UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

PETITIONER AMVAC'S OPPOSITION TO RESPONDENT'S MOTION FOR ACCELERATED DECISION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

Respondent can only be granted the relief it seeks here if there is "no genuine issue of any material fact and [Respondent] is entitled to judgment as a matter of law." 40 C.F.R. § 164.91(a)(7). Respondent has not met this standard. Whether Respondent is entitled to judgment as a matter of law depends on the meaning of the relevant clause of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a(c)(2)(B)(iv) (the "Suspension Provision") (emphasis added below):

> Notwithstanding any other provisions of this Act, if the Administrator determines that a registrant, ***within the time required by the Administrator,*** has failed to take ***appropriate steps*** to secure the data required under this subparagraph . . . . the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which the additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide.

There has never been a case in which a fact scenario approximating the one presented here has been before an ALJ or a court. As a result, no cases have construed the Suspension Provision in view of facts such as those present here. Properly construed, the Suspension Provision requires a facts and circumstances inquiry into the conduct of a registrant and the Environmental Protection Agency's ("EPA") Office of Pesticide Programs ("OPP") during a Data Call In ("DCI"). Such an inquiry is the only way to determine whether AMVAC Chemical Corporation's ("AMVAC's") conduct – the "steps" it took – met the statutory standard.

As explained more fully below, this understanding of the statutory text of the Suspension Provision is reinforced by the legislative history of FIFRA, and consideration of other sections of FIFRA, some enacted in the same Congress as the Suspension Provision, which prove that when Congress intends to draft a provision as narrow as Respondent attempts to read the Suspension Provision, it knows how to do so and uses different language. OPP's historic practices, which

are at odds with Respondent's legal positions in its motion, further reinforce the conclusion that Respondent's position on this issue is incorrect.

Respondent's Motion for Accelerated Decision ("MAD") offers little beyond recitations of the statute and urges an interpretation of the Suspension Provision that is impermissibly narrow because it reads the phrase "appropriate steps" completely out of the statute.

The clear language of the Suspension Provision requires a decision-maker to determine at least three things: (1) what EPA's actual time requirement was, (2) whether the "steps" a registrant took "to secure the data" EPA requested within the time allowed by the Administrator were "appropriate," and (3) facts relevant to whether EPA's existing stocks provision is consistent with FIFRA. None of these questions can be resolved without reference to the facts and, as explained for each data requirement discussed in EPA's Notice of Intent to Suspend ("NOITS"), are not appropriate for resolution based on Respondent's MAD.

The Suspension Provision provides for a hearing to resolve the questions above. Contrary to Respondent's assertions, there is no evidence that the Congress that drafted the Suspension Provision intended the language concerning the matters for resolution at such a hearing to limit exploration of the relevant issues enumerated above; such a result would be illogical and also contrary to the plain language of the Suspension Provision

II. THE LEGAL STANDARDS APPLICABLE TO RESPONDENT'S MOTION

A. Standard for Accelerated Decision

Motions for accelerated decision in the present context are analogous to judicial motions for summary judgment under Rule 56 of the Federal Rules of Civil Procedure ("FRCP"). RAD 40; *see also, e.g.*, *In re BWX Technologies, Inc.*, 9 E.A.D. 61, 74-75 (EAB 2000); *In re Clarksburg Casket Co.*, 8 E.A.D. 496, 501-02 (EAB 1999). The FRCP 56 summary judgment case law thus delineates the standard for evaluating Respondent's MAD.

Under that body of law, the moving party bears the burden of showing that no genuine issue of material fact exists. *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970). In addition, the court must construe the evidentiary material in the light most favorable to the non-moving party, making all reasonable inferences in that party's favor. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1987); *Adickes*, 398 U.S. at 158-59.

Guidance on these issues also comes from rulings of the Environmental Appeals Board ("EAB"). An accelerated decision is appropriate only if "no reasonable decisionmaker" could find in the non-movant's favor, viewing the facts in the light most favorable to the non-movant. *BWX Technologies*, 9 E.A.D. at 75. Thus, rendering an accelerated decision when contradictory inferences may be drawn from the evidence on a material issue is inappropriate. *Rogers Corp. v. E.P.A.*, 275 F.3d 1096, 1103 (D.C. Cir. 2002) (reversing grant of accelerated decision motion in EPA's favor granted by an Administrative Law Judge ("ALJ") and affirmed by EAB).

A factual dispute is *material* where, under the governing law, it might affect the outcome of the proceeding. *Clarksburg Casket Co.*, 8 E.A.D. at 501-02. A factual dispute is *genuine* if the evidence is such that a reasonable factfinder could find for the nonmoving party. *Id.*

The MAD fundamentally misstates the standard on which Respondent's motion must be decided. On this motion, the "dispositive and limited question" is not whether AMVAC "has taken appropriate steps to fulfill the requirements of the DCI within the timeframes required by the agency." MAD 41. To the contrary, resolution of Respondent's motion turns on whether Respondent, as the moving party, has brought forth evidence that, when evaluated against evidence provided by AMVAC and the Grower Petitioners,[1] *with all reasonable inferences*

[1] "Grower Petitioners" as used here refers to Petitioners Grower-Shipper Association of Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., INC.; and Huntington Farms.

drawn in favor of AMVAC and the Grower Petitioners, establishes that no reasonable decisionmaker could find in AMVAC's favor at a hearing.

Respondent's suggestion that its burden of persuasion as the moving party is shifted to AMVAC by virtue of 40 C.F.R. § 160.80(b), MAD 41, is incorrect. Section 160.80(b) establishes only that AMVAC will have the burden of proof ("persuasion") on certain issues *at the hearing*, not when opposing a motion for accelerated decision.[2] The substantive legal burden that will apply at a hearing or trial is relevant to a motion for summary judgment only to the extent that it informs the analysis of whether the non-moving party could conceivably prevail at the hearing/trial after resolving all inferences in the non-moving party's favor. *Anderson*, 477 U.S. at 252-253. Moreover, the legal burden AMVAC will carry at the hearing is the lowest commonly applied burden, *i.e.,* the preponderance of the evidence. *In re Ciba-Geigy Corp.*, 1990 WL 303827, at *3; *In re Bayer Cropscience Lp, & Nichino America, Inc.*, 2016 WL 3221021, at *6.

B. Standard for Suspension Under FIFRA's Suspension Provision

The appropriate legal standard is not well-defined by existing decisional law. EPA provided the Presiding Officer with little beyond recitations of the statute and general assertions concerning the degree of its own discretion which, if accepted, would eviscerate key elements of the relevant statutory language. AMVAC's position concerning the statutory standard is

[2] None of the cases cited by Respondent alter this conclusion. *Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324-25 (8th Cir. 1973) was not considering or describing a ruling on a dispositive motion. Nor was *Stearns Elec. Paste Co. v. E.P.A.*, 461 F.2d 293 (7th Cir. 1972), which likewise involved appellate review, not a dispositive motion before an ALJ. *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 653 (1980) refers to burdens under FIFRA in a footnote by reference to *Env't Defense Fund v. E.P.A.*, 548 F.2d 996 (D.C. Cir. 1976), however, *Environmental Defense Fund* is acutely dissimilar to the current proceeding. It involved appellate review of an "imminent hazard" suspension order entered after a hearing, which itself was held after almost a full year of cancellation hearings.

developed in Sections III.A.(1)-(5), below. In short, the Suspension Provision requires a decision-maker to determine at least three things: (1) what EPA's actual time requirement was, (2) whether the "steps" a registrant took "to secure the data" EPA requested within the time allowed by the Administrator was "appropriate," and (3) facts relevant to whether EPA's existing stocks provision is consistent with FIFRA. This inquiry is required by the Suspension Provision. Further, as discussed in the following sections, the portion of the Suspension Provision providing that the "only matters for resolution [at a hearing] shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend," does not limit the inquiry as Respondent suggests. MAD 8

III. ARGUMENT

As discussed in the Introduction, the text of the Suspension Provision plainly requires a facts and circumstances inquiry to determine if a registrant's conduct was "appropriate," which, as noted above, is the guiding principle of the Suspension Provision. The following sections examine the plain text of the Suspension Provision and the legislative history of both the Suspension Provision and parallel sections of FIFRA, which reinforce AMVAC's reading of the Suspension Provision. AMVAC then proceeds to examine OPP's historical approach to DCIs, which is consistent with AMVAC's reading rather than Respondent's current litigation position (*i.e.*, OPP has never before asserted that suspension is appropriate in a case with facts even remotely approximating this case).

Properly construed, the Suspension Provision requires a decision-maker to determine at least three things: (1) what EPA's actual time requirement was, (2) whether the "steps" a registrant took "to secure the data" EPA requested within the time allowed by the Administrator was "appropriate," and (3) facts relevant to whether EPA's existing stocks provision is consistent with FIFRA. None of these questions can be resolved without reference to the facts and are

therefore ill-suited for resolution at this time in the context of a motion for accelerated decision. There is also no evidence that the Congress that drafted the Suspension Provision intended the stated limitation on the matters for resolution at the hearing to limit exploration of the relevant issues enumerated above; such a result would be illogical.

