**UNITED STATES**
**ENVIRONMENTAL PROTECTION AGENCY**

**BEFORE THE ADMINISTRATOR**

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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,** | ) | **Docket No. FIFRA-HQ-2022-0002** |
| **Petitioners.** | ) | |

# RESPONDENT'S PREHEARING BRIEF

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## I. SUMMARY

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 October 18, 2022 Order on Respondent's Motion to Amend Hearing and Scheduling Order, hereby submits this Prehearing Brief.

Through the record already provided to the Presiding Officer and through development at the hearing, Respondent intends to 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 13 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.

Respondent asserts that while the terms "within the time required by the Administrator" and "failed to take appropriate steps to secure the data required" are not further defined by FIFRA Section 3(c)(2)(B), any relevant legislative history, or implementing regulations, the meaning of both terms is well understood by OPP and pesticide registrants. "[W]ithin the time required by the Administrator" refers to the individual timeframes provided in OPP-issued DCIs for submission of various data requirements, subject to both formal extension of those timeframes by OPP and informal flexibility based on the timeline of registrant submissions and OPP responses. "[A]ppropriate steps" is similarly understood in the context of the directions for response provided in an OPP-issued DCI, the associated time periods provided in the DCI, and statements from OPP concerning the status of data requirements imposed by a DCI, including disposition of registrant requests for waiver of certain data requirements.

Respondent also asserts that 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.

Accordingly, following the hearing, 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.

## II. ARGUMENT

In response to the Presiding Officer's order on prehearing briefs, Respondent addresses specific matters in sections II.A, II.B, and II.C, below. *See* October 18 Order at 2-3.

### A. "[W]ithin the time required by the Administrator"

The term "within the time required by the Administrator" is not further defined by FIFRA Section 3(c)(2)(B)(iv) or the statutory history of that provision, FIFRA more broadly, or the Agency's implementing regulations. Instead, the primary understanding of this term is contained in the "regulatory history" of OPP's use of Section 3(c)(2)(B) DCIs. OPP has historically considered this term to be unambiguous and declined to adopt regulations "to develop new procedures for calling in data," stating "that [FIFRA Section 3(c)(2)(B)] provides EPA with sufficient authority to obtain any necessary data." 71 Fed. Reg. 45720, 45723 (Aug. 9, 2006). Accordingly, Respondent maintains that "the time required by the Administrator" should be read in this context as referring to the time periods set out in the DCPA DCI. *See* RX 4; *cf.* Petitioner

AMVAC's Opposition to Respondent's Motion for Accelerated Decision ("AMVAC Opposition") at 14.[1]

EPA "may issue a Data Call–In notice under FIFRA Section 3(c)(2)(B) at any time if the Agency believes that the data are needed to conduct the registration review." 40 C.F.R. § 155.48; *see* 7 U.S.C. §§ 136a(c)(2)(B), 136a(g)(2). If EPA determines that a DCI is required for registration review, it "shall notify all existing registrants of the pesticide to which the determination relates," and "shall permit sufficient time for applicants to obtain" the data required to be submitted. 7 U.S.C. §§ 136a(c)(2)(B), 136a(c)(2)(A). In the DCPA DCI and OPP-issued DCIs more generally, OPP provided specific timeframes in which registrants must submit data. JX 4 at 3 ("You are required to submit the data or otherwise satisfy the data requirements specified . . . within the time frames provided."); *see also, e.g.*, Generic Data Call-In Notice GDCI-123000-960, Isoxaflutole Registration Review Docket, EPA-HQ-OPP-2010-0979-0012. The "time frames provided" are specific to each individual data requirement, and in the DCPA DCI ranged from 9 to 36 months. JX 4. This language requiring registrants to respond to a FIFRA Section 3(c)(2)(B) data call in "within the time frame provided" pre-dates the Registration Review process, prescribed by Congress in 2007, by at least a decade.[2] OPP has historically interpreted FIFRA Section 3(c)(2)(B) as allowing it to set reasonable timeframes in

[1] Contrary to AMVAC's assertion that Respondent offers "at least three" different definitions of "the time required by the Administrator," Respondent has taken the position that the relevant times for AMVAC to take appropriate steps are those set out in the DCPA DCI. As explained below, Respondent acknowledges that such periods may be formally lengthened through the request for and granting of an extension. Respondent further acknowledges that 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. AMVAC's assertion—that "Respondent states that the registrant must make its submittal sufficiently in advance of such deadline so that EPA (or its third-party contractor) can complete a full review of the data (or waiver request) to determine whether it is "adequate" in OPP's view before the deadline"—is wholly unsupported.

[2] *See* DCPA Reregistration Eligibility Decision at 147, 160, 165, 174 (Nov. 1998), *available at* https://archive.epa.gov/pesticides/reregistration/web/pdf/0270red.pdf; *see also* Pesticide Registration Improvement Renewal Act, Pub. L. No. 110-94 (2007).

which registrants must take appropriate steps in response to a DCI and has provided said response timeframes within the same document requiring submission of data.

The instructions attached to the DCPA DCI—and other DCIs more generally—explain that column 8 "identifies the time frame allowed for submission of the study or protocol identified" and that "[t]he time frame runs from the date of your receipt of the [DCI]." JX 4 at 38. The instructions also note that, for example, by selecting Option 1 a registrant agrees to the following:

> (Developing Data) I will conduct a new study and submit it within the time frames specified in [column] 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the [DCI] and that I will provide the protocols and progress reports required . . . .

*Id*. OPP-issued DCIs further explain that EPA will inform registrants if their request for waiver of data is denied, at which point the registrant "must choose a method of meeting the requirements of this Notice within the time frame provided by this [DCI]." *Id.* at 15.

Respondent is cognizant of the fact that for some requirements of the DCPA DCI, by the time OPP had responded to AMVAC's waiver requests, the "time frame provided" in the DCPA DCI had been completely or mostly exhausted. However, OPP's failure to notify a registrant that its request for waiver is denied (within a time that would still provide the registrant adequate time to complete the study) cannot be interpreted as a "default" decision that the data requirement was or would be waived, as providing an unbounded time for the registrant to provide data, or as otherwise limiting OPP's authority to require timely submission of responsive data. To take that position would clearly contravene the purpose of FIFRA Section 3(c)(2)(B), which requires that EPA call-in data necessary to conduct registration review of a pesticide product.

While OPP does not regularly specify an appropriate time for registrants to submit responsive data after denial of an initial request to waive a data requirement,[3] Respondent maintains that AMVAC, at the very latest, should have provided data within a period equivalent to the original time specified in the DCPA DCI. For example, in the DCPA DCI, OPP provided a 24-month time frame for AMVAC to satisfy Special Study 1072. JX 4 at 33. OPP denied AMVAC's request to waive SS-1072 on June 27, 2016. Accelerated Decision at 14; JX 74. While the original 24-month time frame ended on or about February of 2015, the passing of that date without OPP transmitting its waiver denial did not automatically render AMVAC's waiver request an "appropriate step." Rather, following OPP's denial of the waiver request, AMVAC should reasonably have submitted data, or taken other appropriate steps to secure the data required, no more than 24 months after OPP's denial of the waiver request (*i.e.*, no later than approximately July of 2018). To date, AMVAC has not submitted data responsive to this DCPA DCI data requirement.

