-use products is not unique." Response Brief of Respondent at 39. A brief search of publicly-available databases demonstrates that it is not uncommon for a single company to control the entire United States market for a given pesticide product, including both technical and end-use products.[13]

Additionally, Petitioners' arguments that OPP is required to consider economic benefits before suspending a pesticide under FIFRA Section 3(c)(2)(B) conflate language in OPP's 1991 Existing Stocks Policy concerning existing stocks of pesticide products cancelled under FIFRA

[13] *See, e.g.*, EPA Pesticide Products and Label System, *available at* https://ordspub.epa.gov/ords/pesticides/f?p=113:6:::::P6_XCHEMICAL_ID:3651 (search for active ingredient pyrasulfatole, with a single registrant, Bayer Cropscience LP, for all registered products); https://ordspub.epa.gov/ords/pesticides/f?p=113:6:::::P6_XCHEMICAL_ID:2307 (search for active ingredient ethyl 1-naphthaleneacetate, with AMVAC as the sole registrant for all registered products); https://ordspub.epa.gov/ords/pesticides/f?p=113:6:::::P6_XCHEMICAL_ID:2301 (search for active ingredient ethoprop, with AMVAC as the sole registrant for all registered products).

Section 6 or pesticide products for which labels have been amended under FIFRA Section 3, with language in the same policy specifically addressing the instant situation. Response Brief of Respondent at 37 n.26 (citing Growers' Appeal at 2). Whereas EPA's decision whether to allow the continued sale or use of cancelled products—or products bearing older labels without updated language—clearly involves a risk/benefit analysis, Petitioners ignore that FIFRA Section 3(c)(2)(B) explicitly provides OPP with broad discretion in the area of existing stocks. This reflects the fact that suspension under FIFRA Section 3(c)(2)(B) is intended to serve as an incentive for the submission of outstanding data. The existing stocks provisions of the NOITS are clearly rational when viewed in the context of that incentive structure. Petitioners have repeatedly failed to make any persuasive argument that such an incentive applies only if OPP also justifies any potential market impact. *See* Response Brief of Respondent at 38-39. Furthermore, Petitioners have not provided any specific suggestion as to what existing stocks provision would supposedly comply with their reading of FIFRA, aside from rendering suspension of DCPA a suspension in name only. *Id.* at 39-40; *cf.* Tr. at 28.

Petitioners raised a new legal argument at the hearing concerning the existing stocks provisions of the NOITS, to wit: that the text of FIFRA Section 3(c)(2)(B)—allowing a request for hearing from "a person adversely affected by the [NOITS]"—demonstrates "a clear intent to bring questions of market disruption within the scope of this hearing." 7 U.S.C. § 136a(c)(2)(B)(iv); Tr. at 386; *see also* Tr. at 27. This argument fails for two reasons. First and foremost, while the question of "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA]" is clearly one of the matters within the narrow scope of the hearing under FIFRA Section 3(c)(2)(B)(iv), there is no support for Petitioners' expansive reading in the plain language of the statute. 7 U.S.C. § 136a(c)(2)(B)(iv).

As noted above, both FIFRA Section 3(c)(2)(B)(iv) and OPP's longstanding existing stocks policy reflect that such suspensions serve as an incentive for registrants to submit required data as quickly as possible. 56 Fed. Reg. 29,362-63. Accordingly, existing stocks restrictions issued pursuant to FIFRA Section 3(c)(2)(B) suspensions are generally placed only on entities subject to the provisions of the DCI in question; other entities are generally free to sell, distribute, and use products without restriction. *Id.* at 29,367. Had OPP attempted to impose restrictions on Growers' use of DCPA products in the instant case, Growers could have requested a hearing to challenge OPP's departure from longstanding policy and from the purpose of suspension under FIFRA Section 3(c)(2)(B)(iv). However, OPP imposed no such restrictions and attempted to make clear in the NOITS that there were no restrictions on the use of DCPA products for any entity other than AMVAC. JX 1 at 5 ("Persons other than the registrant subject to this Notice, may continue to distribute, sell, use, 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 product, EPA Registration Number: 5481-495]."). The NOITS placed no restrictions on sale or use of DCPA end-use products at all. *Id.* In fact, there is no legal impediment to a third party applying for a DCPA end-use registration that would be formulated from AMVAC's technical product, or any other registered source of DCPA. The Presiding Officer must make a determination that the provisions of the NOITS are consistent with FIFRA, and can easily do so without consideration of economic impact. Despite Petitioners' attempts to muddy the scope of that determination, it is clear from the record that the existing stocks provisions in this case are consistent with both FIFRA Section 3(c)(2)(B) and OPP's longstanding policy.

Second and relatedly, FIFRA Section 3(c)(2)(B)'s provision for "a person adversely affected" to request a hearing makes no assumption as to the interests or potential evidence that

might be offered by a non-registrant petitioner. As noted above, Growers could have challenged any restrictions on their use of DCPA products, had OPP attempted to impose such restrictions through the NOITS. Petitioners' interpretation of FIFRA Section 3(c)(2)(B) attempts to read in a non-existent statutory consideration of the specific interests at play in the instant case to support its assertion that Congress intended consideration of market disruption.

Respondent also notes that the record does not establish that Growers are likely to experience any impact from suspension of AMVAC's DCPA technical product, and actually suggests that Growers would not be adversely affected. Neither Petitioner provided a specific estimate as to how long supplies of DCPA end-use products would be expected to last, and AMVAC itself maintains that any suspension of the DCPA technical product would be short-lived due to the company's ongoing efforts to satisfy the DCPA DCI. PAX 96 at 3 (Ranganath estimates of available DCPA products and statement that AMVAC is actively working to formulate enough products "to satisfy DCPA EUP demand through the end of 2023 or beyond"); AMVAC Prehearing Brief at 18. Although Growers' initial petition for a hearing was likely proper to allow "the interests of farmers and other consumers [to] be considered before a pesticide's availability [is] restricted," Respondent notes that Growers have not presented evidence establishing an actual adverse impact in this matter; any market disruption remains entirely hypothetical at this juncture. *See In the matter of Envtl. Def. Fund*, 1 E.A.D. 543, 1979 WL 52075 at *12 (Adm'r. 1979).

III. CONCLUSION

For the reasons set forth above and in prior briefing, Respondent respectfully requests that the Presiding Officer enter an order pursuant to FIFRA Section 3(c)(2)(B) finding that AMVAC failed to take appropriate steps to secure the data required by the DCPA DCI within the

time required, suspending AMVAC's DCPA technical product, and implementing the existing stocks provision of the NOITS.

Respectfully submitted,

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Dated: April 7, 2023

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In re FIFRA Section 3(c)(2)(B) Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration
AMVAC Chemical Corporation; Grower-Shipper Association of Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms, Petitioners.
Docket No. FIFRA-HQ-2022-0002

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Respondent's Post-Hearing Brief**, dated April 7, 2023, was sent this day to the following parties in the manner indicated below.

FORREST PITTMAN Digitally signed by FORREST PITTMAN Date: 2023.04.08 00:11:54 -04'00'

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