After discussing the appropriate legal standard, AMVAC discusses in turn each of the data requirements referenced by the EPA in the NOITS and explains why Respondent's summary motion must fail as to each of them.

A. Determining Whether a Registration May be Suspended Under the Suspension Provision Requires a Facts and Circumstances Inquiry

Notably, Respondent's motion offers very little, if any, analysis of the "appropriate steps" standard set forth in the Suspension Provision. The following sections discuss how the plain text of the Suspension Provision requires a facts and circumstances inquiry to determine whether a registration may properly be suspended, and how the legislative history, comparison of the Suspension Provision to other portions of that Act, and EPA's past practice inform the correct reading of that text.

1. *The Plain Language of the Suspension Provision*

As noted above, the Suspension Provision provides in pertinent part:

> Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, ***within the time required by the Administrator***, has failed to take ***appropriate steps*** to secure the data required under this subparagraph . . . the Administrator may issue a notice of intent to suspend such registrant's registration of pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide.

7 U.S.C. § 136a(c)(2)(B)(iv).

FIFRA itself provides no statutory definitions of the key phrases "within the time required," or

"appropriate steps," nor has EPA promulgated any regulations on point.

Determination of the meaning of the Suspension Provision thus must begin by giving effect to "every clause and word" of the provision. *Duncan v. Walker*, 533 U.S. 167, 174 (2001); *Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or.*, 515 U.S. 687, 698 (1995).[3] The clause requiring that registrants "take appropriate steps to secure the data required [by a DCI]" is modified by the adverbial clause "within the time required by [EPA]." This plain language thus gives rise to two of factual questions flagged in the Introduction to this Memorandum: (1) what was the "time required" by EPA, and (2) did the registrant take "appropriate steps" to secure the data within that time?

Use of the word "appropriate" in a statute has a settled legal significance. It is "broad and all-encompassing" and "naturally and traditionally includes consideration of all the relevant factors." *Michigan v. E.P.A.*, 576 U.S. 743, 752 (2015). That there may be debate regarding the factors relevant to whether a registrant's actions were appropriate, or how those factors are to be weighed, itself precludes summary disposition in all but extreme cases (unlike this one). The mechanism for debating or weighing such factors is a hearing and evaluation by the Presiding Office, not an accelerated proceeding based on dueling affidavits.[4]

The phrase "appropriate" in the statute requires the consideration of all relevant factors before suspending a registration. *Michigan*, 576 U.S. at 759-60 (because cost was relevant, EPA

[3] This rule is particularly important when the word in question occupies a pivotal place in the statutory scheme, as "appropriate" does here. *Duncan*, 533 U.S. at 174.

[4] The Suspension Provision is distinct from other statutory provisions, such as the Clean Air Act ("CAA") provision at issue in *Michigan v. E.P.A.,* because in the Suspension Provision, "appropriate" modifies how a regulated party must conduct itself, not EPA. By contrast, the provision at issue in *Michigan* was describing the conditions under which EPA could extend its authority over a new class of power plants. The "appropriate steps" phrase in the Suspension Provision, by contrast, provides a safeguard against overreach by OPP by providing a standard for regulated party conduct.

action not accounting for cost was unlawful). EPA's narrow formulation of the Suspension Provision, however, eliminates many factors logically relevant to whether the registrant's conduct was appropriate. Each of the formulations it offers in the MAD, reads the phrase "appropriate" out of the Suspension Provision entirely. EPA would have the Presiding Officer focus solely on whether data was submitted, not AMVAC's extensive actions in preparing that data and otherwise taking steps to comply with the DCI, or of EPA staff in responding to AMVAC's submissions and challenges to the staff's interpretations. This violates a fundamental canon of statutory construction: that every word in a statutory provision be given effect. *Duncan*, 533 U.S. at 174.

2. *The Legislative History Supports AMVAC's Interpretation of the Suspension Provision*

The direct legislative history of the Suspension Provision further supports the conclusion that a hearing is required to explore issues related to the propriety of a NOITS when relevant facts are disputed. The Suspension Provision was added to FIFRA by Pub. L. No. 95-396, 92 Stat. 819, in 1978, often referred to as the "1978 Amendments." The overall history of the 1978 Amendments was complex, but demonstrates that the phrase "appropriate steps" was not casually employed. For example, the House Agriculture Committee Report for the House version of the 1978 Amendments (H.R. 8681, 95th Cong. (1977)) describes as a "major provision" of the 1978 Amendments the "establish[ment of] procedures governing the generation of additional data that may be required . . ., including [the] provision for requiring all registrants of a pesticide to take *appropriate steps* to secure additional data requested by the agency . . . ."[5]

[5] The Suspension Provision at issue in this proceeding is distinct from the Clean Air Act provision at issue in *Michigan v. EPA*. In the FIFRA context, "appropriate" applies to how a regulated party must act in response to an EPA directive – not how EPA must conduct itself. By contrast, the CAA provision at issue in *Michigan* was interpreted in the context of how EPA could extend its authority over a new class of power plants. This is a completely different

H.R. Rep. No. 95-663 (1977) (italics added). The reference to "appropriate steps," rather than any mention of a fixed timeframe, indicates that the provision is not intended to establish arbitrary deadlines.

The House Agriculture Committee continued, in the summary that followed the enumerated summaries of the bill's "major provisions," to note that "[i]f EPA should require additional data, *adequate time to develop the data must be granted* during which time the pesticide can remain on the market" (emphasis added).

A failure to submit data to EPA by any date certain was not a focus of the Agriculture Committee Report on the bill the House passed, H.R. 8681, 95th Cong. (1977), in connection with the Suspension Provision. This is striking given that the Agriculture Committee Report does discuss, in connection with the "appropriate steps" standard: (1) the 90-day response requirement; (2) failures to participate in arbitration; and (3) failures to reach agreement on joint data development. H.R. Rep. No. 95-663 (1977). The Committee may have believed no discussion of a date was needed given that the Congress also was directing EPA to provide "adequate" time for data development in the language cited above, in what would become 7 U.S.C. § 136a(c)(2)(A).[6] Congress was also aware that independent provisions of FIFRA already existed that would allow EPA to act if the Administrator believed that an approved product did not comply with the FIFRA "unreasonable risk" standard, including on an expedited basis if the Administrator perceived an "imminent hazard," current 7 U.S.C. §§ 136d(b), 136d(c), which had been present in FIFRA since 1947. The Suspension Provision was therefore not

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context from the "appropriate steps" phrase in the Suspension Provision, which provides a standard by which conduct by a regulated entity is judged.

[6] "If . . . the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information." 7 U.S.C. § 136a(c)(2)(A).

focused on addressing risks perceived by Administrator such that its meaning might be altered if EPA cited such a risk.

The report of the Congressional conference committee that synthesized the House version of the 1978 Amendments discussed above (H.R. 8681 and H.R. 7073, 95th Cong. (1977)) and the Senate version (S. 1678, 95th Cong. (1977)) is similar in focus. It reflects that the conferees altered the remedy in the Suspension Provision from cancellation to suspension and chose the House version (which required a hearing) over the Senate version (which did not). It also does not mention a simple lapse in time as a trigger for enforcement. H.R. Rep. No. 95-1560 (Conf. Rep.) (1978). There is no evidence in any of the legislative history that Congress intended to provide EPA with a cudgel with which it could threaten registrants who were actively engaged in discussions with EPA to fulfil data requirements, as opposed to registrants who completely failed to engage with EPA, or participate in data compensation arbitration.

3. *Comparison of the Suspension Provision to other Provisions of FIFRA Confirms that a Facts and Circumstances Inquiry is Required*

The fact that Congress did not intend to create a "date certain" standard without consideration of the circumstances of a registrant's response to a DCI is substantially bolstered by comparing the Suspension Provision to two other parallel sections of FIFRA.

The first is 7 U.S.C. § 136d(e)(1), added by the same 1977 Amendments as the Suspension Provision. It describes when the Administrator must seek to cancel a registration issued conditionally under 7 U.S.C. §136d(e)(1):

> The Administrator shall issue a notice of intent to cancel a [conditional] registration … if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met.

Condition (A) of this provision describes an ongoing obligation of the registrant to

"pursue appropriate action." The Administrator must continually assess the progress towards satisfaction of the condition, stepping in if that progress is not appropriate. Condition A and the Suspension Provision thus appear to be very similar in purpose.[7] By contrast, Condition B, turns solely on the "satisfaction of [a] condition" and the expiration of a fixed period. The registrant's conduct is irrelevant to Condition B. Congress's failure to include a Condition B in the Suspension Provision is fatal to Respondent's effort to read the Suspension Provision as rigidly supporting suspension if a purported deadline has been missed.