EPA acknowledges that issuance of a DCI places a burden on pesticide registrants and, accordingly, provides notice of data likely to be required for the Agency to complete registration review, and an opportunity for registrants and others to comment on proposed data requirements and submission schedules. *See* June 23, 2011 DCPA Registration Review Preliminary Workplan, RX 2 at 8 (anticipating AMVAC's submission of data two years after issuance of DCI). EPA typically receives comments from registrants and other interested stakeholders concerning anticipated data requirements. *See, e.g.*, Cyflufenamid Registration Review Docket, EPA-HQ-OPP-2021-0733-0008, -0009 (comments both from registrant contesting need for proposed DCI requirements and from third party claiming that additional data are required for EPA to make a

[3] FIFRA Section 3(c)(2)(B)(iv) provides OPP with discretion on when to pursue suspension. AMVAC has not alleged that OPP abused its discretion in pursuing suspension.

determination under FIFRA). Absent a comment from the registrant suggesting that a given study cannot be submitted in the anticipated time frame, OPP considers the periods provided in a DCI to be sufficient time for applicants to develop any necessary protocols, obtain the required data, and submit a report to OPP. Even after the issuance of a DCI, registrants may request additional time to respond to a particular data requirement.[4]

**B. "[F]ailed to take appropriate steps to secure the data required"**

The Board previously noted that "appropriate steps" is not defined in FIFRA and ruled that a determination of appropriate steps was factual inquiry for resolution by the Presiding Officer. Remand at 21-22. Respondent maintains that "appropriate steps" should be read in the context of, among other factors, the directions for response provided in the DCPA DCI, the associated time periods provided in the DCPA DCI, and explicit statements from OPP that certain data were still required and not waived.

The Board listed several factors that the Presiding Officer should consider in this factual determination, including the parties' "'course of performance' with respect to [ ] extension requests," "waiver requests and the responses thereto," and the "typicality" of AMVAC's response strategy. *Id.* at 22-23. As this Presiding Officer recognized in the November 4, 2022 Order on Motions for Additional Discovery, though, while such questions may be a factor in the determination of whether AMVAC took appropriate steps, none are significant factors. Order on Motions for Additional Discovery at 3-4 ("[A]lthough the typicality of AMVAC's conduct in

[4] AMVAC devotes a substantial fraction of its filings in this proceeding on the matter of whether OPP requires formal requests for extension of time, whether registrants make such requests, and the "course of performance" between OPP and registrants. However, AMVAC provides no argument as to how extension requests—or a lack thereof—render "the time required by the Administrator" into an indefinite period for registrants to take appropriate steps to secure the data required by an OPP-issued DCI. *Cf.* AMVAC Notice of Exceptions and Appeal Brief ("AMVAC Appeal") at 36; Verified Written Statement of AMVAC Expert Witness Ephraim Gur at 8-9 (implying that AMVAC "engaging with EPA on a consistent basis and keeping [OPP] updated on the status of [its] efforts to meet the data requirements" was sufficient to extend the response period).

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."). Accordingly, when it comes to the "typicality"[5] of AMVAC's strategy of submitting multiple waiver requests, the parties' "course of performance" as to extension requests, and other disputed issues of material fact, the Presiding Officer certainly can "evaluate the credibility of [the parties] witnesses based on live testimony" at the hearing. Remand at 23.

As reflected in FIFRA Section 3(c)(2)(B)(ii) and explained in substantial detail in each OPP-issued DCI, there are several possible registrant responses to a DCI that would, at least initially, constitute "appropriate steps." *See* JX 4 at 38-39 (listing nine potential response types that a registrant can elect in its 90-day response to a DCI). For each of the 13 remaining DCPA DCI data requirements at issue in this case, AMVAC elected to either: "conduct a new study and submit it within the time frame specified" (*see* II.C.1, below); "submit an existing study by the specified due date" (*see* II.C.7, below); "submit by the specified due date, or [ ] cite data to upgrade a study that EPA has classified as partially acceptable" (*see* II.C.6, below); "delet[e] the uses for which the data are required" (*see* II.C.3, 4, 5, below); or "request a waiver of the data requirement" (*see* II.C.2, 8, 9, 10, 11, 12, 13, below). JX 5, att. 3.

As noted in the instructions for OPP-issued DCIs, including the DCPA DCI, a request for waiver of a data requirement does not automatically end a registrant's duty to respond to a DCI and may not constitute "appropriate steps to secure the data required." As explained in the instructions:

[5] Respondent once again highlights that FIFRA Section 3(c)(2)(B)(iv) provides OPP with discretion on when to pursue suspension and maintains that the "typicality" of AMVAC's conduct in this matter ultimately has no bearing on the question of whether it took appropriate steps to satisfy the DCPA DCI data requirements. The fact that EPA rarely seeks suspension of registrations under FIFRA Section 3(c)(2)(B)(iv) should not be interpreted as an endorsement of registrants' decisions to drag out the process of responding to DCIs. *See* Respondent's Opposition to AMVAC Motion for Additional Discovery at 10-11.

> If the Agency determines that the data requirements of this [DCI] do not apply to your product(s), you will not be required to supply the data pursuant to FIFRA section 3(c)(2)(B) or section 4(f)(l)(A). 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.

JX 4 at 15(emphasis in original). Stated plainly, once OPP "determines that the data are required" (*i.e.*, denies a waiver request), the registrant must choose another method of satisfying the DCI data requirement. As explained in II.A, above, Respondent does not argue that AMVAC should have submitted a study within the time period originally specified in the DCPA DCI in instances where OPP's waiver denial was transmitted near or after the end of that original time period. Rather, a reasonable interpretation of FIFRA Section 3(c)(2)(B) and DCIs is that, following OPP's denial of a registrant's waiver request, the registrant must either submit or cite to data to satisfy the DCI data requirement within a time period roughly equivalent to the period of months initially provided in the DCI. A registrant's submission of yet another waiver request or requests—and thus failure to submit or cite responsive data—after OPP denies its initial waiver request should not be considered "appropriate steps."

The Board explicitly ruled "that the legality of the [DCPA DCI] and what it requested is not at issue in this proceeding," stating that AMVAC "could have challenged the [DCPA DCI] when it was issued but did not." Remand at 23. Respondent maintains that, by submitting successive waiver requests similar to those already denied by OPP, AMVAC was in practice challenging the necessity of data required by the DCPA DCI. Rather than accepting OPP's "determination that the data are required" and "choos[ing] a method of meeting the requirements of the [DCPA DCI]," AMVAC instead opted to reiterate its belief that certain data requirements were not necessary. *See* JX 22 at 3 (acknowledging that OPP "would not adopt" AMVAC's desired approach to rely on acute toxicity data but choosing to not to submit the required chronic toxicity study). The instructions included with each OPP-issued DCI provide for a registrant to

submit an initial request that the data requirement be waived, but note that a registrant must actually provide data if OPP denies that request. The language of FIFRA Section 3(c)(2)(B) does not provide for a cycle of back-and-forth discussion between the Agency and registrant as to whether the required data are in fact needed. Any instances of OPP responding to successive waiver requests—with respect to the DCPA DCI and DCIs more generally—reflect an exercise of the Agency's discretion.

