UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

PETITIONER AMVAC CHEMICAL CORPORATION'S
PREHEARING BRIEF

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I. Introduction

This matter comes before the Presiding Officer substantially narrowed. The Notice of Intent to Suspend ("NOITS") alleged that AMVAC had failed to take appropriate steps in connection with twenty individual data requirements. For seven of the twenty, the Office of Pesticide Programs ("OPP") has now deemed them satisfied or stated that it no longer alleges that AMVAC failed to act appropriately in connection with them.[1] Even prior to this narrowing, the fact that AMVAC had submitted data for, or otherwise satisfied, more than fifty other data requirements requested by the Data Call-In ("DCI") – a fact that OPP omits from its brief – made this NOITS unlike any other issued by OPP or any that a hearing had been requested in connection with. In all prior cases, OPP had pursued suspension against registrants who, unlike AMVAC, had not already produced, and had not been involved in a substantial, ongoing effort to produce, large amounts of data requested by OPP. As a result, no ALJ has ever been called upon to parse the statutory framework with the precision that is now asked of the Presiding Officer.[2]

This alone should give the Presiding Officer pause. AMVAC was in the process of spending over three-million dollars to perform and submit a multitude of studies in response to the DCI. This fact, among others that will be presented at the hearing, is squarely inconsistent with OPP's assertion that AMVAC was simultaneously implementing a "strategy" (as OPP baselessly smears in its Prehearing Brief ("OPP Ph'g Br.") at 7) to avoid doing some of the

[1] Respondent's Status Report, Dkt. 44, ¶¶10-13. OPP has not yet confirmed that AMVAC's submission of proposed label amendments in December 2022 moots out four residue chemistry data requirements, even though the proposed amendments are consistent with a December 2022 HED memorandum stating that the four data requirements could be waived if DCPA labels were amended as stated in the memorandum.

[2] While the Environmental Appeals Board ("EAB") provided some useful direction in its September 28, 2022 Decision and Remand Order, discussed herein, the EAB was not called on to reach, and did not reach, the merits of the underlying statutory standard.

studies by submitting multiple and/or unsound requests for waivers. As the facts presented at the hearing will support, AMVAC was making reasonable and well-justified requests for those waivers, and taking other appropriate actions, and it continues to do so.

OPP could have easily, at any time, told AMVAC that no further waiver requests would be considered. But it did not. To the contrary, OPP's Environmental Fate and Effects Division ("EFED") actively entertained and recommended granting waivers in documents dated mere days before the NOITS was issued. There is no regulation, DCI instruction, or industry understanding to support the new rule that OPP articulates for the first time in its Prehearing Brief: that any second attempt to justify a waiver is unallowable, and that a first waiver "denial" re-starts a countdown of the "time required" as set forth in the DCI under 7 U.S.C. § 136a(c)(2)(b)(iv) (the "Suspension Provision"), even if OPP never communicates this to the registrant. OPP Ph'g Br. at 23. The jarring effect such a new rule would have on the broader industry only highlights that OPP's proposal is nothing more than a misguided post-hoc justification for the NOITS, not present during the "course of performance" as between OPP and AMVAC, and unknown to others in the highly regulated pesticide industry who are familiar with OPP's typical conduct of data call-ins.

Waiver requests are not a nefarious evasion of a registrant's responsibilities; they are a valuable tool, explicitly provided for as an option on OPP's own forms, to avoid needless investments of time and energy on the part of both the registrant (in conducting an unneeded study) and OPP (in reviewing one). OPP and registrants commonly engage in an iterative scientific discussion concerning the merits of a waiver. If OPP knows it does not wish to consider further justifications for a waiver, it need only say so.

And yet, OPP's attempt to suspend AMVAC's registration continues. It is now almost exclusively propped up by OPP's contention that AMVAC crossed a line that AMVAC had no reason to know existed and struggles even now to discern. As OPP's justification for the NOITS continues to evolve, it becomes increasingly apparent that the NOITS failed to communicate its factual basis. It included only conclusory legal statements buttressed by a partial list of AMVAC and OPP's communications concerning the DCI. Perhaps the NOITS adequately communicated the rationale on which OPP relied in its Motion for Accelerated Decision ("MAD"), Dkt. 12, *i.e.*, that the data had not been submitted by the original DCI deadline. But it does not contain the novel post-hoc legal arguments and justifications that OPP now offers. None of these are detailed in, or even apparent from, the NOITS itself, nor are they further developed in OPP's pre-filed written testimony, which has not been updated subsequent to the Remand Order.

OPP recently confirmed that the science branches of OPP whose "recommendations" were supplied to AMVAC as the sole evidence of whether OPP was granting or denying AMVAC's waiver requests lacked delegated authority to grant or deny waivers. Only the Pesticide Reevaluation Division ("PRD"), appears to possesses the authority to grant or deny waivers. But, in this case, PRD did no more than occasionally forward the science branches' internal recommendation memoranda to AMVAC. This means that many of OPP's central factual allegations – that a given waiver request was "denied" in a certain document authored by a science branch – are untrue. The Presiding Officer should not permit OPP to proceed or prevail based on a NOITS that did not adequately communicate its own factual and legal basis.

The evidence to be presented at the hearing will show that AMVAC is now proceeding with all possible speed to perform the studies for which it had previously requested waivers and that are still at issue in this proceeding. Oddly, OPP would ignore AMVAC's ongoing work,

instead arguing that a registrant is cut off from taking further steps at OPP's whim. Because OPP never validly established an end date for the "time required" for AMVAC to take "appropriate steps," the Presiding Officer should find AMVAC's current ongoing efforts to be independently sufficient to rule that suspension is not warranted.

