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 REPLY 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 Reply Brief.

II. AMVAC'S GENERAL ARGUMENTS

Respondent maintains that all of AMVAC's arguments—other than those raised for the first time in AMVAC's Post-Hearing Brief ("AMVAC Post-Hr'g Br.")—have been sufficiently addressed in Respondent's prior filings in this matter for the Presiding Officer to make the required determinations. Accordingly, Respondent largely directs the Presiding Officer to such prior filings including, but not limited to its: Post-Hearing Brief ("Resp't Post-Hr'g Br."), Prehearing Brief ("Resp't Pre-Hr'g Br."), Response to AMVAC Requests for Admissions, Interrogatories, and Document Requests ("Resp't Resp. to Disc. Req."), Opposition to AMVAC Motion for Additional Discovery ("Resp't Opp'n to Mot. for Disc."), Response Brief ("Resp't Resp. Br.") filed with the Environmental Appeals Board ("Board"), and Motion for Accelerated Decision ("MAD"), in reply to AMVAC's arguments below.

A. Alleged OPP "Policy"

AMVAC makes a number of related arguments, all of which boil down to some version of OPP allegedly attempting to "enforce [a new policy] without any public notice." AMVAC Post-Hr'g Br. at 32 n.23, 4, 34. Specifically, AMVAC alleges that OPP is attempting to impose a number of changes to DCI compliance on the pesticide industry through language included in Respondent's Prehearing Brief. *Id.* (citing *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106

(2015); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).[1] As the Presiding Officer clearly recognizes, the supposed "policy"—alternately, "rule," "statement of position," or "theory," depending on AMVAC's parlance—was provided in Respondent's brief in direct response to the Presiding Officer's October 3, 2022 and October 18, 2022 scheduling orders, wherein she specifically requested that the parties provide suggested "meaning[s]" of the phrases "within the time required by the administrator" and "failed to take appropriate steps to secure the data required." Dkt. 30, 33; Tr. 209-10. That request is clearly derived from the Board's finding "that the legal standard for determining whether the suspension should take effect is whether, within the time required by the Administrator, AMVAC failed to take appropriate steps to secure the data required by the [DCPA DCI]." Remand at 19. The Board's finding is itself necessary because the meanings of those two terms is not apparent from the plain language of FIFRA Section 3(c)(2)(B) and has not previously been interpreted in policy or caselaw. *Id.* Thus, as the Presiding Officer must apply these standards, she may determine whether Respondent's, Petitioners', or some other set of definitions is appropriate and, consequently, whether AMVAC's conduct in the instant matter satisfied the requirements of FIFRA Section 3(c)(2)(B).

AMVAC makes several arguments concerning waiver requests. AMVAC Post-Hr'g Br. at 4, 13. AMVAC incorrectly reads Respondent's prehearing brief as attempting to justify suspension where an applicant fails to submit data within a period equivalent to the original DCI timeframe following OPP's denial of an initial waiver request, with no consideration of any other

[1] AMVAC presumably cites *Perez* and *Fox Television Stations* to suggest that OPP's supposed "policy" is arbitrary and capricious for failure to provide an adequate explanation for changing its past interpretation. Unlike the situation in *Perez*, OPP did not "issue a new interpretation of a regulation that deviates significantly from one the agency has previously adopted. 575 U.S. at 95. There was no "initial agency action [or] subsequent agency action undoing or revising that [initial] action." 556 U.S. at 515. As noted above, Respondent's briefing to the Presiding Officer does not constitute a new policy, and AMVAC has not alleged that any prior policy ever existed. Had such a policy ever existed, it is doubtful that the Presiding Officer would have requested the specific briefing she did. AMVAC's argument remains premised on the fact that OPP—due to resource constraints—rarely takes the step of seeking suspension where registrants fail to submit data responsive to a DCI.

appropriate steps. *Id.* at 4. That is not the position conveyed in Respondent's brief. Resp't Pre-Hr'g Br. at 5 ("[F]ollowing OPP's denial of the waiver request, AMVAC should reasonably have submitted data, or taken other appropriate steps to secure the data required . . . .") (emphasis added). AMVAC also cites the instructions included in all OPP DCIs in support of its arguments, but crucially omits the additional instructions on the same page. *Compare* AMVAC Post-Hr'g Br. at 13 (citing JX 4 at 15) *with* Resp't Pre-Hr'g Br. at 8 (quoting JX 4 at 15, "If EPA determines that the data are required for your product(s) you must choose a method of meeting the requirements of this [DCI] within the time frame provided by this Notice."). AMVAC attempts to conflate the question of whether the submission of a successive waiver request constitutes an appropriate step under FIFRA Section 3(c)(2)(B) with the separate question of whether the contents of a waiver request are sufficient for OPP to grant it. AMVAC Post-Hr'g Br. at 8, 24 (asserting that "OPP's witnesses largely did not testify that there was anything inappropriate concerning AMVAC's waiver requests.").[2] The purpose of this hearing is not for the Presiding Officer to evaluate the scientific sufficiency of AMVAC's waiver requests to determine whether OPP should have granted the requests, or whether AMVAC's decision to submit successive requests was "meritorious and [thus] constituted appropriate steps." *Cf. id.* at 8.