Were the Presiding Officer to adopt AMVAC's position—that successive requests to waive data requirements constitute "appropriate steps"—OPP essentially would be unable to enforce submission of data in connection with any DCI. Registrants could simply reply to any OPP waiver request denial with a request that the Agency reconsider its position, regardless of the rationale for the successive request. While it may be reasonable—depending on the specific data requirement and circumstances—to provide registrants with extra time to satisfy a DCI data requirement following OPP's denial of an initial waiver request, a successive waiver request should not be interpreted as an "appropriate step" under FIFRA Section 3(c)(2)(B), which then resets the time period in which the registrant is able to respond.

### C. Individual DCPA DCI Data Requirements

In the following subsections, Respondent identifies the evidence that it intends to offer at hearing to demonstrate that AMVAC failed to take appropriate steps to secure the data required by the DCPA DCI.

As an initial matter, the following exhibits are of general or background applicability with respect to all 13 outstanding DCPA DCI data requirements:

JX 1; JX 2; JX 4; JX 5; JX 21; JX 22; JX 65; Verified Written Statement of Jill Bloom; RX 1; RX 2; RX 4; RX 5; Existing Stocks of Pesticide Products, Statement of Policy, 56 Fed. Reg. 29362, 29367 (June 26, 1991).

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

Respondent intends to offer the following additional evidence demonstrating 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:
JX 61; JX 67; JX 74; Verified Written Statement of Christina Wendel.

There is no dispute that AMVAC failed to submit a DCPA chronic sediment (28-day) toxicity special study as required by the DCPA DCI. Order on Respondent's Motion for Accelerated Decision ("Accelerated Decision") at 28 (July 1, 2022). AMVAC initially informed OPP that it intended to conduct the study, and the parties engaged in substantial discussion between April 2013 and September 2015 about various difficulties in performing the study, with AMVAC promising to update OPP of its ongoing efforts in March 2016. *Id.* at 14; JX 61. However, on March 16, 2016, AMVAC instead submitted a waiver request for this data requirement, which OPP promptly denied on June 27, 2016.[6] Accelerated Decision at 14; JX 74.

In that waiver denial, OPP clearly explained that it still required the data but, importantly, provided AMVAC with a–potentially less onerous—alternate method of satisfying the requirement. JX 74. Specifically, while OPP noted that the original "28-day study will remain an outstanding DCI requirement," it proposed to allow AMVAC to conduct a shorter 10-day sub-

[6] On November 22, 2016, AMVAC submitted a "response" to OPP's June 27, 2016 denial of AMVAC's initial waiver request. JX 76. The rationale for waiver proposed in JX 76—that the SS-1072 test organism *L. plumulosus* was not "significantly more sensitive than" another sediment-dwelling organism tested with DCPA—was substantially the same as that offered in AMVAC's March 16, 2016 waiver request. *See* JX 74. AMVAC contested the need for this data, asserting that both the 28-day SS-1072 and the 10-day alternate study "would provide no information of merit." JX 76 at 4.

chronic toxicity study, the results of which OPP would consider in determining whether to waive the requirement for the original chronic toxicity study.[7] *Id.*; *see also* AMVAC Response to RFA 3. AMVAC never conducted either the original 28-day chronic toxicity study or the shorter 10-day sub-chronic toxicity study that OPP said it would consider in deciding whether waiver of the original data requirement was appropriate. Accelerated Decision at 15. Rather, on February 18, 2018, AMVAC submitted a second[8] waiver request for this data requirement. JX 67. In the October 16, 2020 Data Delay Letter, OPP denied AMVAC's second waiver request, again reiterated that the original 28-day chronic toxicity data were needed, and once more provided AMVAC with the option to perform the 10-day sub-chronic toxicity study which OPP said it would consider as part of a future waiver request for the chronic study. Accelerated Decision at 16; JX 21.

Rather than initiate either the 28-day chronic toxicity study required by the DCPA DCI and reaffirmed by OPP in two waiver request denials, or the shorter 10-day sub-chronic toxicity study that OPP twice offered as a potential means of justifying waiver of the original study, AMVAC instead informed OPP that it disagreed with the need for the study. Accelerated Decision at 16-17; JX 22. In that response, AMVAC acknowledged that OPP was not waiving the requirement[9] and that OPP "insisted on retaining the requirement for the chronic study." JX

[7] In a March 27, 2017 email follow-up to an earlier phone conference, OPP indicated that it would "confirm [ ] whether a clean/negative 10-day study negates the need for the 21-day [sic] study." JX 33. Irrespective of the fact that—after that 2017 email—AMVAC made a successive request for waiver in 2018 that was denied in 2020, OPP's statements concerning the possibility of waiving the 28-day study based on the result of the 10-day study cannot be interpreted as waiving, or tolling the period for completion of, the 28-day study required by the DCPA DCI.

[8] On November 22, 2016, AMVAC submitted a "response" to OPP's denial in JX 74. JX 76.

[9] AMVAC seeks to recast OPP's statements concerning the need for AMVAC to submit a study in response to this DCPA DCI data requirement, arguing that OPP never actually denied AMVAC's waiver request and that OPP indicated it would potentially waive the requirement without further action taken by AMVAC. *See* AMVAC Responses to RFAs 1-5.

22. However, in a mischaracterization of the parties' communications to that point, AMVAC stated that it would not perform the special study required by the DCI until OPP had validated[10] the guideline for 28-day chronic toxicity study and would not perform the alternate 10-day sub-chronic toxicity study unless OPP specifically issued a DCI requiring it. *Id.*

As the Presiding Officer correctly noted, it is clear that OPP never sought to require AMVAC to perform both studies. Accelerated Decision at 29. Rather, OPP on multiple occasions attempted to provide AMVAC with a means by which it could support a successive waiver request. *Id.* AMVAC's argument that OPP was attempting to "move the goalposts" by allowing performance of the 10-day sub-chronic study as an alternative means of addressing the data requirement is disingenuous and without merit. OPP offered the alternate approach because it could be done in less time and was less-resource intensive but made clear that completion of the 10-day study might not ultimately allow OPP to waive the requirement for a 28-day chronic toxicity study. *Id*. The record is clear that OPP was not requiring AMVAC to submit the alternate sub-chronic study in addition to the original chronic study, or that the original chronic study was not still required. In both the 2016 waiver request denial and in the 2020 Data Delay Letter, OPP clearly stated that the 28-day chronic toxicity study required by the DCPA DCI was still necessary and was not waived, but provided AMVAC with an option for generating data to potentially justify waiving the data requirement. JX 74; JX 21; Accelerated Decision at 29-30. AMVAC's misleading arguments concerning this data requirement should not distract from the fact that OPP repeatedly reiterated the need for the data required by the DCPA DCI, and OPP's

[10] While OPP does participate in development of standard guideline methods for conducting studies, there is no requirement in FIFRA or its implementing regulations that OPP establish a guideline or otherwise "validate" a study prior to requiring registrants to submit necessary data. As previously explained, 40 C.F.R. § 158.30 provides that OPP "may require the submission of additional data or information" beyond the specific OCSPP Guideline studies referenced in 40 C.F.R. Part 158. MAD at 5-6.

suggestion for how AMVAC could potentially justify a waiver of the data requirement should not be construed as placing an additional burden on the company. *Cf.* AMVAC Opposition at 37-38.