The second parallel section of FIFRA is actually two very similar provisions in close proximity to each other: 7 U.S.C. §§ 136a-1(d)(6) and 136a-1(f)(3), which were added by the 1988 Amendments to FIFRA, Pub. L. No. 100-532, 102 Stat. 2654. They created a similar Condition A/Condition B structure in the context of FIFRA Section 4 "Reregistration."[8]

7 U.S.C. § 136a-1(d)(6) reads:

> The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed [in the Suspension Provision] if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide [pursuant to "Phase Two" of Reregistration] or (B) the registrant has not submitted such data to the Administrator within [the Phase Two] time period.[9]

Like 7 U.S.C. § 136d(e)(1), discussed above, this provision establishes one condition in which appropriate action is relevant and one condition in which it is not. By contrast, whether a registrant has taken "appropriate steps" is relevant to *any* inquiry under the Suspension Provision. And "[w]here Congress includes particular language in one section of a statute but

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[7] A registrant's action (or "steps") might be appropriate at time X (for instance, a 90-Day response) but not at time Y (for instance, a 12-Month Response).

[8] Reregistration under Section 4 has since completed. Reregistration was driven by statutorily fixed timelines for both EPA and registrants to complete specified tasks, unlike the Suspension Provision.

[9] 7 U.S.C. § 136a-1(f)(3) creates the same "Condition A/Condition B" structure for Phase 4 of Registration Review and so is not set forth in full here.

omits it in another . . ., it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

The 1977 Congress was responsible for both the Suspension Provision and 7 U.S.C. §136d(e)(1), and so it is clear that Congress intended to create different criteria for the two provisions. Later, the 1988 Congress that drafted 7 U.S.C. §§ 136a-1(d)(6) and 136a-1(f)(3), was also focused on the appropriate standard of registrant conduct in response to requirements for additional data. The 1988 Congress even specifically revisited and amended 7 U.S.C. §§ 136a(c)(2)(B)(ii) and 136a(c)(2)(B)(iii) to clarify that failures to provide a 90-Day response or split an arbitrator's fee would trigger a suspension proceeding. The 1988 Congress, however, did not update the Suspension Provision to follow the Condition A/Condition B structure. H.R. Rep. No. 100-939 (1988).

In sum, in the MAD, Respondent appears to advocate for a "Condition B" system for non-Reregistration DCIs, in which the failure of a registrant to meet a deadline is independently sufficient to suspend a registration. Respondent is bound, however, by the Suspension Provision, which requires only consideration of whether a registrant's actions were appropriate, not whether a deadline was missed. The Suspension Provision thus requires a facts and circumstances inquiry not amenable to resolution through the context of a motion for accelerated decision.

4. *The Position EPA is taking in the Notice of Intent to Suspend is Inconsistent with the Office of Pesticide Programs' Historic Practice*

In light of the facts presented, OPP's attempt to suspend AMVAC's Dimethyl Tetrachloroterephthalate ("DCPA") Technical registration is unprecedented. EPA maintains a

list of currently suspended pesticide registrations on its OPP webpage.[10] An examination of the available notices for these suspensions reveals that in many cases where EPA has issued a NOITS, the registrants failed to provide an initial response to the relevant DCI notice within the required 90 days, failed to submit *any* data in response to the relevant DCI, or both. Our research has found no instances where a NOITS was issued after a registrant engaged in extensive ongoing communications with OPP commensurate with what AMVAC did in this case, or where OPP moved to suspend the relevant registration notwithstanding such extensive, ongoing engagement by the registrant.

Issuing a NOITS under the current circumstances is also inconsistent with the longstanding practice and procedure of the OPP with respect to DCIs. As is detailed in the Verified Written Statement of AMVAC Witness Ephraim Gur ("Gur (AMVAC) Statement") ¶¶ 21-29, OPP's longstanding practice in these matters has been to engage in iterative back-and-forth discussions and interactions with the registrant. This is particularly true where, as here, the DCI involves new or non-guideline study requirements that have not been fully developed, and it can take an inordinately long time for the registrant and OPP to reach a point where a study can be initiated and completed. *Id.* at ¶¶ 25-29. OPP's longstanding and consistent prior practice has been to engage in such an iterative process. Therefore, its decision to summarily cut short its interactions and communications with AMVAC, with no notice or indication that it was planning to do so, is unprecedented in OPP practice and procedure. *Id.* at ¶ 44.

This new and unprecedented interpretation by OPP works an "unfair surprise" to

[10] EPA, *Suspension of Registrants under FIFRA* (last updated Mar. 7, 2022), https://www.epa.gov/pesticide-reevaluation/suspension-registrations-under-fifra#:~:text=If%20a%20registrant%20fails%20to,EPA%20may%20suspend%20the%20pesticide.

regulated parties, and on that basis alone, the Presiding Officer should be skeptical of it. *Cf. Long Island Care at Home, Ltd. v. Coke*, 551 U. S. 158, 170 (2007); *Kisor v. Wilkie*, 139 S. Ct. 2400, 2418, (2019).[11] Respondent's position in the pending MAD also appears to be a "convenient litigating position," intended to insulate OPP from a fair examination of the facts, rather than a reflection of decades of DCI practice. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012).

5. *Respondent's New Narrow View is Incompatible with the Statute*

Respondent quotes the statutory phrase in characterizing the question presented – whether AMVAC has, within the timeframes required by EPA, failed to take "appropriate steps." MAD 39. Respondent does not, however, examine what "appropriate steps" means or how the decision maker is supposed to apply the phrase. Instead, Respondent essentially reads the phrase "appropriate steps" out of the statute, which is impermissible.

Respondent similarly offers at least three formulations of what "the time required by the Administrator," might mean and never clearly takes a position but all of EPA's alternatives are impermissibly narrow. EPA considers that "the time required": (1) may be the time set out in the DCI, MAD 1; (2) could be extended by EPA or based on just request from the registrant, MAD 22, 43; or (3) could be extended as may be reasonable based on "the timeline of EPA's responses." MAD 46 (implying that on certain facts, it may be possible to "articulate a legally-cognizable reliance interest created by the timeline of EPA's responses").

Respondent also offers a few possible alternatives as to the second question, *i.e.*, what a

[11] Administrative Law Judges should not defer to internal agency statutory interpretations under any of the *Chevron/Auer/Skidmore* administrative deference doctrines which apply to Article III courts, as EPA appears to imply at MAD 8. *In re Liphatech, Inc.*, 2014 WL 1012749, at *90 n.57 (2014) ("Because the [Environmental Appeals] Board is the final decision maker for the Agency, the concepts of *Chevron* and *Skidmore* deference do not apply to its deliberations").

registrant must do in "the time required." At one point, EPA says the registrant must submit data (or a waiver request) by the deadline as determined above. MAD 12. Elsewhere, Respondent states that the registrant must make its submittal sufficiently in advance of such deadline so that EPA (or its third-party contractor) can complete a full review of the data (or waiver request) to determine whether it is "adequate" in OPP's view before the deadline. MAD 22.[12]

At bottom, Respondent likely does not engage with the statutory standard because in its view, the standard need not be clearly articulated if it is to be the arbiter of that standard.[13] However, for the reasons discussed above, the Suspension Provision does not provide OPP the breadth of discretion is asserts. Congress is well aware of how to require regulated parties to perform a specified act by a date certain. Several parallel provisions of FIFRA do just that. The Suspension Provision is structured differently from those and, as a result, requires a facts and circumstances inquiry that is not amenable to resolution without a hearing except in extreme cases where a registrant's conduct before EPA bears no resemblance to the facts here.

B. The Suspension Provision Expressly Provides for Rather Than Prohibits the

[12] Requiring that EPA be able to confirm adequacy of submitted materials within "the time required by [the Administrator]" would require that registrants submit those materials an unknown amount of time before any applicable deadline, so that EPA could complete that internal review. EPA's suggestion that a registrant may be suspended if it submits a study by the applicable deadline that EPA (perhaps much) later deems inadequate in some particular is inconsistent with the statute and thus incorrect. MAD 1.

[13] If EPA really believes the standard is as cut and dry as they urge, it is conspicuous that they offer so many facts in support of their request for suspension. *E.g.*, NOITS, JX 1, Attachment III; five Verified Witness Statements; twenty-nine (29) pages of factual discussion in the MAD. All of this would be unnecessary of the only inquiry were whether a study had been submitted before the date in the DCI or in compliance with a formally granted extensions. EPA's flagging confidence in a standard that does not consider whether the steps taken by the registrant were appropriate in view of the facts becomes most apparent in the Bloom statement, which concedes that it is "not unusual for registrants to fail to meet some deadlines for registration review DCIs" but AMVAC's conduct has been "abnormal[]," Bloom (EPA) Statement at 4-5, and also at MAD 46 (conceding that the "factual and legal basis for suspension" may vary between studies). There would be no such variation in the strength of EPA's case if the standard can only be met by submitting a study (or having a waiver approved) the DCI deadline or a formal extension.