Respondent maintains that, although OPP has entertained successive waiver requests in the past due to the extreme resource commitment of pursuing suspension, a successive waiver request—especially one that is substantially similar in rationale to one previously-denied—should

[2] Although not clearly articulated, AMVAC also apparently argues that the fact OPP granted several waivers in the same 2022 document wherein it denied other AMVAC waiver requests should be viewed as proof that the action of requesting a successive waiver request was appropriate under FIFRA Section 3(c)(2)(B). AMVAC Post-Hr'g Br. at 7 (citing JX 69, JX 79). Curiously, AMVAC has no issue whatsoever with labelling a supposed EFED "recommendation" to waive a study as an actual waiver, while denigrating "recommendations" to deny in the same document as legally insufficient. *See* JX 79 (issued by EFED).

not be interpreted as an "appropriate step" under FIFRA Section 3(c)(2)(B). Resp't Pre-Hr'g Br. at 9; Resp't Opp'n to Mot. for Disc at 10-11. The fact that "AMVAC maintained a consistent position,"—*i.e.*, that certain data requirements should be waived—is of no import. *Cf.* AMVAC Post-Hr'g Br. at 14.[3] In a similar vein, AMVAC also asserts that the additional support it provided in successive waiver requests constituted appropriate steps, and that OPP's entire case is based simply on "how long the DCI took, [thus] there must be inappropriate conduct in there somewhere." AMVAC Post-Hr'g Br. at 3, 14. This argument is easily dismissed; one need only examine Respondent's repeated descriptions of the individual failures to take appropriate steps in its many briefing documents. *See, e.g.*, Resp't Post-Hr'g Br. at 2-4 (describing numerous inappropriate steps taken by AMVAC with respect to SS-1072).

B. Alleged OPP "Motivations"

AMVAC makes a number of statements concerning OPP's alleged motivations for issuance of the NOITS, with a variety of theories as to how said motivations should affect this proceeding. Pre-eminent among those is the NOITS is now inappropriate because AMVAC submitted[4] the CTA study during the course of this proceeding. AMVAC Post-Hr'g Br. at 1. Accompanying this argument is the baseless assertion that OPP issued the NOITS not in order to obtain all of the data needed for risk assessment, but rather "as a de-facto cancellation proceeding" under FIFRA Section 6. *Id.* at 41; Growers Post-Hr'g Br. at 15. As noted previously,

[3] Respondent notes that AMVAC's assertion of "unrebutted" testimony from Gur that multiple waiver requests for the same data requirement are typical is absurd on its face. *Cf.* AMVAC Post-Hr'g Br. at 35. Both OPP and AMVAC witnesses testified that while registrants do engage in scientific conversations with OPP, the use of successive waiver requests is unusual. Resp't Post-Hr'g Br. at 12-13.

[4] With respect to AMVAC's assertion that the CTA was submitted on the schedule previously promised by the company, Respondent notes that the initial CTA submission was deficient, necessitating AMVAC's submission of an amended final CTA in August 2022.

OPP has been completely transparent—perhaps overly-so—in describing its motivations in this matter, and has followed proper procedure under FIFRA to obtain the data necessary to make well-informed risk assessments. Resp't Resp. Br at 12-16. The fact that OPP mentioned potential anomalous thyroid risk concerns—for which it required additional data to properly evaluate—in the NOITS does not invalidate the clearly lawful process of seeking suspension under FIFRA Section 3(c)(2)(B). OPP's mere mention of the concerning preliminary CTA data in the NOITS is of no legal import; such comments concerned only one of the outstanding data requirements addressed in the NOITS. As noted to the Board, were OPP to publish a notice of intent to cancel DCPA under FIFRA Section 6(b) based on a risk assessment developed prior to the submission of necessary data, AMVAC would have no doubt argued that cancellation was premature because OPP lacked the data necessary to support cancellation. Petitioners in this case also seemingly assert that the only useful data still outstanding at the time of the NOITS was the CTA study; they maintain that any other still-outstanding data is a mere sideshow. Growers Post-Hr'g Br. at 6.