* * *

AMVAC files this prehearing brief in response to the Presiding Officer's October 18, 2022 Order on Respondent's Motion to Amend Hearing and Scheduling Order, Dkt. 33 (the "Scheduling Order"). The Presiding Officer requested briefing on the meaning of the phrases "failed to take appropriate steps to secure the data required" and "within the time required by the Administrator" as they are used in the Suspension Provision. The Presiding Officer also requested that the Parties identify the evidence that they expect will be offered at the hearing relevant to whether AMVAC met the statutory standard and identify any asserted factual errors in the Presiding Officer's Order on Respondent's Motion for Accelerated Decision ("MAD Order"), Dkt. 28, or the EAB's Decision and Remand Order.

Sections II and III of this Brief provide AMVAC's discussion of the meaning of the two statutory clauses. Section IV summarizes the evidence that AMVAC expects to introduce or adduce at the hearing which will establish that its conduct cannot support this NOITS. Section V discusses the relevance of the fact that several of OPP's factual assertions in the NOITS concerning the denial of waivers appear to be false and that OPP's justification for the NOITS has now evolved to the point that it is no longer evidence from the NOITS itself. Section VI responds to the Presiding Officer's request for identification of prior factual errors.[3]

[3] The Presiding Officer did not request any prehearing briefing on the procedural and/or factual history of this case, or the propriety of EPA's Existing Stocks order, and AMVAC accordingly omits these topics from this brief.

II. THE PHRASE "FAILED TO TAKE APPROPRIATE STEPS TO SECURE THE DATA REQUIRED"

As the EAB confirmed, determining whether "appropriate steps" were taken within the meaning of the Suspension Provision requires a facts-and-circumstance inquiry. *In Re AMVAC Chemical Corporation*, 18 E.A.D. 769, 789-90 (EAB 2022) ("Remand Order"). The EAB also confirmed that the meanings of the critical words "appropriate" and "steps" are properly informed by reference to the "contemporary, common meaning" of those terms. *Id.* The EAB observed that "appropriate" is defined as "specially suitable: fit, proper" according to Webster's Third New International Dictionary 106 (1993 ed.) and that "step" is defined as "an action, proceeding, or measure often occurring as one in a series." *Id.* at 790.

While the EAB determined the meaning of "appropriate steps" was sufficiently clear that it could reverse the MAD Order, the EAB was not called upon to apply the legal standard to a fully developed set of facts. As explained immediately below, however, the EAB's Remand Order does provides useful guidance on the interpretation of the standard for that purpose.

A. Dictionary Definitions

Because the EAB has already concluded that actions short of submitting data may constitute appropriate "steps," there appears to be no remaining dispute that all of AMVAC's actions that will be discussed in the context of the hearing were "steps" – the critical question is whether they were "appropriate." Remand Order at 782. The EAB referred to Webster's Third New International Dictionary 106 (1993 ed.) for relevant definitions, observing that "appropriate" is defined as "specially suitable: fit, proper." Reference to "suitable," "fit" and "proper" in the same dictionary (either the 1981 or 1993 editions) shows that "proper" means "marked by suitability, rightness, or appropriateness" and one meaning of "suitable" is "appropriate from the viewpoint of a propriety." Propriety is further defined as "the standard of

what is socially acceptable in conduct, behavior, speech." "Suitable" means "adapted to a use or purpose," and that "fit" may mean "adapted to an end, object or design." *Id.*

The concepts of adaptation, suitability, and acceptability provide useful context for analysis under the "appropriate steps" standard in the Suspension Provision. The EAB has already confirmed this – specifically, by confirming that whether AMVAC's steps were "appropriate" requires an analysis of both the "course of performance," of this DCI (*i.e.*, how AMVAC and OPP interacted on this DCI) and "typicality" – how OPP generally handled DCI responses during the relevant period. Remand Order at 790.

B. Course of Performance

The Remand Order confirms that the "course of performance" between OPP and AMVAC on this DCI is "highly significant" to determining whether AMVAC's conduct was appropriate. *Id.* The EAB specifically identifies the "parties' 'course of performance' with respect to how they handled extension requests" to be material as to whether the submission by AMVAC of only one such request early in the course of the DCI (to which OPP never responded) was appropriate. *Id*.

It is unclear from OPP's Prehearing Brief if OPP intends to argue that course of performance evidence is relevant only to the extension request issue, *see* OPP Ph'g Br. at 7. Regardless, there is no basis in the EAB's opinion, logic, or the definitions of "appropriate" supplied therein, that course of performance evidence should be limited to any one issue. Based on the Remand Order, it is clear that course of performance as to all relevant issues – notably, how the parties handled waiver requests and label amendments, OPP's own substantial delays, and the fact that AMVAC was diligently completing many other studies that were never at issue in this proceeding, is highly significant.