Necessary Facts and Circumstances Inquiry

The Suspension Provision states that a registrant, or other "person adversely affected" by a NOITS may request a hearing, at which,

> [t]he only matters for resolution … shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend . . ., and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [subchapter II of Chapter 7 of Title 7 of the U.S. Code].

7 U.S.C. § 136a(c)(2)(B)(iv).

The only possible predicate for suspension under the Suspension Provision (that is, the only possible "basis" for a suspension under that section) is a finding by the Administrator that a registrant "within the time required by the Administrator, … failed to take appropriate steps to secure the data required [by a Data Call In]." The "action that served as the basis" language in the second portion of the provision quoted above can only refer to the substantive "appropriate steps" standard laid out in the first section quoted above. It provides no more of a limitation than one would expect under the statutory scheme.

Respondent asserts repeatedly, seemingly based on the "only matters" language in the provision above, that the scope of the hearing is "limited," MAD 41-43. But Respondent points to no authority that bars development of factual testimony concerning whether AMVAC: (1) did in fact take appropriate steps within the time required by the administrator; (2) what the "time required by the Administrator" actually was; and (3) factual circumstances informing whether the proposed existing stocks provision is consistent with FIFRA.[14]

As discussed above, Congress ensured that a hearing would be available to explore these

[14] AMVAC does believe that there may be certain matters reserved for consideration by Article III courts, including the statutory sufficiency of time provided by EPA, and issues related to EPA's technical determinations concerning waivers. AMVAC does not waive its right to raise these or other appropriate issues in a subsequent proceeding.

issues, as well as issues relating to existing stocks. The Conference Committee chose the House version of the bill that created the Suspension Provision (which required a hearing) over the Senate version (which did not). H.R. Rep. No. 95-1560 (Conf. Rep.) (1978). This is clear evidence that Congress believed that a hearing should be available at which a registrant could defend its compliance with the statutory standard.

C. Genuine Issues of Material Fact Require a Hearing on EPA's Proposed Suspension of DCPA

The history of AMVAC's interactions with EPA as the parties jointly attempted to navigate AMVAC's responses to the DCI, is long and complex. EPA has chosen to take a kitchen sink approach and asserts that AMVAC has failed to comply with the Suspension Provision for 20 studies, rather than the single study it asserts is actually preventing it from performing a human health risk assessment, which AMVAC submitted yesterday with MRID 51931701. As explained below, Respondent's fact assertions are incomplete, inaccurate, and insufficient to deny AMVAC the right for a full hearing on all allegations raised by EPA in the NOITS.

As set forth above, any reasonable interpretation of the statutory standard for suspension requires an inquiry into: (1) what the "time required by the Administrator" was; and (2) whether the steps taken by the registrant during that time were appropriate. In some situations, unlike what is presented here, these inquiries may be relatively straightforward.[15] For example, if EPA sets a deadline in the DCI and never has any response or correspondence from or with the receiving registrants, then it may be appropriate for an ALJ to find that the "time required" was

[15] In fact, in all prior cases AMVAC is aware of in which EPA has sought suspension under the Suspension Provision, the facts involve an outright failure to respond, submit a waiver, or begin developing data. This NOITS has presented the Presiding Officer with a case of first impression on a multitude of issues.

the time originally set out in the DCI and the registrant did not take "appropriate steps" during that time. The same might be true where EPA has not itself been responsible for delays in the process.

Here, however, Respondent asks the Presiding Officer to navigate well outside the established legal standards described above to answer these two questions. The only way to avoid doing so would be to adopt a view of the legal standard for "appropriate steps" that is impermissibly narrow, *i.e.*, that only the deadline in the DCI (or perhaps any formally requested and granted extension) can be considered, and that a registrant's submittal of a study within that timeframe is a *sine qua non* to establish that a registrant has taken "appropriate steps." This interpretation would not only be inconsistent with the law, as explained above, but also inconsistent with EPA's well-established practice of it being (in the words of one of EPA's prepared witness statements) "not unusual for registrants to fail to meet some deadlines for registration review DCIs"[16] without penalty. As the testimony of Ephraim Gur demonstrates, it would also mean that most registrants would find themselves in violation of the statutory standard. Gur (AMVAC) Statement.

The complex and novel facts of this case effectively compel the Presiding Officer to apply the legal standard for accelerated decisions to a factual scenario never before posed in a case litigating the Suspension Provision. This unique case raises issues such as, at what point do delays caused by EPA (which are inherent in the DCI process) attain legal significance? One year? Three? Is it of legal significance if EPA, through its conduct, causes a registrant to have an objectively reasonable belief that the quarterly updates it is providing (and other correspondence) have apprised EPA of an updated schedule for data completion? Only with a

[16] Bloom (EPA) Statement at 4-5.

more complete understanding of the facts than Respondent has presented in the MAD can the Presiding Officer evaluate whether a reasonable decisionmaker could find in AMVAC's favor, drawing all inferences in AMVAC's favor where there is contradictory testimony.

The following sections highlight where relevant but contradictory testimony has already be presented that raises a genuine issue of material fact and therefore precludes the suspension of AMVAC's registration of DCPA technical through a motion for accelerated decision.

1. *Studies for Which AMVAC Requested Waivers in its Initial Response to the NOITS*

a. Facts Common to the Waiver Studies

There is no dispute that AMVAC provided a timely "Initial Response" or "90-Day" response to the DCI on April 29, 2013. *See* JX 5. There is also no dispute that in the Initial Response, AMVAC requested waivers for seven (7) of the twenty (20) data requirements at issue in this proceeding.[17] There is also no dispute that requesting a waiver is an appropriate response to a DCI requirement. *See* 40 C.F.R. § 158.45, MAD 6. Where a dispute begins to emerge is when and how EPA denied these waivers. This is relevant to both what the time required by the Administrator was and whether AMVAC's conduct was appropriate.

EPA asserts that it denied AMVAC's waivers for the two E-Fate studies on March 21, 2014. Verified Written Statement of EPA Witness Stephen Wente ("Wente (EPA) Statement") at 6-7. EPA asserts that it denied the four Ecological Effects waivers also on March 21, 2014 (NOITS at 11-16, although EPA witness Wendel concurs with this only as to Guideline 840.4500/5400 and makes no claim as to when the other three were denied). Critically, EPA's

[17] These were all for the degradate TPA, Guideline 835.4300 and 835.4400 Environmental Fate studies, *see* Wente (EPA) Statement at 6-7, and a Guideline 850.1350, three Guideline 850.1400, and a Guideline 840.4500/5400 Ecological Effects Study. Wendel (EPA) Statement at 3, 5, 8. AMVAC later requested a waiver for a Guideline 835.4200 soil metabolism study after initially indicating it would cite existing data.

references to a March 21, 2014, denial of waivers are based on the date of the document in which EPA determined those waivers should be denied. MAD 14-15. AMVAC witnesses assert, however, that these documents were not provided to AMVAC until three years later in March of 2017. *See* Verified Written Statement of AMVAC Witness Richard S. Freedlander ("Freedlander (AMVAC) Statement") at 9; Wood (AMVAC) Statement at 3, discussing JX 36, 37. This is a key fact dispute that requires resolution after hearing.

Viewed in the light most favorable to AMVAC, based on the evidence available for purposes of evaluating Respondent's MAD, the sequence plays out as follows. AMVAC submits seven timely waiver requests in April, 2013. AMVAC hears nothing from EPA until almost four (4) years later, in March, 2017. By then, by no fault of AMVAC, the nominal DCI deadlines for each of the studies for which a waiver was requested is long past (more than three years for the Ecological Effects studies and two years for the E-Fate studies, according to the DCI, JX 4).

In view of this sequence, EPA cannot credibly claim that the nominal deadlines from the DCI were still in force.[18] Nor can it credibly claim that AMVAC was required to submit requests for extension to permit EPA to continue EPA's review of information timely submitted by AMVAC.

Moreover, after finally receiving EPA's first responses to its timely waiver requests in 2017, and thus being aware of EPA's thinking concerning the waivers in March of 2017, AMVAC provided more information to EPA in February, 2018, including data from additional

[18] As discussed in Section III.A.3, EPA itself has acknowledged that it would make sense to "stop the clock" on DCI time frames when waiver requests are received. As discussed in the expert testimony of Mr. Gur, it is rare for registrants to submit extension requests to accompany waiver requests and EPA sometimes actively discourages this practice because of the burden it places on the industry. Gur (AMVAC) Statement at 8-9.

studies where appropriate. Freedlander (AMVAC) Statement at 14-15, discussing *Daphnia* study relevant to the Ecological Effects studies referenced in n. 9). This approach was specifically endorsed by EPA. Freedlander (AMVAC) statement at 10, discussing EPA recommendations in JX 66.

