

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

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

**NOTICE OF EXCEPTIONS
AND APPEAL BRIEF
OF AMVAC CHEMICAL CORPORATION**

TABLE OF CONTENTS

TABLE OF CONTENTS..... ii

I. Introduction and Summary 1

II. Standard of Review..... 8

III. Background..... 9

 A. Factual and Statutory Background..... 9

 B. Procedural Background..... 10

IV. Argument 11

 A. The Order Incorrectly Construes the Terms of the Suspension Provision and So Applies and Incorrect Legal Standard 12

 1. The Order Misconstrues the Plain Language of the Suspension Provision, as Confirmed by its Legislative History and is Inconsistent with the Overall Structure of FIFRA 13

 a. The Decision Below Misconstrues the Plain Language of the Suspension Provision 13

 b. The Legislative History Supports AMVAC’s Interpretation of the Suspension Provision 16

 c. The Order’s Appeal to the Broader Scheme of FIFRA and the October 2022 Registration Review Deadline is Misplaced 19

 2. The Holding That EPA May at Any Time after Submittal Deem a Study “Unacceptable” and Suspend a Registration under 7 U.S.C. § 136a(c)(2)(B) Would Fundamentally Alter the FIFRA Regulatory Scheme 23

 3. The Order Defers Inappropriately to the Office of Pesticide Programs 27

 4. Case Law Cited in the Order Does Not Support Narrowing the Scope of a Suspension Hearing..... 30

 B. The Order Failed to Resolve Genuinely Disputed Facts in AMVAC’s Favor and Obscures Which Facts Were Material to its Analysis 31

 C. AMVAC is Entitled to a Determination as to Whether it Took Appropriate Steps with Respect to Every Study That EPA Asserts is a “Basis for the Suspension” 38

 D. OPP’s Existing Stocks Order is Inconsistent with FIFRA..... 39

V. Conclusion 39

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986).....	31
<i>Atochem N. Am., Inc. v. EPA</i> , 759 F. Supp. 861 (D.D.C. 1991).....	30, 31
<i>In re Bayer Cropscience LP</i> , 17 E.A.D. 228 (EAB 2016).....	8, 31
<i>Bennett v. Spear</i> , 520 U.S. 154 (1997).....	14, 15
<i>In re BWX Technologies</i> , 9 E.A.D. 61 (EAB 2000).....	8, 9, 33
<i>Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.</i> , 467 U.S. 837 (1984).....	27, 29
<i>In re Clarksburg Casket Co.</i> , 8 E.A.D. 496 (EAB 1999).....	31
<i>Consent Agreements and Proposed Final Orders for Animal Feeding Operations</i> , 2006 WL 478143 (EAB 2006).....	27
<i>In re Dominion Energy Brayton Point, LLC</i> , 12 E.A.D. 490 (EAB 2006).....	28, 29
<i>FCC v. AT&T Inc.</i> , 562 U.S. 397 (2011).....	13
<i>Hechavarria v. Sessions</i> , 891 F.3d 49 (2d Cir. 2018), <i>as amended</i> (May 22, 2018).....	29
<i>INS v. Cardoza-Fonseca</i> , 480 U.S. 421 (1987) (Scalia, J., concurring)	22
<i>Keene Corp. v. United States</i> , 508 U.S. 200 (1993).....	15
<i>In re Lazarus, Inc.</i> , 7 E.A.D. 318 (EAB 1997).....	27

<i>Michigan v. EPA</i> , 576 U.S. 743 (2015).....	13
<i>In re Mobil Oil Corp.</i> , 5 E.A.D. 490 (EAB 1994).....	27
<i>Nat. Res. Def. Council v. EPA</i> , 99 F.R.D. 607 (D.D.C. 1983).....	20
<i>Nat'l Fam. Farm Coal. v. EPA</i> , 966 F.3d 893 (9th Cir. 2020)	23
<i>Reckitt Benckiser, Inc. v. Jackson</i> , 762 F. Supp. 2d 34 (D.D.C. 2011).....	26, 27
<i>Rogers Corp. v. EPA</i> , 275 F.3d 1096 (D.C. Cir. 2002).....	8
<i>United States v. Diebold, Inc.</i> , 369 U.S. 654 (1962).....	31
<i>Whitman v. Am. Trucking Ass'ns</i> , 531 U.S. 457 (2001).....	26
Statutes	
7 U.S.C. § 136(bb).....	9
7 U.S.C. § 136a-1(d)(6)	22
7 U.S.C. § 136a-1(f)(3).....	22
7 U.S.C. § 136a(a).....	9
7 U.S.C. § 136a(c)(2)(A)	17
7 U.S.C. § 136a(c)(2)(B).....	24
7 U.S.C. § 136a(c)(2)(B)(i).....	1, 12, 16
7 U.S.C. § 136a(c)(2)(B)(ii).....	<i>passim</i>
7 U.S.C. § 136a(c)(2)(B)(iii).....	12, 14, 15, 16
7 U.S.C. § 136a(c)(2)(B)(iv).....	<i>passim</i>
7 U.S.C. § 136a(c)(7).....	21
7 U.S.C. § 136a(g)(1)(A)	22

7 U.S.C. § 136a(g)(1)(A)(iii)(I)	5
7 U.S.C. § 136a(g)(1)(A)(v)	6, 22, 37
7 U.S.C. § 136d(b)	20, 26
7 U.S.C. § 136d(c)	20
7 U.S.C. § 136d(d)	18
7 U.S.C. § 136d(e)	20
7 U.S.C. § 136d(e)(1).....	14, 17, 22, 23
7 U.S.C. § 136j.....	26
Pub. L. No. 95-396, 92 Stat. 819 (1978).....	12
Pub. L. No. 104–170, 110 Stat. 1489 (1996)	21, 22
Pub. L. No. 110-94, 121 Stat. 1000 (2007).....	22
Other Authorities	
40 C.F.R. § 22.20	8
40 C.F.R. § 22.20(a).....	8
40 C.F.R. § 158.45	31
40 C.F.R. § 158.45(a).....	10
40 C.F.R. § 158.45(b)(1).....	10
40 C.F.R. §§ 164.20-164.111.....	11
40 C.F.R. § 164.80(a).....	21
40 C.F.R. § 164.91	8
40 C.F.R. § 164.121(g)	21
40 C.F.R. § 164.191	11
123 Cong. Rec. 25,701 (July 29, 1977)	17
65 Fed. Reg. 24,586, 24,587 (Apr. 26, 2000)	22
87 Fed. Reg. 25,262, 25,263 (Apr. 28, 2022)	27

Concise Oxford Dictionary of Current English (6th ed. 1976).....	13
EPA, <i>EPA Announces Updated Schedule, Completes Safety Assessments and Decisions for Hundreds of Pesticides to Address Risk and Ensure Safe Pesticide Use</i> (Dec. 2, 2021), https://www.epa.gov/pesticides/epa-announces-updated-schedule-completes-safety-assessments-and-decisions-hundreds	6
Fed. R. Civ. P. 56.....	8
H.R. 8681, 95th Cong. (1977)	16, 17
H.R. Rep. No. 95-663 (1977).....	17

Notice of Exceptions

AMVAC Chemical Corporation (“AMVAC”) files this Notice of Exceptions and requests that the Environmental Appeals Board (“EAB”) review and reverse the July 1, 2022, Order on Respondent’s Motion for Accelerated Decision issued by the Office of Administrative Law Judges in the above-captioned case, Dkt. FIFRA-HQ-2022-0002, Dkt. No. 28. Pursuant to the July 8, 2022, EAB Order Governing Procedures for Registration-Related Appeals Under [FIFRA], Appellants are filing the below Appeal Brief together with this Notice of Exceptions.

