BEFORE THE ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In re	)	
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AMVAC Chemical Corporation	)	**Appeal No. FIFRA 22-01**
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	)	
Docket No. FIFRA-HQ-2022-02	)	
	)	

RESPONSE BRIEF OF RESPONDENT

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I. INTRODUCTION

Pursuant to 40 C.F.R. § 164.102 and the Administrative Law Judge's ("ALJ") July 1, 2022 Order on Respondent's Motion for Accelerated Decision ("Order"), the Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs, of the U.S. Environmental Protection Agency[1] ("Respondent" or "OPP") respectfully submits this response to AMVAC Chemical Corporation's ("AMVAC") and Grower-Shipper Association of Central California, J&D Product, Ratto Bros., Inc., and Huntington Farms (collectively, "Growers") July 21, 2022 Notices of Exceptions and Appeal Briefs. For the reasons discussed below, the Board should deny the exceptions to the Order, and enter a final decision pursuant to 40 C.F.R. § 164.103 upholding the ALJ's accelerated decision and finding that:

1. Petitioner AMVAC has failed to take appropriate steps to secure the data required by OPP's January 31, 2013 Data Call-In ("DCI") GDCI-078701-1140 and has thereby failed to take the action that served as the basis for OPP's April 28, 2022 Notice of Intent to Suspend ("NOITS") the registration of AMVAC's registered pesticide product, Technical Chlorthal Dimethyl (EPA Registration Number 5481-495), containing the active ingredient dimethyl tetrachloroterephthalate ("DCPA"); and
2. OPP's determinations in the NOITS with respect to the disposition of existing stocks of the product Technical Chlorthal Dimethyl are consistent with the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*

The scope of this proceeding is limited by the plain language of FIFRA Section 3(c)(2)(B)(iv) and AMVAC's arguments concerning matters outside that scope are impermissible and without merit. AMVAC's failure to take appropriate steps with respect to any

[1] References to the EPA Administrator's authorities in this brief use the generic terms "EPA" or "Agency."

one outstanding data requirement is sufficient to justify suspension; the evidence before the Board is sufficient to conclude that no genuine dispute of material fact exists as to several outstanding requirements and, accordingly, Respondent is entitled to judgment as a matter of law.

Pursuant to 40 C.F.R. § 164.103, on issuance of the Board's final decision upholding the Order, the NOITS would immediately become effective and the registration of the product Technical Chlorthal Dimethyl would be suspended until AMVAC complies fully with the 2013 DCI.

II. STATEMENT OF THE CASE

In the Order, the ALJ accurately describes the relevant statutory and regulatory provisions at issue in this matter. Order at 2-4. A more-detailed discussion of FIFRA generally, OPP's registration review of pesticide active ingredients, data call-ins, and suspension proceedings under FIFRA Section 3(c)(2)(B)(iv) may be found in Respondent's Motion for Accelerated Decision ("Motion"). Motion at 3-9.

For the most part, the ALJ accurately describes the factual background relevant to OPP's registration review of DCPA, including the issuance of the 2013 DCI, AMVAC's submissions of data in response to the DCI, and OPP's actions in response. Order at 4-17. In discussion of individual data requirements, below, Respondent notes several minor factual discrepancies—none of which constitute genuine disputes of material fact or otherwise affect Respondent's entitlement to judgment as a matter of law in this matter.

The procedural history is described in the Order. Order at 1-2. Briefly: on April 28, 2022, OPP issued the NOITS. JX 1. On May 27, AMVAC filed its Request for Hearing and Statement of Objections ("Request for Hearing"). On June 13, Respondent filed its Motion. On June 21, AMVAC filed its Opposition to Respondent's Motion for Accelerated Decision ("Response").

On July 1 the ALJ issued the Order granting Respondent's Motion. On July 21, AMVAC filed its Notice of Exceptions and Appeal Brief ("Appeal"), and Growers filed their Notice of Exceptions and Appeal Brief ("Growers Appeal").

III. STANDARD OF REVIEW

This FIFRA Section 3(c)(2)(B)(iv) suspension proceeding is subject to the provisions of 40 C.F.R. Part 164, which provides that the Board

> shall, on appeal or review from an [ ] accelerated order of the [ALJ], issue its final decision and order, including its rulings on any exceptions filed by the parties; such final order may accept or reject all or part of the initial or accelerated decision of the [ALJ] even if acceptable to the parties.

40 C.F.R. § 164.103.[2] Accordingly, the Board reviews an ALJ's factual and legal conclusions on a *de novo* basis. *Cf. Bayer CropScience LP*, 17 E.A.D. 228 at *25 (EAB 2016). The record, including witness statements provided in lieu of direct testimony during the parties' pre-hearing exchanges, are sufficient for the Board to conclude that no genuine dispute of material fact exists, and that Respondent is entitled to judgment as a matter of law. 40 C.F.R. § 164.91(a)(7). Respondent provides discussion herein to supplement its Motion and allow for the Board's resolution of this matter, as AMVAC's Response and the Appeals refer to evidence and arguments raised for the first time after Respondent filed the Motion.

While under 40 C.F.R. § 164.80(a), Respondent "has the burden of going forward to present an affirmative case,"[3] under § 164.80(b) "the ultimate burden of persuasion shall rest with the proponent of the registration." *Id.* (citing *Bayer*, 17 E.A.D. 228 at *25).

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[2] 40 C.F.R. Part 164 is analogous to 40 C.F.R. Part 22, the regulations governing assessment of civil penalties and enforcement under FIFRA and other environmental statutes administered by EPA. *Cf.* 40 C.F.R. § 22.30(f).

[3] While 40 C.F.R. § 164.3 provides that "suspension hearings" are governed by subpart C, the text of subpart C make clear that it applies not to data-submission suspension hearings under FIFRA Section 3(c)(2)(B)(iv), but rather to expedited suspensions under FIFRA Section 6(c). *Cf.* 40 C.F.R. § 164.120; 7 U.S.C. 136d(c). The provisions of 40 C.F.R. Part 164, subpart B, including § 164.80, apply to proceedings "other than expedited hearings."

> Therefore, AMVAC, as the proponent of DCPA's registration, must meet its burden by either rebutting the Agency's prima facie case for suspension, or demonstrating by a preponderance of the evidence that it has not failed to take the action that served as the basis for the notice of intent to suspend DCPA's registration and that the Agency's determination on existing stocks is not consistent with FIFRA.

Id. Additionally, as many of AMVAC's arguments are contingent upon strained interpretations of the record, it is important to note that "a court need only draw favorable inferences [for the party opposing accelerated decision] as to a fact at issue if such inferences are reasonably probable." *BWX Technologies, Inc.*, 9 E.A.D. 61 at *13, n.22 (EAB 2000) (citing *Sylvia Dev. Corp. v. Calvert Cnty.*, 48 F.3d 810, 818 (4th Cir. 1995)). "Permissible inferences must still be within the range of reasonable probability, however, and [summary judgment is appropriate] when the necessary inference is so tenuous that it rests merely upon speculation and conjecture." *Id.*; *see also id.* at *10 (noting that the standard for granting accelerated decision is similar to the summary judgment standard of FRCP 56).

IV. ARGUMENT

Respondent first responds to several of AMVAC's arguments concerning this suspension proceeding more broadly. Respondent then demonstrates that there is no genuine dispute of material fact with respect to whether AMVAC took appropriate steps to satisfy many of the outstanding data requirements.