There is no dispute that AMVAC's February, 2018, submission addressed all the studies discussed in this section, *see* n. 16. It is uncertain, however, when EPA actually reviewed AMVAC's February 2018 submission. *See* Wood (AMVAC) Statement at 7 (discussing technical issue with EPA CDX system that may have prevented EPA from being aware of February 2018 Waiver Request until August of 2020 or later); Wente (EPA) Statement at 7 (not mentioning a delay in receipt of the 2018 Waiver Requests); October 16, 2020 Data Delay Letter, JX 21 (referring, in n. 5 for the studies discussed in this section[19] to the EPA correspondence denying waivers dated in 2014 that AMVAC contends it did not receive until 2017, and nowhere referencing AMVAC's 2018 submission). A hearing will shed light on this important issue.

Furthermore, after receiving the October 16, 2020 Data Delay Letter, JX 21, it is undisputed that AMVAC provided additional information as requested by EPA in December of 2020, even though the Data Delay Letter did not acknowledge the February 2018 Waiver Request or indicate if it had been received or reviewed. Wood (AMVAC) Statement at 8. It is also undisputed that EPA provided no further response until April 2022, when it released two Memoranda denying AMVAC's Ecological Effects and Environmental Fate waiver requests at the time it also issued the NOITS. JX 69, JX 79 (both dated April 19, 2022).

[19] Except for the Guideline 840.4500/5400 study, for which the Initial Response waiver request is not acknowledged at all.

Therefore, in the light most favorable to AMVAC it appears that AMVAC submitted timely waivers in 2013, did not hear back until 2017, submitted additional information in 2018 (in part based on new studies at EPA's suggestion), and did not receive a substantive response from EPA until the NOITS had already been issued in 2022.

At the very least, this presents a triable issue of fact as to whether AMVAC acted reasonably under the circumstances and whether EPA's conduct reasonably led AMVAC to believe that the original deadlines were no longer applicable (as to these and the other studies discussed below), and that it was not until the issuance of the NOITS that EPA made its position concerning the passage of deadlines clear.

AMVAC recognizes that there is a dispute as to the *adequacy* of the additional information provided by AMVAC in 2018 and 2020 concerning the waivers it submitted, and whether AMVAC's responses demonstrate "appropriate steps" towards satisfaction of the DCI in light of EPA's unilateral delays.

b. Facts Specific to Certain Waiver Studies

i. Guideline 835.4300 TPA Aerobic Aquatic Metabolism Study

For the Guideline 835.4300 TPA Aerobic Aquatic Metabolism Study only, AMVAC has determined that the response it provided in February of 2018 misled EPA into believing that AMVAC would be conducting a new study rather than stating that EPA should consider an already-submitted study in connection with the TPA data requirement, as AMVAC intended to convey. JX 68. AMVAC's intent was to direct the agency to a previously submitted study, MRID 49307515, Nelson, T. (1984) An Aerobic Aquatic Soil Metabolism Study with (Carbon 14)- Dacthal. Unpublished study prepared by SDS Biotech Corporation. 44 p. This was the same study that AMVAC submitted to EPA in January of 2014 to fulfil the DCPA Guideline

835.4300 requirement, which is no longer outstanding.

When AMVAC stated in JX 22, in response to JX 21, "[t]he Agency's rationale for not requiring further studies for DCPA also applies to TPA," it intended to convey that EPA should consider the study referenced in connection with TPA as well as DCPA. AMVAC did not determine that there had been a miscommunication about AMVAC's intent between sending in JX 22 in 2020 and the issuance of the NOITS in 2022 because there was no further communication with the agency that would have alerted AMVAC to the issue. *See generally* Freedlander (AMVAC) Statement at 18-19. Only after AMVAC saw how EPA had characterized JX 22 in the NOITS, at 9, and the written statement of Stephen Wente, did AMVAC realize that EPA had misconstrued JX 68 and JX 22. While AMVAC could have been clearer in its communications, resolving all inferences in AMVAC's favor still requires a finding that AMVAC made a good faith effort to comply with the requirement by directing EPA's attention to MRID 49307515. As noted above, AMVAC did not understand that there had been a breakdown in communication until reviewing documents provided recently. There are grounds upon which a rational decisionmaker could find that AMVAC took appropriate steps, in view of this and the Agency's conduct in connection with the waivers more broadly and the Data Delay letter as discussed in Sections III.C.1.a and III.C.2. A hearing is appropriate under the circumstances so that the Presiding Officer can hear testimony from Messrs. Wente, Freedlander, and Wood to elicit all facts relevant to this data requirement.

ii. Guideline 835.4200 and Guideline 835.4400 Anaerobic Metabolism Studies

For the Guideline 835.4200 study, EPA provided an additional study-specific response, JX 77, in addition to the March 2014 document not received until 2017 as discussed above (JX 66). JX 77 stated that EFED "believe[d] that a reliable anaerobic soil metabolism study for TPA

is still needed for risk assessment," but stated that EFED "will [conservatively] assume stability [for risk assessment purposes] in the absence of a [TPA Guideline 835.4200] study." As discussed in Section III.C.2, this contributed to AMVAC's understanding that additional attempts to avoid unnecessary studies through supplemental waiver requests would not be misplaced. AMVAC even provided a round of supplemental information in December 2020; EPA's October 16, 2020 letter had referenced waivers submitted in 2016 rather than more recent ones submitted in 2018. Freedlander (AMVAC) Statement at 21. AMVAC did not receive any response until the NOITS. A reasonable decisionmaker could conclude, on the facts above, that AMVAC took appropriate steps to satisfy the DCI requirement within the time allowed by EPA.

iii. Guidelines 850.1350; Guideline 850.5400; and Guideline 850.1400 Fish Early Life Stage Studies (TPA)

In addition to the facts set forth concerning the studies for which waivers were originally timely requested in the Initial Response generally, it is of note that AMVAC was responding to constructive agency suggestions to conduct alternate tests on which waivers could be reevaluated in connection with this study. Freedlander (AMVAC) Statement at 14-15 (850.1350, 850.5400); 10-13 (850.5400). AMVAC heard nothing concerning this approach between 2020 and the time the NOITS was issued in April of 2022. A factfinder could determine that AMVAC was acting reasonably in attempting to follow the path EPA laid out for it in connection with these studies.

2. *The Importance of the October 16, 2020 Data Delay Letter*

Relevant to all data requirements subject to the NOITS, it is noteworthy that EPA's October 16, 2020 "Data Delay Letter," JX 21, suggested that all outstanding data requirements could, as of Oct. 2020, still be "timely" completed by AMVAC:

EPA would like to remind AMVAC that completion and submission of required

> studies will not necessarily lead to changes in the risk estimates or safety factors used in the Draft Risk Assessment. These data are required by the DCI and, *if submitted in a timely manner*, EPA expects to use them in Registration Review to assess the risks of the chemical.

JX 21 (emphasis added). A consideration of whether AMVAC took *appropriate steps within the time required* must consider EPA's statements relevant to what would be considered timely. A reasonable decision maker could find that a statement such as the above, alone or in combination with other statements and actions of EPA, suggested to AMVAC that the time for final action on certain data requirements had not passed, and in fact would not occur until some future point, and that in the interim, there would be additional discussion between EPA and AMVAC concerning those requirements. This was the entire purpose of the Data Delay Letter, JX 21, to solicit a response concerning how AMVAC intended "to satisfy the remaining data requirements," which AMVAC provided. JX 22; Wood at 7-8.

Additionally, in the data delay letter and in many other instances, EPA indicated that certain data would not prevent risk assessment but would only cause EPA to have to use conservative assumptions:

> The Agency will rely upon data available at the time when the risk assessments are being developed. Where the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments.

JX 21; *see also* Freedlander at 8, 13, 16, 21 (discussing selected instances of the Agency noting this). Viewed in the light most favorable to AMVAC, these repeated references to EPA's ability to proceed with risk assessment even without certain studies would affect what might constitute an "appropriate step" under the circumstances. At a minimum, in conjunction with other statements which, viewed in the light most favorable to AMVAC, suggested that AMVAC and EPA were engaged in an ongoing dialogue in which AMVAC still had the opportunity to timely comply with outstanding data requirements, the statements about the possible use of conservative

assumptions in risk assessment for certain studies would have reasonably caused AMVAC to believe that there was additional time for discussion with the agency concerning those studies.

3. *The CTA Study*

Any factual disputes regarding whether AMVAC failed to meet the data requirement for the CTA study in the DCI are now moot because AMVAC submitted the final report for the CTA study to EPA on June 20, 2022, (MRID 51931701). Thus, the CTA study can no longer serve as a basis for a suspension of AMVAC's DCPA technical registration.

Even if whether AMVAC took appropriate steps to meet the CTA data requirement in connection with the study as it was recently submitted to EPA, a reasonable decisionmaker considering the uncontroverted facts (as summarized in the Verified Written Statement of AMVAC Witness Ann Jonynas ("Jonynas (AMVAC) Statement")), could find that AMVAC's actions constituted "appropriate steps."

