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

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

[PROPOSED]
REPLY BRIEF
OF AMVAC CHEMICAL CORPORATION

Introduction

OPP's response brief ("OPP Resp. Br.") concedes that the statutory language central to this case, 7 U.S.C. § 136a(c)(2)(B)(iv) (the "Suspension Provision"), may properly be read to require a "more detailed examination" of whether a registrant has taken appropriate steps in response to a Data-Call In ("DCI") than was undertaken by the ALJ.[1] OPP's assertion that it may nonetheless prevail on its Motion for Accelerated Decision ("MAD") is not persuasive because AMVAC has raised genuine disputes of material fact that preclude granting the MAD as to each data requirement at issue. The Board cannot lawfully limit the inquiry to whether studies were submitted, and OPP fully accepted them, as the ALJ did.[2] The EAB must evaluate all facts and circumstances relevant to whether AMVAC was taking "appropriate steps" to respond – an inquiry that necessarily extends to consider AMVAC's substantial efforts to comply, as well as OPP's conduct in creating delays, the substance of EPA's communications to AMVAC, and the fact that OPP did not make many of its concerns about certain completed studies (or its ability to complete risk assessment) known until the same time as it issued the Notice of Intent to Suspend ("NOITS").

The procedural history here is important. AMVAC requested an evidentiary hearing on May 27, 2022. The ALJ scheduled the hearing to occur from July 8 through July 10, 2022. OPP filed the MAD arguing that no hearing was necessary to suspend AMVAC's registration on June 13, even before the prehearing exchange (on June 17, which included the verified witness

[1] OPP Resp. Br. at 6 ("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 … .") (emphasis added).

[2] OPP asserts that the ALJ somehow considered "appropriateness in an overarching sense." OPP Resp. Br. at 6. A review of the ALJ's Order shows that submittal and acceptance of studies was dispositive, even if it discussed other considerations on its way to that conclusion, and the Order did not ultimately consider appropriateness in any meaningful sense. *See* Order at 23.

statements and exhibits). In the MAD, OPP argued that the only factual examination necessary to suspend a registration was whether a registrant had actually submitted all the data required by the DCI at the time a NOITS was issued. MAD at 8. Accepting that erroneous argument, the ALJ incorrectly granted the MAD on July 1, 2022, (the "Order") and canceled the hearing.[3]

The ALJ's narrow interpretation of the Suspension Provision effectively nullified the statutory requirement that suspension only be allowed if a registrant failed to take "appropriate steps." Even though the evidentiary record in this matter (the verified written statements and the parties' exhibits) is voluminous, there has been no opportunity for the parties to directly challenge each other's simultaneously filed factual assertions, or explore the rationale for certain decisions or delays, by way of depositions, cross-examination, or rebuttal evidence.

OPP has now conceded that the Suspension Provision's "appropriate steps" inquiry may be read to require a "more detailed examination" of the facts underlying a registrant's actions and does not contest AMVAC's argument that the deference afforded by the ALJ to OPP was inappropriate. OPP Resp. Br. at 6. A proper examination of the propriety of AMVAC's conduct cannot be resolved on the half record present. OPP continues to assert that it may prevail on an accelerated motion, but OPP cannot prevail under the correct, statutorily required "more detailed examination" of appropriateness standard at the summary judgment phase absent the improper deference the ALJ gave OPP, because AMVAC has put forward facts both generally, and with respect to each data requirement,[4] based on which a reasonable decisionmaker could find in

[3] The Order supported its interpretation based on independent analysis of the Suspension Provision and FIFRA as a whole, combined with excessive deference to OPP.

[4] As a general, overarching example of why OPP should not prevail on its summary motion, an AMVAC expert witness, who has worked with EPA on 40 DCIs over the past three decades, testified that AMVAC's response to the DCI was typical. Gur Statement ¶ 43. OPP disagrees and asserts that AMVAC's behavior was "abnormal[]" in certain ways. Bloom Statement at pp. 4-5. Mr. Gur's statement, which is probative of whether AMVAC's course of conduct was

AMVAC's favor (particularly when those facts are construed in the light most favorable to AMVAC, as they must be when a tribunal resolves a summary motion, as discussed in more detail in the final section of this Reply).