Appeal Brief

I. Introduction and Summary

This case requires interpretation of a rarely invoked provision of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136a(c)(2)(B)(iv) (the “Suspension Provision”). That provision allows EPA to suspend a pesticide registration if the Administrator determines that a registrant “failed to take appropriate steps” to generate data requested by EPA in a formal data-call in (“DCI”).¹ The Suspension Provision (*italics added*) reads in pertinent part as follows:

[I]f 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 . . .

[t]he only matters for resolution [at a hearing requested by the registrant to challenge the suspension] shall be whether the registrant has *failed to take the action that served as the basis for the notice of intent to suspend*

7 U.S.C. § 136a(c)(2)(B)(iv).

The Chief Administrative Law Judge’s (ALJ’s) decision below holds that a registrant

¹ 7 U.S.C. § 136a(c)(2)(B)(i) authorizes EPA to require registrants of a particular pesticide to submit additional data needed to support their registrations.

(here, AMVAC) that has not submitted only one of many data requirements identified by a DCI (here, approximately 89) at the time EPA issues a notice of intent to suspend cannot successfully defend against suspension, regardless of the steps that it has taken and even if the failure to submit was a result of delays attributable to EPA. In the ALJ's view, nothing short of either EPA's formal agreement that a study is not necessary (*i.e.*, "waived") or actually submitting the study can constitute the required "appropriate step" toward "secur[ing] the data required." *Id.*

This holding is inconsistent with the plain language of FIFRA, the statute's legislative history, and the statute's overall structure. The "action that serve[s] as the basis" for a notice of intent to suspend is a failure to take "appropriate steps" to produce data or validly request waivers, and a registrant is entitled to a hearing and a determination by a neutral adjudicator as to whether the activities it undertook to respond to a DCI constituted such steps. *See infra* Section IV.A.1, pp. 13-23.

As more fully described below, the facts establish that AMVAC took significant actions to respond to the DCI. The overall timeline was affected at many points by delay attributable to EPA, the novelty of several of the studies EPA asked AMVAC to perform, or other factors beyond AMVAC's control; this is not a case in which the registrant simply refused to take steps to provide the data EPA sought. It was thus wholly improper for the ALJ to grant an accelerated decision against AMVAC and cut off AMVAC's right to a hearing. The statute requires an analysis of whether AMVAC's actions were "appropriate steps," not merely whether AMVAC actually submitted the data before EPA issued the notice of intent to suspend. But no such analysis was performed. This failure, along with several other errors made by the ALJ, requires the EAB to conclude that the Motion for Accelerated Decision was improperly granted, and that a hearing should be held to assess AMVAC's conduct under a clarified legal standard.

A clear and correct decision by the EAB is also needed because EPA’s notice of intent to suspend, and the ALJ’s decision, embody a seismic shift in how EPA conceives of, and applies, its authority under the Suspension Provision. In a sworn written statement filed with the ALJ, AMVAC’s expert witness testified that AMVAC’s response was “typical of how registrants address data call-ins” and that the communications and correspondence between EPA and AMVAC were “typical of what registrants routinely experience” with DCIs of this type. Verified Written Statement of AMVAC Witness Ephraim Gur (“Gur (AMVAC) Statement”) ¶ 43. The only atypical thing about this case, according to AMVAC’s expert witness, is that AMVAC was ambushed with a notice of intent to suspend even though prior EPA correspondence (to which AMVAC had timely responded) had conveyed no sense of urgency, and in fact stated that EPA would be able to move ahead with the human health and environmental risk assessments required for registration review with the data AMVAC already had provided or that EPA otherwise possessed. *Id.* ¶¶ 43-44, Joint Exhibit (“JX”) 21. Thus, interpreting EPA’s authority to be as broad as it asserts would work as an unfair surprise to AMVAC and other registrants, because the only way to avoid suspension would be to interact with the agency in a manner fundamentally inconsistent with the course of dealing EPA has established with registrants over the past several decades. Under such an interpretation, EPA would be able to suspend vast numbers of registrations, belonging to many registrants, based on longstanding standard conduct, and even if EPA’s own conduct contributed substantially to any delays.²

² As an additional example, allowing suspension on the basis of the CTA Study (which was included in the notice of intent to suspend, but not addressed at all by the ALJ in the Order even though it is the study central to understanding potential risk concerns the Agency has cited as support for the existing stocks provision) would sanction Agency power to suspend a registrant even where the Agency and the registrant had been working collaboratively to develop and

The Order on Respondent’s Motion for Accelerated Decision (Dkt. No. 28) (“Order”) below also embodies other errors. The first of these, if allowed to stand, would fundamentally alter the FIFRA statutory scheme: the Order holds that, even if a registrant submits a study in response to a DCI, EPA may seek suspension at any later time if the agency determines that a submitted study was not “acceptable” to EPA, even if it is “scientifically sound.” Order at 26; JX 56 at 2, 23. The Order holds that in such circumstances a registrant has no practical defense against a notice of intent to suspend in front of the agency because of deference to the agency on its determination concerning the “acceptability” of the study.

This cannot be the law. In this case, EPA first informed AMVAC of the Agency’s concerns regarding a study *more than eight (8) years after the data had been timely submitted* (in January 2014) and the Agency raised those concerns *concurrently with the issuance of the notice of intent to suspend* in April of 2022. Holding that EPA can suspend a registration in such circumstances gives EPA immense and effectively unreviewable authority under the Suspension Provision. That authority would be far more potent than any EPA has previously been understood to possess under the Suspension Provision or any other FIFRA provision. *See infra* Section IV.A.2, pp. 24-27.

The Order also errs in failing to consider that EPA’s own conduct may be relevant to whether a registrant’s actions were appropriate. In this case, EPA did not share with AMVAC its belated reviews of studies that had been submitted in the past and received no comment from the Agency until the same day the Agency issued the suspension notice. It allowed AMVAC no time to respond in any way, much less substantively, to the Agency’s concerns. Finding in these

execute a complex study (and numerous required precursor studies to that study) as discussed in more detail *infra* p. 28.

circumstances that a registrant did not take “appropriate steps” perversely incentivizes EPA not to share the results of its own reviews in a timely manner, in order to maintain maximum leverage over registrants. EPA caused many other delays which are discussed below as well.

The Order makes several attempts to justify its erasure of the “appropriate steps” inquiry from the statute. The EAB should reject each:

- First, the Order asserts that a failure to submit data is “by definition not ‘appropriate.’” Order at 23. Instead of presenting findings of fact and applying a legal standard consistent with the Suspension Provision to those facts,³ the Order ignores factual disputes and adopts a legal standard so narrow that – short of a mix-up in the Agency’s mailroom – no facts could save a registrant. Indeed, even identifying such a mix-up would not save a registrant, because EPA might, without any opportunity for review, determine that the study located in the mailroom after many years was not “acceptable” to EPA under the standard embodied in the Order.
- Second, the Order improperly relies on the language in the Suspension Provision that “[t]he only matters for resolution [at a hearing requested by the registrant to challenge the suspension] shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend,” (hereinafter, “NOITS”) Order at 22, to confirm an unduly narrow view of the inquiry the ALJ was assigned. The “only matters” clause cannot properly be used to read the “appropriate steps” inquiry out of the statute. Congress would not have established an “appropriateness” standard and provided a right to a hearing where facts relevant to that standard cannot be explored. *See infra* Section IV.A.1, pp. 13-23.
- Third, the Order errs in concluding that the question of whether a registrant has taken “appropriate interim steps” is “more suitable for the science and technical experts within [the Office of Pesticide Programs]” than the Office of Administrative Law Judges. Order at 21, n.24.⁴ Such extreme deference eviscerates the statutorily mandated “appropriate steps” inquiry, is contrary to EAB guidance, and is a disavowal of the ALJ’s duty to review the matter. *See infra* Section IV.A.3, pp. 27-30.
- Fourth, the Order misconstrues EPA’s impending October 2022 deadline for registration review (*see* 7 U.S.C. § 136a(g)(1)(A)(iii)(I)) as yet another basis to disregard the “appropriateness” inquiry in the Suspension Provision. But the registration review deadline and the Suspension Provision are unrelated. The October

³ Part of the basis of AMVAC’s appeal is the Order’s failure to clearly state facts found, and conclusions of law made. *See infra* Section IV.B, pp. 31-38.