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.

**2. Guideline 835.4300, TPA Aerobic Aquatic Metabolism**

Respondent intends to offer the following additional evidence demonstrating that AMVAC failed to take appropriate steps to secure the TPA aerobic aquatic metabolism data required by the DCPA DCI within the time required by the Administrator:
JX 36; JX 66; JX 67; Verified Written Statement of AMVAC Fact Witness Richard S. Freedlander; Verified Written Statement of Stephen Wente.

The parties previously agreed that OPP did not waive the data requirement,[11] and that on February 22, 2018, AMVAC stated its intention to submit a new study, but never did so. AMVAC Opposition at 22-23; Freedlander Statement at 19; JX 36, JX 66, JX 67 at 16. AMVAC attempts to construe that clear statement of intention as a "clerical error," and argues that OPP should have read three different AMVAC communications—submitted in 2014, 2018, and 2020—as together constituting a second waiver request in response to OPP's 2014 denial of the first waiver request. Freedlander Statement at 17-19; AMVAC Opposition at 22-23.

[11] *Supra* n.8; *infra* section II.E.3.

In its 2014 waiver request, AMVAC's justification was to defer completion of this study using TPA until completion of the same study using DCPA, at which point AMVAC would "then [ ] perform an ecological risk assessment of [ ] TPA using the endpoint determined for DCPA."[12] JX 5 at 20-21. AMVAC submitted the DCPA study in January 2014. AMVAC Opposition at 22. In OPP's denial of AMVAC's 2014 waiver request, it stated that "Additional Data [is] Needed for Risk Assessment," and specifically "den[ied] the waiver request to defer the TPA study until DCPA studies are completed." JX 66 at 2, 5.

On February 22, 2018, AMVAC submitted a "Response to EPA Memorandum dated March 21, 2014." JX 67. In that document, AMVAC stated "that we intend to submit a study report that addresses this [aerobic aquatic metabolism] requirement by providing appropriate fate data for both DCPA and TPA." *Id.* at 16. The response contained no suggestion that "[OPP] should consider [the] already submitted [DCPA] study in connection with the TPA data requirement," or even that AMVAC was still seeking waiver of this data requirement. *Cf.* AMVAC Opposition at 22. The course of action that AMVAC suggests was its true intention—directing OPP to a previously-submitted DCPA aerobic aquatic metabolism study—had already been rejected by OPP in its March 21, 2014 denial of AMVAC's waiver request. JX 66. In addition to contesting the retroactive interpretation of AMVAC's February 22, 2018 statement, Respondent notes that it was not reasonable for AMVAC to simply re-assert the same—previously denied—rationale in support of waiver of the TPA aerobic aquatic metabolism study. That action did not constitute an appropriate step toward fulfilling the data requirement.

In the October 16, 2020 Data Delay Letter, OPP once again informed AMVAC that its waiver request was denied, and that the requirement remained outstanding. JX 21 at 4. In its

[12] AMVAC presumably intended this statement to convey that OPP would be able to perform its registration review risk analysis for TPA using a DCPA degradation half-life.

December 17, 2020 response to the Data Delay Letter, the entirety of AMVAC's argument concerning this data requirement was:

> The Agency's rationale for not requiring further studies[13] for DCPA also applies to TPA. 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 2. Although AMVAC's response stated its disagreement with OPP's conclusion that TPA metabolism data were necessary, it contained no discernable indication that AMVAC was citing to the previously submitted DCPA study in an attempt to fulfill the TPA data requirement. Taken as a whole, it is not clear how AMVAC's 2014 data submission for the DCPA study, its 2018 rebuttal to OPP's denial of the TPA waiver request, and its 2020 rebuttal to the Data Delay Letter would constitute "a good faith effort to comply with the [data] requirement," to say nothing of each of those documents examined individually, as OPP did prior to this suspension proceeding. *Cf.* AMVAC Opposition at 23.

AMVAC's latest position—that the company was in fact directing OPP to a previously-submitted study despite its clear statement in 2018 that it "intend[ed] to submit a study report"—is substantially different than its position at the time it requested a hearing in this matter. *See* Request for Hearing at 81-82. In its Request for Hearing, AMVAC echoed Respondent's view of the record, to wit: that "AMVAC informed OPP that it intended to submit a study providing appropriate fate data for DCPA and TPA" in February 2018, but never submitted that study. *Id.* at 82. Prior to filing its opposition to Respondent's Motion for Accelerated Decision ("MAD"), AMVAC's only argument concerning this data requirement was the incorrect assertion that OPP first made its position (*i.e.,* denial of waiver requests) known in documents delivered

[13] Respondent contests AMVAC's characterization of the Data Delay Letter. It neither contained a rationale for "not requiring further studies" nor did it propose any future plans to waive those requirements. *Cf.* AMVAC Opposition at 23.

simultaneously with the NOITS. *Id.* AMVAC's argument on this data requirement is contingent on a retroactive interpretation—which conflicts with its prior statements—of several documents submitted to OPP over approximately six years. *See* AMVAC Opposition at 22-23. Even if one accepts AMVAC's post-MAD change of position, the company admits that the record was sufficient to "misle[a]d" OPP as to AMVAC's intended course of action. AMVAC Responses to RFAs 17, 19.

The record clearly demonstrates that AMVAC failed to take appropriate steps to secure the TPA aerobic aquatic metabolism data required by the DCPA DCI within the time required by the Administrator. OPP twice informed AMVAC that its request to waive this data requirement was denied. Depending on which version of AMVAC's timeline one utilizes, AMVAC either mislead OPP into believing that the company would submit a responsive study or simply stated its disagreement with OPP's waiver denial. Neither would constitute appropriate steps to secure the data required.