Thus, the proper action for this Board is to remand this matter to the Office of Administrative Law Judges for the evidentiary hearing that AMVAC has requested. At that proceeding, witnesses can be cross-examined, rebuttal evidence supplied, and the appropriateness of AMVAC's steps to respond to the DCI fully evaluated.

The remainder of this brief first discusses (at pp. 4-5) how the concessions and shifts in OPP's Resp. Br. simplify the decision now before the Board. AMVAC then discusses how OPP's argument that it still prevails under the correct statutory standard and the correct standard for addressing summary motions fails. *See* pp. 5-11. Within this discussion, AMVAC addresses OPP's misrepresentation of a key document (at pp. 7-9) and OPP's improper attempt to introduce a new exhibit (at pp. 9-10). To assist the Board in reviewing the genuine material disputes concerning each data requirement, and the existing stocks determination, AMVAC provides a reference table in **Exhibit A**.

"appropriate," must be accepted as true for purposes of resolving a summary motion. Testing these assertions at a hearing is required to complete the inquiry called for in the statute. With respect to specific data requirements, AMVAC refers the EAB to **Exhibit A** to this Reply.

OPP's Shifts in Position Confirm that a Hearing is Required in this Matter

OPP's Resp. Br. concedes (or does not challenge) several central points raised by AMVAC. First, OPP now concedes that requiring a "more detailed examination" is a "permissible reading" of the Suspension Provision, OPP Resp. Br. at 6.[5] OPP provides no support (based on statutory text, history, purpose, or otherwise) for the contrary interpretation applied by the ALJ's Order, which looked only at submittal and acceptance and did not consider "appropriate steps" – even in any "overarching sense," as OPP claims the Order did. OPP thus fails to counter AMVAC's arguments that put the Suspension Provision in the proper context, as presented in AMVAC's App. Br., Section IV.A.1, pp. 13-23. In fact, OPP does not even affirmatively state in its appeal brief that the "submittal/acceptance only" interpretation is its *preferred* interpretation or is for some reason the better of the two readings it deems "permissible" – OPP merely asserts it can prevail even if a "more detailed examination" is conducted. OPP Resp. Br. at 6.

Second, regarding the improper deference to OPP that permeated the ALJ's Order, OPP offers only that it may prevail absent any deference.[6] OPP had previously declared itself the "sole authority" concerning compliance with the "appropriate steps" standard, MAD at 41, and the Order treated it as such. *E.g.*, Order at 21 n.24. Absent improper deference, the MAD

[5] OPP's shift can be seen also by comparing the "i.e." clauses it inserts into the statutory language in the MAD at 8 ("whether the registrant submitted the data") compared with the appeal brief at 5 ("whether the registrant 'failed to take appropriate steps to secure the data'").

[6] *Compare* AMVAC App. Br. Section IV.A.3, pp. 27-30 *with* OPP Resp. Br. at 19 n.13. In arguing that it can still prevail on its summary motion absent the deference the ALJ afforded, OPP claims to "paraphrase" an argument advanced by AMVAC. OPP Resp. Br. at 19. In fact, OPP has mischaracterized and misapplied text from AMVAC's argument that expert "judgment on a technical issue" is not needed to see that OPP and AMVAC were working collaboratively on the CTA data requirement. OPP replaces language in brackets to suggest AMVAC was stating – for eight wholly separate studies – that the record is so simple that a summary motion is easily granted. This is not a "paraphrase" by any definition of the term.

cannot be granted based on the genuine disputes of material fact raised by AMVAC and the Grower Petitioners.

Third, OPP agrees with AMVAC that the October 2022 statutory deadline for OPP to complete registration review of DCPA (and other pesticides) is not directly legally relevant to the DCI process.[7] OPP maintains that the deadline "provides context for OPP's actions in this matter." OPP Resp. Br. at 11. AMVAC agrees that the deadline could be relevant withing the "more detailed examination" needed to determine if AMVAC acted appropriately. On the facts here, framed nicely by OPP's mischaracterization of JX 21 as discussed at pp. 7-9 below, OPP's communications to AMVAC concerning the deadline actually *support* the conclusion that AMVAC's actions were appropriate.