⁴ The Order concedes that there might be something it refers to as an “appropriate interim step[] to provide necessary data” that would preclude a suspension, but disclaims any intent to examine whether AMVAC’s conduct met that standard based on deference to OPP. Order at 21, n.24.

2022 deadline constitutes a clear congressional command *to EPA* of when action is expected, but it does not permit EPA to conduct an end-run around established procedures – to wit, through the Suspension Provision – for taking products off the market on an expedited basis. If EPA seeks changes based on the results of registration review, EPA must pursue them through either voluntary agreement with registrants or by initiating cancellation proceedings. 7 U.S.C. § 136a(g)(1)(A)(v) (registrations are not to be canceled “as a result of the registration review process” – the *de facto* impact of a suspension – without a standard cancellation proceeding).⁵

In addition to these errors, the ALJ repeatedly did not properly resolve contested inferences in AMVAC’s favor before granting an accelerated decision. In fact, contrary to legal principles governing motions for accelerated decisions, the Order repeatedly resolves contested facts *against* AMVAC. For instance, it is plainly improper to conclude that AMVAC was here involved in an “interminable” process, *see* Order at 21-22, as to the studies that were a basis for the notice when a sworn expert statement before the ALJ, provided by AMVAC, described the facts presented as typical of a registrant-EPA exchange. Gur (AMVAC) Statement ¶ 43. But the ALJ nonetheless appears to have found that AMVAC’s conduct was “interminable” or in some way “abnormal.” These characterizations were drawn from the factual testimony of EPA witnesses in their declarations and amount to an adoption of facts as presented by the Agency. Order at 6, 21-22, 23. These findings are not warranted, and plainly inappropriate for an ALJ resolving a motion for accelerated decision. This and other failures to resolve disputed facts in AMVAC’s favor are discussed in *infra* Section IV.B, pp. 31-38.

Another error warranting reversal and remand is that, in concluding that there is no need

⁵ Moreover, EPA already has conceded that it will not meet this deadline for perhaps as many as 100 registration review cases. *See* EPA, *EPA Announces Updated Schedule, Completes Safety Assessments and Decisions for Hundreds of Pesticides to Address Risk and Ensure Safe Pesticide Use* (Dec. 2, 2021), <https://www.epa.gov/pesticides/epa-announces-updated-schedule-completes-safety-assessments-and-decisions-hundreds>. But EPA has not instituted suspension proceedings in any of those cases. These facts negate the claim in the Order that failure to timely complete registration review is an unthinkable “violation of law,” Order at 31, such that the Suspension Provision must be read to permit the suspension of AMVAC’s registration prior to October 2022.

to review a registrant's actions with regard to each allegedly unmet data requirement, the Order ignores the structure of the Suspension Provision. Order at 7-8. While it may have been more burdensome for the ALJ to consider each allegedly unmet data requirement, doing so is required by FIFRA and simple logic. Here, the Administrator's authority to maintain a suspension in force ends when "the registrant has complied fully with the requirements that served as a basis for the suspension." *Id.* at 4 (citing 7 U.S.C. § 136a(c)(2)(B)(iv)). So that the registrant and EPA will know when the Administrator's authority to maintain a suspension ends, the tribunal must determine which data requirements *alleged* to be a basis for the notice by the EPA Office of Pesticide Programs ("OPP") are in fact a *valid* basis for the notice. A suspension could not be maintained if the only data requirement still outstanding was one for which the ALJ ruled the registrant had been taking appropriate steps. *See infra* Section IV.C, pp. 38-39.

Finally, AMVAC appeals the determination in the Order that the Administrator's determination regarding existing stocks is consistent with FIFRA. AMVAC incorporates by reference the arguments presented in the appeal brief of the additional petitioners. As explained therein, the existing stocks order has the potential to work an undue hardship on growers solely as a result of the structure of the supply chain.

For the reasons summarized above and described in more detail below, the EAB should find that the Motion for Accelerated Decision was improperly granted. This is the first case under the Suspension Provision where a complex set of facts involving substantial efforts to comply on the part of the registrant must be reviewed under the "appropriate steps" framework provided by Congress. The EAB should clarify that the law requires a factual inquiry into whether a registrant acted appropriately with respect to each of the data requirements – i.e., whether AMVAC's actions to fulfill the DCI were reasonable under the circumstances presented,

with appropriate consideration of the fact that EPA caused or contributed to many of the delays about which it now complains. The EAB should remand this matter to the ALJ for the hearing specifically envisioned by the statute.

II. STANDARD OF REVIEW

The EAB reviews factual and legal determinations of the Office of Administrative Law Judges on a *de novo* basis, with “all of the powers which it would have [if it had been] making the initial decision.” *In re Bayer Cropscience LP*, 17 E.A.D. 228, 259 (EAB 2016) (quoting 5 U.S.C. § 557(b)). The decision under review here is a decision on EPA’s Motion for Accelerated Decision, issued before any hearing was held. Therefore, the EAB must determine whether EPA’s Motion was properly granted under 40 C.F.R. § 164.91. The language of that regulation tracks the language of 40 C.F.R. § 22.20, which the EAB has held, in turn, should be interpreted consistently with Federal Court summary judgment principles under Fed. R. Civ. P. 56. *In re BWX Technologies*, 9 E.A.D. 61, 74-75 (EAB 2000).

The decision below can be upheld only if “no genuine issue of material fact exists,” 40 C.F.R. § 22.20(a), and thus only if “no reasonable decisionmaker” could resolve any material issue of fact in AMVAC’s favor, viewing the facts in the light most favorable to AMVAC. *BWX Technologies*, 9 E.A.D. at 75. It is inappropriate to render an accelerated decision when contradictory inferences may be drawn from the evidence (which in this case included sworn fact and expert witness statements from each party, as well as extensive exhibits) on a material issue. *Rogers Corp. v. EPA*, 275 F.3d 1096, 1103 (D.C. Cir. 2002) (reversing grant of accelerated decision motion in EPA’s favor granted by an ALJ and affirmed by EAB). Even where a non-movant will bear the burden of persuasion if a matter proceeds to a hearing or trial, all justifiable inferences must nonetheless be drawn in the non-movant’s favor. *BWX Technologies*, 9 E.A.D.

at 76-77. Similarly, even a failure of the Order under review to make clear what inferences were drawn, and why, may be a basis for remand. *Id.* at 78-79.

III. BACKGROUND

A. Factual and Statutory Background

Facts concerning the pesticide at issue here, Dimethyl Tetrachloroterephthalate (“DCPA”) (EPA Reg. No. 5481-495), are presented in AMVAC’s Request for Hearing and Statement of Objections (Dkt. No. 4) (“Hearing Request”) at ¶¶ 19-27, and in the Verified Written Statement of AMVAC Fact Witness Niamh McMahon (“McMahon (AMVAC) Statement”), provided as a part of the prehearing exchange in this matter, at ¶¶ 8-13. Information concerning EPA’s notice of intent to suspend DCPA is set forth in the Hearing Request at ¶¶ 2-7.

The statute under which EPA seeks to suspend AMVAC’s DCPA registration, 7 U.S.C. § 136a(c)(2)(B)(iv), requires an inquiry into whether AMVAC took “appropriate steps” in response to EPA’s request for data. Because this matter centers on proper interpretation of the statutory standard, the standard is discussed in greater detail in subsections IV.A.1-IV.A.3 of the Argument section below, pp. 13-30.