**3. Guideline 860.1300, Nature of the Residue: Poultry**

**4. Guideline 860.1340, Residue Analytical Method: Livestock Commodities**

**5. Guideline 860.1480, Milk/Meat/Poultry/Eggs**

**6. Guideline 860.1900, Field Accumulation in Rotational Crops**

Respondent intends to offer the following additional evidence demonstrating that AMVAC failed[14] to take appropriate steps to secure the four above-listed Guideline Series 860 residue data required by the DCPA DCI within the time required by the Administrator: (3) nature

[14] As noted in the parties' January 6, 2023 Joint Set of Stipulated Facts, AMVAC submitted proposed labels on December 28, 2022, with the intention of implement label amendments specified in OPP's December 9, 2022 memorandum. *See* JX 89, 90. OPP is currently reviewing the proposed labels and will notify the Presiding Officer if the status of these four data requirements are waived or if OPP is otherwise no longer pursuing suspension under the April 28, 2022 NOITS.

of the residue (poultry), (4) residue analytical method (livestock), (5) milk/meat/poultry/eggs residue, and (6) field accumulation in rotational crops.

JX 38; JX 41; JX 44; JX 45; JX 46; Verified Witness Statement of AMVAC Fact Witness Jon C. Wood; Verified Written Statement of Danette Drew.

Both parties agree that the relevant question pertaining to these four data requirements is whether AMVAC's proposed amendments to the labels for its DCPA pesticide products[15] are sufficient for OPP to consider waiver of these four data requirements. *See* AMVAC Opposition at 30. The record clearly demonstrates that neither AMVAC nor the Presiding Officer could reasonably conclude that the proposed label amendments are adequate for that purpose or that AMVAC has otherwise taken appropriate steps to fulfill these four data requirements.[16]

Following issuance of the DCPA DCI, the parties engaged in a back-and-forth discussion concerning whether OPP would waive these four data requirements. AMVAC Opposition at 28-29; MAD at 26-30. AMVAC does not contest that, by March 27, 2017 at the latest, OPP had provided written notice that it was not waiving the residue data requirements, but that it would reconsider waiver if AMVAC made certain specified changes to its product labels, including a prohibition on the planting of crops without an established tolerance for residues of DCPA to previously-treated fields and to implement a minimum 8-month "plant-back interval" ("PBI") for crops with an established tolerance for residues of DCPA. AMVAC Opposition at 29; Wood Statement at 3; MAD at 31.

[15] AMVAC largely declined to respond to Respondent's RFAs 6-12, pleading ignorance as to "what proposed labels the [RFAs] refer[ ] to." Respondent is unaware of any proposed language—other than the proposed labels already in the record as JX 41, JX 44, JX 45, and JX 46—which might have addressed OPP's concerns raised in JX 38.

[16] The label changes AMVAC highlights in its Opposition would also be insufficient for OPP to consider waiver of the four residue data requirements. *See* AMVAC Opposition at 28-30; JX 41, JX 44, JX 45, JX 46. AMVAC's changes only deleted uses listed on the DCPA technical label, not the end-use product labels.

Language appearing on AMVAC's end-use DCPA product labels as of August 11, 2014, reads as follows:

> Replanting crops other than those included on this label in DACTHAL W-75 treated soil within 8 months of application may result in crop injury. If replanting is required because of an early crop failure, the planting of onions, seeded cucurbits, potatoes, tomatoes, eggplants or peppers at this time may result in crop injury. However, all crops on this label may be planted following harvest of a DACTHAL W-75 treated crop.

JX 38 (Emphasis added). In an August 11, 2014 submission, AMVAC provided information concerning rotational crop restrictions and, importantly, proposed to maintain the same label language. *Id.* On March 27, 2017, OPP informed AMVAC that keeping the original rotational crop label language was not sufficient to waive the data requirements, stating:

> [OPP] has determined that the following rotational crop restrictions are appropriate: **Rotation to a crop with an established tolerance for residues of DCPA (40 CFR 180.185) is permitted with a minimum plant back interval of 8 months; rotation to any other crop is not permitted.**
>
> **All labels for DCPA use on agricultural crops should be modified to reflect the appropriate rotational crop restrictions. The specific crops and permissible plant back interval are listed in Table 1 below. Provided that the correct label modifications are made, additional field rotational crop data are not needed and the 860.1900 data requirement will be considered fulfilled for DCPA. If rotation to crops without current tolerances for DCPA is desired, full rotational crop studies may be performed at the desired plant back intervals for those crops so that appropriate tolerance levels may be determined.**

JX 38 (Emphasis in original). In this document, OPP clearly informed AMVAC that, to consider waiving the residue data requirements of the DCPA DCI, AMVAC would need to make certain specific changes to its DCPA pesticide product labels. *Id.* at 2. Critically, the label language would be required to "prohibit" rotation to any crop without an established tolerance for residues of DCPA, and to only permit rotation to any crop with an established tolerance for residues of DCPA after an 8-month PBI. *Id.* at 2-3. Without these changes, additional data are necessary to

determine the level of DCPA residues in crops planted after DCPA application and, accordingly, AMVAC would need to submit the four studies required by the DCPA DCI.

On June 8, 2017, AMVAC submitted proposed label amendments for the DCPA technical product at issue in the NOITS and for one of its end-use DCPA products. JX 44; JX 45. The proposed amendments included the removal of several crops from the technical label and several application methods from the end-use label. JX 44 at 6; JX 45 at 22. However, the proposed labels included no changes to the crop-rotation PBI language specifically addressed in OPP's JX 38. *Compare* JX 38 at 2 *with* JX 45 at 25 (redline page 7 of 15); *see also* AMVAC Response to RFA 10. That is, AMVAC once again proposed to keep its existing PBI language despite OPP's statement that the existing language was insufficient to waive the residue data requirements. On May 23, 2019, AMVAC re-submitted the amended DCPA technical label to OPP. JX 46; Wood Statement at 4. To date, OPP has not received proposed label amendments containing the specified PBI restrictions. As late as March 23, 2021, AMVAC maintained that the revised labels it submitted in 2017 and resubmitted in 2019 were sufficient for OPP to waive the four residue data requirements. Wood Statement at 5; AMVAC Opposition at 29-30.

AMVAC asserts that the proposed label amendments submitted to OPP would "eliminate the need for the [ ] residue studies." AMVAC Opposition at 30. That position is wholly unjustifiable. OPP clearly stated that the PBI language on AMVAC's existing end-use DCPA labels was insufficient to waive the data requirements and provided clear directions for changes that AMVAC could make for OPP to consider waiver. JX 38. The existing label language, quoted above, does not prohibit the planting of crops without an established DCPA tolerance in fields where DCPA had previously been applied, and does not restrict the planting of crops with an established DCPA tolerance to an 8-month PBI. *Id.* Rather, the language simply stated that

replanting crops "other than those included on [the] label . . . may result in crop injury." *Id.* In JX 38. OPP clearly stated that its concern with the PBI was not with respect to potential crop injury, but rather with respect to the lack of data about potential residues of DCPA being present on crops planted after DCPA application. *Id.* Despite these clear instructions from OPP, AMVAC instead opted to make unrelated changes to its DCPA labels and to ignore OPP's specified concerns when it submitted proposed language in 2017 and 2019. JX 45; *see also* JX 44, JX 46, AMVAC Response to RFA 11.