Fourth, OPP does not contest AMVAC's argument that AMVAC's Request for Hearing entitles AMVAC to a determination as to whether it took "appropriate steps" as to all 20 data requirement in the NOITS. All 20 data requirements must be assessed because OPP's authority to maintain any suspension that may go into effect is tied to AMVAC's satisfaction of the data requirements for which it is adjudged to have failed to have taken appropriate steps, *even if* only one of those requirements could support a suspension.[8]

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[7] OPP Resp. Br. Section IV.C.1, pp.11-12 & n.7. Far from "mere[ly] mention[ing]" this deadline, *id.* at 11, the ALJ's Order refers to it repeatedly; the entirety of the Order's "Conclusion" is a discussion of why allowing AMVAC's registration to remain in effect past the deadline was something the ALJ could not "countenance." *Compare* Order at 31 *with* OPP Resp. Br. at 11 n.7 ("Respondent offers a minor correction to one statement in the Order's conclusion. […]").

[8] AMVAC agrees with OPP's Resp. Br. at 18 n.12 that the ALJ's Order addressed nine "studies." Sometimes a DCI may require multiple studies under a single "guideline" number (*e.g.*, for multiple species) and AMVAC has occasionally referred in this proceeding to such studies as constituting a single "data requirement." OPP's note is based on a nomenclature of referring to each study as a "data requirement." There is no apparent substantive disagreement between the parties concerning the scope of the ALJ's Order, or the NOITS.

A Hearing is Required Under the Correct Summary Judgment Standard

OPP implicitly recognizes that the MAD (and the Order) lack sufficient foundation when the correct statutory standard is applied, and impermissible deference to OPP is not applied. This is evident because OPP resorts urging a flawed interpretation of the standard for granting summary motions. Essentially, OPP asks the EAB to declare that no genuine disputes of fact exist because the facts are *so one-sided* that the EAB can evaluate each of the 20 data requirements and hold that *no reasonable factfinder* could find that AMVAC took "appropriate steps" as to any data requirement.[9] There is no basis for such a finding. The EAB would have to ignore the fact that there is conflicting sworn written testimony provided by sixteen witnesses: six AMVAC fact witnesses, two AMVAC expert witnesses, five OPP fact witnesses (four of whom reserved their right to provide *expert testimony in rebuttal*), and the Grower-Petitioners' one fact and two expert witnesses, as well as one-hundred-and-forty-three (143) exhibits collectively offered by the parties in the prehearing exchange. In fact, as more fully discussed below, OPP itself continues to (improperly) submit new testimony to the EAB to bolster its case as to already-disputed facts.

This record shows that a factfinder could readily determine that AMVAC had consistently taken appropriate steps for all data requirements, particularly in light of the extensive delays created entirely by EPA. The facts on which a decisionmaker could reach such a finding have been set forth in the prior briefing of the parties (and the witness statements and

[9] AMVAC does not assert, as suggested in OPP's Resp. Br. at 18 (citing AMVAC's App. Br. at 39), that the EAB may only either: (1) affirm the ALJ's Order as to the sub-set of data requirements discussed therein; or (2) remand for a full hearing concerning all data requirements in the NOITS. On *de novo* review of fact and law, the EAB may apply the accelerated decision standard to some or all data requirements and may also remand some or all of the data requirements to the ALJ for further proceedings, with any degree of guidance for such proceedings that the EAB sees fit.

exhibits cited therein), as summarized, with respect to each individual data requirement at issue, in **Exhibit A**.

Two additional matters which demonstrate the existence of material factual disputes which relate directly to statements made for the first time in OPP's appeal brief are discussed below, before this Reply concludes with a discussion of OPP's misapplication of the summary motion standard generally.

(1): *OPP's Mischaracterization of JX 21*

As noted above, OPP asserts that it may prevail even under the correct substantive standard, without deference, because the evidence is so one-sided that the MAD may still be granted. OPP Resp. Br. at 6. OPP's first supporting claim for this assertion, through which it apparently seeks to frame the entire inquiry, is that OPP "regularly reminded AMVAC that additional data were required for OPP to complete registration review of DCPA." OPP Resp. Br. at 7. OPP offers a sole citation for the alleged "regular" reminders, Joint Exhibit ("JX") 21. But JX 21 simply does not say what OPP asserts that it does. In fact, AMVAC would reasonably have interpreted it to mean the opposite.

JX 21 is an October 16, 2020, letter from OPP to AMVAC that is among the most frequently cited exhibits by both parties in this briefing. Its subject line is "Notification of Outstanding Data Requirements, and Anticipated Registration Review Schedule for DCPA." The letter is concise. Its text is only two half-pages preceding a table, which shows OPP's understanding of the status of each data requirement OPP asserted was not yet satisfied.