EPA made its request for data in January of 2013. EPA requested that AMVAC satisfy approximately 89 new data requirements. These data requirements relate to DCPA’s effects on various categories of flora and fauna (“ecological effects”), how DCPA degrades once in the environment (“ecological fate”) and DCPA’s potential effects on humans. This data was requested so that EPA could re-confirm its prior conclusion that DCPA met the statutory standard for registration, *i.e.*, that its use does not cause “unreasonable adverse effects on the environment” as that term is defined in FIFRA. 7 U.S.C. §§ 136a(a); 136(bb).

A data requirement can be satisfied by submission of a new study or through the grant of a waiver. EPA grants waivers if a registrant establishes that a study is not needed or, in the words of EPA's pertinent regulation, if "sufficient data are [already] available to make the determinations required by the applicable statutory standards." 40 C.F.R. § 158.45(a).⁶ AMVAC has submitted data, or obtained waivers, for more than three-quarters of the data EPA had requested (*i.e.*, for all of the 89 data requirements except the 20 referenced in the NOITS). EPA contends that AMVAC's conduct with respect to the remaining 20 falls below the statutory standard that AMVAC take "appropriate steps" to respond to EPA's request for data. A summary of AMVAC's extensive efforts to provide data to EPA in response to EPA's request can be found in the McMahon (AMVAC) Statement at ¶¶ 14-25. Specific information concerning AMVAC's response to EPA's request for information is set forth in the written statements of AMVAC witnesses Freedlander, Porter, McMahon, Jonynas, and Wood and is also discussed below. AMVAC requested the instant agency review process to vindicate its position that its efforts satisfy the statutory standard.

B. Procedural Background

EPA transmitted the NOITS to AMVAC on April 27, 2022, JX 1, and published information concerning the notice in the Federal Register the following day. JX 2. AMVAC timely filed its Hearing Request with the Office of Administrative Law Judges ("OALJ") pursuant to 7 U.S.C. § 136a(c)(2)(B)(iv) on May 27, 2022. The Grower-Shipper Association of

⁶ Registrants are "encouraged to discuss a data waiver request with the Agency before developing and submitting supporting data, information, or other materials." 40 C.F.R. § 158.45(b)(1). The need for a study may also be obviated if the registrant amends its label to restrict the manner in which the pesticide is used. AMVAC took this approach for four of the twenty data requirements at issue in the notice of intent to suspend, but the ALJ's Order now under review did not analyze these four requirements.

Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms (collectively, the “Grower Petitioners”) also requested a hearing the same day (Objection and Request for Hearing by Grower Petitioners (Dkt. No. 3)).

The OALJ issued a prehearing order supplementing the procedures otherwise applicable under 40 C.F.R. §§ 164.20-164.111 and scheduled a hearing for July 6-8, 2022. The EPA OPP, Respondent below, filed a Motion for Accelerated Decision pursuant to 40 C.F.R. § 164.191 on June 13, 2022 (Dkt. No. 12). Pursuant to the prehearing order, the parties filed their prehearing exchange materials on June 17, 2022 (Dkts. No. 13-18). The prehearing exchange materials consisted of several verified written witness statements from each party, Joint Exhibits (“JX”) 1-86 and individual exhibits from each party,⁷ and associated materials required by the prehearing order. AMVAC and the Grower Petitioners filed oppositions to the Motion for Accelerated Decision on June 21, 2022 (Dkt. Nos. 19, 20). EPA did not file a Reply in support of its Motion. On July 1, 2022, OALJ issued an Order on Respondent’s Motion for Accelerated Decision, granting the Motion in full and canceling the hearing set for July 6-8. This appeal followed.

IV. ARGUMENT

The EAB should conclude that the Motion for Accelerated Decision was improperly granted, for four main reasons, which we explain below in the following subsections:

- subsection IV.A, pp. 12-31, discusses why the scope of the ALJ’s analysis was unduly narrow and did not engage in the analysis required by the statute. The decision either (or both) incorrectly interpreted the governing statute or improperly deferred to EPA;
- subsection IV.B, pp. 31-38, discusses the failure of the Order to clearly identify its legal and factual conclusions, and discusses specific factual inferences that were not properly drawn in view of the standard for deciding motions for accelerated decision;

⁷ Petitioner AMVAC’s Exhibits (“PAX”) 1-44; Grower Petitioners’ Exhibits (“PGX”) 1-5; and Respondent’s Exhibits (“RX”) 1-9.

- subsection IV.C, pp. 38-39, discusses why the structure of FIFRA requires a reviewing tribunal to render an opinion as to the appropriateness of a registrant’s conduct for each study that EPA includes in a NOITS, which the ALJ did not do; and
- subsection IV.D, p. 39, incorporates by reference arguments concerning the existing stocks provision presented in the appeal brief of the Grower Petitioners.

A. The Order Incorrectly Construes the Terms of the Suspension Provision and So Applies an Incorrect Legal Standard

The 1978 Amendments to FIFRA, Pub. L. No. 95-396, 92 Stat. 819 (1978), authorize EPA to “call in” additional data to support the registrations of previously registered pesticides. When EPA does so, it is referred to as a “Data Call-In” or “DCI.” The subsection creating the authority for DCIs is codified as 7 U.S.C. § 136a(c)(2)(B)(i). Two additional subsections of the same provision added by the 1978 Amendments are relevant to this case. Subsection (2)(B)(ii) requires that a DCI recipient provide evidence within 90 days that it is taking “appropriate steps” to secure the required data. And Subsection (B)(iv) authorizes EPA to issue a NOITS if a registrant fails to “take appropriate steps to secure the data” required by the DCI “within the time required by the Administrator.”⁸

As noted earlier, Subsection (B)(iv) is referred to in this brief as the “Suspension Provision,” and is quoted immediately below. The plain language of its central feature – the “appropriate steps” inquiry, the relevant legislative history, and the overall statutory context, make it clear that Congress created a standard that centered on the propriety of a registrant’s conduct, not on solely whether data is submitted to EPA by any fixed date. The Order errs by failing to recognize this and by precluding a hearing to consider the propriety of the conduct of the registrant here.

⁸ 7 U.S.C. § 136a(c)(2)(B)(iii) address other circumstances not at issue here, such as where, unlike here, there are multiple registrants of products containing the same active ingredient. Here, it is undisputed that AMVAC is the only registrant of the relevant active ingredient, DCPA.

1. *The Order Misconstrues the Plain Language of the Suspension Provision, as Confirmed by its Legislative History and is Inconsistent with the Overall Structure of FIFRA*
 - a. The Decision Below Misconstrues the Plain Language of the Suspension Provision

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

[I]f 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 . . .

[t]he only matters for resolution [at a hearing requested by the registrant to challenge the suspension] shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend

7 U.S.C. § 136a(c)(2)(B)(iv). The Order wrongly interprets this language as creating an all-or-nothing inquiry: either a registrant submitted a study (and EPA has fully reviewed and accepted it) by the time EPA issues a NOITS or not. Order at 23, 26. That is, the Order reads the phrase “appropriate steps” out of the statute.

To start with, the ordinary definitions of both “appropriate” and “step” (neither of which are defined in FIFRA) preclude the conclusion that Congress created a standard that looks only to final submittal/acceptance.⁹ “Appropriate” is defined as being “suitable or proper.” The Concise Oxford Dictionary of Current English (6th ed. 1976). In *Michigan v. EPA*, 576 U.S. 743, 752 (2015), the Supreme Court observed that the word “appropriate,” when used in a statute, denotes a “broad and all-encompassing” inquiry and “naturally and traditionally includes consideration of all the relevant factors.” “Step” is defined as a “measure taken esp. as one of a series in some course of action.” Oxford Dictionary, 1976, *supra*. Neither of these terms, based on their plain meanings and as confirmed by the Supreme Court’s analysis, suggests an inquiry

⁹ When a statute does not define terms, courts look first to the ordinary meaning of those terms, which may be ascertained by reference to dictionaries. *FCC v. AT&T Inc.*, 562 U.S. 397, 403 (2011).

that can be satisfied only by a single act as the Order concludes.