AMVAC engaged in extensive and iterative discussions and interactions with EPA to craft protocols for numerous precursor studies and generate the data required to meet the CTA data requirement from the issuance of the DCI in 2013 through the time it was submitted. The scope of this interaction is not reasonably in dispute; the statements of Jonynas (AMVAC) and Mendez (EPA) amply support a conclusion that EPA was kept up to date on what was going on with all the stages of the process. EPA notes many of these same facts and interactions but omits several key facts in the chronology of the CTA study history where EPA caused delays and significantly contributed to the length of time it took AMVAC to fulfill this data requirement.

For example, EPA witness Mendez indicates that EPA completed its review of the initial protocols for the CTA study on November 19, 2013, Mendez (EPA) Statement at 3, but fails to mention that EPA's review was not provided to AMVAC until 11 months later on October 21, 2014. Jonynas (AMVAC) Statement at 7. In addition, Mendez indicates that EPA told AMVAC

to consult a 2005 EPA CTA guidance document to design the study protocols. *Id*. at 3. Mendez' testimony, however, omits the fact that EPA did not provide AMVAC with the 2005 guidance until October 23, 2014, well after issuance of the DCI and after AMVAC had expended time and resources to prepare and submit initial protocols to EPA that were then rejected. Jonynas (AMVAC) Statement at 7. The 2013 DCI made no mention of the 2005 guidance, Freeman (AMVAC) Statement at 7, which was generally known to exist, even to specialists working in the CTA field at that time, Freeman (AMVAC) Statement at 7.

Jonynas' uncontroverted testimony also shows that AMVAC was, on numerous occasions, directed by EPA not to proceed with certain preliminary studies that were necessary to conduct the definitive CTA study until after EPA had approved the protocols for those studies and/or reviewed the results of other preliminary work. Jonynas (AMVAC) Statement at 4. In some cases, EPA admits that even though a protocol was "adequate" EPA nonetheless made additional requests for modification. Mendez (EPA) Statement at 6. Additionally, EPA now asserts that is has concerns based on certain range finding studies even though it reviewed them and approved moving forward in view of them. *Id*. at 6-7. Jonynas' testimony further shows that collectively it took EPA approximately 40 months in total to review and approve all the various protocols for the range finding studies and the definitive study for the DCPA CTA data requirement. Freeman (AMVAC) Statement at 6.

This is longer than the total time in which AMVAC was supposed to satisfy the requirement. No reasonable fact finder would conclude, in light of this and the extensive interactions, that the "time required" by the Agency was actually 24 months, or in fact any length of time shorter that what the Agency ultimately understood it was going to take, as they were kept up to date at all times and never advised that any subsequent "deadline" was approaching or

had been missed.

Ms. Mendez states that on average it takes 3 to 5 years after a CTA study is required in a DCI to conduct the definitive study and submit it to EPA to complete the data requirement. Mendez (EPA) Statement at 3. AMVAC, however, was only provided a timeframe of 2 years to do this. JX 4. The testimony of AMVAC expert witness Freeman concludes that based on facts and chronology provided in Jonynas' testimony (including all the interactions between the parties, and the delays in receiving approvals and other reviews from EPA), it was not unreasonable that it took 9 years for AMVAC to complete the definitive CTA study and submit it to EPA. Freeman (AMVAC) Statement at 8.

Based on the above, a reasonable factfinder, taking into account all of the uncontroverted facts provided in the statements of Jonynas and Freeman, and resolving contradictory inferences in AMVAC's favor, could conclude that AMVAC acted appropriately at all times related to the CTA study; that AMVAC worked as diligently as possible to complete all precursor work and the study itself, and that because AMVAC kept EPA continually up to date and EPA understood the time required, there is no artificial passed deadline that renders suspension appropriate.

4. *Series 860 Residue Chemistry Studies*

The Series 860 residue chemistry studies present a unique question in the context of this proceeding because AMVAC's approach to this data requirement was different than the rest; AMVAC's response to the data requirement (after initially and timely providing EPA additional data regarding a prior study, which EPA rejected, *see* JX 5 Attachment 3 (AMVAC's explanation) and JX 30 (EPA's October 23, 2013 response addressing all four requirements)) was to inform EPA that it would update DCPA labels to obviate the need for the studies. *See generally* Verified Written Statement of AMVAC Witness Julie Porter ("Porter (AMVAC) Statement") at 2-6, Wood (AMVAC) Statement at 2-6. JX 30 generally indicated that the

Guideline 860.1300, 860.1340, and 860.1480 studies might not be needed based on satisfaction of Guideline 860.1900. *See also* Verified Written Statement of EPA Witness Danette Drew ("Drew (EPA) Statement") at 4, 6, 7. AMVAC had timely submitted additional information that it believed would satisfy the Guideline 860.1900 requirement, but this additional information was deemed insufficient by EPA. *See* JX 28 (HED July 7, 2014 Response). AMVAC shortly thereafter (on August 11, 2014) provided EPA with additional information concerning the Guideline 860.1900 requirement. *See* JX 32.

EPA authored a memorandum in response, dated February 17, 2015, specifying label language that EPA thought would be "appropriate" in view of the "available rotational crop data." JX 32. This information was *not provided to AMVAC until about two years later*, however. *See* Wood (AMVAC) Statement at 3. EPA's Verified Witness Statement of Danette Drew does not refer to any subsequent activity after the drafting of this memorandum. Drew (EPA) Statement at 8-9. After finally receiving JX 32, and after a phone conference with EPA, AMVAC submitted label modifications it believed would satisfy EPA's request. Wood (AMVAC) Statement at 4. AMVAC was responsive to EPA requests from that point, including for additional label modifications in 2019. The October 16, 2020 Data Delay letter, in which EPA was of course focused on what requirements were outstanding, stated that the "Study Status" of the Guideline 860.1300, 860.1340, 860.1480, and 860.1900 data requirements, "In review" and that "label amendments [have been] submitted to satisfy [the requirements]." JX 21.

On March 23, 2022, only about a month before the NOITS would be issued, Jill Bloom from Pesticide Reevaluation Division ("PRD") contacted AMVAC by phone and discussed the status of these label amendments with Jon Wood of AMVAC. Wood (AMVAC) Statement at 5. Ms. Bloom then sent an email asking for copies of prior submissions, stating, "It would be very

helpful if you could provide copies of the relevant submissions. If you have the dates of the submissions and any associated cover letters or other contemporaneous correspondence that were sent with them, that would also be helpful." JX 50. AMVAC send the requested summary, and the prior correspondence, two days later. *Id.* Neither the statements of EPA witnesses Jill Bloom nor Danette Drew discusses this time period and so the testimony of Mr. Wood is uncontroverted, even though any inferences would have to be resolved in AMVAC's favor in resolving this motion in any event.

Based on the above, a reasonable factfinder could conclude that AMVAC acted appropriately at all times related to these studies. The only brief delay in its response is explained by the fact that an EPA 2015 Memorandum was not transmitted to AMVAC until 2017. After that, AMVAC believed it was finalizing label amendments that would be acceptable to EPA (based on EPA's own suggestion) and would eliminate the need to the Series 860 residue studies. The October 16, 2022 letter suggested that EPA was reviewing the proposed amendments. One month before the NOITS was issued, EPA reached out asking for copies of prior correspondence in a manner that raises the inference that that correspondence had not been substantively reviewed by EPA at that point. EPA's timeline in the NOITS does not mention this outreach. JX 1 at 18-22. EPA's present contention that the label amendments submitted by AMVAC do not eliminate the need for the data are irrelevant (even if true) because AMVAC was not aware of this contention until the issuance of the NOITS and its review of the Drew (EPA) Statement. AMVAC reasonably understood the EPA to be actively reviewing its submissions at all times prior to the NOITS and so was not on notice that any updated proposals were required.

5. *The DCPA Fish ELS Studies*

AMVAC timely indicated in its initial response to the DCI on April 29, 2013, JX 5, that it

would submit existing data for the Fish Life-Cycle Toxicity Guideline for DCPA. EPA's witness statement asserts that this data was never submitted. Verified Written Statement of EPA Witness Christina Wendel ("Wendel (EPA) Statement") at 5. In fact, a trout study was submitted to EPA on January 30, 2014. Freedlander (AMVAC) Statement at 2. EPA ultimately accepted the trout study, but still required performance of the Guideline study on bluegill sunfish and sheepshead minnow. AMVAC's attention was brought to the 2 missing studies in October of 2020, in the Data Delay Letter which referenced two EPA documents from 2019 that AMVAC had not previously been provided. Freedlander (AMVAC) Statement at 2. These documents showed that EPA had not completed its review of the trout study that was submitted in 2014 until 2019. *Id.* at 2-3 AMVAC quickly initiated these studies. *Id.* at 3.