Particularly with respect to data requirements for which AMVAC sought waivers, JX 21 is significant because it was EPA's final formal correspondence prior to the issuance of the

NOITS in April of 2022.[10] A quick review of JX 21, reveals that OPP did not say that OPP could not complete its risk assessments. Quite the opposite, JX 21 states that OPP:

> "will rely upon data available at the time when the risk assessments are being developed" and "[w]here the Agency is lacking data [for a risk assessment], conservative assumptions may be used in their place to complete the risk assessments."

OPP never during the DCI response process, until concurrently with the issuance of the NOITS, stated that it believed it did not have data required to complete a risk assessment (and thus registration review). The claim in OPP's Resp. Br., at p. 9, that OPP advised AMVAC that it could not complete risk assessments at any time prior to the NOITS, let alone that it did so "regularly," is false. JX 21, OPP's sole citation for the claim of "regular[] remind[ers]," states that risk assessments would proceed with whatever data was available, and that AMVAC might have to live with "conservative assumptions" if it did not provide more data before the risk assessments began.

OPP's Resp. Br., at p. 10, citing an OPP witness statement (Bloom) confirms:

> OPP's statement that it may make conservative assumptions is clearly not a statement that the data are no longer needed [which AMVAC does not assert[11]]; 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.

As confirmed by AMVAC's expert, registrants sometimes allow risk assessments to proceed with conservative assumptions and then either accept resulting restrictions or modify their labels

[10] AMVAC timely responded to JX 21. *See* JX 22; Wood Statement ¶¶ 43-48. AMVAC devoted a section of its MAD Opp. to JX 21, *see* MAD Opp. Section III.C.2, pp. 24-26.

[11] Additionally, OPP persists in its appeal brief to try to re-cast AMVAC's argument that AMVAC behaved appropriately by requesting waivers (and providing support for those waivers) as an argument that OPP had no basis to request the data in the first place. OPP's citations are to cases in which registrants argued OPP lacked legal authority to request data at all. AMVAC makes no such claim. Requesting waivers is encouraged and expressly provided for in regulations promulgated by OPP. *Compare* OPP Resp. Br. Section IV.B *with* AMVAC App. Br. Section IV.A.4.

post-risk assessment to permit continued registration of the product. Gur Statement ¶ 39. Registrants do so with the knowledge that if a conservative risk assessment determines a label change is needed, and they are not willing to make that change, they will face a cancellation proceeding potentially unarmed with data with which to dispute EPA's findings.

Taken collectively, JX 21, and the written statements of Bloom and Gur amply supports the inference that registrants may proceed at their own risk if they continue to seek waivers after OPP advises that a lack of data may result in a "conservative" risk assessment, but that doing so is not inherently inappropriate or even out of the ordinary. Thus, continuing discussions about waivers after receiving a communication like JX 21 (in which OPP raises the specter of "conservative" assumptions) is different than arguing for a waiver after receiving an ultimatum like the one OPP imagines JX 21 to be in its appeal brief at p. 10. AMVAC's course of conduct – continuing to pursue waiver requests it felt were justified – was appropriate.

(2): *EPA's Improper Attempt to Introduce a New Exhibit*

OPP's introduction of Exhibit RX 10 for the first time with its appeal brief, *see* OPP Resp. Br. at 35, is procedurally improper. This document was not included in OPP's prehearing exchange. *See* ALJ Dkt. No. 18. The parties were on notice that any materials not included in that exchange would not be considered by the ALJ except upon motion. OALJ Dkt. 8 at 3. OPP made no such motion to the ALJ and provides no argument now as to why RX 10 should be considered by the EAB, nor does OPP even alert the Board that it is introducing something not presented to the ALJ. AMVAC objects to its introduction on this basis alone.[12]

The most salient aspect of EPA's attempt to introduce RX 10 is that it shows that OPP

[12] AMVAC does not ultimately contest the authenticity of the document and would be prepared for its witness to answer questions about it if the ALJ allowed it to be presented at a hearing.