Despite acknowledging that the statutory deadline for OPP to complete registration review of DCPA has no bearing on this matter, AMVAC includes a number of unexplained references thereto. AMVAC Post-Hr'g Br. at 2, 33. As noted previously, the deadline was cited only as context for OPP's decision on whether or not to pursue suspension, not as a legal justification of the NOITS. Resp't Resp. Br at 11-12; Remand at 18 ("FIFRA Section 3(g) only imposes a requirement on the Administrator to complete registration review; it does not provide a deadline for a registrant to submit data in response to a [DCI]."). Additionally, the fact that Congress extended the statutory deadline for OPP to complete registration review for many pesticide products, including DCPA, does not suggest that OPP must now reconfigure its timelines for completing these myriad processes to accommodate AMVAC's professed need for additional time to submit studies responsive to the DCPA DCI.

AMVAC notes that studies responsive to the nine outstanding data requirements "are well underway" but does not explain the relevance of that fact. AMVAC Post-Hr'g Br. at 2. As explained previously, the post-NOITS initiation of studies does not constitute an appropriate step under FIFRA Section 3(c)(2)(B). Resp't Pre-Hr'g Br. at 28-29.

AMVAC also alleges that Respondent "disavowed" OPP witness Jill Bloom's statements—that AMVAC's conduct was "abnormally dilatory and repetitive"—as a factual basis for issuing the NOITS. AMVAC Post-Hr'g Br. at 14. AMVAC is correct that those descriptors do not constitute the legal standard that OPP must show to suspend a pesticide product; that standard was clearly laid out by the Board in the Remand. However, Respondent maintains that Bloom's statements do constitute a useful description of AMVAC's conduct in this matter. *See, e.g.*, Resp't Post-Hr'g Br. at 12-13 (noting that both OPP and AMVAC witnesses generally testified to 10 years being a very long time to complete a DCI and multiple waiver requests for the same data requirement being unusual). The fact that AMVAC was abnormally dilatory and repetitive in responding to the DCPA DCI does not entitle OPP to prevail in this matter. However, the facts supporting Bloom's characterization of AMVAC's conduct are the same ones that Respondent cites as proof that AMVAC failed to take appropriate steps, in accordance with the Board's Remand.

C. Conservative Assumptions

AMVAC includes a number of semi-novel arguments concerning OPP's ability to make conservative assumptions during registration review, presumably for the purpose of demonstrating that the NOITS is no longer necessary. The company asserts that "none of the [nine currently outstanding data requirements] are necessary for OPP to move forward with the

risk assessment process." AMVAC Post-Hr'g Br. at 2. AMVAC's assertion that OPP normally used conservative assumptions misses the point entirely. *See* AMVAC Post-Hr'g Br. at 11. As previously explained, the fact that OPP sometimes does proceed with risk assessment while making conservative assumptions does not mean that such data are no longer needed. Resp't Pre-Hr'g Br. at 21-22; Resp't Post-Hr'g Br. at 5-7; Resp't Resp. Br. at 8-9. The Freedlander testimony cited by AMVAC does not address the fundamental question of whether data was still required. Under AMVAC's preferred statutory regime, EPA could re-assess a pesticide already on the market with little or no data submitted by a registrant, make conservative assumptions in risk assessment, and then be forced to enter into a post-risk assessment process with the registrant to slowly reduce anticipated risks based on submission of data to "refine" those initial conservative assumptions, all while the product continues to be sold and used. Such an argument is clearly at odds with the structure and purpose of FIFRA. *Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324-25 (8th Cir. 1973) ("[T]he registrant has a continuing burden of proof to establish that its product is entitled to registration.").

Respondent again notes that, in the communications where OPP stated that "conservative assumptions may be used [ ] to complete risk assessment," OPP also clearly stated that waiver requests for those data requirements were denied, that the data was still outstanding, and specifically asked for AMVAC to "provide a response [ ] indicating how [AMVAC] intend[s] to satisfy the remaining data requirements, including a timeline for the generation and submission of outstanding data." AMVAC Post-Hr'g Br. at 10 (quoting JX 21); *see also* Resp't Pre-Hr'g Br. at 22; JX 21 at 1-2. With respect to JX 21, AMVAC's hyper-focus on one phrase as justification for the course of action that the company intended to take anyway—not submitting data—while

ignoring other specific language and the larger context of OPP communications, is emblematic of this entire proceeding.