In the Order, the ALJ correctly ruled that there is no genuine dispute of material fact that AMVAC failed to take the action that served as the basis for the NOITS and that OPP's determinations with respect to the disposition of existing stocks of the DCPA technical product are consistent with FIFRA. Order at 34. The ALJ also correctly ruled that any single failure by AMVAC may serve as the basis for suspension of its DCPA technical registration. Order at 7-8. Accordingly, Respondent directs the Board's attention to several of the data requirements

addressed in the NOITS for which AMVAC's failure to comply with the 2013 DCI are particularly egregious or its arguments opposing accelerated decision least convincing. *Infra* sections IV.F.1-4. All of the data requirements included in the 2013 DCI are considered necessary for OPP to complete its registration review of DCPA unless specifically waived by OPP. *See* Order at 3-4. Neither AMVAC's belief that certain data are not necessary nor OPP's statements that it could "make conservative assumptions" where required data were not submitted excuses AMVAC from the requirement to take appropriate steps to comply with the 2013 DCI. Order at 27. Additionally, the fact that AMVAC submitted several studies in response to outstanding data requirements after OPP issued the NOITS is not sufficient to defeat suspension; OPP must still evaluate whether AMVAC's submissions comply fully with the requirements that served as the basis for the suspension of the registration. Order at 24. In addition to the clear language of FIFRA Section 3(c)(2)(B)(iv) providing an opportunity for OPP to evaluate such submissions when determining whether to re-instate a suspended registration, Respondent also notes that allowing the mere submission of data without review and a determination that the study complies with the DCI would defeat the purpose of a suspension proceeding.

A. The ALJ's Ruling that the Scope of this Proceeding is Limited was Correct and Should be Upheld by the Board

In the Order, the ALJ correctly ruled that the scope of this suspension proceeding is limited by the plain language of FIFRA Section 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). Order at 19-23. Thus, "[t]he only matters for resolution at [a]hearing shall be:"

> (1) "whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide" (i.e., whether the registrant "failed to take appropriate steps to secure the data required" by the DCI); and

(2) "whether [OPP's] determination with respect to the disposition of existing stocks is consistent with [FIFRA]."

7 U.S.C. § 136a(c)(2)(B)(iv).

AMVAC argues that the ALJ read the words "take appropriate steps" out of the statutory language. Appeal at 13. Rather, the Order indicates that the ALJ did indeed consider whether appropriate steps were taken at least in a broad sense. Order at 23 ("The fact that AMVAC has attempted but failed to provide the data to [OPP] is by definition not 'appropriate.'"). Further, the Order suggests an examination of appropriateness against the backdrop of OPP's need to complete registration review. Order at 22. Finally, the Order explains that it would be contrary to FIFRA's purpose—to ensure that pesticides do not present unreasonable adverse effects—to read the suspension provision as allowing interminable "appropriate" steps toward complying with data requirements imposed in a DCI. Order at 21 ("Even if AMVAC were taking only appropriate steps toward producing required data and acting entirely in good faith, but continually failing to actually provide the data, it would undermine FIFRA's mandate that a pesticide not remain registered unless OPP determines that it can be used without causing "any unreasonable risk to man or the environment."). Taken together, it is clear the ALJ did consider appropriateness in an overarching sense.

While Respondent agrees that this is a permissible reading of the statute, Respondent acknowledges another permissible interpretation is that suspension may only be granted after more detailed examination of the steps taken to comply with each data requirement that could be an independent basis for suspension. However, even if the Board determined that such an examination is necessary, it is clear that AMVAC has not taken appropriate steps to satisfy the 2013 DCI. Respondent directs the Board's attention to several data requirements that were the

basis for OPP's NOITS for which it is clear AMVAC has not taken appropriate steps—or for several, any steps—to comply with the DCI.

Throughout the past nine years, OPP has acknowledged AMVAC's steps towards satisfying the 2013 DCI, including in an October 16, 2020 letter (the "Data Delay Letter"), but has regularly reminded AMVAC that additional data were required for OPP to complete registration review of DCPA. JX 21. In the NOITS, the Motion, and in its prehearing exchange, Respondent further acknowledges that AMVAC took some steps towards satisfying the data required by the 2013 DCI,[4] but notes that multiple data requirements remained outstanding or were still in review.[5] While AMVAC took appropriate steps towards complying with many of the data requirements listed in the 2013 DCI, its actions with respect to approximately 20 data requirements do not constitute "appropriate steps," and accordingly constitute grounds for suspension of AMVAC's DCPA technical product under FIFRA Section 3(c)(2)(B)(iv).

As described in the Order and Respondent's Motion, the 75-day period for completion of the hearing and issuance of a decision further indicates the scope of FIFRA Section 3(c)(2)(B)(iv) hearings must be narrow. Order at 20-21, Motion at 42-43. A full review of the technical sufficiency of a registrant's submissions is not possible in that time period. In any event, a deep examination of the record is unnecessary for most, if not all, of the outstanding data requirements at issue in the instant case. The record before the Board clearly demonstrates

[4] AMVAC characterizes its actions as diligently responding to all but 20 of the approximately 80 data requirements contained in the 2013 DCI, at which point OPP issued the NOITS with no notice. Appeal at 19, n.17. Although not immediately relevant to this suspension proceeding, as of October 17, 2020, more than 40 data requirements remained outstanding with action required by AMVAC. JX 21. That fact, coupled with substantial additional evidence, paints a different picture of the circumstances, to wit: that OPP accommodated myriad delays on AMVAC's part and was forced to repeatedly request the same data and reiterate the reasons for needing said data.

[5] Respondent notes that, in many cases, it specifically informed AMVAC that certain studies were still being reviewed by OPP, as a means of indicating that the relevant data requirement was not considered satisfied or waived at the time.

AMVAC's numerous failures to take appropriate steps towards securing the data required by the 2013 DCI, including, among others: stating that it did not intend to submit a required study based on a belief that OPP did not need the data; submitting a study on a single species where the 2013 DCI called for data on three species; failing to submit a required study after informing OPP that it would do so; failing to make specified label changes that OPP would need to consider waiver of four required studies; and resubmission of seven waiver requests after OPP denied the initial requests. After reviewing the record and submissions made during the prehearing exchange in this proceeding, Respondent offers brief explanations of why AMVAC's steps were not appropriate, below.

B. The ALJ was Correct in Ruling that OPP's Rationale for Requiring the Data Listed in the 2013 DCI is Outside the Scope of this Proceeding

As the ALJ correctly explained in the Order, AMVAC's attempt to attack OPP's need for the data required by the 2013 DCI is precluded by statute. Order at 4 (citing *Atochem N.A. v. EPA*, 759 F. Supp. 861, 863 (D.D.C. 1991) ("At the hearing, the validity of [DCI] data requirements may not be challenged. . . ."); *Bayer*, 17 E.A.D. 233 at *5). AMVAC declined an opportunity to comment on OPP's proposed data requirements, and OPP denied the company's subsequent requests that OPP waive those requirements; AMVAC cannot now argue that those unsatisfied requirements are unnecessary merely because OPP noted the possibility of making conservative assumptions in OPP's risk analyses. The Board should dismiss AMVAC's proposed restructuring of OPP's registration review process and should affirm the Order. *See generally* Motion at 42-43.

In the Order, the ALJ correctly ruled that AMVAC's argument—that certain data were not needed by OPP—is unpersuasive. Order at 27. While the ALJ characterized that argument as "veiled" and only addressed it with respect to a single data requirement, many of AMVAC's

positions are premised in one way or another on this assertion. *See, e.g.*, Response at 23-24 (arguing that OPP statements concerning conservative assumptions "contributed to AMVAC's understanding that additional . . . waiver requests would not be misplaced").

AMVAC's position as to data on the primary environmental degradation product of DCPA, tetrachlorophthalic acid ("TPA"), largely proceeds on two such lines of reasoning. First, AMVAC argues that OPP stated it would not require certain data on TPA so long as a similar study on DCPA was submitted. Request for Hearing at 62. AMVAC calls attention to OPP's May 31, 2011 Preliminary Problem Formulation for the Ecological Risk Assessment of [DCPA] ("PPF"), which provides:

> No data have been submitted on the major degradate, TPA. TPA forms at high levels relative to parent chemical, it is expected to be more mobile than DCPA, and is expected to be somewhat persistent. Therefore, availability of a relatively comprehensive dataset on the toxicity and environmental fate of TPA is needed. However, a more limited testing strategy will be considered in lieu of a comprehensive data submission if one is proposed.