It would have been very easy for Congress to create a simple “all-or-nothing” inquiry, focused solely on whether data is in EPA’s hands (and accepted by EPA). All Congress would have had to do would have been to leave out the clause containing “appropriate” and “steps,” so that the provision would have read, “*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 . . .*” 7 U.S.C. § 136a(c)(2)(B)(iv). But Congress did not. The decision below thus violates a “cardinal principle of statutory construction” that every clause and word of a statute is to be given effect if possible. *Bennett v. Spear*, 520 U.S. 154, 173 (1997); it attributes no significance to the words “appropriate” and “steps.”

Further confirmation that Congress intentionally chose not to craft the Suspension Provision as narrowly as the Order finds comes from another section of FIFRA was added by the same 1978 Amendments as the Suspension Provision, 7 U.S.C. § 136d(e)(1). Its different wording creates precisely the “all-or-nothing” inquiry that the Order sees in the Suspension Provision. That section reads:

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.*

Id. (emphasis added). Congress in 1978 therefore knew how to create an “all-or-nothing” provision, as embodied in the “(B)” condition immediately above. *Id.*

In 1988, Congress amended FIFRA again and did not replace the different language of Section (2)(B)(iv), even though it did make some other revisions to 7 U.S.C. §§ 136a(c)(2)(B)(ii)

and (iii).¹⁰ Where Congress has omitted language from one portion of a statute but not another, the omission (here, the omission of an “all-or-nothing” clause in the Suspension Provision) must be presumed to be intentional. *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993).¹¹

The context of the Suspension Provision further supports that the ALJ erred in its fundamental statutory interpretation. As noted above, the related FIFRA provision 7 U.S.C. § 136a(c)(2)(B)(ii) requires a registrant to “provide evidence ... that it *is taking* appropriate steps” to respond within 90 days after it receives the DCI (emphasis added). That is, failure to respond at all in 90 days is grounds for initiation of suspension proceedings, but if a registrant demonstrates it “is taking” appropriate steps as of the 90-day mark, suspension is not permitted. Congress thus clearly has recognized that something short of full and final submittal of the study can be an “appropriate step” at a certain point in time.¹²

The Order also is incorrect in reasoning that because the Suspension Provision uses the phrase “the action that served as the basis for the notice” in the “only matters” clause (rather than repeating the “appropriate steps” language verbatim), the “only matters” language narrows or clarifies the scope of the inquiry. Order at 23.¹³ That reasoning ignores the text and structure of

¹⁰ Clarifying that failures to provide an initial 90-day response to a DCI, or failing to agree with other registrants on the terms of a data development arrangement were grounds for suspension under the Suspension Provision.

¹¹ This, of course, is consistent with the surplusage canon described in *Bennett*, 520 U.S. 154 (1997) under which courts favor interpretations that give meaning to all statutory terms where possible.

¹² The Order correctly does not ever suggest that the nominal deadlines set forth in the DCI (which ranged from 1-3 years after receipt of the DCI) are the point in time at which “appropriate steps” should be judged in this case, or that these deadlines have any significance beyond the fact that it would be plainly arbitrary for EPA to issue a notice of intent to suspend *before* their passage.

¹³ This discussion in the Order, at 23, occurs in the Order’s discussion of the legislative history, but it is in essence a plain language argument (*i.e.*, by using certain words in the actual statute Congress must have intended a certain result). The Order refers to the addition of the “only matters” language by “later amendment.” Presumably this is a reference to the amendment by

7 U.S.C. §§ 136a(c)(2)(B)(i)-(iv). A hearing under the Suspension Provision could address one of several shortcomings EPA might allege concerning a registrant’s response to a DCI – failure to take appropriate action, to negotiate a joint data development procedure, or failure to comply with a data development agreement or an arbitration decision. 7 U.S.C. § 136a(c)(2)(B)(iv).¹⁴

The phrase, “the action that served as the basis for the notice” may (in fact must) refer to whichever of these violations EPA alleges. If the Administrator alleges failure “to comply with the terms of an agreement or arbitration decision,” then of course a hearing requested in response would focus on whether the registrant had complied with the arbitration decision. *Id.* Likewise, a hearing requested for which the “basis for the notice” was an alleged failure to take appropriate steps would naturally address that contention. The “only matters” language can only be properly read as referring back to the possible bases for suspension, one of which is the failure to take “appropriate steps.” Congress did not create a legal standard in the beginning of the Suspension Provision and then, later in the same section, provide the opportunity for a hearing at which it would be forbidden to fully explore whether that standard had been complied with. That is what both the Agency and the ALJ would have this tribunal believe.

b. The Legislative History Supports AMVAC’s Interpretation of the Suspension Provision

The legislative history of the Suspension Provision confirms that Congress intended a factual inquiry into the registrant’s “appropriate steps” before suspension could be ordered. The hearing provision originated in the House, and the House Agriculture Committee Report for the House version of the 1978 Amendments (H.R. 8681, 95th Cong. (1977)) described as a “major

the 1978 Conference Committee itself during the reconciliation – there was no modification of this language by any subsequently enacted law.

¹⁴ The 1988 Amendments later added text to 7 U.S.C. §§ 136a(c)(2)(B)(ii) and (iii) specifying that failures to comply with those sections would also be resolved using the procedure in (B)(iv).

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” H.R. Rep. No. 95-663 (1977). The report also noted (referring to what is now 7 U.S.C. § 136a(c)(2)(A)) 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.” *Id.* (emphasis added). Thus, the focus of the report is on “appropriate steps” to develop data not creating a fixed end date as this same Congress did in Section 7 U.S.C. § 136d(e)(1) as discussed above. During Senate debate on S. 1678, which would later be passed and then reconciled with H.R. 8681 in Conference Committee as discussed below, a floor statement supports the conclusion that ensuring that registrants were spurred to appropriate action rather than required to complete studies by any date certain was the focus (“[t]he approach adopted would encourage the prompt undertaking of defensive testing by making it impossible for firms to continue to market products where data gaps exist unless they *promptly begin* their own tests”)¹⁵ 123 Cong. Rec. 25,701, 25,710 (July 29, 1977) (emphasis added).

A Conference Committee reconciled H.R. 8681 and S. 1678. It substituted suspension for cancellation as a remedy for a failure to take appropriate steps (or fail to perform any of the other acts required by 7 U.S.C. §§ 136a(c)(2)(B)(ii)-(iv)) and chose to permit a hearing (a provision of the House Bill). The Order, at 23, finds the key takeaway to be that the Conference Committee settled on a hearing with the “only matters” language attached, and so the legislative history

¹⁵ Similarly, “[t]he Administrator may cancel a registration if the registrant fails to enter into arbitration, fails to honor a compensation agreement or arbitrator’s decision, or fails *to make appropriate arrangements* for the development of required defensive data.” (emphasis added). 123 Cong. Rec. 25,701, 25,710 (July 29, 1977).

supports (in the Order’s view) a narrow inquiry at any hearing. The Order reasons that the portion of the Suspension Provision stating that:

[t]he only matters for resolution [at a hearing requested by the registrant to challenge the suspension] shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend[,]

7 U.S.C. § 136a(c)(2)(B)(iv), “strictly limits what the hearing is intended to resolve, which is whether the registrant did or did not fail to provide the required data.” Order at 23.