Respondent also strongly contests AMVAC's implied argument that OPP should be required to move forward with risk assessment before determining if data required by a DCI is actually required. *See* AMVAC Post-Hr'g Br. at 11. Not only does AMVAC blatantly mis-state the context of both Gur and Bloom's respective hearing testimony, but the suggested order of events—DCI issued, no data submitted, OPP forced to make conservative assumptions, risk assessment completed, OPP tells registrants that data is still needed—has no basis in FIFRA, historical practice, or common sense. *See* Tr. at 400 (Gur stating that some data requirements are driven by older, pre-DCI risk assessments and agreeing that OPP normally does not conduct risk assessments before determining if data is actually required); Tr. at 239-40 (Bloom specifically noting that OPP would not proceed with risk assessment and a registration review interim decision if a registrant could provide needed data within the matter of "months or a year"). The work-arounds that OPP has employed in the past to proceed with its statutory duty in the face of registrants failing to provide required data should not be interpreted as justification for AMVAC's conduct in this matter.

D. Supplementing Witness Statements and/or Amending the NOITS

AMVAC repeatedly complains that OPP witnesses decided not to alter their testimony submitted in June 2022. AMVAC Post-Hr'g Br. at 3; AMVAC Pre-Hr'g Br. at 3. Respondent is unsure as to what about the facts of this matter have changed to necessitate amended fact witness testimony. AMVAC's choice to "supplement" its own witnesses' testimony provided little additional factual information while calling the credibility of some witnesses into question

through prior inconsistent statements and testimony clearly altered to conform with the company's subsequent legal pleadings. Resp't Post-Hr'g Br. at 10-14.

AMVAC also takes issue with the fact that the original NOITS, issued by OPP on April 28, 2022, "has not been updated or re-issued" during the course of this proceeding. AMVAC Post-Hr'g Br. at 32, 36. This argument largely proceeds on the same line as that addressed in section II.A of this brief—that OPP has adopted a new "policy" through its briefing to the Presiding Officer—and asserts that the NOITS should have been updated to include new due dates for various DCPA DCI data requirements based on "mechanical timing rules." *Id.* at 4-5. As with OPP witness statements, the facts of this case have not changed in such a way as to require amendment of the NOITS. Where facts have changed—such as AMVAC's submission of data responsive to DCPA DCI data requirements listed in the NOITS—OPP has in good faith provided status reports to the Presiding Officer that Respondent no longer alleges certain violations. *See, e.g.*, Respondent's Status Report and Joint Stipulations, Dkt. 44. That process, whereby OPP makes a determination that AMVAC has taken appropriate steps to submit required data, is clearly contemplated in both the DCPA DCI and FIFRA Section 3(c)(2)(B) more broadly. JX 1 at 3-4. Respondent has not "*de facto* amended the NOITS" through legal pleading as the basic allegations remain the same and the question of legal sufficiency is yet to be decided by the Presiding Officer. *Cf.* AMVAC Post-Hr'g Br. at 32. Nothing about OPP's case has "shift[ed]"; the essential story of AMVAC submitting a waiver request, OPP denying that request, and AMVAC never submitting the data for the nine remaining requirements has remained constant. *Cf.* AMVAC Post-Hr'g Br. at 33.

AMVAC also asserts that OPP should have re-issued the NOITS to include some mention of the supposed new "policy" or to more closely align with the language laid out in the

Board's Remand. AMVAC Post-Hr'g Br. at 32. The company claims that the NOITS is deficient as-issued for "fail[ing] to adequately apprise AMVAC, the public, or other registrants of the specific grounds on which OPP is seeking suspension." *Id.* In contrast to AMVAC's professed confusion as to the basis for suspension, the NOITS clearly included reference to FIFRA Section 3(c)(2)(B), listed the "actions which are the bases of" the NOITS, and noted that AMVAC could avoid suspension by demonstrating that it had "taken appropriate steps to comply with the [DCPA DCI]." JX 1 at 2-4, 7-29. Although the record of this matter has developed additional documents other than those listed in the NOITS itself, there has never been any confusion as to what conduct—AMVAC's failure to submit data responsive to the DCPA DCI—constituted the specific grounds supporting suspension of the DCPA Technical product. *See* AMVAC Req. for Hr'g at 2 (responding to NOITS, alleging that "AMVAC has been taking appropriate steps to comply with [the DCPA DCI] since immediately after the time it was issued."). The fact that the NOITS and the parties' initial litigation filings did not utilize the precise language laid out in the Remand—as a standard that the Presiding Officer must apply to the record—does not render the NOITS or this proceeding deficient.