JX 65 at 2. AMVAC ignores multiple direct statements in the PPF that a "full suite of aquatic toxicity studies [ ] are requested for [ ] DCPA [and] TPA, to increase certainty in the risk estimation." *Id.* at 52. AMVAC also ignores the fact that all aspects of the DCPA registration review, including the additional data that OPP proposed were necessary in the PFF, were subject to public comment.[6] RX 1; Motion at 10-11. Although registrants routinely submit comments when registration review dockets are opened, including comments as to proposed data requirements, neither AMVAC nor any other entity submitted a comment. Motion at 5, 10-11.

[6] AMVAC implies that the opportunity for public comment on the PFF did not provide "a meaningful opportunity to 'help shape the content of the DCI.'" Appeal at 35. AMVAC offered no direct testimony to support this view of OPP's administrative procedures, or to rebut Respondent's uncontested assertion that "it is common for registrants and other stakeholders to submit comments concerning the anticipated data requirements," but argues it should have been provided the opportunity to rebut Respondent's position at a hearing. Appeal at 35; Bloom Statement at 3. It is not clear what relevant purpose such a rebuttal would serve, as OPP clearly provided a pre-DCI opportunity for comment as to these DCPA and TPA data requirements.

Despite OPP's specific statement that "a more limited testing strategy" for TPA could be proposed, AMVAC did not do so. *Id.* Accordingly, OPP issued the 2013 DCI largely unchanged. AMVAC thus argues that an OPP proposal, made prior to OPP finalizing the data required for DCPA registration review in the 2013 DCI, should be read as eliminating the need for certain data requirements outlined in that later document and that, accordingly, AMVAC's repetitive requests that OPP waive those data requirements constituted appropriate steps in complying with the DCI. Request for Hearing at 62-63. Such an argument is obviously based on faulty logic.

Second, AMVAC argues that, after the company's initial responses to the 2013 DCI, 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 2013 DCI were no longer required. *See, e.g.*, Response 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 Board to infer 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. Response at 24-26. AMVAC's reliance on their incorrect inference, that OPP was no longer requiring the studies listed as outstanding or still in review, was not appropriate.

C. The Notice of Intent to Suspend is an Independent OPP Action

1. The October 2022 Registration Review Deadline is Separate from this Suspension Proceeding

AMVAC asserts that the ALJ's mere mention of the October 1, 2022 statutory deadline for OPP to complete registration review of DCPA—and all other currently-registered pesticide active ingredients—"alone is sufficient to compel reversal and remand." Appeal at 20; *see* 7 U.S.C. § 136a(g)(1)(A)(iii). It is important to note that the statutory deadline, and indeed the registration review process for DCPA, has no automatic[7] effect on AMVAC's registration.[8] Even if OPP's registration review concluded that DCPA does not meet the standard for registration under FIFRA, OPP would still need to initiate a cancellation proceeding for any registered products. 7 U.S.C. § 136a(g)(1)(A)(v) ("No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of [FIFRA Section 6]."). Respondent maintains that the statutory deadline is relevant only as it provides context for OPP's actions in this matter. FIFRA Section 3(c)(2)(B)(iv) provides OPP with discretion on when to pursue suspension; it is not limited to scenarios where OPP will or is likely to miss the statutory deadline without registrants

[7] Respondent offers a minor correction to one statement in the Order's conclusion. Even if AMVAC's product is suspended at the conclusion of this proceeding, that suspension will not result in AMVAC being unable to "maintain its registration in effect." See Order at 31. Unlike cancellation, a DCI suspension is a temporary restriction of a registration, with a clearly defined process for lifting the suspension, whereas FIFRA provides no means of reinstating a cancelled registration aside from re-applying to register the same product. *Compare* 7 U.S.C. § 136a(c)(2)(B)(iv) (suspension) *with* 7 U.S.C. § 136d(b) (cancellation). It is important also to note that the statutory registration review deadline, and indeed the registration review process for DCPA, has no immediate direct effect on AMVAC's registration. Even if OPP's registration review concluded that DCPA does not meet the standard for registration under FIFRA, OPP would need to pursue additional regulatory action, such as initiating a cancellation proceeding, before any registered products are cancelled. 7 U.S.C. § 136a(g)(1)(A)(v) ("No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of [FIFRA Section 6].").

[8] As the issuance of an NOITS is a discretionary action, OPP briefly explained its risk concerns as part of its reasoning for taking such action but did not claim they were the basis for suspension. AMVAC has not alleged that OPP abused its discretion in pursuing suspension, but rather chose to contest the factual and legal bases upon which the NOITS is premised. Accordingly, the alleged motivation behind the NOITS is not relevant to this appeal.

submitting the necessary information. There is no requirement that OPP pursue suspension within a certain time frame of a registrant's failure to provide data.

The statutory registration review deadline was not the basis for the issuance of the NOITS. Indeed, the only mentions of the statutory deadline in the record appear in the October 16, 2020 Data Delay Letter, in which OPP stated its intention to complete registration review of DCPA by October 1, 2022, and in the NOITS, which simply noted OPP's prior mention of the deadline in the Data Delay Letter. JX 21, JX 1. Nevertheless, OPP's inability to conduct the risk assessment needed for registration review played an important role in determining whether to exercise its discretion to issue the NOITS. The approaching deadline can and should be a factor in considering the appropriateness of the steps taken by AMVAC to comply with a DCI that was issued many years ago for the express purpose of ensuring OPP had the necessary data to complete registration review. While OPP is normally accommodating with respect to data submission timelines, that accommodation should not be interpreted as a lack of authority. OPP may use its statutory information-gathering authorities, including FIFRA Section 3(c)(2)(B)(iv) suspension proceedings, towards the goal of completing registration review.

2. The Notice of Intent to Suspend is Not an Attempt to Circumvent Cancellation Procedures

AMVAC argues that OPP's "primary motivating factor[9] for the suspension action" is not actually to motivate submission of the outstanding data requirements, but rather is an attempt to circumvent FIFRA Section 6 cancellation procedures. Appeal at 26-27, n.29; *see* 7 U.S.C. § 136d. AMVAC argues that OPP has "a substantive safety concern" as to data regarding thyroid effects potentially caused by DCPA, but that OPP opted to pursue suspension under FIFRA Section 3(c)(2)(B)(iv) as a means of removing DCPA from the market rather than pursue a

[9] *Supra* n.8.

lengthier and broader cancellation proceeding. Appeal at 24-27. AMVAC seizes on a statement in the NOITS, which reads in relevant part:

> [D]ue to these outstanding DCI data requirements, including but not limited to a study of the thyroid toxicity of DCPA, the Agency is not able to complete a human health risk assessment. Specifically, due to the lack of data examining the fetal thyroid toxicity of DCPA, the Agency is not able to complete a scientifically robust and defensible human health risk assessment. Preliminary data evaluated by EPA provides evidence that the fetus is potentially more sensitive to thyroid function compared to the mother in animal studies. Given the potential fetal sensitivity, EPA has concerns for exposures to pregnant females. Applying a standard uncertainty factor (typically a ten-fold factor) to account for these missing data may not be health protective based on EPA's review of these preliminary data.

JX 2 at 1-2. AMVAC acknowledges, and has apparently never disputed, that additional data are necessary to properly evaluate DCPA's potential thyroid effects, as evidenced by the company's ongoing discussions with OPP concerning submission of the comparative thyroid assay ("CTA") required by the DCI. Appeal at 28-29, Response at 28-28. Additionally, the record before the Board is replete with evidence that OPP has repeatedly expressed a need for other data requirements. JX 74, JX 21. As explained above, the fact that OPP may be forced to make conservative assumptions in its risk assessments does not render those data requirements fulfilled or unnecessary. AMVAC reads an ulterior motive into OPP's clear statement concerning the need for the CTA, claiming with no support that OPP is attempting to "circumvent cancellation procedures." Appeal at 26.