The case cited by the EAB concerning the relevance of "course of performance, "

Alabama v. North Carolina, 560 U.S. 330, 346 (2010), also examines a situation in which a party was obligated to take "appropriate steps" and was alleged to have failed to do so. The Supreme Court held that the parties' actions shape what is appropriate and cited to the Restatement (Second) of Contracts § 202 (Am. Law Inst. 1981). That section states that "[w]here an agreement involves repeated occasions for performance by either party with knowledge of the nature of the performance and opportunity for objection to it by the other, any course of performance accepted or acquiesced in without objection is given great weight in the interpretation of the agreement." *Id.* §202(4). This is consistent with the concepts brought forward by the dictionary definitions discussed above and furnishes a key principle in this case: even if OPP might have had grounds to object to AMVAC's conduct in requesting, or seeking to further justify, a waiver after EFED had once recommended against granting it, or taking some other action, OPP's failure to object (and in fact, to continue reviewing additional justifications) supports a finding that AMVAC's conduct was "appropriate" in the context of the response to the DCI. How AMVAC expects evidence concerning course of performance to confirm that it took appropriate steps is set forth in Section IV.

C. Typicality

OPP strenuously resists the EAB's conclusion that typicality is material to whether an action is appropriate. *See* OPP Ph'g Br. at 6 (typicality not "significant factor[]"); *id.* at 7 n.5 ("'typicality' of AMVAC's conduct . . . has no bearing on . . . whether it took appropriate steps . . . ."). OPP curiously cites the Presiding Officer's denial of certain of AMVAC's discovery requests directed to typicality for the premise that typicality is not a "significant factor[]." *Id.* at 6-7, citing Order on Motions for Additional Discovery at 3-4, Dkt. 40 (the "Discovery Order"). The Discovery Order did not rule that typicality was not a "significant factor." It observed only that typicality may carry "less weight than the steps AMVAC actually did or did not take to

respond to the DCI." Discovery Order at 3-4.

AMVAC agrees that its own conduct is central. Evidence that AMVAC's conduct was consistent with that of other registrants would not be *dispositive* that AMVAC's conduct was appropriate. Evidence of typicality is material, however, to help *confirm* that the conduct in the course of performance between AMVAC and OPP was "suitable" and "acceptable" (*i.e.*, appropriate, per the definitions) in the broader context of how OPP administered data call-in responses at the time.[4]

To the extent there is any doubt, for example, that OPP was willing to entertain further justifications for waiver requests from AMVAC in the course of performance of the DCPA DCI, such doubt could be dispelled when the evidence shows that OPP accepted this practice in the context of other DCIs at the relevant times. Such evidence would be particularly probative if it shows, as AMVAC expects it will, that not only was OPP *sometimes* willing to entertain further justifications, it is typically willing to do so. How AMVAC expects evidence concerning typicality to confirm that it took appropriate steps is set forth in Section IV.

III. THE PHRASE "WITHIN THE TIME REQUIRED BY THE ADMINISTRATOR"

The EAB's guidance concerning "course of performance" and "typicality," as set forth in the prior sections, applies to the meaning of the "time required" phrase as well. The EAB rejected a rigid approach whereby only the timeframes in the DCI control, in favor of an analysis of "course of performance" and "typicality" as discussed above. OPP initially contended that the deadlines in the DCI were controlling, *e.g.*, MAD at 44, but has now retreated from this position.

[4] AMVAC has not, in any prior filing, advanced a selective enforcement claim, *i.e.*, a claim that EPA's issuance of the NOITS was invalid because EPA selected AMVAC for enforcement invidiously or in bad faith. AMVAC reserves the right to advance such a claim if evidence supporting it is developed at hearing.

OPP now asserts that the "time required" clock resets, apparently in secret, to the amount of time originally provided in the DCI if and when OPP first denies a waiver request. OPP Ph'g Br. at 3 n.1 ("basic tenets of fairness may provide registrants with additional time to respond to a data requirement where the timing of OPP's denial of an *initial* waiver request would leave insufficient time remaining . . . .") (emphasis added). OPP also confirms how its new theory would operate for the DCPA Leptocheirus data requirement. It explains that AMVAC should have "submitted data, or taken other appropriate steps . . . no more than 24 months [the applicable DCI time frame] after OPP's denial of the [data] waiver request[s]." *Id.* at 5.

OPP's "time required" retrenchment hinges on several faulty premises and, even if it were correct, it does not support OPP's desired result. Its first faulty premise is that any further attempt to justify a waiver request "should not be considered" an appropriate step. *Id.* at 8. This is plainly inconsistent with the EAB's Remand Order as discussed above. OPP argues for this novel limitation solely to reach its desired goal in this ligation by sidestepping the analysis required by the EAB that favors AMVAC; OPP's proposed hard and fast rule is heretofore unknown to the industry and is inconsistent with OPP's prior practice.

OPP's second faulty premise is that it assumes there is a clear point in time at which a waiver is "denied." Many documents that OPP contends were "denials" are, on their face, only recommendations from EFED to PRD. This is relevant to the "course of performance" as between the parties regardless of whether the waivers were or were not legally effective; receipt of an internal EFED "recommendation" to PRD is inarguably different in character from receipt of a firm PRD conclusion that a waiver is denied. The evidence will show that neither EFED nor PRD ever clearly informed AMVAC that a waiver was denied and that no further attempts to justify it would be considered. To the contrary, further attempts were considered and, in several

cases, changed EFED's conclusion.

A third problem with OPP's theory is that it ignores the potential that other statements by OPP might, within the "course of performance," indicate that the registration review process would proceed to a further phase with the data then available, after which waivers would be reconsidered. AMVAC expects the evidence will show, as summarized in Section IV, that the course of conduct as between AMVAC and OPP provides no basis to conclude that any valid time limitation had expired at the time that the NOITS was issued.