Both of these studies began on March 21, 2021. The bluegill study (conducted on allowed alternative species fathead minnow) has already been submitted on June 7, 2022, (MRID 51926601). The sheepshead minnow study is expected to be provided on July 15, 2022. *Id.* at 3; Wendel (EPA) Statement at 5. A factfinder could reasonably conclude that AMVAC acted appropriately because it provided a timeline initial response and initiated work on the two additional species studies shortly after EPA's October 2020 communication. Similar to the CTA study, the Presiding Officer should also conclude that, as a matter of law, now that one of these studies has been submitted (with the other soon to follow) they cannot be a basis for suspension.

6. *The DCPA Seedling Emergence Study*

The testimony is uncontroverted that AMVAC submitted a Guideline 850.4100 study to EPA in January of 2014, after timely indicating its intention to do so in its Initial Response to the DCI in 2013. *See generally* Freedlander (AMVAC) Statement at 4-5; Wendel (EPA) Statement at 5-6. This study was deemed acceptable for EPA as to all crops tested except for

lettuce. *Id.* Critically, however, EPA did not provide its assessment of the study to AMVAC (attached to a memorandum dated January 6, 2022, JX 59) until the same time the NOITS was issued. *See* Verified Written Statement of AMVAC Witness Niamh McMahon ("McMahon (AMVAC) Statement") at 5 (discussing first receipt of JX 59 and numerous other documents in April of 2022). A reasonable factfinder could conclude, based on this testimony, that AMVAC took appropriate steps to submit the study in 2014. A reasonable factfinder could conclude that the issues EPA has identified with respect to lettuce only, *see* Wendel (EPA) Statement at 7, do not negate the inference that AMVAC's steps in initially submitting the study were appropriate. A contrary finding would mean that any time EPA identifies an issue with a submitted study after it has been submitted, the submitting registrant is, as a matter of law, subject to a potential suspension proceeding even if, based on the facts of this case, EPA took eight (8) years to identify and communicate its concerns. AMVAC is discussing the identified issues with the lab and will provide EPA with additional data as required. Freedlander (AMVAC) Statement at 5-6. It has responded appropriately in view of the fact that EPA's review was supplied at the same time as the NOITS.

7. *Guideline No. 850.2100 Acute Avian Oral Toxicity (Passerine)*

For this data requirement, there is no dispute that AMVAC timely indicated in its initial response that it would conduct the needed study, or that AMVAC provided a protocol for that study with its initial response in April of 2013. JX 5; Jonynas (AMVAC) Statement at 24; Wendel (EPA) Statement at 6-7. There is also no dispute that EPA subsequently told AMVAC that a particular version of the protocol had been accepted from other registrants, or that AMVAC proceeded to run the protocol suggested by EPA. Jonynas (AMVAC) Statement at 24, JX 53. AMVAC also advised EPA via email on March 6, 2014 that it "would like to request a

time extension until 10/30/2014" and inquired whether EPA "would like a formal request" for such an extension. *Id.* It is uncontroverted that EPA never responded in the seven months before AMVAC would ultimately submit the study. *See* Verified Written Statement of EPA Witness Julie Bloom ("Bloom (EPA) Statement") (the recipient of the email) and Wendel (EPA) Statement (discussing the study). *See also* MAD 22 n. 13 ("EPA does not have a written record granting AMVAC's request in writing . . ..").

This lack of response by EPA early in the DCI process has ramifications for the "appropriate steps" inquiry *far beyond just this study*. Viewed in the light most favorable to AMVAC, EPA's complete lack of a response to an inquiry about whether an extension request was necessary supports the inference that AMVAC reasonably believed EPA did not require such extension requests, at least for studies for which AMVAC informed EPA about its progress, if not all studies.

It is also uncontroverted that EPA did not provide a response concerning the study submitted in 2014 until the same time as the NOITS was issued in 2022 (with the review being dated in December of 2021). Jonynas (AMVAC) Statement at 25; McMahon (AMVAC) Statement at 5 (referring to receipt of JX 55). In view of this, AMVAC's actions are appropriate regardless of EPA's conclusion that were not shared until 8 years after the study was submitted. The history of this guideline requirement provides a case study in how EPA's own actions cannot possibly be irrelevant to the "appropriate steps" inquiry. It is uncontroverted that EPA's untimely revealed concern with the 2014 study would have required AMVAC to test at levels AMVAC did not believe to be consistent with the Guideline at the time of the testing. Jonynas (AMVAC) Statement at 25. This issue could already have been timely addressed if EPA had completed its review in a timely manner. AMVAC took appropriate steps

at all times prior to issuance of the NOITS.

8. *The DCPA Chronic Sediment Toxicity Chironomus Special Study*

The factual record leading up to and including the submittal of the SS-1069 (non-guideline) Chronic Sediment Toxicity – *Chironomus dilutus* ecological effects study does not appear to be in dispute. After AMVAC timely provided a protocol with its Initial Response in April of 2013, JX 5, EPA reviewed the protocol and provided comments (including revisions) in October of 2014. Freedlander (AMVAC) Statement at 6, Wendel (EPA) Statement at 8. AMVAC then initiated the study and submitted it after it was complete two years later in March of 2016. *Id.* At this point Respondent's witness provides no further dates, *see* Wendel (EPA) Statement at 8-9, and so the testimony of AMVAC's witnesses Freedlander and McMahon is uncontroverted. The uncontroverted Freedlander and McMahon testimony is that, as with several other studies, AMVAC did not receive any response from EPA until concurrent with the issuance of the NOITS in April of 2022. Freedlander (AMVAC) Statement at 7; McMahon (AMVAC) Statement at 5. The response that was received in 2022 was initially reviewed and signed in January of 2017. Freedlander (AMVAC) Statement at 7, referring to JX 63.[20] The response from EPA determined the study to be "scientifically sound", *i.e.,* not unacceptable but classified it as "supplemental" because of potential solvent control issues. Freedlander (AMVAC) Statement at 7. This is a technical laboratory issue that is beyond

[20] For this study and the several others for which EPA-generated documents were not provided to AMVAC until years after they were authored, *see* McMahon (AMVAC) Statement at 5, the EPA staff that authored those documents may have been unaware that the documents had not been transmitted to AMVAC. EPA staff therefore may have formed the opinions that contributed to the issuance of the NOITS (*i.e.*, that AMVAC was taking an excessively long time to respond) during a time period when AMVAC had nothing to respond to for these data requirements. EPA's witnesses provide no testimony concerning the circumstances that led to the large amount of reviews being communicated to AMVAC concurrent with the NOITS.

AMVAC's control. A reasonably decisionmaker resolving contradictory inferences in AMVAC's favor, could find that AMVAC's actions, as set forth above, constituted appropriate steps.

9. *The DCPA Mysid Life-Cycle Chronic Toxicity Test*

AMVAC has provided uncontroverted testimony that it submitted a study to address Guideline No. 850.1350 Mysid Life-Cycle Chronic Toxicity Test, on January 30, 2014. Freedlander (AMVAC) Statement at 3-4. Wendel (EPA) Statement at 4, acknowledges receipt of this study but does not specify the time of receipt, or of any subsequent action. The uncontroverted testimony is therefore that EPA initially reviewed this study in October of 2016, but that the review was not finalized internally until December of 2021, and the review was not provided to AMVAC until April of 2022 concurrent with the NOITS. Freedlander (AMVAC) Statement at 3-4; McMahon (AMVAC) Statement at 5. EPA's review, not provided until six years after study submittal, concurrent with the NOITS, indicated that the study was "scientifically sound" and classified the study as "supplemental, may be used for risk characterization." Freedlander (AMVAC) Statement at 4; JX 56. Thus, even in view of the testimony of Wendel (EPA) Statement at 4 concerning potential limitations of the data submitted, a reasonable decision maker could conclude that AMVAC took appropriate steps to run and submit the study based on the protocol. The fact that EPA asserts that it cannot "confidently refine [certain] conclusion[s] further," Wendel (EPA) Statement at 4, based on data obtained from a scientifically sound study is not relevant to the statutory standard for suspension, *i.e.*, that AMVAC took appropriate steps within the time required to submit the data. Even if it were relevant, it would be plainly inconsistent with the statute to rule that EPA may suspend a registration based on limitations of a study that EPA had under review for years, did not find to

be unacceptable and for which EPA did not share its review until concurrent with a NOITS.