In issuing the NOITS, OPP is following proper procedure under FIFRA. OPP issued the 2013 DCI to obtain data necessary to determine whether DCPA continued to meet the standard for registration under FIFRA as required by FIFRA Section 3(g). Following AMVAC's repeated failures to submit the required data, OPP issued the NOITS pursuant to FIFRA Section 3(c)(2)(B)(iv). If the required data ultimately demonstrates a risk of unreasonable adverse effects, OPP may then initiate cancellation proceedings in which it would be required to

demonstrate the reasons and factual basis requiring cancellation. 7 U.S.C. § 136d(b)(1). OPP's use of its information gathering authorities prior to seeking any hypothetical cancellation or change to a registration is the correct sequence of events.

As noted above, suspension of a registration is a temporary restriction, and AMVAC is currently submitting data that could result in OPP lifting the suspension. This includes AMVAC's June 20, 2022 submission of a CTA study, which OPP is diligently reviewing in the context of both this suspension proceeding and registration review of DCPA more broadly. Appeal at 28. Assuming that AMVAC submits the remaining outstanding data, or demonstrates that it has taken appropriate steps to satisfy the 2013 DCI (*e.g.*, by making label changes that would obviate the need for certain data), OPP would lift the suspension and AMVAC would again be free to sell, distribute, and use its registered DCPA technical product. Any hypothetical cancellation proceeding for DCPA products would be contingent upon OPP completing risk assessments of the chemical (for which OPP needs the outstanding data), making a determination that DCPA's continued use would result in "unreasonable adverse effects on the environment," and taking appropriate regulatory action such as initiating a cancellation procedure. *See* 7 U.S.C. § 136d. Even if at some point OPP pursues cancellation, that process could be lengthy, during which time AMVAC would be able to sell, distribute and use its DCPA technical product so long as a suspension was not still in place.

AMVAC relies heavily on *Reckitt Benckiser Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011) in support of its argument that OPP is attempting to suspend the DCPA registration when it should actually initiate a cancellation proceeding. Appeal at 26-27. Unlike the instant case, in which OPP genuinely lacks data "to complete a scientifically robust and defensible human health risk assessment," *Reckitt* involved a situation in which OPP had already concluded that certain

pesticide products would present unreasonable risks. 762 F. Supp. at 38. Accordingly, OPP sought to mitigate those risks through requiring registrants to either make changes to the products' labels or to voluntarily cancel their products, and threatened enforcement action against registrants who did not comply by asserting that the existing labels were "misbranded" pursuant to FIFRA Section 12, 7 U.S.C. § 136j. *Id.* at 38-40. The court ruled that FIFRA "does not permit the agency to proceed by use of a misbranding proceeding to effectuate a cancellation. *Id.* at 40-41. Here, in contrast, OPP is not attempting to address unreasonable adverse effects on the environment, either through mandatory label changes or cancellation. Rather, OPP is using the authority afforded to it to ensure it has the required data it needs to make a determination on unreasonable adverse effects. The suspension authority in FIFRA Section 3(c)(2)(B)(iv) is wholly separate from a finding of unreasonable adverse effects to support a cancellation under FIFRA Section 6(b). 7 U.S.C. §§ 136a(c)(2)(B)(iv); 136d(b).

Under AMVAC's incorrect application of *Reckitt*, the mere possibility of a "negative risk conclusion" as to a pesticide product would preclude OPP, should it mention the possibility, from taking any regulatory action without first conducting a full cancellation hearing. Were the Board to adopt that position, there is no plausible scenario under which OPP could pursue suspension under FIFRA Section 3(c)(2)(B)(iv) if it were transparent about its uncertainty in assessing risks. OPP does not issue DCIs for data that it already possesses, or that it does not need to assess the risk posed by a pesticide. Contrary to AMVAC's assertion that OPP is merely "plead[ing] 'uncertainty'" to indefinitely suspend a product and thereby "avoid the scrutiny [of] a cancellation hearing," OPP's authority to call in data under FIFRA Section 3(c)(2)(B) is based on OPP being able to "determine that additional data or information are needed to conduct the review." Appeal at 27, n.29; 7 U.S.C. § 136a(c)(2)(B). Stated another way, OPP has the authority

to call in data to resolve uncertainties. If OPP is in possession of data to make a determination that a pesticide poses unreasonable adverse effects, OPP may act to initiate cancellation as to some or all uses of the pesticide and/or to implement necessary mitigation measures. 7 U.S.C. § 136d(b). Indeed, 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. There is no indication that Congress intended to create such a Catch-22.

D. The ALJ's Ruling that Post-NOITS Submission of Data does not Negate Suspension was Correct and Should be Upheld by the Board

In the Order, the ALJ correctly ruled that a registrant's submission of a potentially-responsive study, after OPP has issued a notice of intent to suspend, is not sufficient to negate the possibility of a suspension based on that missing data. Order at 24-25. The ALJ correctly notes that OPP would not have adequate time to review a registrant's data submission within the 75-day window provided for resolution of a suspension proceeding under FIFRA Section 3(c)(2)(B)(iv). *Id.* FIFRA Section 3(c)(2)(B)(iv) provides that a suspended registration shall be reinstated after OPP determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration. In order to lift such a suspension of AMVAC's DCPA technical product, OPP would need to first determine that AMVAC has taken appropriate steps to satisfy all of the data requirements of the 2013 DCI upon which the suspension is based.

Accepting AMVAC's argument—that its recent submissions negate the applicable DCI requirement as a basis for suspension—would create a precedent in which registrants could hurriedly submit essentially any type of data, or request that OPP waive the data requirement,

after OPP issues a NOITS and thereby escape suspension, so long as the submission is purportedly responsive to a DCI. AMVAC's preferred interpretation of FIFRA Section 3(c)(2)(B)(iv) would provide an unrealistically short deadline for OPP to determine whether a post-NOITS submission satisfied the data requirement. FIFRA Section 3(c)(2)(B)(iv) clearly contemplates that OPP must make a positive determination that the registrant has complied with the data requirement prior to lifting the suspension. Allowing evasion of suspension through post-NOITS but pre-suspension submissions would render OPP's authority under this section essentially meaningless. OPP will expeditiously evaluate all AMVAC data submissions and will, as required by Section 3(c)(2)(B)(iv), make a determination as to whether AMVAC has complied fully with the requirements that served as the basis for the suspension of the registration.

E. The ALJ's Ruling that AMVAC's Failure to Comply with Any One DCI Data Requirement is Sufficient to Justify Suspension of the Technical Registration was Correct and Should be Upheld by the Board

In the Order, the ALJ correctly ruled that AMVAC's failure to comply with any single one of the 20 outstanding data requirements included in the NOITS is sufficient to justify suspension of the DCPA technical registration under FIFRA Section 3(c)(2)(B)(iv). Order at 7-8; *see* 7 U.S.C. § 136a(c)(2)(B)(iv). AMVAC does not contest this point, but instead argues that Respondent has not demonstrated the legal and factual basis for suspension as to each of the individual data requirements. Response at 3-4. Although Respondent maintains that all 20 outstanding data requirements constitute grounds for suspension of AMVAC's DCPA technical registration, Respondent directs the Board towards 8 data requirements in particular for which AMVAC has no plausible defense to the Motion. *Infra*, sections IV.F.1-4.

F. The ALJ's Ruling that AMVAC Failed to Take Appropriate Steps to Secure the Data Required by the 2013 DCI was Correct and Should be Upheld by the Board

AMVAC argues that it "is entitled to a determination of whether it took appropriate steps for each of the 20 studies OPP discussed in the NOITS." Appeal at 38.[10] As discussed in the previous section, the ALJ correctly ruled otherwise. Even assuming that argument were correct does not, however, require the denial of OPP's Motion for Accelerated Decision or require a hearing before AMVAC's registered product may be suspended. Pursuant to 40 C.F.R. § 164.91(a), the ALJ[11] may "render an accelerated decision in favor of [Respondent] as to all or any portion of the proceeding." (Emphasis added). AMVAC does not contest the ALJ's conclusion that "any single [failure to take appropriate steps] can form the basis for issuing a notice of suspension. Appeal at 38-39. Rather, AMVAC argues that the only two options before the board are to either affirm the Order with respect to the 9 data requirements[12] only, or to remand to the ALJ for a full hearing on all 20. Appeal at 39. Both aspects of that argument are without merit. First, as the Board reviews the Order *de novo*, it may decide this matter based on any factual or legal basis it determines is appropriate. *Bayer* 17 E.A.D. 228 at *25.