OPP complains that if the Presiding Officer finds "that successive requests to waive data requirements" could constitute "appropriate steps" then "OPP essentially would be unable to enforce submission of data in connection with any DCI" because registrants could always restart the clock with another waiver request. OPP Ph'g Br. at 9. OPP's apparent broader policy concern is unavailing. First, the Presiding Officer's decision, though it may consider typicality, will turn primarily on the course of conduct as between OPP and AMVAC. Second, it is well-within PRD's power to avoid the outcome it fears. PRD need only clearly inform registrants when it denies a waiver, that the denial is final, and that the registrant has the original DCI timeframe to supply the data or be subject to a NOITS. OPP could do this on a case-by-case basis, or it could do so as a broader policy matter. But OPP cannot escape the fact that it did not do so with AMVAC.

IV. EVIDENCE EXPECTED AT THE HEARING

In this section AMVAC first discusses the evidence it expects to present or adduce at the hearing that will show that it took appropriate steps as to <u>all</u> data requirements remaining at issue. Following this discussion, the remaining sub-sections discuss expected evidence relevant to four sub-categories of data requirements at issue in the hearing: TPA Ecotoxicology (5);

DCPA Chronic Leptocheirus (1); TPA Environmental Fate (3); and Residue Chemistry (4). AMVAC does not attempt, in these sections, to lay out each and every fact it believes will be adduced at hearing, rather, it focuses on the central facts and the broader findings which it expects those facts will compel.

A. Evidence Relevant to All Requirements Still at Issue

With respect to all data requirements at issue, AMVAC expects to show first that OPP communicated that it could and would conduct a risk assessment; specifically that it stated it would complete one in June of 2021 regardless of whether it received any additional data. This established an expected course of performance whereby OPP would conduct the risk assessment, as it stated it would, and then would reconsider the need for additional data. Not only was this approach communicated by OPP clearly in this case, the evidence will also show that it was common for OPP to take this approach, and even to proceed to issue further decision documents after conducting a risk assessment when data was still outstanding.

AMVAC plans to establish that OPP never claimed that it could not conduct a risk assessment until it provided the NOITS, and other documents, to AMVAC in April of 2022. AMVAC will rely primarily on JX 21; JX 65; JX 66; JX 77; other EFED memoranda provided at the time of the NOITS; the testimony of Messrs. Gur and Freedlander; cross examination testimony of OPP's witnesses; and publicly available documents pertaining to the registration reviews of other chemistries to establish this point.

Second, relevant to all data requirements at issue, AMVAC expects to show that OPP's new "one waiver denial" theory[5] is completely at odds with OPP's course of conduct with

[5] That theory appearing to be that: (1) any subsequent attempt to justify a waiver is *de facto* not appropriate; and (2) that the initial denial secretly re-starts the "time required" clock to the amount of time originally set forth in the DCI.

AMVAC in this case and with its historical practice. EFED in this matter recommended granting waivers concurrent with the NOITS, proving both that subsequent waiver requests can constitute "appropriate steps" and that the "time required" is not fixed in the unworkable and novel manner OPP now suggests. AMVAC further expects to show that OPP's new theory is completely alien to the manner that registrants have historically interacted with OPP in response to DCIs. AMVAC will rely primarily on JX 66; JX 69; JX 74; JX 77; JX 79; other EFED memoranda provided at the time of the NOITS; the testimony of Messrs. Gur and Freedlander; and the cross-examination testimony of OPP's witnesses to establish this point.

Third, relevant to all data requirements at issue, AMVAC expects to show that even if some version of OPP's "one waiver denial" theory was correct and might get OPP to its desired result as against another registrant, it cannot be applied to find against AMVAC here. A standard that would require registrants to initiate studies when the conduct of the parties indicated that there was still a potential to have further scientific discussion with EFED would be absurd. Here, OPP did not communicate that any waiver was denied in a manner that informed AMVAC that no further waiver requests would be considered. PRD chemical review managers consistently passed along further justifications provided by AMVAC to EFED even after EFED's initial denial recommendation had been provided. And EFED did in fact recommend granting waivers after considering such further justifications. This is a key element of the course of performance as between the OPP and AMVAC in this case. AMVAC will rely primarily on JX 66; JX 69; JX 74; JX 77; JX 79; other EFED memoranda provided at the time of the NOITS; the testimony of Messrs. Gur and Freedlander; cross examination testimony of OPP's witnesses and publicly available documents pertaining to the registration reviews of other chemistries to establish this point.

Fourth, relevant to all data requirements at issue, AMVAC expects to show that in prior cases in which OPP has issued a NOITS, OPP has typically provided a warning to the registrant of its intent to do so. AMVAC does not assert that it is owed such a warning, or that the failure to so warn invalidates the NOITS – but rather that AMVAC reasonably and properly would have expected, based on OPP's typical conduct, that OPP would at least have indicated its concern that it could not complete a risk assessment to AMVAC prior to issuing the NOITS. Such a communication could have, but critically did not, re-establish a "time required" for further action on which OPP might have validly issued a NOITS. AMVAC expects to rely on the statements of Mr. Freedlander and Mr. Gur and cross examination of OPP witnesses to establish this point.

Common to all points above is that OPP could have, but did not, re-establish a "time required," in the course of performance of this DCI within which AMVAC had to take certain steps after the original DCI time frames had long passed (and OPP now concedes the original time frames no longer applied). OPP's failure to do so is fatal to the NOITS.