E. Disposition of AMVAC Waiver Requests

AMVAC slightly modified its recent position that OPP never actually denied the company's waiver requests. AMVAC Post-Hr'g Br. at 6, 35-36. Respondent's prior briefing largely addresses these points. Resp't Pre-Hr'g Br. at 29-31. The parties clearly understood that PRD's transmittal of EFED memoranda to AMVAC constituted denial of the company's waiver requests. *Id.* However, AMVAC now asserts that the question of whether AMVAC understood the disposition of its waiver requests "miss[es] the point," and attempts to merge a separate late-

arising argument—that OPP was required to "foreclose" any further scientific discussion in order to deny a waiver request. AMVAC Post-Hr'g Br. at 6-7; AMVAC Pre-Hr'g Br. at 2. AMVAC essentially argues that, absent a communication from OPP "that no further waiver requests would be considered," the "existence of [an] ongoing dialogue" precludes any finding that a registrant failed take appropriate steps to comply with a DCI. *Id.* It attempts to read into FIFRA Section 3(c)(2)(B) a requirement for advance notice that does not exist. *Cf.* FIFRA Section 14(a)(2), 7 U.S.C. 136l(a)(2) (requiring a "written warning" to pesticide applicators violating FIFRA before EPA can assess a civil penalty). The company provides no support for this position aside from the notion that OPP rarely seeks suspension based on such failures. OPP's willingness to work with registrants to obtain data outside of the confines of the DCI deadlines, and its reticence to pursue suspension even against recalcitrant registrants, should not be taken as a bar on the agency's use of its statutory enforcement authority. In AMVAC's interpretation, any post-waiver-denial communication from OPP concerning a data requirement that does not make clear there will be "no further discussion of waivers" serves as a bar to using its suspension authority. AMVAC Post-Hr'g Br. at 3, 8.[5]

AMVAC also apparently argues that, even in documents where OPP clearly stated that the company's waiver requests were denied (*e.g.*, JX 21), the denial was not sufficient because of some combination of OPP not: (1) specifically referencing and adopting EFED memoranda, (2) specifically referencing all AMVAC communications directed to a given data requirement, and (3) sufficiently "analyz[ing] or respond[ing]" to AMVAC's technical arguments. AMVAC Post-

[5] Here again, AMVAC professes that a denial is not a denial until OPP provides AMVAC with some undefined, crystal clear statement that it is the "final" denial, yet has no concern with the possibility of waiver requests granted in the same documents possibly being insufficiently final. AMVAC would not doubt object, as they should, were OPP to issue a document reneging on its earlier waiver grants communicated through means supposedly unacceptable to AMVAC.

Hr'g Br. at 36-37, 20-21, 27. Once again, AMVAC betrays its essential belief that OPP does not have the final say in whether a data requirement is still needed. Rather than accept that OPP still required the data listed in the DCPA DCI, AMVAC maintains that OPP's failure to justify that determination to AMVAC's satisfaction should invalidate the NOITS.

F. Conduct of Parties

AMVAC continues to allege that the primary question in this matter is whether the company's and OPP's actions were "typical." AMVAC Post-Hr'g Br. at 4, 13. Respondent maintains that this issue has been appropriately briefed to the Presiding Officer who, in many respects, has already ruled as to the relevance of evidence to that effect. Resp't Pre-Hr'g Br. at 6-7; Resp't Opp'n to Mot. for Disc. at 6-9; Order on Mot. for Add'l Disc. at 3-4 ("[A]lthough the typicality of AMVAC's conduct in relation to other registrants may not be totally meaningless, it carries less weight than the steps AMVAC actually did or did not take to respond to the DCI in this specific registration review of DCPA."). In an attempt to distract from its own conduct however, AMVAC simply lists delays attributable to OPP—delays Respondent has not contested from the initial pre-hearing exchange to the present day. *See, e.g.*, AMVAC Post-Hr'g Br. at 4. AMVAC clearly interprets the scope of such a "facts and circumstances inquiry" to be much broader than the plain text of the Board's Remand. *Id.* at 4, 13 (quoting Remand at 22). AMVAC ignores that the Board addressed "course of performance" only "with respect to how [the parties] handled extension requests" and "typicality" in a similarly limited fashion, as those terms appeared in opposing witness statements. Remand at 22. Regardless of how the Presiding Officer ultimately interprets the Remand, the facts and circumstances with respect to the remaining nine data requirements are sufficiently clear to justify suspension of AMVAC's DCPA product.