Even if the Board accepts AMVAC's argument that a hearing is necessary to determine whether the company took appropriate steps to comply with certain of the data requirements listed in the DCI, the record before the Board clearly establishes the factual and legal basis

[10] As AMVAC itself notes, the approximately 2500-word Exhibit 1, attached to AMVAC's 13,985-word Appeal brief, could be viewed as inconsistent with the Board's July 8, 2022, Standing Order setting a 14,000-word limit for FIFRA-related briefs. Appeal at 37. The Board should therefore not consider the Exhibit. *See City of Taunton*, 17 E.A.D. 105 at * 19 (EAB 2016).

[11] This authority necessarily also extends to the Board, through its authority to "accept or reject all or part of the [ ] accelerated decision of the [ALJ]." 40 C.F.R. § 164.103.

[12] AMVAC asserts that the ALJ addressed only six outstanding data requirements in the Order. Appeal at 39. The Order clearly addresses nine studies: two DCPA fish toxicity, three TPA fish toxicity, two mysid, one marine diatom, and one chronic sediment toxicity. Order at 8-17.

required to suspend AMVAC's registration for the outstanding data requirements; eight in particular are discussed in sections IV.F.1-4, below. To paraphrase AMVAC's own argument, "[e]ven a layman could look at the [ ] record of communications regarding [these eight] stud[ies]" and conclude that AMVAC has not provided any plausible explanation for its failure to comply; "no technical expertise is required." *Cf.* Appeal at 29.[13] None of the myriad reasons AMVAC offers as justification for its non-compliance with respect to these eight data requirements even plausibly raise genuine disputes of material fact. *Cf.* Appeal at 2 (asserting "delay attributable to EPA, the novelty of several of the studies EPA asked AMVAC to perform, or other factors beyond AMVAC's control"); Appeal at 4 (asserting that AMVAC first learned of certain deficiencies "concurrently with the issuance of the [NOITS]"); Appeal at 24 (asserting "that EPA could proceed with a risk assessment" by making conservative assumptions). Accordingly, the Board can and should determine that AMVAC has failed to take appropriate steps to satisfy these requirements and allow the suspension of AMVAC's product to become effective.

1. DCPA Chronic Sediment Toxicity (Leptocheirus) Data

The ALJ properly found that there is no genuine dispute of material fact and that Respondent is entitled to judgment as a matter of law with respect to this data requirement. Order at 28-30. Whereas AMVAC contests the reasonability of its actions with respect to several outstanding data requirements, the approach it pursued for this data requirement is stark in the longstanding failure to take any steps towards satisfying the 2013 DCI. There is no dispute that AMVAC failed to submit a DCPA chronic sediment (28-day) toxicity special study as required

[13] Similarly, AMVAC's argument that the ALJ improperly deferred to OPP's expertise is of no import to the Board's ability to uphold the Order's suspension of AMVAC's product. *See* Appeal at 27-30. The Board need not defer to OPP expertise in order to conclude that AMVAC failed to take appropriate steps to comply with the 2013 DCI. The record is clear with respect to these data requirements.

in the 2013 DCI, pursuant to OPP's authority under 40 C.F.R. § 158.30. *Id.* at 28. With respect to this data requirement, AMVAC's repeated failures to take appropriate steps to secure these data are most egregious, and its arguments in the Response most baseless. *See* Response at 36-38. 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. Order 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. Order 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 would allow AMVAC to conduct a shorter 10-day sub-chronic toxicity study, the results of which OPP would consider in determining whether to waive the requirement for the original chronic toxicity study. *Id.* AMVAC never conducted either the original 28-day chronic toxicity study or the shorter 10-day sub-chronic toxicity study that OPP would consider when deciding whether waiver of the original data requirement was appropriate. Order at 15. Rather, on February 18, 2018, AMVAC simply submitted a second 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 was 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. Order at 16; JX 21.

Rather than initiate either the 28-day chronic toxicity study required by the 2013 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. Order at 16-17; JX 22. In that response, AMVAC acknowledged that OPP was not waiving the requirement and that OPP "insisted on retaining the requirement for the chronic study." JX 22. However, in a mischaracterization of the history of this data requirement, AMVAC stated that it would not perform the special study required by the DCI until OPP had validated[14] 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 ALJ correctly noted in the Order, it is clear that OPP never sought to require AMVAC to perform both studies. Order at 29. Rather, OPP on multiple occasions attempted to provide AMVAC with a means by which it could support a subsequent 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 it may not ultimately allow OPP to waive the requirement for a 28-day chronic toxicity study. *Id.*; *see also* Response at 37-38. 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

[14] 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 prior to requiring registrants to submit necessary data. *See generally* Motion at 4-6.

the 28-day chronic toxicity study required by the 2013 DCI was still necessary and was not waived, but provided AMVAC with an option for generating data to potentially justify a future waiver request. Order 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 2013 DCI, and OPP's 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. Response at 37-38. The Board should affirm the ALJ's determination that AMVAC failed to take appropriate steps to satisfy the *Leptocheirus* chronic sediment toxicity study, that no genuine dispute of material fact exists, and that Respondent is thus entitled to judgment as a matter of law.

2. DCPA Fish Early Life-Stage (Bluegill Sunfish and Sheepshead Minnow) Data

The ALJ properly found that there is no genuine dispute of material fact and that Respondent is entitled to judgment as a matter of law with respect to these two data requirements. Order at 24-25. There is no dispute that AMVAC failed to submit DCPA fish early life-stage studies for a freshwater, warmwater species (*e.g.*, bluegill sunfish), and an estuarine/marine species (*e.g.*, sheepshead minnow) responsive to 40 C.F.R. § 158.630, explained in further detail in Guideline No. 850.1400, as required in the 2013 DCI. *Id.* at 24; Motion at 18-19.

AMVAC's justification for its failure to satisfy this data requirement is not clearly stated in its filings before the ALJ and the Board, but is implicitly based on OPP's failure to reiterate that a Guideline 850.1400 study was required on bluegill sunfish and sheepshead minnow until it issued the October 16, 2020 Data Delay Letter. *See* Response at 30-31. AMVAC notes that it submitted a DCPA fish early life-state study conducted using one of the required species,

rainbow trout, on January 30, 2014. Response at 31; Freedlander Statement at 2. AMVAC then notes that its "attention was brought to the 2 missing studies" when OPP issued the October 16, 2020 Data Delay Letter, at which point the company "quickly initiated these studies." Response at 31. AMVAC also calls attention to the fact that OPP's review of the rainbow trout study was not formalized until February 2019. *Id.*; Request for Hearing at 53-54. Although not clearly stated, AMVAC apparently argues that the 2014 submission of the DCPA rainbow trout study constituted appropriate steps towards complying with the 2013 DCI, and there was no reasonable indication that these two studies addressed in the NOITS were necessary until OPP re-iterated its need for the data in 2020. *See id.*

This argument fails. The DCI clearly notes the need for multiple Guideline 850.1400 studies, using different species. JX 4 at 31, 35 ("Preferred test species are rainbow trout, [ ] bluegill sunfish, [ ] and sheepshead minnow); 40 C.F.R. § 158.630 (requiring submission of studies on two freshwater species and, conditionally, a saltwater species).[15] AMVAC does not explain how its submission of the trout study would also satisfy the required data for other species. OPP also notes that the trout study submitted was not conducted pursuant to OCSPP Guideline 850.1400, but rather OECD guideline 215, which does not include the endpoints required by the OCSPP guideline. JX 69 at 11. Accordingly, OPP designated the trout study as "supplemental."[16]

In its initial 90-day response to the DCI, AMVAC did not explain that it planned to submit a single study, or that OPP should consider that single study as satisfying the data

[15] *See also* Ecological Effects Test Guidelines, OCSPP 850.1400: Fish Early Life Stage Toxicity Test, at 4.