B. Evidence Relevant to Individual Groups of Data Requirements

1. *TPA Ecotoxicology*

This group includes the Guideline 850.1400 Fish ELS, 850.1350 Chronic Mysid, and 850.4500 Algal Toxicity (for the marine diatom only). All three guidelines' requirements relate to DCPA's degradate, TPA. In addition to the facts relevant to all studies, above, AMVAC further expects to show that it undertook a specific limited testing protocol suggested by EFED – to conduct acute and chronic studies of another species, *daphnia magna* – which EFED stated would enable it to reconsider granting waivers for the data requirements in this group. AMVAC submitted the final *daphnia* study prior to receiving the so-called Data Delay Letter and followed up with a full report and additional analysis shortly thereafter.

The evidence will show that AMVAC did not receive EFED's recommendation not to

grant the waiver for these studies following review of the *daphnia* data until concurrently with the NOITS and that that document that AMVAC received concurrently with the NOITS did recommend granting other waivers based on the suggested testing approach. Following EFED's suggestion to provide the *daphnia* data as a first step was clearly appropriate. The evidence will also show that AMVAC's correspondence with OPP in which AMVAC requested or further justified its waiver requests had scientific merit, was based upon grounds on which OPP has historically granted waivers and was never duplicative of prior submissions.[6] AMVAC will rely primarily on JX 5; JX 66; JX 67; JX 21; JX 22; JX 69; and PAX 45; the testimony of Messrs. Gur and Freedlander; and cross examination testimony of OPP's witnesses to establish these points.

2. *DCPA Leptocheirus*

This group includes a single Special Study, identified as SS-1072, for chronic lifecycle testing of *leptocheirus plumulosus* exposed to DCPA. In addition to the facts relevant to all studies listed above, AMVAC expects to show that its waiver request for the study was reasonable both from a technical perspective and because chronic testing with this species was not practicable at the relevant time (and remains problematic even at the time of the NOITS).

The evidence will show that AMVAC reasonably requested that OPP notify it if OPP developed or learned of a protocol it believed to be practicable, and that OPP never did so until concurrently with the NOITS. The evidence will also show that AMVAC's correspondence with OPP, in which it requested or further justified its waiver requests had scientific merit, was based upon grounds on which OPP has historically granted waivers, and was not duplicative of prior

[6] AMVAC does not concede that it must conclusively establish all of the expected findings referenced in its prehearing brief to prevail; a subset of these (and the other facts AMVAC discusses herein) may be sufficient to establish compliance with the statutory standard.

submissions. AMVAC also expects to show that, while OPP indicated that AMVAC could conduct a different study that was not in the NOITS, OPP refused to formally substitute the alternate study for the *leptocheirus* chronic study or formally request that the alternate study be performed. AMVAC will rely primarily on JX 5; JX 21; JX 22; JX 33; JX 60; JX 62; JX 69; JX 71; JX 72; JX 74; JX 75; and JX 76; the testimony of Messrs. Gur and Freedlander; and cross examination testimony of OPP's witnesses to establish these points.

3. *TPA Environmental Fate*

This group includes three environmental fate metabolism studies for DCPA degradate TPA; Guideline 835.4200 (anaerobic soil), 835.4300 (aerobic aquatic), and 835.4400 (anaerobic aquatic). In addition to the facts relevant to all studies listed above, AMVAC expects to show that its waiver requests had scientific merit, were based upon grounds on which OPP has historically granted waivers, and were not duplicative of prior submissions. In particular, with respect to conducting a risk assessment, the evidence will show that AMVAC was urging EFED to make worst case assumptions for purposes of risk assessment, *i.e.*, that TPA should be assumed to be "stable" – to not degrade – under each of the relevant conditions for purposes of risk assessment. OPP stated that it could and would do this.

The evidence will also show that TPA is not expected to degrade in a manner that can be accurately reflected in laboratory studies. Therefore, it was reasonable for AMVAC to seek waivers for the studies even if EFED communicated that a better understanding of the degradation of TPA was needed, because these studies would not be expected to supply useful information due to the nature of TPA and the studies themselves. The evidence will additionally show that EFED has for the first time recently conceded that a "longer than standard" study might be needed. AMVAC will rely primarily on JX 5; JX 21; JX 22; JX 57; JX 66; JX 67; and JX 77-79; the testimony of Messrs. Gur and Freedlander; and cross examination testimony of

OPP's witnesses to establish these points.

4. *Residue Chemistry*

This group includes the four Guideline Series 860 residue chemistry studies identified in the NOITS (860.1300, 860.1340, 860.1480, and 860. 1900). Unlike the other studies remaining at issue, AMVAC indicated that it would address these DCI requirements by updating its product labels to remove permitted uses of DCPA such that the studies would no longer be required. The evidence will show that AMVAC engaged in a lengthy back-and-forth with OPP, including both PRD and OPP's Registration Division to update various labels consistent with OPP's requirements. The evidence will establish that AMVAC understood that the amendments it was proposing would address OPP's concern and permit waiver of these data requirements, notwithstanding that OPP now points to a specific memorandum from 2015, which was not provided to AMVAC until 2017, as conclusively establishing the only amendments AMVAC might have proposed that would have constituted "appropriate steps" towards eliminating the need for these data requirements.