AMVAC also resurrects its dormant argument that, in failing to warn the company that FIFRA Section 3 suspension was being considered, OPP was impermissibly breaking from its typical practices. AMVAC Post-Hr'g Br. at 9-10, 12. While Respondent obviously agrees with AMVAC that it is uncommon for OPP to issue a NOITS, the typicality of that action has no bearing on the question of whether AMVAC took appropriate steps to comply with the DCPA DCI. *Id.* Respondent once again re-iterates that there is no statutory or regulatory requirement for OPP to issue a warning to AMVAC or other registrants prior to issuing a NOITS.

III. AMVAC'S ARGUMENTS ABOUT DATA REQUIREMENTS

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

As previously briefed, the factual and legal bases demonstrating that AMVAC failed to take appropriate steps with respect to this data requirement have never been genuinely disputed. Respondent briefly addresses several new claims contained in AMVAC's Post-Hearing Brief. First, AMVAC continues its attempts to distract from the "appropriate steps" analysis to focus on whether its waiver requests were "repetitive." AMVAC Post-Hr'g Br. at 20, 27. As noted above, OPP witness Bloom's statements about the "repetitive" and "dilatory" nature of AMVAC's conduct are not the factual or legal basis of the NOITS. However, AMVAC's essential position is that if the company makes any changes or additions to a waiver request at all—regardless of the basic argument for waiver being the same—OPP and the Presiding Officer cannot fairly characterize such successive requests as "repetitive." Whether AMVAC's waiver requests were repetitive is not the statutory standard. However, the same facts that support OPP's

characterization of successive waivers as "repetitive" also go to show that AMVAC was not taking "appropriate steps" in satisfying the DCPA DCI.

In fact, AMVAC admits that it submitted "additional information" after receiving OPP's denial of its second waiver request for the SS-1072 data. AMVAC Post-Hr'g Br. at 27. AMVAC also asserts—apparently for the first time—that OPP statements concerning conservative assumptions provide cover for the company's choice not to submit *leptocheirus* data. AMVAC Post-Hr'g Br. at 21-22. This is despite the fact that OPP was always crystal clear that the SS-1072 data requirement was not waived and in stating the options available: either submit data responsive to SS-1072 or conduct the alternate 850.1740 study. Resp't Post-Hr'g Br. at 2-3.

With respect to the alternate study, AMVAC's testimony and argument that the alternate 850.1740 study was not a reasonable request from OPP fails for two reasons. *See* AMVAC Post-Hr'g Br. at 22. First and foremost, OPP never attempted to force AMVAC to substitute the study; it merely noted that the SS-1072 data required by the DCPA DCI remained outstanding and provided a possible way that AMVAC could justify its waiver request. Second, although Respondent does not contest that having an OPP-issued DCI would potentially make it easier for AMVAC to defend its data compensation rights in FIFRA arbitration, it was still AMVAC's choice to neither pursue the alternative study nor fulfill the original data requirement. Respondent also notes that issuing a new DCI certainly would not constitute a "minor administrative burden." *See* MAD at 4-7 (describing the lengthy process of developing, approving, and issuing a DCI).

Additionally, AMVAC's assertion that OPP should have "validated" the SS-1072 study prior to making it binding upon the company is a mis-statement of EPA's authority. *See* AMVAC Post-Hr'g Br. at 23. While OPP promulgated regulations in 40 C.F.R. Part 158

outlining the kinds of data routinely required to make regulatory judgements under FIFRA about the risks and benefits of a pesticide product, the Agency retains maximum flexibility to require other types of data. MAD at 5-6 (quoting 40 C.F.R. 158.30). This includes requiring the submission of studies not addressed by finalized—*i.e.*, "validated"—OCSPP Guidelines. *Id.* Furthermore, while OPP was at one point aware that certain labs were experiencing difficulty in conducting *leptocheirus* studies, testimony at the hearing established that such issues had largely been resolved by 2017, including by the lab with which AMVAC was contracting to perform the work. Resp't Post-Hr'g Br. at 3 n.2. AMVAC's discussion of when OPP made its evaluations of such successful studies available is inapposite; there is no requirement that OPP inform a registrant that other registrants have successfully completed the same type of study. *Cf.* AMVAC Post-Hr'g Br. at 23.