AMVAC also argues that it lacked notice that the proposed label amendments were insufficient, and that the company reasonably believed it had taken appropriate steps to satisfy the DCPA DCI. AMVAC Opposition at 30. AMVAC points to OPP's statement in the October 16, 2020 Data Delay Letter that OPP was still reviewing[17] the proposed label amendments, and to the fact that OPP did not reject the second proposed label language prior to issuing the NOITS in April 2022, as evidence that the company believed the proposed language was sufficient for OPP to waive the residue data requirements. *Id.* OPP's review of the proposed language is irrelevant to the question of whether AMVAC took (or believed it had taken) appropriate steps to satisfy the 2013 DCI. As explained above, OPP clearly noted that AMVAC's existing language with respect to crop rotation and PBI was insufficient for OPP to consider waiver of those data requirements and provided specific changes AMVAC would need to implement in order for OPP to consider waiver. JX 38. Despite clear instructions, AMVAC opted to submit proposed labels

[17] There is no obligation under FIFRA or its enabling regulations for OPP to reiterate that its prior denial of a waiver request is still effective, or that the reasoning offered for that denial still stands. The record does not indicate that OPP had reconsidered its position (*i.e.*, JX 38) against waiving the residue chemistry data requirements of the DCPA DCI without the specified label changes. The fact that OPP may not have reviewed AMVAC's subsequent label language at the time of the Data Delay Letter is not an indication that the—unchanged—plant-back language was now acceptable. It was reasonable for AMVAC to interpret JX 21 as indicating that OPP was still reviewing AMVAC's most recent proposed label submissions. However, it was not reasonable for AMVAC to assume that language identical to that already rejected by OPP would now constitute a reason to waiver the data requirements.

with unchanged crop rotation and PBI language. After choosing to ignore the clearly specified changes, AMVAC cannot now claim to have reasonably believed that its unrelated label changes were sufficient to eliminate the need for data pertaining to residues of DCPA on crops planted after application of DCPA to a field.

Given AMVAC's professed belief—that the label changes proposed prior to OPP's issuance of the NOITS are sufficient for OPP to consider waiving the data requirements—is demonstrably unreasonable, the record clearly demonstrates that AMVAC failed to take appropriate steps to secure the nature of the residue (poultry), residue analytical method (livestock), milk/meat/poultry/eggs residue, and field accumulation in rotational crops data required by the DCPA DCI within the time required by the Administrator. Without label changes accomplishing the purposes clearly laid out by OPP in JX 38, AMVAC should have taken steps to satisfy these four DCPA data requirements.

**7. Guideline 835.4200, TPA Anaerobic Soil Metabolism**

**8. Guideline 835.4400, TPA Anaerobic Aquatic Metabolism**

Respondent intends to offer the following additional evidence demonstrating that AMVAC failed to take appropriate steps to secure the two above-listed Guideline Series 835 metabolism data required by the DCPA DCI within the time required by the Administrator: (7) TPA anaerobic soil metabolism and (8) TPA anaerobic aquatic metabolism.
JX 37; JX 77; JX 78; JX 79; Verified Written Statement of Stephen Wente.

There is no dispute that AMVAC failed to submit these studies required by the DCPA DCI. AMVAC requested multiple 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. AMVAC argues that, after denying the company's initial requests to waive these data requirements, OPP made statements that it could make conservative assumptions in its registration review risk evaluations,

which AMVAC interpreted to mean that various data requirements from the DCPA DCI were no longer required. *See, e.g.*, AMVAC Opposition at 25. It is true that OPP must often proceed with registration review risk analyses despite incomplete data, and that doing so requires it to make conservative assumptions. Bloom Statement at 4. OPP's statement that it may make conservative assumptions is clearly not a statement that the data are no longer needed; rather, such statements serve to caution registrants that the lack of data may result in onerous restrictions that could be reduced or eliminated with more data. *Id.* at 4, 6. Additionally, in many of the documents where OPP made this statement with respect to DCPA, OPP also clearly stated that AMVAC's waiver requests were denied and that the data requirements were still outstanding or still in review. *See, e.g.*, JX 21. AMVAC urges the Presiding Officer to rule that, by noting the possibility of making conservative assumptions, OPP was waiving or otherwise rendering outstanding data requirements no longer necessary, despite clear statements to the contrary. AMVAC Opposition at 24-26; AMVAC Response to RFA 26 (arguing that statements regarding conservative assumptions "could be construed as a full or conditional waiver all data requirements discussed therein"). AMVAC's reliance on this incorrect inference—that OPP was no longer requiring the studies listed as outstanding or for which AMVAC's successive waiver requests were still in review—was not appropriate. Where OPP decided that certain data were no longer necessary, it clearly indicated that the data requirements were waived. *See, e.g.*, JX 37 at 5.

The fact that OPP may decide to move forward with its registration review of DCPA using conservative assumptions does not justify AMVAC's failure to submit the required data. 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 77, JX 21. OPP clearly stated that "a reliable anaerobic soil

metabolism study for TPA is still needed for risk assessment," and that "understanding the [anaerobic aquatic] dissipation of TPA is a critical risk assessment question." JX 77 at 3; JX 37 at 6. OPP never indicated that it intended to waive these data requirements.

Additionally, as explained in the MAD, OPP's intention in providing its final set of waiver request denials—including with respect to this study—concurrently with the NOITS was to avoid yet another round of receiving and reviewing data waivers similar to those AMVAC had previously submitted and EPA had previously denied. MAD at 47. AMVAC's decision to submit successive waiver requests for these data requirements after OPP denied the first requests, coupled with a failure to follow up with OPP as to the status of those follow-on waiver requests, was not an appropriate step. AMVAC understood that OPP did not agree with the rationales for waiving these data requirements, but opted to risk not initiating the studies while awaiting OPP's decision on the successive waiver requests. *Id.*

The record clearly demonstrates that AMVAC failed to take appropriate steps to secure the TPA anaerobic soil metabolism and TPA anaerobic aquatic metabolism data required by the DCPA DCI within the time required by the Administrator. OPP clearly denied AMVAC's requests to waive these data requirements; OPP statements concerning "conservative assumptions" did not constitute implicit or explicit waivers of the DCPA DCI data requirements.

**9. Guideline 850.1350, TPA Aquatic Invertebrate Life-Cycle, Estuarine/Marine Mysid**

**10. Guideline 850.1400, TPA Fish Early Life-Stage (Rainbow Trout)**

**11. Guideline 850.1400, TPA Fish Early Life-Stage (Bluegill Sunfish)**

**12. Guideline 850.1400, TPA Fish Early Life-Stage (Sheepshead Minnow)**

**13. Guideline 850.4500, TPA Algal Toxicity Test, Tier 1/II (Marine Diatom)**

Respondent intends to offer the following additional evidence demonstrating that AMVAC failed to take appropriate steps to secure the five above-listed Guideline Series 850 environmental effects data required by the DCPA DCI within the time required by the Administrator: (9) TPA aquatic invertebrate life-cycle (estuarine/marine mysid); (10) TPA fish early life-stage (rainbow trout); (11) TPA fish early life-stage (bluegill sunfish); (12) TPA fish early life-stage (sheepshead minnow); and (13) TPA algal toxicity (marine diatom).
JX 37; JX 69; Verified Written Statement of Christina Wendel.