The evidence will show that AMVAC's understanding that the 2015 memorandum was not a conclusive statement of OPP's requirements was bolstered by the fact that the so-called Data Delay Letter, JX 21 at 5, stated the following with respect to these data requirements, "[i]n review; label amendments submitted to satisfy guideline," and that AMVAC and OPP continued to work on label amendments through 2021 with no further mention of the 2015 memorandum. The evidence will further show that OPP's Health Effects Division ("HED") issued, subsequent to the NOITS, a memorandum setting forth requirements different from those contained in the 2015 document which HED asserted would be sufficient to permit waiver of the four studies and that AMVAC has now submitted label amendments consistent with the 2022 HED memorandum. AMVAC will rely primarily on JX 4; JX 5; JX 21; JX 26-29; JX 31-41; JX 43-

48; JX 50; JX 89; JX 90; the testimony of Mses. Porter and McMahon and Mr. Wood; and cross examination testimony of OPP's witnesses to establish these points.

C. Evidence of Post NOITS Action

AMVAC will demonstrate at the hearing that it is currently conducting all of the studies for the data requirements for which it previously requested waivers. With respect to the four residue chemistry studies remaining at issue, AMVAC has submitted label amendments consistent with a detailed memo from HED laying out what amendments would be needed to permit waiver of the remaining four residue studies. This testimony will be provided through Ms. McMahon. This will establish that AMVAC is presently taking all "appropriate steps" under any possible definition of the terms, because AMVAC is proceeding as rapidly as possible to conduct all of the relevant studies and has already submitted the proposed amendments.

OPP has already, in view of information provided after April of 2022, decided to retract its allegation that AMVAC failed to take appropriate steps within the time required as to several data requirements. *See* Respondent's Status Report, Dkt. 44, ¶¶10-13 (deeming one data requirement satisfied based on post-NOITS submissions and indicating that OPP is "no longer alleging that AMVAC failed to take appropriate steps" with respect to six other data requirements). For several of these, as will be established through Ms. McMahon, AMVAC supplied data or further explanations of previously submitted data to OPP after the issuance of the NOITS.

OPP should conclude, based on the fact that AMVAC is now conducting studies with all possible speed on all remaining data requirements, that AMVAC is taking "appropriate steps" and that the entire hearing is moot. OPP's failure to do so can be based only on an assertion that the "time required" for taking appropriate action in connection with the April 27, 2022 NOITS has ended and so AMVAC's current conduct is irrelevant (notwithstanding OPP's apparent

acceptance of other post-NOITS conduct to narrow the case).

The evidence at the hearing will establish that OPP's proposed limitation on the "time required" is artificial and unenforceable for the reasons discussed above. Because there was no relevant enforceable deadline based on the "course of performance" of the DCI, the Presiding Officer should conclude that AMVAC's currently ongoing "appropriate steps" are being taken within the "time required" under the Suspension Provision and a suspension should not issue.

Any suspension under the current NOITS, should it ever be put into effect following a decision of the EAB adverse to AMVAC, would be almost immediately rescinded. AMVAC would be able to immediately assert, consistent with the mandatory final clause of 7 U.S.C. § 136a(c)(2)(b)(iv), that its registration "shall be reinstated by the Administrator . . . [because it] has complied fully with the requirements that served as a basis for the suspension[.]" OPP previously contended that once a suspension issues, only OPP's *acceptance* of submitted data (not just submittal, but discretionary acceptance) is sufficient to require that it be lifted. MAD at 41 (asserting "sole authority" to determine grounds for suspension and reinstatement). The EAB corrected OPP's misunderstanding with respect to its "sole authority" to do so. The EAB observed that all of the references to "complied fully" in the Suspension Provision (in the third, fifth, and eighth sentences) "must refer back to the 'appropriate steps' language in the first sentence." Remand Order at 782. Therefore, based on the EAB's clear conclusion in this regard, there is no statutory basis for the application of alternate or additional criteria (other than "appropriate steps") to govern the lifting of a suspension after it is entered.

OPP's only possible response to a demand for reinstatement would be that the "time required" remains the same even post suspension, and so a suspended registration could never be reinstated because no new steps would ever be within the forever-expired time required.

AMVAC's interpretation (that the "time required" is re-set to at least a reasonable duration to complete studies upon suspension) is consistent with the intent of the provision as developed in prior briefing on the legislative history – to encourage registrants to develop data. The alternative interpretation – that the time required remains forever expired, and a suspended registration could, in the Administrator's sole discretion, remain forever suspended even after data was submitted, is contrary to the text and would be an absurd interpretation of the Suspension Provision.

V. THE NOITS IS LEGALLY DEFICIENT

The evidence will show that several factual assertions central to the NOITS are incorrect. Most notably, AMVAC expects the evidence to show that only PRD, and only certain officials within PRD, possess the necessary delegated legal authority to grant or deny waivers in connection with registration review DCIs; no one in EFED or HED possesses this legal authority.[7] This is consistent with EFED's use of the "recommendation" terminology in its memoranda. It is also consistent with a statement made by OPP in connection with a response to a request for admission in this matter.[8]

Based on this lack of authority, statements made in the NOITS that "[t]he Agency denied" specific waivers through the transmittal of certain EFED documents are untrue. OPP's only attempt to rebut this fact appears to be an argument that the EFED recommendations were

[7] OPP suggests, in its Ph'g Br. at 31, that AMVAC's delegation argument proves too much; that if EFED can't deny waivers then it also can't grant them and so all data requirements for which EFED recommended granting waivers would still be outstanding. AMVAC will defend its reliance on non-legally effective EFED memoranda recommending waivers be granted, in the absence of other communications from EPA, under the "appropriate steps" inquiry as may be required.

[8] OPP Response to AMVAC Req. for Admis. 19 ("Respondent further notes that EFED and HED only make recommendations that a waiver request be granted; the decision to waive or not waive data rests with PRD.")

imbued with the necessary delegated authority by implication because they were transmitted to AMVAC by PRD personnel. OPP Ph'g Br. at 29-30. AMVAC will explore that contention to the degree possible at the hearing and will further address it in post-hearing briefing.