B. TPA Environmental Fate Data Requirements, Generally

Respondent maintains that the factual and legal bases for suspension based on these three data requirements have been sufficiently briefed. AMVAC doubles down on its argument that OPP's statements about conservative assumptions *de facto* waived the data requirements, or at the very least removed any obligation for AMVAC to take any action. AMVAC Post-Hr'g Br. at 24-30; *see* Resp't Post-Hr'g Br. at 5-8. It also attempts to tie AMVAC witness Gur's entirely unprompted conjecture about "bioaccumulation" into a hypothetical future conversation with OPP about the need for additional studies. AMVAC Post-Hr'g Br. at 26. That entire topic is without any connection to the pre-hearing record. AMVAC similarly tries to anchor its discussion of PAX 85 to the OCSPP Guideline studies actually at issue in this case. *Id.* at 28-29. Respondent's prior briefing on this matter is sufficient to address the bulk of AMVAC's

argument. Resp't Post-Hr'g Br. at 7-8. Respondent must, however, strongly contest AMVAC's bald assertion that PAX 85 was "reasonably read to be [implicitly] incorporated by reference into [OCSPP] test guideline." Incorporation by reference of any document is subject to stringent limitations and approval; it is not undertaken accidentally or without clear intention to do so. *See, e.g.*, 1 C.F.R. Part 51. OCSPP Guidelines are explicitly codified into 40 C.F.R. Part 158. *See, e.g.*, 72 Fed. Reg. 60934. There is no evidence that OPP ever incorporated PAX 85 into a guideline or Part 158 by reference, as OPP never considered the document to be "binding" on the Agency or regulated entities and never "explicitly relied upon [the document] in a formal decision." *ACLU v. National Security Agency*, 925 F.3d 576, 597-98 (2nd Cir. 2019) (discussing whether a document referred to in an agency statement is incorporated by reference, either expressly or through "*indications* that an agency relates to the document as binding").

With respect to the Guideline 850.4300 TPA data requirement—for which AMVAC, in an alleged "clerical error," promised to submit a responsive study that it never intended to submit—the company apparently now argues that OPP must demonstrate an intent to mislead, but provides no support for that position. AMVAC Post-Hr'g Br. at 30-31. Submission of data responsive to a DCI is not subject to an "intent" test; the question is whether AMVAC actually took appropriate steps to satisfy the DCPA DCI. AMVAC also attempts to confuse the timeline of what OPP knew. AMVAC Post-Hr'g Br. at 31. There is no dispute that OPP denied AMVAC's first waiver request for the 850.4300 study in 2017, and that the "inadvertent" promise to conduct a study was provided in 2018. Resp't Pre-Hr'g Br. at 13. Thereafter, OPP re-iterated that the (first) waiver was denied in the October 2020 Data Delay Letter. JX 21. In its December 2020 response to JX 21, AMVAC stated only that "The Agency's rationale for not

requiring further studies for DCPA also applies to TPA.[6] Further, evidence has been provided that TPA is very stable and would not degrade during the course of a laboratory-based study." JX 22 at 1. At no point until its appeal brief to the Board did AMVAC ever allege that it had made a clerical error in suggesting that a study would be submitted, or that it was actually pointing OPP to a previously-submitted DCPA study. Resp't Resp. Br. at 24-25. At the hearing and in its brief, however, AMVAC attempts to make the case that "OPP was not in fact misled." AMVAC Post-Hr'g Br. at 31. That entire argument is premised on a brief exchange at the hearing, wherein OPP witness Wente initially expressed confusion at AMVAC's cross examination but tacitly acknowledged that the December 2020 communication was asking OPP to look at old data. Tr. at 137. Had AMVAC at any time attempted to explain its intention to OPP, as AMVAC's counsel did during cross examination, this data requirement may well have not been subject to the NOITS. However, the record here speaks for itself; AMVAC clearly stated its intent to submit a new study responsive to the DCPA DCI, and OPP was clearly acting in accordance with that stated intent in the agency's subsequent actions.

IV. PETITIONERS' ARGUMENTS ABOUT EXISTING STOCKS

Petitioners' post-hearing briefs for the first time describe the existing stocks remedy that would supposedly comply with FIFRA, "elimination only of the limited prohibition on AMVAC's use of DCPA Technical in its possession as of the effective date of any suspension to formulate other pesticide products, *i.e.*, DCPA end-use products." AMVAC Post-Hr'g Br. at 37.

[6] Respondent notes that AMVAC's 2020 characterization of OPP's "rationale" is not accurate. JX 22 presumably refers to JX 77, which is the February 7, 2017 EFED memorandum referenced in the October 2020 Data Delay Letter (JX 21). In JX 22 and continuing through the present, AMVAC ignores that JX 77 explicitly stated "that the results [of the DCPA metabolism study] can be applied to TPA; therefore, EFED believes that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment." JX 77 at 3.