But the Order misreads the plain language of the “only matters” language *supra* pp. 15-16. Properly understood, the “only matters” language is just a cross reference that ensures that, depending on which of the various failures under 7 U.S.C. §§ 136a(c)(2)(B)(ii)-(iv) is alleged, the hearing will have a scope commensurate with that allegation. It does not limit the hearing in any way. Thus, once the “only matters” clause is properly understood, the key takeaway is that the Conference Committee elected to have a hearing as opposed to no hearing. This confirms that Congress anticipated that fact issues would have to be considered to resolve whether “appropriate steps” had been taken (or other violations of *id.* §§ 136a(c)(2)(B)(ii)-(iv) had or had not occurred), and that the inquiry would require more than simply checking as to whether data had been submitted by some calendar date. A far more reasonable conclusion for why Congress added the “only matters” language is that Congress sought to clarify that a hearing under the Suspension Provision would not have the full scope of a cancellation hearing under *id.* § 136d(d) which the Suspension Provision refers to.¹⁶

The Order, at 22, also cites a section of the Conference report discussing the fact that the Suspension Provision allows EPA to enforce defensive data requirements (*i.e.*, data requirements EPA requires in a DCI). But this does nothing to support the narrow interpretation in the Order.

¹⁶ Cancellation hearings can go on for months and involve National Academy of Science reports and expert testimony on toxicological issues.

As enacted, the Suspension Provision is an effective enforcement tool because registrants will still understand that they may be obligated, as AMVAC is here, to defend their actions to EPA by demonstrating the appropriateness of their compliance actions. Excessively narrowing the right to a hearing is not necessary to allow EPA to “enforce” defensive data requirements.¹⁷

c. The Order’s Appeal to the Broader Scheme of FIFRA and the October 2022 Registration Review Deadline is Misplaced

The Order incorrectly seeks to bolster its erroneous statutory construction with two further efforts to read “appropriate steps” out of the statute. It asserts first that giving any significance to the “appropriate steps” language would “undermine FIFRA’s mandate” by “inviting registrants to spend an interminable amount of time attempting to provide data without actually providing it.” Order at 21. It also asserts that allowing for an “appropriate steps” inquiry would somehow “shift to EPA the burden” of justifying AMVAC’s entitlement to a registration.

The first contention fails because it proceeds based on a factual inference that is not properly drawn at this phase of the proceeding. AMVAC’s course of conduct here cannot properly be characterized as an “interminable” process: the testimonial statements of AMVAC fact witnesses and experts are replete with explanations of their reasonable activities, and there is no dispute that EPA itself was years late in responding to various AMVAC efforts to obtain clarifications and data reviews.¹⁸ Drawing an inference on this disputed fact issue against

¹⁷ The Agency is fully capable of setting up boundaries – study scoping, due dates – and holding a registrant to them. If it thought that a registrant was intentionally dragging its feet, the EPA could say as much and could set firm deadlines, failing which a suspension could be issued. As shown below, that is not what happened here. What had been a lengthy, complex interaction between EPA and AMVAC during which the registrant satisfied 69 data requirements and had (on what it reasonably believed was a mutually acceptable calendar) endeavored to complete others, was summarily cut short without advance notice to AMVAC before the NOITS.

¹⁸ *E.g.*, Freedlander (AMVAC) Statement ¶¶ 19-20 (EPA initially reviewed study submitted in January 2014 in October of 2016, completed review in December of 2021, but did not provide review to AMVAC until April 2022 with notice of intent to suspend); 53 (March 2014 document not provided until March 2107); 136 (no response to waiver correspondence between December

AMVAC is thus wholly inconsistent with the standard for decision on a Motion for Accelerated Decision. *See supra* Section II, pp. 8-9. We address the Order’s many errors of this sort in *infra* Section IV.B, pp. 31-38. Even without all those other examples, however, the ALJ’s failure on this issue alone is sufficient to compel reversal and remand.¹⁹

The second contention, that engaging in an “appropriate steps” inquiry would unduly shift the burden of maintaining a registration from AMVAC to EPA, is also meritless. At the outset, it is ironic that the Order would raise this concern, when, in the midst of a suspension proceeding, the Agency moved for an accelerated decision that effectively denies AMVAC the opportunity to carry the very burden of which EPA complains. With the ALJ’s Order, no registrant would ever be able to demonstrate “appropriate steps.” Surely, this cannot be what the drafters of the Suspension Provision had in mind.

Under FIFRA, once a registration is granted, a registrant does not have a free-floating burden to take any and all actions EPA staff might assert are needed to maintain its registration. The registrant has a protectable property right in its FIFRA registration.²⁰ A registrant also has several statutorily well-defined obligations to supply data and defend its entitlement to its registration, but these are always to be enforced in proceedings with defined due process protections.²¹ And at all such hearings, EPA must make out a prima facie case before the burden

2020 and filing of notice in April 2022); McMahon ¶ 26 (describing twenty-eight (28) documents never received by AMVAC until after the notice of intent to suspend was issued).

¹⁹ Because the Order is founded on an improper inference, it is effectively an advisory opinion concerning circumstances under which suspension might be justified rather than a proper exercise in deciding a motion for accelerated decision.

²⁰ *E.g., Nat. Res. Def. Council v. EPA*, 99 F.R.D. 607, 609 (D.D.C. 1983).

²¹ These include (1) Data-Call Ins (implicating the Suspension Provision); (2) cancellation proceedings initiated under 7 U.S.C. § 136d(b) (if the Administrator determines, after registration, that a product does not comply with the registration standard); (3) emergency suspension proceedings under *id.* § 136d(c) (if the Administrator determines a product presents an imminent hazard); and (4) conditional registration cancellations under *id.* § 136d(e) (if a

flips to the registrant to defend its product. 40 C.F.R. § 164.121(g) (expedited hearings); 40 C.F.R. § 164.80(a) (all other types of hearing mentioned above). Thus, a registrant's obligation to defend its product only arises after EPA makes one of several statutorily required showings; it cannot arise solely because of obligations that apply to EPA, such as the October 2022 deadline discussed below.

That deadline is wholly an administrative target for EPA; EPA itself expressly has disclaimed, in the record of this case, any link between the impending October 2022 deadline and the need to complete any studies under the DCI. EPA's October 16, 2020, letter, JX 21, stated: "[EPA] will rely upon data available at the time when the risk assessments [in support of registration review] are being developed. Where the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments." The letter continued, "if [the outstanding data required by the DCI are] submitted in a timely manner, EPA expects to use them in Registration Review to assess the risks of the chemical." *Id.* The letter did not suggest that the pending deadline in any way altered AMVAC's obligation to work towards fulfilling the DCI requirements. EPA stated for the first time in a Memorandum dated March 21, 2022, but not provided to AMVAC until the NOITS was issued, that it was not capable of proceeding with a risk assessment. *See* PAX 43, received concurrently with the notice; McMahan (AMVAC) Statement ¶ 26.

Moreover, the deadline for completing certain registration reviews was initially added to FIFRA in 1996 by the Food Quality Protection Act. Pub. L. No. 104-170, 110 Stat. 1489

registrant is alleged to have not complied with a condition of a registration issued under *id.* § 136a(c)(7)).

(1996).²² In 2007, FIFRA was amended to include the October 2022 date and to impose a firm requirement rather than a “goal” on EPA. Pub. L. No. 110–94, 121 Stat. 1000 (2007). Either enactment could have amended the “appropriate steps” inquiry or added an alternate “all-or-nothing” provision, as Congress has done in 7 U.S.C. §§ 136a-1(d)(6), 136a-1(f)(3), and 136d(e)(1). But Congress did not.

The ALJ erred by importing her own notion that “overall statutory intent” favoring “efficient[] complet[ion] of registration review” required “narrowing the issues,” Order at 21, for a hearing under the Suspension Provision. When interpreting statutes, a court may not re-write a statute to vindicate “unenacted legislative intent” even if the court perceives such intent. *See, e.g., INS v. Cardoza-Fonseca*, 480 U.S. 421, 453 (1987) (Scalia, J., concurring). Here, moreover, no resort to “unenacted legislative intent” is even necessary. The enacted statutory text shows that Congress, aware of the perennial problem of EPA’s reviews of pesticide registrations being behind schedule, made clear that EPA’s failure to timely complete registration review would not prejudice registrants: if EPA seeks changes based on the results of registration review, EPA must pursue them through either voluntary agreement with registrants or by initiating cancellation proceedings. 7 U.S.C. § 136a(g)(1)(A)(v).²³ Thus, contrary to the

²² The initial section was codified at 7 U.S.C. § 136a(g)(1)(A) and read, “[t]he Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations. The goal of these regulations shall be a review of a pesticide’s registration every 15 years. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 6.” Pub. L. No. 104–170, 110 Stat. 1489, 1491-92 (1996).