The fact that OPP's statements in the NOITS were *legally incorrect* provides another independent ground to declare the NOITS deficient. This is not a simple transposed date, or the omission of a minor communication. This goes to the heart of the matter – AMVAC's conduct in connection with requesting and supporting waiver requests. Whether waivers were in fact denied is not a peripheral consideration; OPP's new theory of how the "time required" might be established turns on the date of waiver denials.

This proceeding has been plagued from the beginning by the fact that OPP conclusorily asserted in the NOITS that AMVAC failed to take "appropriate steps" and did not provide any detailed support for that assertion save for a partial chronology of interactions between AMVAC and OPP in Attachment III to the NOITS. Now that OPP has formally retreated from asserting that the DCI supplied the "time required" criteria of the statutory standard, it is even more evident that the NOITS fails to specifically allege when the "time required" expired. OPP's attempt to salvage the NOITS from this deficiency relies on its new post-hoc legal justification that waiver denials (specifically, only the first one) re-start the "time required" clock.

Many of OPP's other post-hoc justifications likewise appear nowhere in the NOITS, *e.g.*, its argument that some of AMVAC's waiver requests (or further justifications) were too similar to prior requests. Additionally, the consideration that seems to have most centrally motivated OPP to issue the NOITS – the lack of satisfaction of the CTA data requirement, which OPP

asserted prevented HED from completing a risk assessment – has now been resolved.[9] The revelation that the "denials" alleged in the NOITS were not legally valid is merely emblematic of the larger issues with the NOITS.

For these reasons, the Presiding Officer should declare the NOITS legally deficient for failure to adequately apprise AMVAC, the public, or other registrants what OPP even alleged AMVAC failed to do; OPP's theory has been a moving target that has prejudiced AMVAC to the extent it was been forced to defend itself against OPP's conclusory statements and evolving justifications. *Cf.* 5 U.S.C. § 554(b) (requiring regulated parties be "timely informed of . . . (1) the time, place, and nature of the hearing; (2) the legal authority and jurisdiction under which the hearing is to be held; and (3) the matters of fact and law asserted."); *In re Asbestos Specialists, Inc.*, 4 E.A.D. 819, 829 (EAB 1993) (observing that amendment may be appropriate so that the complaint will "more clearly [state] both the allegations against Respondent and [EPA's] rationale for the [sanction].") To avoid further prejudice to AMVAC, OPP should not be permitted to *de facto* continually amend and supplement the NOITS through evolving justifications and theories in its briefing.

VI. FACTUAL ERRORS IN PRIOR DECISIONS

The Scheduling Order requested that the Parties identify, in their prehearing briefs, any factual errors regarding the history of this matter set out in the MAD Order or the EAB's Remand Order. The enumerated list below provides AMVAC's response, subject to the following qualifications:

First, AMVAC has focused on factual assertions or findings. To the extent it refers

[9] AMVAC plans to offer testimony at the hearing that the CTA study, which OPP has accepted, allows EPA to proceed with the analysis that it stated it could not undertake when the NOITS was issued. This testimony will be provided by Ms. Jonynas.

below to an assertion that could be characterized as a legal conclusion, it is not AMVAC's intention with this list to address any findings of law.

Second, AMVAC has not addressed some factual assertions contained within sections of the MAD Order that were rejected by the EAB, specifically the sections concerning the scope of the hearing and the effect of the 2022 registration review deadline.

Third, AMVAC has not addressed factual assertions related to data requirements which are no longer at issue in this matter, specifically the DCPA fish and mysid data requirements.

Fourth, AMVAC disagrees with, but does not uniquely identify below, all instances in which a quote from an OPP witness statement could be construed as being set forth as a factual finding rather than a reference to OPP's position. *E.g.*, MAD Order at 5 (citing Bloom Statement at 3 concerning comments on work plans).

Fifth, in some cases, the MAD Order refers to the date of a document without specifying when it was transmitted to AMVAC. While not an error, AMVAC asserts that the dates of transmittal are important in this case and will establish all relevant dates in testimony and evidence at the upcoming hearing.

Sixth, AMVAC disagrees with all instances in the MAD Order in which the Presiding Officer makes an assertion concerning AMVAC's subjective motivations or speculates concerning its potential future conduct, *e.g.*, MAD Order at 30 ("Apparently . . . undertaking this abbreviated study was not to AMVAC's liking . . . ."); *id.* at 34 ("the record suggests that AMVAC may continue to unhurriedly, if at all, provide the requisite studies[.])"

Seventh, AMVAC disagrees with any statement in the MAD Order or Remand Order that concludes that a particular document constituted a "denial" of a waiver request, at least from the perspective that it was issued with proper legal authority or would provide the one-time "time

required" re-set under OPP's new theory. As set forth in Sections II-IV, *supra*, the extent to which a particular document was or should have been interpreted as a recommendation, a final denial, or something in between, will be further explored through testimony at the hearing.