Petitioners fail to acknowledge that, even under their preferred existing stocks provision, such stocks would eventually be exhausted; it is not clear how the allegedly-more-rapid onset of product unavailability constitutes a legal infirmity for the NOITS. *See* Growers Post-Hr'g Br. at 12. Other than this delineation—which is apparently based on the fact that no other registrant could formulate end-use products from AMVAC's Technical at the present moment—all of Petitioners' arguments have previously been addressed. Resp't Post-Hr'g Br. at 14-18; Resp't Pre-Hr'g Br. at 27-28; Resp't Resp. Br. at 37-41. AMVAC asserts that, were the Presiding Officer to allow formulation—the only economically-useful use of DCPA Technical—AMVAC would still have "incentive to timely complete the remaining studies." AMVAC Post-Hr'g Br. at 43. As AMVAC declined to provide an estimate of how much DCPA Technical it anticipated being able to import, the practical difference—if any—between AMVAC's desired outcome and a suspension-in-name-only cannot be ascertained by reference to the record in this matter.

Petitioners still point to inapplicable risk-based suspension and cancellation considerations in OPP's existing stocks policy while ignoring the sections of that policy that clearly address FIFRA Section 3(c)(2)(B) suspensions. AMVAC Post-Hr'g Br. at 39; Growers Post-Hr'g Br. at 8-10. They also resurrect their erroneous argument, first made before the Board, that the NOITS was not based on AMVAC's failure to submit data, but rather on risk-based concerns. AMVAC Post-Hr'g Br. at 39 at 40-42; Growers Post-Hr'g Br. at 11, 18-20.[7] Growers also re-iterate their argument that any suspension must ensure continued availability of end-use products, ignoring that for DCPA and a considerable number of other pesticide products, the

[7] Growers resurrect their argument that the existing stocks provisions are "irrational" because the provisions are too lenient. Growers Post-Hr'g Br. at 19 (noting that the NOITS allowed for continued use and sale of DCPA products after the effective date of the suspension). Respondent has explained in substantial detail why the language of FIFRA Section 3(c)(2)(B), OPP's longstanding existing stocks policy, and the facts of this case did not support restrictions on Growers' use of DCPA end-use products. Resp't Resp. Br. at 37-39.

(not-actually) ”unique” market structure would render the products immune from FIFRA Section 3 suspensions. Growers Post-Hr’g Br. at 3; *see* Resp’t Post-Hr’g Br. at 15 n.13; Resp’t Resp. Br. at 38. AMVAC also asserts that a balancing test not described in OPP’s existing stocks policy is necessary, weighing potential economic impacts against the alleged value of the still-outstanding studies. *Id.* at 42. Here again, AMVAC seeks to place itself as the arbiter of what data is actually needed, asserting that OPP cannot continue with the NOITS given that the data AMVAC deems most valuable has already been submitted. *See also* Growers Post-Hr’g Br. at 6.

Growers misread the Board’s decision with respect to the existing stocks provisions of the NOITS were appropriate. Growers Post-Hr’g Br. at 4-5. In the 29-page Remand, the Board thoroughly assessed the Accelerated Decision, and offered substantial guidance with respect to the matter of how “appropriate steps” should be evaluated in the context of FIFRA Section 3(c)(2)(B). Contrary to Growers’ assertion that the Board “explicitly declined”[8] to address the existing stocks provisions of the NOITS, the brevity and clarity of the one page in the Remand dedicated to those provisions are stark. Remand at 27-28. While the Board clearly ordered the Presiding Officer to address the question of “appropriate steps” before turning to the legality of the existing stocks provision, the Board *emphasized*—on its own accord—the clearly-applicable language from OPP’s longstanding existing stocks policy. Remand at 27. Growers also join AMVAC in its attempt to vastly expand the scope of the “typicality” assessment ordered by the Board, incorrectly asserting that the Presiding Officer must determine whether the existing stocks provision of the NOITS is “typical,” not just whether the provision is consistent with FIFRA. Growers Post-Hr’g Br. at 7.

[8] If Growers’ reference to is with respect to footnote 14 of the Remand, Respondent asserts that the Board was clearly declining to take a position as to whether AMVAC took appropriate steps, leaving that determination to the Presiding Officer through her application of the Board’s analysis on review. Remand at 28.

V. 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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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 Reply Brief**, dated April 21, 2023, was sent this day to the following parties in the manner indicated below.

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