[16] Pursuant to 40 C.F.R. § 158.70, OPP "will determine whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable." Supplemental studies are at least partially useful for risk assessments, but have some deficiencies. RX 8. For example, a study may be classified as supplemental where it provides acceptable data for some species subject to a given data requirement and guideline, but is unacceptable for remaining species subject to that data requirement or guideline. *Id.*

requirement. *See* JX 5 at 18-19. Contrary to AMVAC's framing, this data requirement is not structured as the requirement for data on a single species. This timeline is illustrative of AMVAC not taking "appropriate steps" to satisfy data requirements. As correctly ruled in the Order, AMVAC's choice to "wait[] until it received OPP's Outstanding Data Letter in 2020 to begin studies involving the other necessary fish species is not appropriate." Order at 24. AMVAC did not take appropriate steps to satisfy this data requirement. The Board's inquiry to this matter should begin with the 2013 DCI, not the October 16, 2020 Data Delay Letter where OPP reminded AMVAC that the bluegill sunfish and sheepshead minnow data were still outstanding.

Although AMVAC submitted bluegill sunfish and sheepshead minnow studies on June 7 and 30, 2022, respectively, OPP has not yet evaluated the submissions to determine if they are acceptable; therefore, those studies are not sufficient to evade suspension in this proceeding. Order at 24. OPP will expeditiously evaluate the June 7, June 30, and any future submissions and will, pursuant to Section 3(c)(2)(B)(iv), make a determination as to whether AMVAC has complied fully with the requirements that served as the basis for the suspension of the registration. Rather, the Board should affirm the ALJ's Order and render the suspension effective.

3. TPA Aerobic Aquatic Metabolism Data

There is no genuine dispute of material fact and Respondent is entitled to judgment as a matter of law with respect to this data requirement. Motion at 13-15. Although these data requirements were not among the bases for the ALJ's determination, "the Board has the authority to uphold a finding [ ] on grounds different from those relied on by a Presiding Officer." *Richard Rogness and Presto-X Co.*, 7 E.A.D. 235 at *9 (EAB 1997) (citing *SEC v. Chenery Cop.*, 318 U.S. 80, 88 (1943)). AMVAC had notice of, and responded to, these additional bases for suspension of its DCPA product. *Id.*; *see* Request for Hearing; Response. In the Motion and

Wente Statement, Respondent describes the reasons why this study is needed, and why AMVAC's submissions do not constitute appropriate steps to satisfy the 2013 DCI. The parties agree that OPP did not waive the data requirement, and that on February 22, 2018, AMVAC stated its intention to submit a new study, but never did so. Response 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 2021, respectively—as together constituting a second waiver request in response to OPP's 2014 denial of the first waiver request. Freedlander Statement at 17-19. Response at 22-23.

In its 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."[17] JX 5 at 20-21. AMVAC submitted the DCPA study in January 2014. Response at 22. In OPP's denial of AMVAC's waiver request, dated March 21, 2014,[18] 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

[17] 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.

[18] This waiver denial document was not transmitted to AMVAC until March 17, 2017.

requirement," or even that AMVAC was still seeking waiver of this data requirement. *Cf.* Response at 22. The course of action that AMVAC now suggests its true intention—directing OPP to the 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. Although interpretation of AMVAC's February 22, 2018 statement is not necessary to justify suspension of the DCPA technical product, Respondent maintains that it was not reasonable for AMVAC to simply re-assert the same rationale in support of waiver of the TPA aerobic aquatic metabolism study and consider that to be 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 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[19] 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 with the [data] requirement," to say nothing of each of those documents examined individually, as OPP did prior to this suspension proceeding. *Cf.* Response at 23.

[19] 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.

AMVAC correctly notes that the standard for accelerated decision requires the resolution of all inferences in AMVAC's favor. Response at 23. However, the alleged inference with respect to this data requirement is far from "reasonably probable," and is insufficient to defeat accelerated decision on this issue. *See BWX*, 9 E.A.D. at *13, n.22. Indeed, the alleged ambiguity that AMVAC asks the Board to resolve in its favor—whether the company was actually directing OPP to a previously-submitted study despite its clear statement in 2018 that it "intend[ed] to submit a study report"—is so tenuous that AMVAC itself apparently did not believe any ambiguity existed 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 the Response, AMVAC's only argument concerning this data requirement was the incorrect assertion that OPP first made its position known in the NOITS. *Id.* AMVAC asks the Board to resolve an alleged ambiguity first created by AMVAC's retroactive interpretation of its prior statements. Response at 22-23. Absent that non-existent inference, the record demonstrates that AMVAC did not take appropriate steps to satisfy the TPA aerobic aquatic metabolism data requirement from the 2013 DCI and, accordingly, that no genuine dispute of material fact exists and Respondent is entitled to judgment as a matter of law.

4. Residue Chemistry Data

There is no genuine dispute of material fact and Respondent is entitled to judgment as a matter of law with respect to the four residue chemistry data requirements. *See* Motion at 26-32. In the Motion and in the Drew Statement, Respondent describes the reasons data are needed for the four studies listed below, and explains why AMVAC's submissions do not constitute appropriate steps to satisfy the 2013 DCI.

- Nature of the Residue: Poultry (Motion at 26);
- Residue Analytical Method: Livestock Commodities (Motion at 27);
- Meat/Milk/Poultry/Eggs (Livestock Feeding Study) (Motion at 29); and
- Field Accumulation in Rotational Crops (Motion at 30).

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 are sufficient for OPP to consider waiver of these four data requirements. *See* Response at 30. The record clearly demonstrates that neither AMVAC nor the Board could reasonably conclude that the proposed label amendments are adequate for that purpose or that AMVAC has taken appropriate steps to fulfill these data requirements.[20]

Following OPP's issuance of the 2013 DCI, the parties engaged in a back-and-forth discussion concerning whether OPP would waive these four data requirements. Response at 28-29; Motion 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. Response at 29; Wood Statement at 3; Motion at 31.

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

[20] Although not necessary for the Board to affirm suspension, the label changes AMVAC highlights in its Response would also be insufficient for OPP to consider waiver. *See* Response 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.

> 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.* In a February 15, 2015 document,[21] OPP determined 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 2013 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 2013 DCI.

[21] AMVAC asserts this document was first provided to the company on or about March 27, 2017. Response at 29; Wood Statement at 3.

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 February 17, 2015 document. *Compare* JX 38 at 2 *with* JX 45 at 25 (redline page 7 of 15). 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 24, 2021, AMVAC maintained that the revised labels it submitted in 2017 and 2019 were sufficient for OPP to waive the four residue data requirements from the 2013 DCI. Wood Statement at 5; Response at 29-30.

AMVAC asserts that the proposed label amendments submitted to OPP would "eliminate the need for the [ ] residue studies." Response 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 the February 17, 2015 document, 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 label amendments when it submitted proposed language in 2017 and 2019. JX 45; *see also* JX 44 and JX 46.

AMVAC also argues that it lacked notice that the proposed label amendments were insufficient, and that the company reasonably believed that it had taken appropriate steps to satisfy the 2013 DCI. Response at 30. AMVAC points to OPP's statement in the October 16, 2020 Data Delay Letter that OPP was still reviewing 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 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 proposed label changes are sufficient for OPP to consider waiving the data requirements—is demonstrably unreasonable, the record demonstrates that AMVAC failed to take appropriate steps to satisfy the

four residue chemistry data requirements from the 2013 DCI and, accordingly, that no genuine dispute of material fact exists and that Respondent is entitled to judgment as a matter of law.