There is no dispute that AMVAC failed to submit these studies required by the DCPA DCI. AMVAC Opposition at 19-21. AMVAC requested multiple waivers for these requirements in 2013 and 2020,[18] which were denied in 2017 and 2022, respectively. Accelerated Decision at 25-28; JX 5, JX 37, JX 22, JX 69. As explained above in section II.C.7-8, the fact that OPP may decide to move forward with its registration review of DCPA using conservative assumptions about the toxicity of TPA to aquatic invertebrates does not justify AMVAC's failure to submit

[18] The Accelerated Decision states that AMVAC's second waiver request for this data requirement was submitted in 2018. Accelerated Decision at 26. However, AMVAC did not submit a second waiver request until December 17, 2020, in response to OPP's October 16, 2020 Data Delay Letter, in which OPP informed the company that these data requirements remained outstanding. JX 21, JX 22. OPP did not, and does not, interpret JX 67 as a separate waiver request. AMVAC provided "rebuttals" to OPP's denial of the first waiver requests, including apparent mischaracterizations of the clear waiver denials in JX 37 as actually constituting an OPP "proposal" that AMVAC only be required to conduct studies of TPA in daphnids, at which point OPP would presumably make an affirmative determination that "additional aquatic organism testing is warranted." JX 67 at, *e.g.*, 10.

data responsive to these five DCPA DCI Guideline Series 850 data requirements. OPP's statements concerning conservative assumptions or the decision to move forward with risk assessment should not be interpreted as waiving certain DCPA DCI data requirements. 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. In the 2017 denial, OPP clearly stated that "[t]oxicity data is needed for TPA," and explained that "a full suite of studies may or may not be subsequently required" based on the results of a more "limited set of toxicity tests." JX 37 at 7 (emphasis in original). OPP never indicated that it intended to waive these data requirements if AMVAC only submitted the more limited data.

Additionally, as explained in the MAD, OPP's intention in providing its final set of waiver request denials—including with respect to this study—concurrently with the NOITS was to avoid yet another round of receiving and reviewing data waivers similar to those previously denied. MAD at 47. As the Presiding Officer previously concluded, AMVAC's decision to submit second waiver requests for these data requirements after OPP denied the first requests, coupled with a failure to follow up with OPP as to the status of those second waiver requests, was not an appropriate step. Accelerated Decision at 25. AMVAC understood that OPP did not agree with the company's rationales for waiving these data requirements, but still opted to risk not initiating the studies listed above while awaiting the outcome of the more limited toxicity studies. *Id.*; JX 67.

The record clearly demonstrates that AMVAC failed to take appropriate steps to secure the TPA aquatic invertebrate life-cycle (estuarine/marine mysid), TPA fish early life-stage (rainbow trout), TPA fish early life-stage (bluegill sunfish), TPA fish early life-stage

(sheepshead minnow), and TPA algal toxicity (marine diatom) data required by the DCPA DCI within the time required by the Administrator. OPP clearly denied AMVAC's requests to waive these data requirements; OPP statements concerning "conservative assumptions" did not constitute implicit or explicit waivers of the DCPA DCI data requirements.

**14. Status of Other Data Requirements**

As noted in Respondent's status reports, dated October 21, 2022 and December 23, 2022, OPP considers the following data requirement from the DCPA DCI to be satisfied:

- Special Study, DCPA Comparative Thyroid Assay.

As further explained in Respondent's status reports, while OPP does not consider the following DCPA DCI data requirements to be satisfied, Respondent is no longer alleging that AMVAC failed to take appropriate steps to secure the listed data requirements, and hence will not pursue suspension under the April 28, 2022 NOITS based on:

- Guideline 850.2100, DCPA Acute Avian (Passerine);
- Guideline 850.4100, DCPA Seedling Emergence (Lettuce only);
- Guideline 850.1350, DCPA Aquatic Invertebrate Life-Cycle, Estuarine/Marine Mysid;
- Special Study 1069, DCPA chironomous.

While OPP has not yet determined that the following two DCI data requirements have been satisfied, Respondent is no longer alleging that AMVAC failed to take appropriate steps to secure the listed data requirements, and hence will not pursue suspension under the April 28, 2022 NOITS based on:

- Guideline 850.1400, DCPA Fish Early Life-Stage (Bluegill Sunfish);
- Guideline 850.1400, DCPA Fish Early Life-Stage (Sheepshead Minnow).

Accordingly, these seven DCI data requirements are no longer ripe for consideration during the hearing scheduled to begin January 24, 2022. However, Respondent is not waiving its ability to seek suspension under FIFRA Section 3(c)(2)(B)(iv) in a later-issued notice of intent to suspend, based on further review by OPP.

## D. Factual Errors

Although there are minor characterizations of documents in the Accelerated Decision for which Respondent would differ, it does not consider those to fall within the context of "factual errors" contemplated in the Presiding Officer's October 18, 2022 Order. *See, e.g.*, *supra* n.18.

## E. Other Matters

### 1. Existing Stocks Provisions

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 from the Accelerated Decision must stand. Accelerated Decision at 31-34; *see also* Response Brief of Respondent at 37-41; MAD at 47-51. Neither AMVAC nor Grower Petitioners have alleged a plausible theory as to how the existing stocks provisions of the NOITS are inconsistent with FIFRA. Both petitioners make a number of irrelevant arguments, including that the NOITS failed to place restrictions on end-use DCPA products and end users, that suspension would create "market impacts," and that the NOITS' reference to potential risk concerns for DCPA invalidates OPP's reliance on its policy of not allowing sale or distribution of products suspended under FIFRA Section 3(c)(2)(B). *See* Response Brief of Respondent at 37-41. The provisions of the NOITS with respect to existing stocks of AMVAC's DCPA technical product are clearly consistent with FIFRA and should become effective on the Presiding Officer's

finding that AMVAC failed to take appropriate steps to secure the data required by the DCPA DCI, within the time required therein.

**2. Post-NOITS Initiation of Studies is Not an Appropriate Step**

AMVAC may seek to introduce evidence that it has engaged with contract laboratories to initiate studies, that contract laboratories have initiated studies, or that it will take other steps to submit data intended to address several of the still-outstanding DCPA DCI data requirements. As the Presiding Officer recognized, AMVAC's decision to submit successive waiver requests and to otherwise take no steps towards securing the data required by the DCPA DCI until after OPP issued the NOITS was "not a reasonable course of action." Accelerated Decision at 24. Although the Board ordered a consideration of whether AMVAC failed to take appropriate steps to secure the data required by the DCPA DCI within the time required by the Administrator, it gave no indication that such post-NOITS actions to initiate the process of securing data should be interpreted as appropriate. While the Presiding Officer may determine that the time period for AMVAC to take appropriate steps for a given data requirement was extended beyond the period initially provided in the DCPA DCI, there is no reasonable interpretation of FIFRA Section 3(c)(2)(B)(iv) or the record of this matter that AMVAC's obligation to comply with the remaining data requirements began only when OPP issued the NOITS.