desperately needs EAB to stretch the summary judgment standard beyond its breaking point to find the MAD can be properly granted. OPP wishes to use RX 10 to cross-examine/impeach an AMVAC witness on a matter central to whether AMVAC's conduct of a study submitted in 2014, to which OPP did not object until 2022, was appropriate. *See* OPP Resp. Br. at 34-35 & n.23. AMVAC's Director of Toxicology, Ms. Jonynas, testifies that the study could not have been performed, in one particular, in the way OPP now asserts it should have been. Jonynas Statement ¶¶ 2, 155. OPP, through the testimony of its Biologist, Ms. Wendel, disagrees. OPP Resp. Br. at 35. This is inarguably a genuinely disputed material fact that precludes summary judgment as to this data requirement, with or without RX 10.[13]

OPP Misstates the Standard for Resolving Motions for Accelerated Decision; the MAD Must be Denied Under the Correct Standard

In summarizing the standard for reviewing motions for accelerated decision, OPP continues to incorrectly refer to the burdens that would apply at a hearing, *see* OPP Resp. Br. at 3-4. These burdens affect disposition of a summary motion only insofar as they frame the inquiry into what a reasonable decisionmaker could or could not find, following a hearing, viewing all summary judgment evidence in the light most favorable to the non-movant. AMVAC carries no burden when resisting summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986).

Moreover, in the same standard of review section, and in one of its argument sections, OPP takes out of context a quotation concerning the summary judgment standard. OPP asserts

[13] If OPP had timely raised this objection, a technical discussion could have been had and the study conducted many times over by now (if doing so were necessary). Instead, OPP waited eight (8) years after the study was timely submitted to raise its objection, revealing the objection to AMVAC the same day it issued the NOITS. McMahon Statement ¶ 26, referring to first transmittal of JX 55, the DER for MRID 49477601, in April of 2022. This is yet another reason that OPP should not be able to suspend AMVAC's registration based on this study.

that all necessary inferences in AMVAC's favor must be "reasonably probable" for the MAD to be denied. OPP Resp. Br. at 4, 27 (citing *BWX Technologies, Inc.*, 9 E.A.D. 61 (EAB 2000)). This reference is misleading, insofar as it suggests that something like a preponderance of the evidence standard (with the burden on AMVAC) should be applied when deciding the MAD. Although *BWX Technologies* does use this phrase in n.22, it is only used as shorthand for the familiar summary judgment principle that follows, *i.e.*, that a litigant's right to a hearing (or trial) should only be cut off where the evidence is so one-sided that, even viewing it in the light most favorable to the non-movant, no factfinder could rule in the non-movant's favor following a hearing. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986); *Anderson*, 477 U.S. at 252. *See* AMVAC MAD Opp. at 2-4; App. Br. at 8-9.

Summary judgment is properly granted only where inferences necessary for a non-movant to prevail are "so tenuous that [they] rest[] merely on speculation and conjecture." *BWX Technologies, Inc.*, n.22. Under the appropriate substantive and summary motion standards, genuine disputes of material fact remain as to each data requirement. Based on the briefing as summarized in **Exhibit A**, and the further information supplied above, it is clear that the inferences needed to conclude that AMVAC was acting appropriately at all times are not "tenuous" at all and are based on substantial factual and expert testimony rather than "speculation and conjecture."

Conclusion

Applying the correct substantive and accelerated decision frameworks to the facts, the EAB cannot properly conclude that the MAD can be granted as to any data requirement. The only way OPP could prevail on a summary motion would be if the EAB were prepared to blindly defer to OPP's one-sided assessment that AMVAC failed to take appropriate steps. The EAB

cannot lawfully do that. *See* AVMAC App. Br. Section IV.A.3, pp. 27-30. Moreover, OPP makes no attempt to justify its entitlement to any deference for purposes of resolving a summary motion as discussed above. Even if the EAB did improperly conclude that the MAD could be granted as to a single data requirement, the matter would still have to be remanded for a hearing on the others.

The EAB should remand this matter to the OALJ for a hearing, as envisioned by 7 U.S.C. § 136a(c)(2)(B)(iv), at which the witnesses can be cross-examined, rebuttal evidence supplied, and the propriety of AMVAC's conduct concerning each of the 20 data requirements included in the NOITS fully evaluated.

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CERTIFICATION

I certify that the foregoing Reply Brief contains 3,963 words, exclusive of the caption and certifications based on the word count of the word-processing system used to prepare this document.

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