5. TPA Environmental Effects Data

The ALJ correctly found that no genuine dispute of material fact exists and that Respondent is entitled to judgment as a matter of law with respect to these five data requirements:

- TPA Aquatic Invertebrate Lifecycle, Estuarine/Marine Mysid Data (Order at 10-12, 26-28);
- TPA Fish Early Life-Stage (Rainbow Trout) Data (Order at 9-10, 25);
- TPA Fish Early Life-Stage (Bluegill Sunfish) Data (Order at 9-10, 25);
- TPA Fish Early Life-Stage (Sheepshead Minnow) Data (Order at 9-10, 25); and
- TPA Algal Toxicity (Marine Diatom only) Data (Order at 12-13, 28).

Order at 25-28. There is no dispute that AMVAC failed to submit these studies, as required in OPP's 2013 DCI. *Id.* at 26; Response at 19-21. AMVAC requested multiple waivers for these requirements in 2013 and 2020, which were denied in 2017 and 2022, respectively.[22] Order at 25-28; JX 5, JX 37, JX22, JX 69.

As explained above, 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 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 21. In the 2017 denial, OPP clearly stated that "[t]oxicity data is needed for TPA," and

[22] The Order states that OPP denied AMVAC's first waiver requests in 2014. Order at 26. That denial was not transmitted to AMVAC until 2017. JX36. The delayed transmittal makes no difference with respect to this proceeding, as AMVAC has not submitted the required data in the more than four years following its receipt of the waiver denials. The Order also states that AMVAC's second waiver request for this data requirement was submitted in 2018. Order 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, 22. OPP did not interpret JX 67 as a second waiver request.

explained that "a full suite of studies may or may not" be required based on the outcome of a more-limited set of toxicity data." 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 Motion, 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. Motion at 47. As held in the Order, 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 a reasonable course of action. Order at 25. AMVAC understood that OPP did not agree with the rationales for waiving these data requirements, but opted to risk not initiating the studies listed above while awaiting the outcome of the more limited toxicity studies. *Id.*

6. DCPA Aquatic Invertebrate Lifecycle, Estuarine/Marine Mysid Data

Based on the narrow scope of review outlined in the Order, AMVAC did not take appropriate steps to fulfill this data requirement. Order at 25-26. Although OPP did not notify AMVAC that the submitted study was denied until 2022, the October 16, 2020 Data Delay Letter noted that the study was still under review and had not yet been satisfied. JX 21.

7. TPA Anaerobic Metabolism Data

The evidence before the Board demonstrates that no genuine dispute of material fact exists and that Respondent is entitled to judgment as a matter of law with respect to these two data requirements:

- TPA Anaerobic Soil Metabolism Data (Motion at 12);
- TPA Anaerobic Aquatic Metabolism Data (Motion at 15).

There is no dispute that AMVAC failed to submit these studies, as required in OPP's 2013 DCI. Response at 19-21. AMVAC requested waivers for these requirements in 2013 and 2020, which were denied in 2017 and 2022, respectively. JX 5, JX 37, JX 77, JX 22, JX 79.

As explained above, 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. In 2017, 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 Motion, 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. Motion at 47. 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 a reasonable course of action. 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 waiver requests. *Id.*

8. DCPA Acute Avian Oral Toxicity Data

AMVAC submitted this study on September 30, 2014. Response at 33. However, this study clearly did not satisfy the data requirement from the 2013 DCI in one key respect. Motion at 22-23, Wendel Statement at 6-7. This study was required so that OPP could assess risks for passerine birds resulting from birds ingesting material with residues of DCPA resulting from

application. *Id.* The estimated upper-bound residues (*i.e.*, the amount of DCPA found on crops treated with DCPA at legally-permitted rates of application) are more than twice the maximum concentration of DCPA tested in this study. *Id.* The OCSPP Guideline that this study was performed under, 850.2100, clearly states that testing should be conducted up to 2,000 mg/kg bodyweight "or the maximum expected environmental residue concentration [("EEC")], whichever is higher." (Emphasis added).[23] Additionally, AMVAC did not conduct this study in accordance with the protocol that it agreed to use, which also clearly states testing at up to "2,000 mg/kg bodyweight or at a dose equivalent to the calculated field exposure level, whichever is the higher." Motion at 23; RX 10 at 5.1. As explained in OPP's Data Evaluation Record prepared for this AMVAC submission and the transmitting memo, "[i]f application rates result in higher estimated exposure concentrations on dietary items than the concentration tested in this study, additional data may be required," and AMVAC "may need to switch to a dietary-based test paradigm." JX 55 at 2, JX 59 at 5. At currently-registered use rates, DCPA EECs could be more than two times the dose AMVAC tested in this study, as calculated with EPA's publicly-available T-REX model used to estimate exposures and potential residues.[24] Accordingly, there may be effects to birds, including lethal effects, that could occur from expected exposure concentrations that were not tested.

9. DCPA Seedling Emergence Data (Lettuce Only)

Respondent adopts the discussion of this data requirement contained in its Motion and in the Wendel Statement. As with the acute avian oral toxicity study discussed above, AMVAC did

[23] AMVAC asserts that the version of Guideline 850.2100 in effect at the time the study was conducted prohibited testing at higher rates. Joynas Statement at 25. It is not clear what prohibition AMVAC refers to, as the most recent version of the Guideline is dated January 2012, which predates both the study and the DCI.

[24] T-REX Model, *available at* https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/t-rex-version-15-users-guide-calculating-pesticide.

not conduct the seedling emergence test using concentrations up to those that are expected based on DCPA application rates. Wendel Statement at 6. There were several other errors in the conduct of this study that AMVAC was or should have been aware of. *Id.* AMVAC's belief that this study satisfied the 2013 DCI was not reasonable.

10. DCPA Chronic Sediment Toxicity (Chironomus) Data

Based on the narrow scope of review outlined in the Order, AMVAC did not take appropriate steps to fulfill this data requirement. *See, e.g.*, Order at 25-26 (analogous to DCPA mysid data). Although OPP did not notify AMVAC that the submitted study was denied until 2022, the October 16, 2020 Data Delay Letter noted that the study was still under review and had not yet been satisfied. JX 21. As noted in the Motion, the results of this study were likely affected by the solvent used. Motion at 24. Although this data requirement was not conducted pursuant to an OCSPP Guideline, the 2013 DCI had recommended that AMVAC use the EPA Office of Research and Development's Test Method 100.5,[25] which provides "[t]he concentration of solvent used must not adversely affect test organisms." JX 4 at 32, 34.

11. DCPA Comparative Thyroid Assay Study

Respondent adopts the discussion of this data requirement contained in its Motion and in the Mendez Statement. On June 20, 2022, AMVAC submitted a study in response to this data requirements. OPP is currently evaluating that study and is engaged in conversation with AMVAC with respect to several aspects of the June 20 CTA. AMVAC has expressed its intention to submit an amended version of the June 20 CTA by August 5, 2022.

[25] EPA Test Method 100.5: Life Cycle Test for Measuring the Effects of Sediment-associated Contaminants on Chironomus tentans, *available at* https://www.nemi.gov/methods/method_summary/9323/.

G. The ALJ's Ruling that OPP's Determinations as to Existing Stocks are Consistent with FIFRA was Correct and Should be Upheld by the Board

In the Order, the ALJ correctly ruled that OPP's determination with respect to existing stocks of AMVAC's registered DCPA technical product were consistent with FIFRA. Order at 31-34. As explained in the Order, and described in further detail in the Motion, FIFRA explicitly provides OPP with broad discretion in determining how existing stocks of a suspended product may be used. Order at 32; Motion at 47-48; *see also Cedar Chem. Co.*, 2 E.A.D. 584 at *3 n.7 (EAB 1988) ("existing stocks determinations are made under FIFRA § 6(a)(1), which vests broad discretion in the Administrator . . ."). As the ALJ correctly noted, OPP's longstanding, publicly-available policy generally does not allow continued sale or distribution of a product suspended as a result of the registrant's failure to comply with a DCI. Order at 32; 56 Fed. Reg. 29362, 29367 (June 26, 1991).[26] Such suspensions under FIFRA Section 3(c)(2)(B)(iv) are intended to incentivize registrants to submit required data in a timely manner; a prohibition on use of existing stocks of a suspended product "gives teeth" to EPA's enforcement authority. Order at 32. AMVAC acknowledges that the effect of suspending its technical product—the only product at issue in this matter—would be "alleviated" by deviating from OPP's general practice and allowing continued use of the product during the term of the suspension. Response at 41; Ranganath Statement at 2.