A NOITS does not simply represent OPP's final statement that given data are required, that any outstanding waiver requests are actually denied, and that a registrant should now begin the process of generating responsive data. Rather, it is a notice that a registrant has already failed to take appropriate steps within the time required and that OPP is seeking suspension of the subject pesticide product unless "the registrant has satisfied [OPP] that the registrant has complied fully with the requirements." FIFRA Section 3(c)(2)(B)(iv). The determination of whether a registrant failed to take appropriate steps within the time required necessarily concerns

actions taken prior to OPP's issuance of the NOITS. In contrast, the determinations of whether a registrant's post-NOITS actions are sufficient to withdraw the NOITS or to lift a suspension are focused on OPP's determination of whether "the registrant has complied fully with the requirements." *Id.* Initiation of a study does not represent "full compliance." Were that the case, a registrant could prevent or lift a suspension merely by demonstrating that it has, in response to OPP's issuance of a NOITS, taken the first step towards generating required data. As noted numerous times throughout this proceeding, OPP will continue to expeditiously evaluate all AMVAC data submissions and will, as required by FIFRA Section 3(c)(2)(B)(iv), determine whether AMVAC has complied fully with any requirements that serve as the basis for suspension of its DCPA technical product.

**3. Disposition of AMVAC Waiver Requests**

AMVAC apparently now argues that OPP never actually denied many of the waiver requests at issue in this proceeding. *See, e.g.*, AMVAC Response to RFA 13. Essentially, its position is that while OPP's Environmental Fate and Effects Division ("EFED") and Health Effects Division ("HED," together with EFED the "Science Divisions") prepared detailed memoranda outlining the reasons that AMVAC's waiver requests were insufficient, and why the data required by the DCPA DCI were still necessary, those memoranda only contained "recommendations" that OPP's Pesticide Re-evaluation Division ("PRD") deny the waiver requests. *Id.* (discussing JX 66). Thus, AMVAC argues that it did not understand its waiver requests to be "denied" since the Science Division memoranda did not "connote finality." *Id.* That position both strains credulity and conflicts with AMVAC's prior statements that it understood OPP to have "denied the waiver requests." *See, e.g.*, Request for Hearing at 81.

Respondent acknowledges that OPP has utilized varying methods for informing AMVAC and other registrants of the disposition of waiver requests. In some instances, OPP's PRD

provided its own transmittal memoranda addressing the status of waiver requests and summarizing the contents of attached Science Division memoranda that contained more detailed discussion of outstanding data requirements. *E.g.*, JX 90, JX 89. In other instances, PRD transmitted Science Division memoranda with email statements that the memoranda were "the formal response from the Environmental Fate and Effects Division (EFED) of OPP." JX 75 (emphasis added), JX 74. In still other, primarily older, instances, PRD simply transmitted the Science Division memoranda to AMVAC as OPP's response to waiver requests. *E.g.*, JX 66. In all instances, the transmission of OPP's position to AMVAC was completed by PRD staff. Prior to December 2, 2022, neither AMVAC nor any other party asserted that Science Division memoranda were insufficient to convey OPP's position as to the relevant DCPA DCI data requirements still being required. *See* JX 67 (AMVAC discussing EFED memorandum JX 66 as "the Agency's memorandum"); *cf.* AMVAC Motion for Production of Delegation Documents (implying that OPP's denial of waiver requests was not completed by personnel with appropriate delegated authority). While the parties' distinction between EPA, the Agency, OPP, PRD, and EFED has occasionally been imprecise in communications, any argument that AMVAC was confused as to OPP's position on DCPA DCI data requirements due to imprecise organizational references is clearly contradicted by the record.

In any event, by no later than October 16, 2020, AMVAC received clear, unequivocal notice that PRD considered AMVAC's waiver requests denied for remaining DCPA DCI data requirements. JX 21. In the Data Delay Letter, OPP's PRD specifically noted that "[a] substantial portion of the data required in the [DCPA] DCI . . . is outstanding." *Id.* PRD further listed the outstanding data requirements in a table, specifically noting in the column "Study Status": "Waiver request denied; outstanding." *Id.* AMVAC's basis for asserting that JX 21 did not

"den[y], or re-iterate[] the denial of, any waiver request" is unclear. *Cf.* AMVAC Response to RFA 15.

Furthermore, even if the Presiding Officer adopts AMVAC's position that Science Division memoranda constitute only "recommendations" for OPP to waive a given data requirement, the effect would not be to AMVAC's benefit. If AMVAC sincerely understood documents that the parties have previously, non-controversially, discussed as "denying" a waiver request (*e.g.*, JX 66) as actually only containing "recommendations," then it admits to taking no action on a substantial number of other data requirements for which OPP's Science Divisions "recommended" waiver, but which OPP supposedly never waived with "finality."[19] As noted above, AMVAC's prior actions and statements in this matter suggest that it clearly understood JX 66 and other Science Division memoranda, transmitted by PRD to the company, as conveying OPP's disposition of the company's waiver requests. For example, in response to OPP's transmission of JX 66, AMVAC believed it necessary to file "rebuttal[s]" either outlining the steps that AMVAC intended to take to secure certain data (JX 67 at 16, Guideline 835.4300) or contesting OPP's waiver denials (*e.g.*, JX 67 at 5, SS-1072). However, for those data requirements that OPP waived (*e.g.*, JX 66 at 5, Guideline 835.1240), AMVAC offered no commentary in either JX 67 or any other document. If AMVAC truly understood JX 66 and similar documents as "recommendations" only, it never took any steps to request or confirm that OPP finalize the waiver of many DCPA DCI data requirements, and acted for all intents and purposes as if said data requirements were in fact waived.

[19] Under 40 C.F.R. § 158.45(c), OPP must "inform the applicant in writing of its decision" whether to grant or deny a waiver request.

## III. CONCLUSION

The terms "within the time required by the Administrator" and "failed to take appropriate steps to secure the data required" are not further defined by FIFRA Section 3(c)(2)(B), any relevant legislative history, or implementing regulations, but the meaning of both terms is clearly explained in OPP-issued DCIs and in communications between OPP and registrants. As explained above, the record for the 13 remaining DCPA DCI data requirements 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. Additionally, the existing stocks provisions of the NOITS are clearly consistent with FIFRA.

Accordingly, following the hearing, the Presiding Officer should enter an order 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 upholding the existing stocks provision of the NOITS.

Respectfully submitted,

FORREST PITTMAN

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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 Prehearing Brief**, dated January 6, 2023, was sent this day to the following parties in the manner indicated below.

FORREST PITTMAN
Digitally signed by FORREST PITTMAN
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