²³ “No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section [136d of this title].” EPA, Pesticides; Procedural Regulations for Registration Review, 65 Fed. Reg. 24,586, 24,587 (Apr. 26, 2000). *Id.*, cited in the Order at 21, further confirms this (“If EPA determines that a pesticide no longer meets the statutory standard [following registration review], it should not remain registered. In this event, EPA may need to pursue other actions such as cancellation under other statutory authority.”).

assertion in the Conclusion in the Order, at 31, even if EPA does determine that a particular registration should be canceled as a result of registration review, that registration would still remain in effect, until completion of a cancellation hearing at which all relevant issues could be raised. This undercuts the assertion in the Conclusion of the Order that AMVAC in some way would be “reward[ed]” if its registration remains in place after the registration review deadline. *Id.* EPA’s registration review deadline is statutorily irrelevant to whether any products “remain registered.” Order at 21.²⁴

Finally, the Order’s assertion that “limiting the scope of this proceeding in this manner is consistent with the 75-day time limit for this proceeding” set out in the Suspension Provision also is incorrect. Order at 20. Indeed, the ALJ’s analysis in this context of the importance of the 75-day “deadline” is wholly inconsistent with her conclusion of the narrowness of the substantive standard for suspension, *i.e.*, that the only question is whether a study was submitted and accepted by EPA, with EPA receiving extreme deference on whether a study is “acceptable.” If that were the case, 75-days seems like a curiously *long* time limit to place on the process. And the same 75-day time frame is used in the statute when the hearing concerns whether a registrant has “failed to initiate and pursue appropriate action toward fulfilling any condition imposed” under a conditional registration. 7 U.S.C. § 136d(e)(1). This confirms that Congress believed 75 days was a sufficient time to perform factual inquiries into whether conduct was appropriate.

²⁴ The Order, at 21, cites dicta in *Nat’l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 918 (9th Cir. 2020) stating that “the registration review process serves as a backstop to ensure that pesticides do not remain registered once new data has shown them to be harmful to humans or the environment.” This case addressed (and largely rejected) a challenge to EPA’s registration of a pesticide. In this passage, the Court is merely stating that its holding will not preclude future reviews by EPA following the statutory registration review procedure if new data becomes available.

2. *The Holding That EPA May at Any Time after Submittal Deem a Study “Unacceptable” and Suspend a Registration under 7 U.S.C. § 136a(c)(2)(B) Would Fundamentally Alter the FIFRA Regulatory Scheme*

After reading the “appropriate steps” inquiry out of the statute, the Order goes further to find that even if EPA receives a study “on time,” the Agency may suspend a registration if it at any later date concludes that the study is “lacking necessary data points.” Order at 26. This finding is wholly inconsistent with FIFRA.

To understand the stunning breadth – and error – of this holding, it is first necessary to understand to what the “necessary data points” language in the Order refers. The study in question evaluated the toxicity of the active ingredient in AMVAC’s product to a species of marine invertebrate – a “mysid” – a small shrimp-like crustacean. It is undisputed that EPA’s review determined that the study was “scientifically sound” and could be used for risk characterization. JX 56 at 2, 23. But the Agency’s review noted that the study did not produce a “definitive NOAEC” – a definitive level at which no effect was observed.

The witness statement from the EPA staffer responsible for review of this study, Ms. Wendel, states that EPA could proceed with a risk assessment without the data points that would identify a NOAEC by using assumptions, but that there would be elevated levels of uncertainty. Verified Written Statement of EPA Witness Christina Wendel (“Wendel (EPA) Statement”).²⁵ Calling the absent data points “necessary” improperly resolves a factual inference in favor of EPA.²⁶ Because the issue at hand is whether AMVAC was failing to take “appropriate steps” by

²⁵ This sworn testimony parallels the language in the October 16, 2020, letter from EPA to AMVAC, which stated that “conservative assumptions may be used ... to complete the risk assessments.” JX 21. The review of the study, JX 56, had already been initially performed four years prior to EPA’s December 2020 letter, which referred to the study as being “In review.” JX 21. EPA’s review was not concluded until a year later, in 2021, and was not revealed to AMVAC until April 2022. See McMahon (AMVAC) Statement ¶ 26.

²⁶ See *infra* Section IV.B, pp. 31-38 for further discussion regarding this and other improperly drawn inferences.

timely submitting this study, the only plausible way AMVAC's conduct would not have been appropriate would be if AMVAC had reason to know that the study was deeply flawed and/or would not permit EPA to proceed with risk assessment when it submitted it. The record contains no suggestion of this. The Order's deference to EPA on this issue would put no practical limit on the sorts of study anomalies to which EPA could point, even within "scientifically sound" studies, to justify suspension.

Moreover, if this conclusion stands, EPA could assert such grounds for suspension against any registrant at any time. Here, EPA sat on a timely-submitted study for *more than eight years* before informing the registrant that it viewed it as being insufficient – and did not do so until *the exact same time it issued the notice of intent to suspend*. EPA's delay robbed AMVAC of the opportunity to respond to EPA's concerns and potentially re-run the study if needed. If EPA had timelier informed AMVAC of its concerns with the study (perhaps shortly after EPA's contractor reviewed the study in November of 2016 instead of in April of 2022) then AMVAC's response to such timely submitted concerns could also be evaluated against the appropriate steps standard.²⁷

The EAB, unlike the OALJ, must not put its "imprimatur," Order at 31, on a license for EPA to engage in such conduct. Affirmation of the Order would give EPA broad and previously unknown power to remove products from the market that is plainly inconsistent with the carefully balanced due process requirements of FIFRA. Such a holding would eviscerate

²⁷ This is one of several instances in which EPA's conduct is relevant to determining whether AMVAC's conduct was appropriate. Other examples include: (1) EPA's substantial contribution to the overall time it took to resolve various issues during this DCI by taking many years to perform and forward reviews; (2) telling AMVAC that EPA could proceed to the risk assessment phase absent certain data required by the data call-in; and (3) being in close contact with AMVAC concerning various studies but never stating that the process was taking an unacceptable amount of time.

provisions heretofore understood to serve as EPA’s primary avenues for removing products from the market by sanctioning a virtually unreviewable EPA power to suspend a registration based on dissatisfaction with a DCI study. EPA would have no reason to initiate a cancellation proceeding under 7 U.S.C. § 136d(b), based on substantive concerns it might have with a pesticide meeting the statutory standard, if EPA could merely allege that a single study regarding a pesticide’s registrability, years after submission of the study, introduced undue amounts of “uncertainty” into the Agency’s analyses. In short, if it affirms the Order, the EAB would be accepting a classic “elephant in a mousehole” interpretation of a statute that courts are instructed to avoid. *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001). This outcome would be clear error.