Growers make a number of related arguments that attempt to paint the existing stocks provision of the NOITS as "irrational and unreasonable." Grower Appeal at 9. One argument proceeds from the fact that the NOITS does not place restrictions on third parties' use of

[26] In their appeal, Growers quote the 1991 existing stocks policy, noting that "[w]here there are no significant risk concerns associated with the cancellation of a pesticide, the Agency will generally allow unlimited use of existing stocks. . . ." Growers Appeal at 2 (quoting 56 Fed. Reg. at 29367). While that is true for cancelled products, Growers conveniently omit the policy's discussion of why suspension under FIFRA Section 3(c)(2)(B) presents a different, non-risk-based, rationale for disallowing continued sale or use of a product. *See* 56 Fed. Reg. at 29363 (recognizing broad statutory discretion under FIFRA Section 3(c)(2)(B)).

AMVAC's DCPA technical product. Growers Appeal at 9-10. Growers allege that this fact creates logical inconsistencies in the existing stocks provisions of the NOITS because there would be no difference in risk between AMVAC continuing to formulate its end-use products from the suspended technical product and a third party's hypothetical use of the suspended technical product for the same reason. *Id.* Growers also argue that, because AMVAC is the only company that holds a registration for the technical product to be suspended and is also the only company that holds registrations for the end-use products formulated from that technical, the suspension would in effect also terminate the supply of all DCPA end-use products not subject to suspension. Grower Appeal at 4-7. Growers argue that despite the clear statutory language providing broad discretion for OPP with respect to existing stocks provisions for products suspended under FIFRA Section 3(c)(2)(B), such a market impact "cannot reflect Congress' intent." Grower Appeal at 7. Neither Growers nor AMVAC provide any support for their assertion that Congress only intended to allow suspension of one registrant's pesticide product in situations where users of the product would be able to purchase it from an alternate supplier.[27] That position, not OPP's, is the less logical by far as to adopt Grower's standard would essentially render any registrant with a monopoly on a given pesticide product immune from meaningful suspension. Were the Board to allow AMVAC to continue formulation of DCPA end-use products in an attempt to avoid market disruption, AMVAC would have no incentive to ever submit the outstanding data and lift the suspension, which would take effect in name only.[28]

[27] Such a suspension would better fit a situation where OPP sought a FIFRA Section 3(c)(2)(B)(iv) suspension of a single registrant's product based on that registrant's failure "to participate in . . . a joint data development arrangement" with other registrants of the same chemical. *See* 7 U.S.C. § 136a(c)(2)(B)(ii)-(iii).

[28] In any event, Respondent reiterates and incorporates by reference its argument in the Motion that the purpose of FIFRA is not to avoid market disruption. Motion at 47-51.

Both issues alleged by Growers are easily explained by the circumstances, and neither constitute evidence that the existing stocks provisions of the NOITS are inconsistent with the purpose of FIFRA. As with most recent DCIs, the 2013 DCI was issued with respect to registrants of the technical product only, as technical registrants are more likely to be large companies capable of supplying the required data, and who can pass the cost of said data on to registrants who purchase the technical product for formulation into end-use products. AMVAC's status as the sole registrant of both the technical and end-use products is not unique and should not provide any insulation from the effects of suspension; such arrangements reflect business decisions, including a technical registrant's willingness to sell a product for formulation into other products by other parties. OPP recognized that no other parties presently hold a registration for a DCPA end-use product. However, there has been no legal impediment to a third party applying for a DCPA end-use registration that would be formulated from AMVAC's technical product. Accordingly, OPP merely wanted to clarify that this hypothetical third party would not be barred by OPP from using any AMVAC technical product they may possess prior to suspension to formulate its end-use product, since the third party would not have been subject to this suspension order.

In their Responses and Appeals, AMVAC and Growers are intentionally vague as to what existing stocks provision would supposedly be consistent with FIFRA. The only solution suggested was to allow AMVAC to continue formulating end-use products from whatever stockpile of the suspended technical exists at the time the suspension goes into effect. Response at 41. This proposed outcome would appear to prolong the supply of DCPA end-use products, but do nothing to address the underlying fact that suspension could cause a market disruption, which they argue is inconsistent with FIFRA. AMVAC did not offer any direct testimony as to

how much additional end-use product could be formulated from existing stocks of its DCPA technical product after suspension, despite providing highly specific figures for how much end-use product has already been formulated. *See* Ranganath Statement.

Growers also argue that, because the NOITS references OPP's uncertainty as to the CTA data required by the 2013 DCI, "[t]he existing stocks provision is improperly based on 'risk concerns,'" and should accordingly be subjected to a different standard than other existing stocks provisions issued pursuant to FIFRA Section 3(c)(2)(B)(iv). Growers Appeal at 7-9. As explained in the Motion and in this Response Brief, the existing stocks provisions of the NOITS are consistent with OPP's policy and historic practice. The fact that OPP referenced potential risk concerns associated with the outstanding data does not negate the broad discretion with respect to existing stocks under the statute and does not require OPP to weigh market impacts when deciding whether to allow continued use of a suspended product. As explained above, the purpose of issuing the 2013 DCI was to resolve uncertainties with respect to whether continued DCPA use poses a risk of unreasonable adverse effects on the environment. In any event, potential risk concerns would weigh in favor of OPP not allowing for further sale, distribution, and use of existing stocks by anyone.

Although the ALJ correctly notes that "the fastest and surest way to limit the economic harm" resulting from suspension would be for AMVAC to comply with the 2013 DCI, OPP maintains that such consideration of economic impacts is outside the narrow scope of this proceeding. Motion at 49. AMVAC offers no explanation as to how the existing stocks provisions of the NOITS are inconsistent with FIFRA, aside from pointing out possible impacts to users of DCPA end-use products. *See* Response at 38-41. However, the purpose of FIFRA is not, as implied by AMVAC, to ensure that agricultural users maintain a continued supply of a

specific pesticide, but rather for OPP to ensure that the pesticide's continued use will not cause unreasonable adverse effects, which requires registrants to submit necessary data so that risks can be assessed. Accordingly, the existing stocks provisions of the NOITS are consistent with FIFRA, and Respondent is entitled to judgment as a matter of law.

V. CONCLUSION

For the reasons stated above, Respondent respectfully requests that the Board affirm the ALJ's Order, and find that:

1. AMVAC has failed to take appropriate steps to comply fully with the data requirements of OPP's January 31, 2013 Data Call-In GDCI-078701-1140 and has thereby failed to take the action that served as the basis for OPP's April 28, 2022 Notice of Intent to Suspend the registration of AMVAC's registered pesticide product, Technical Chlorthal Dimethyl (EPA Registration Number 5481-495); and
2. OPP's determinations in the NOITS with respect to the disposition of existing stocks of the product Technical Chlorthal Dimethyl are consistent with FIFRA.

On issuance of the Board's final decision affirming the Order, the NOITS would immediately become effective and the registration of the product Technical Chlorthal Dimethyl would be suspended until AMVAC complies fully with the 2013 DCI.

Respectfully submitted,

FORREST PITTMAN

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CERTIFICATION

I hereby certify that the foregoing **Response Brief**, dated July 28, 2022, contains 13,970 words, exclusive of the caption, table of contents, table of authorities, and certifications, based on the word count of the word-processing system used to prepare this document.

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Response Brief**, dated July 28, 2022, was sent this day to the following parties in the manner indicated below.

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