10. *The DCPA Leptocheirus Chronic Sediment Toxicity Study*

The testimony concerning the Leptocheirus Chronic Sediment Toxicity Study, Special Study "SS" 1072 is largely consistent between the parties through 2016. *See* generally Porter (AMVAC) Statement at 6-8, Wendel (EPA) Statement at 9. AMVAC submitted a protocol for review with its timely Initial Response in April of 2013. EPA reviewed that protocol and provided comments in March of 2014. *Id.* AMVAC proceeded to submit a series of updates to update EPA concerning difficulties being experienced with executing this protocol on an industry wide basis. The study was proving so difficult to execute that an ad hoc group of the North Atlantic Regional Chapter of the National Society for Environmental Toxicology and Chemistry ("NACSETAC") had been convened in Vancouver to discuss the difficulties. Porter (AMVAC) Statement at 6-8. EPA does not acknowledge these issues in the testimony of its witnesses but does so in a June 27, 2016, document responding to a waiver request by AMVAC for this study. JX 39. The waiver denial agreed that AMVAC's assertions that DCPA showed only "minor toxicological effects" in relevant comparable species for which data was available and that sediment dwelling organisms such as Leptocheirus "display[ed] a much lower level of sensitivity" to other organisms for which data was available were "consistent with … study reports" EFED was reviewing. JX 39 at 2.

After acknowledging the "challenges some laboratories have experienced running the chronic sediment toxicity test," EPA refused to waive the study, but offered that AMVAC could instead perform a different guideline study, an acute study under Guideline 850.1740. JX 38 (dated June 27, 2016, not transmitted to AMVAC until July 18, 2018 per JX 75). AMVAC supplied additional data in support of its waiver request on November 22, 2016. Freedlander

(AMVAC) Statement at 23-24, referring to JX 76. EPA's witness testimony concerning this data requirement does not refer to this additional request, which was substantive. JX 76. EPA's October 16, 2020 Data Delay letter, JX 21, also does not refer to JX 76. Nor does the NOITS, JX 1 at 25, or a waiver response transmitted also in April of 2022 with the NOITS, JX 69. *See* McMahon (AMVAC) Statement at 5. This raises the inference that EPA has not reviewed the substantive November 2016 submission, JX 76. JX 69 refers only to the earlier submission in 2016 (Project Number: 100/AQU/028 rather than -031).

AMVAC then awaited confirmation from EPA that EPA would consider the guideline requirement satisfied if the alternate acute study EPA suggested did not show any effects. AMVAC was waiting for a response from EPA concerning this until at least March of 2017. Wood (AMVAC) Statement at 7. AMVAC does not have a record of the exact time that EPA confirmed that it would not fully waive SS-1072 even if the proposed alternate Guideline 850.1740 showed no effects, however, EPA's position was clarified by at least October of 2020 in the Data Delay Letter. JX 21. AMVAC timely responded to the Data Delay Letter, JX 22; Wood (AMVAC) at 7-8 and advised that it would await validation of a chronic study (*i.e.*, a workable protocol for SS-1072) or confirmation that Guideline 850.1740 was being formally included in the DCI. EPA did not respond until 2022, again indicating that Guideline 850.1740 would be required in addition to, not instead of, SS-1072. JX 1 at 25-26.

A reasonable decisionmaker could conclude that AMVAC's requests for waivers of the SS-1072 chronic study represented appropriate steps solely in view of the fact that the Leptocheirus chronic protocol was not working and had not been validated. AMVAC's assertions concerning the limited toxicity of DCPA for the relevant species/medium are additional but cumulative reasons why its waiver requests represented appropriate steps.

It is further reasonable for AMVAC to insist that EPA formally add an alternate, additional Guideline 850.1740 study to the DCI. Otherwise there would be no meaningful restriction on EPA's ability to "move the goalposts" on what the scope of the DCI even is. The Presiding Officer should not find that EPA may support a suspension order on the basis of non-performance of a study that was not included in the DCI in the first instance without formal amendment of the DCI. Even if the Presiding Officer determines that suspensions based on data requirements not formally added to the DCI are legally possible, it is still the case that, resolving all inferences in AMVAC's favor, AMVAC acted appropriately. It provided a timely response to the Data Delay Letter, (JX 22, responding to JX 21) in which it clearly set out a position reasonable under the circumstances described above and did not receive any further communication from EPA until the same time as the NOITS.

Asking for the study to be added to a DCI formally is also reasonable (cumulative and apart from the rationale above) because the best evidence that a study is eligible for data compensation is if it was formally included in a DCI. If AMVAC performed the Guideline 850.1740 and EPA eventually concluded that it did not shed light on the need for the SS-1072 study and did not otherwise incorporate it into a risk assessment, AMVAC would have difficulty obtaining compensation for the study in a potential future arbitration.

The Presiding Officer also should not rule in EPA's favor on a summary motion where the facts suggest that EPA did not review, comment on, or discuss as the basis of its NOITS, a substantive waiver request made by AMVAC, *i.e.*, the November 2016 waiver request, JX 76.

11. *Is the Existing Stocks Provision Consistent with FIFRA?*

A hearing is necessary to evaluate whether EPA's provisions for existing stocks for technical grade DCPA set forth in the NOITS are consistent with FIFRA. AMVAC does not

dispute that EPA has some discretion under FIFRA in connection with existing stocks provisions. But whether a particular provision is appropriate is a fact-specific exercise. EPA's existing stocks provision as set out in the NOITS is not rational. And, certain facts underlying EPA's conclusions regarding the appropriate restrictions on the use of stocks for DCPA technical have changed since April 28, 2022, when EPA published the NOITS.

The existing stocks provision in the NOITS allows for the continued sale, distribution and use of end-use products made from AMVAC's technical prior to the effective date of the suspension order. The provision would also allow the sale, distribution and use of end-use products formulated after the effective date of the suspension using existing stocks of AMVAC technical in the hands of third parties. However, the existing stocks provision would not allow AMVAC to do the same. But, end-use products sold and distributed to growers are formulated only by AMVAC, not third parties. McMahon (AMVAC) Statement at 2; Verified Written Statement of AMVAC Witness Suneet Ranganath ("Ranganath (AMVAC) Statement") at 1-2. This highlights how the restriction proposed by EPA may harm growers in a manner that would not have occurred if AMVAC was not the sole producer of DCPA available to them. The fact that a market impact will occur solely because of the structure of the supply chain is illogical.

In addition, EPA has explained that its decision regarding existing stocks provisions was directly impacted by the fact that it lacked information on potential thyroid effects needed for assessing dietary risks for the human health risk assessment that would be provided by the CTA study. Without these data, EPA claimed that it was unable to determine the magnitude of the risks associated with the continued use of technical DCPA existing stocks. JX 2 a 25,263, MAD at 49 (justifying its existing stocks provision for DCPA based on lack of thyroid data for risk assessment).

First, it is important to recall that EPA has mechanisms it can use to restrict sale and distribution if it believes that a health risk exists. The Suspension Provision is not one of these mechanisms. DCIs of course do enable EPA to obtain data it needs to re-evaluate health risks but, as noted above in Section III.C.(3), the data from the CTA study is now in EPA's hands. The study was submitted on June 20, 2022.

AMVAC's expert witness has reviewed the CTA study, and concludes that it was done according to the protocol approved by EPA, it provides scientifically valid data, and the data are sufficient for EPA to complete the human health risk assessment. Freeman (AMVAC) Statement at 3-6. EPA states that it will screen the CTA study quickly to ensure that the study is acceptable and if so, the results will be integrated into the risk assessment. Mendez (EPA) Statement at 7. EPA should not be permitted to use the Suspension Provision to justify an existing stocks provision grounded on the uncertainty of certain health concerns that can be resolved by a study that has been submitted.

The written direct testimony of R. Smith, C. Valadez, and S. Fennimore (filed by the Grower Group petitioners) provides factual and expert testimony demonstrating the need for DCPA end-use products and the disruptive impacts to growers if sufficient supplies of such products are not available which is a potential in the near future based on the Statement of AMVAC witness Ranganath.

As of June 17, 2022, the estimated existing amount of DCPA end-use products available for sale and distribution would be insufficient to satisfy more than half of the growers needs for the remainder of 2022. Ranganath (AMVAC) Statement at 2. The number of growers that could be adversely impacted by end use product shortages could be even higher if growers attempt to stockpile product currently available for purchase. *Id*.

Given the uncertainty as to when any possible suspension order may take effect, the exact impact of the suspension on availability of end use products for 2022 and beyond is not known. But any expected shortage resulting from the suspension could be alleviated if AMVAC were permitted to formulate end-use products from available existing stocks of technical DCPA at the time a potential suspension goes into effect. A hearing is appropriate so that the growers' concerns (and facts regarding the supply of DCPA if a suspension were to go into effect) can be fully evaluated before the Presiding Officer to determine whether EPA's existing stocks provision is consistent with FIFRA.

IV. CONCLUSION

For the reasons set forth above, Respondent's Motion for Accelerated Decision must be denied. Genuine issues of material fact remain as to whether AMVAC's DCPA registration is properly subject to suspension under the Suspension Provision, and whether EPA's existing stocks provision is consistent with FIFRA. A hearing is the appropriate forum for the parties to fully develop the record for the Presiding Officer's consideration.

Date: June 21, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Petitioner AMVAC Chemical Corporation's Opposition to Respondent's Motion for Accelerated Decision**, was sent on June 21, 2022, to the following parties in the manner indicated below.

/s/ *Hume M. Ross*
Hume M. Ross

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