Eighth, AMVAC disagrees with instances in which the MAD Order characterized the clarity of a document in the MAD Order, *e.g.*, MAD Order at 29 ("clear and unequivocal"), to the extent that such characterization could be construed as a finding of fact prior to the hearing. Subject to these qualifications, AMVAC asserts that the following factual errors exist in the MAD Order and/or the Remand Order:

1. Both the MAD Order and the Remand Order incorrectly refer to the Federal Register notice publishing the NOITS (JX 2) as the NOITS (JX 1). *E.g.*, MAD Order at 1; Remand Order at 777 (referring to JX 1 as the "Notice Letter" and JX 2 as the "DCPA NOITS"). Pursuant to the documents themselves, JX 1 is the NOITS ("You are receiving this Notice of Intent to Suspend . . . .") and JX 2 publishes the NOITS ("This notice … publishes a [NOITS]"). This is consistent with the ALJ's publication of JX 1 as Dkt. 1 in this matter identified as the NOITS. The Parties have also stipulated that JX 1 is the NOITS. *See* Joint Set of Stipulated Facts ¶3.

2. Although statements regarding OPP's statutory deadline to complete registration review were correct at the time made in the MAD Order and the Remand Order (*i.e.*, the deadline was October 1, 2022 when those documents were issued), Congress has now moved the deadline to October 1, 2026. *See* Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (passed in December of 2022 and signed into law on December 29, 2022) Sec. 711, Registration Review Deadline Extension.

3. The MAD Order, at 2, incorrectly states that OPP's initial prehearing exchange

was filed on June 21, 2022. Although this is the date indicated on the docket, AMVAC's records indicate that Respondent's prehearing exchange materials were provided on June 17, 2022.

4. The MAD Order, at 6, incorrectly states that JX 21, the so-called "Data Delay Letter" was issued on October 26, 2020. It was actually issued on Oct. 16, 2020. JX 91.

5. The MAD Order, at 20, incorrectly characterizes AMVAC's assertions. AMVAC does assert that certain extraordinary circumstances were responsible for delays, *e.g.*, issues at the lab performing the CTA study and the difficulties with performing the DCPA *leptocheirus* study, as discussed in the statements of Ms. Jonynas and Mr. Freedlander, respectively. AMVAC also alleges that deadlines for production were "unfeasible" (*e.g.*, the CTA and *leptocheirus* studies) and now to the extent that OPP may assert the existence of certain deadlines based on its new legal theory. AMVAC also now alleges that deadlines for data production may yet "remain outstanding," MAD Order at 20, to the extent that no enforceable deadline established by OPP has passed.

6. The MAD Order, at 21, incorrectly stated that "various data gaps . . . prevent EPA from conducting a complete analysis[.]" It is unclear what the MAD Order means by "complete analysis" and AMVAC objects to this conclusion on that basis. Evidence will be provided to show that OPP stated it could and would conduct a risk assessment with the existing dataset. JX 21; Testimony of Mr. Freedlander.

7. The MAD Order, at 25, incorrectly asserts that AMVAC "bore the risk" that the *daphnia* data would not cause OPP to waive certain data requirements. This statement has no citation in the MAD Order, and AMVAC expects the testimony at the hearing will establish that it would be unreasonable to interpret, in the context of the Parties' course of performance, AMVAC as bearing the risk of a suspension based on the outcome of the *daphnia* studies given

that EFED suggested the very approach taken.

8. The MAD Order, at 25, incorrectly asserts that AMVAC "doubled down" on anything. In JX 67, AMVAC stated that it would follow the strategy set out by EFED in JX 66. JX 66 was the first time that EFED suggested the acute and chronic *daphnia* studies as a specific limited testing strategy. In general, with respect to the TPA Ecotoxicology data requirements that remain at issue; JX 67 is not a further "justification" of a waiver request, or a separate waiver request, but rather a statement that AMVAC would follow EFED's suggestion in JX 66.

9. The MAD Order, at 27-28, appears to conclude that AMVAC should have followed up with OPP between December of 2020 and the issuance of the NOITS. AMVAC believes that the testimony at the hearing will establish that it is not necessary, typical, or expected for registrants to follow up with OPP on the facts presented.

10. The MAD Order, at 29 n.28, cites 40 C.F.R. § 152.91. The quote from the regulation is correct, but, to the extent that it is provided as a factual (or legal) finding, AMVAC will demonstrate that, based on course of performance and typicality, registrants are permitted to further justify waiver requests that OPP does not initially grant.

11. The MAD Order, at 30, incorrectly states that "completing the [*leptocheirus*] study was never beyond [AMVAC's] control." AMVAC expects that the testimony at the hearing, primarily that of Mr. Freedlander, will establish that completing this study was beyond AMVAC's control.

12. The Remand Order, at 775, refers to the DCI as consisting of "thirty-five data requirements[.]" The Parties have been referring to individual studies, rather than OPPTS Guidelines, as being "data requirements" in this matter. If a single Guideline study was required for both DCPA and TPA, the Parties have referred to this as two "data requirements." Likewise,

if more than one species was required to be tested, each species has been referred to as a separate "data requirement." Under this convention, the quantity of data requirements in the DCI is described in the written testimony of Ms. McMahon ¶¶20-22 and McMahon Ex. A.

VII. CONCLUSION

For the last eight months, AMVAC has endured the cost, disruption, and reputational damage of OPP's evolving attempts to establish that AMVAC failed to take appropriate steps in response to the DCI. The hearing will establish that OPP remains unable to prove its claim and that AMVAC acted appropriately at all relevant times and continues to act appropriately now. The resources of all parties to this litigation are better directed elsewhere. AMVAC looks forward to the hearing and moving one step closer to putting this matter behind it.

Date: January 13, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Petitioner AMVAC Chemical Corporation's Prehearing Brief**, was sent on January 13, 2023, to the following parties in the manner indicated below.

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Dated January 13, 2023