For similar reasons, a prior EPA attempt to circumvent cancellation procedures correctly have been met with extreme skepticism and rejected by a Federal Court. In *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011), pesticide manufacturers objected to EPA’s refusal to initiate statutory cancellation procedures. EPA believed the then-approved label presented unreasonable risk, and EPA tried to remove the product from the market by asserting that using the approved label would be “misbranding” under 7 U.S.C. § 136j.²⁸ *Id.* at 45. The Court ruled that EPA could not bypass a cancellation hearing. Allowing EPA to use FIFRA’s misbranding procedures to remove products from the market, the Court ruled, would “effectively cancel the registrations without following the regulatory procedures provided in Section 6,” which establishes a “detailed, multi-step process that EPA must follow when it wants to cancel or suspend a registration.” *Id.* at 43, 49. The Court refused to “allow[] EPA to avoid the

²⁸ EPA had concluded, in a formal risk management decision document, that unless certain mitigations were added to the label, the products would not meet the FIFRA registration standard (*i.e.*, they would pose an unreasonable risk).

rigorous cancellation process Congress provided for in the statute.” *Id.* at 42-43.²⁹

3. *The Order Defers Inappropriately to the Office of Pesticide Programs*

Footnote 24 of the Order asserts that decisions about whether a registrant took “appropriate steps” are “better made” by “officials in [the Office of Pesticide Programs]” because those officials are granted discretion under the statute (presumably, by the “may” clause in the Suspension Provision) to determine when to issue a NOITS. With this conclusion, the footnote provides yet another basis for vacating and remanding the Order: it contradicts the well-established principle that the ALJ and the EAB should not defer to agency determinations as a reviewing Article III court might under *Chevron* or related doctrines.³⁰

The Order acknowledges this contradiction but tries to sidestep it by casting all relevant elements of the “appropriate steps” inquiry as matters implicating the Agency’s “technical

²⁹ Indeed, the EPA conduct accepted as appropriate by the Order is even more extreme than the conduct prohibited by *Reckitt Benckiser*. EPA has made no secret that a primary motivating factor for the suspension action is a substantive concern it has with the safety of DCPA. *See* JX 2, 87 Fed. Reg. 25,262, 25,263 (Apr. 28, 2022) (discussing uncertainty regarding thyroid effects). If that is the case, and if EPA’s concerns are sufficiently well-grounded, its proper course is to initiate cancellation proceedings. It is no response to say that in *Reckitt* the EPA possessed the data needed to reach its negative risk conclusion whereas here it does not. EPA repeatedly told AMVAC that it could proceed with risk assessment, even if it would have to use conservative assumptions. *E.g.*, JX 21. In fact, it was not until a memo dated March 21, 2022, PAX 43, which was not sent to AMVAC until the same day the notice was issued in the Federal Register, April 28, 2022, *see* McMahon (AMVAC) Statement ¶ 26 (referring to the document by its regulations.gov identifier) that EPA asserted it would not be able to complete a human health risk assessment. Even then, testimony in a full cancellation hearing would establish that EPA routinely completes human health thyroid risk assessments with data of the type presently available to it. EPA could always plead “uncertainty” under the deferential standard in the Order to avoid the scrutiny that would attach to its conclusions in a cancellation hearing.

³⁰ *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). Footnote 24 in the Order cites to *Consent Agreements and Proposed Final Orders for Animal Feeding Operations*, 2006 WL 478143, at *9 n.21 (EAB 2006). The lack of “circular” deference by internal agency decision making units is a bedrock principle predating the EAB itself, which the EAB has also repeatedly reaffirmed. *See, e.g., In re Mobil Oil Corp.*, 5 E.A.D. 490, 508-509 & n.30 (EAB 1994) (internal Agency tribunals are not bound by outside judicial deference doctrines) (referring to consistency of this holding with decisions of EPA adjudicatory offices predating the EAB); *In re Lazarus, Inc.*, 7 E.A.D. 318, 351 n.55 (EAB 1997).

expertise” and then asserting that OPP should be given deference under a narrow exception. But this reference to the “technical expertise” exception is misplaced. That exception is nowhere near as broad as it is applied by the Order; rather, it applies only where EPA is challenged on an issue that is “fundamentally technical in nature.” *In re Dominion Energy Brayton Point, LLC*, 12 E.A.D. 490, 510 (EAB 2006). Only where there are “bona fide differences of expert opinion or judgment on a technical issue,” is there precedent for ALJ or the EAB to defer to another Agency office. *Id.* (collecting cases). That is not the case here, where legal issues, and other issues that do not turn on expert opinion predominate. Even where there are issues that may implicate technical expertise, deference is not properly applied by the ALJ or EAB to resolve a summary motion, as occurred in the Order, as discussed in more detail below.

In this case, many of the required determinations relevant to the “appropriate steps” inquiry do not require an “expert opinion or judgment on a technical issue” as *Dominion Energy* refers to. There is nothing technical about the reasons for delay of the study that the NOITS identified as most important, the CTA Study.³¹ This study took as long as it did (it was submitted on June 20, 2022) in large part because there was no pre-established procedure; numerous precursor studies had to be (and were) designed by AMVAC and EPA, collaboratively, and were executed successfully by AMVAC. Additional delays arose from events beyond AMVAC’s control (a flood and a ransomware attack at the lab conducting the study). AMVAC was providing EPA with regular updates about its progress. *See generally* Verified Written Statement of AMVAC Witness Ann Jonynas (“Jonynas (AMVAC) Statement”)

³¹ The “CTA Study” refers to a study that was very novel in 2013 when the DCI was issued, and which is still relatively uncommon today. McMahan (AMVAC) Statement ¶ 19; Verified Written Statement of AMVAC Witness Elaine Freeman (“Freeman (AMVAC) Statement”) ¶ 26. It examines a pesticide’s potential effects on thyroid function.

¶¶ 9-144. Even a layman could look at the voluminous record of communication regarding this study and conclude that AMVAC was taking appropriate steps to satisfy the data requirement. And no technical expertise is required to determine that, if a registrant submits a study on time and then receives no response from EPA for eight years (until the same day as the notice to suspend was issued), any possible lack of appropriate conduct is on the part of EPA, not the registrant.

The Order also does not specify which of two possible types of deference it is applying in various places. The first potential form of deference would be traditional *interpretive* deference, in which an Article III court defers to an agency's interpretation of a statute the Agency is charged to implement, as established by the Supreme Court's *Chevron* decision, *supra* n.30. Footnote 24's reference to decisions about "appropriateness" being "better made" by "officials in OPP" could be read to imply that this form of deference is being brought to bear. But this form of deference is foreclosed by the EAB precedents referenced above. *See supra* n.30. And even if this were not the case, it would be inappropriate to offer interpretive deference where there is no gap in the statutory language for an Agency to fill.³²

Alternatively, perhaps the ALJ intended to refer to the *factual* deference that the EAB has acknowledged sometimes may be invoked when there is a "bona fide difference[] of expert opinion or judgment on a technical issue" between an EPA office and a litigant.³³ But invoking that principle to decide a motion for accelerated decision would be wholly inconsistent with the

³² *E.g., Hechavarria v. Sessions*, 891 F.3d 49, 56 (2d Cir. 2018), *as amended* (May 22, 2018) ("Chevron deference is appropriate only when [statutory] language is ambiguous and the intent of Congress unclear."). The Order appears to disclaim the existence of an ambiguity when it states that limiting the scope of the inquiry "abid[es] by the plain language of the statute." Order at 20. This would render *Chevron* deference inappropriate even if the EAB had not foreclosed its use as a general matter.

³³ *Dominion Energy Brayton Point*, 12 E.A.D. at 510.

requirement that, when deciding a summary motion, factual disputes must be resolved in the favor of the non-movant if any reasonable decisionmaker could do so at a hearing. *See supra* Section II, pp. 8-9. The EAB should hold that this form of deference is cannot properly be applied when resolving summary motions concerning compliance with the Suspension Provision. Holding that the entire “appropriate steps” inquiry can be put into the “technical deference” box would write the hearing out of the statute and would be an abdication of the ALJ and EAB’s role as a neutral adjudicators.³⁴

4. *Case Law Cited in the Order Does Not Support Narrowing the Scope of a Suspension Hearing*

This section of the Order also cites *Atochem N. Am., Inc. v. EPA*, 759 F. Supp. 861, 864 (D.D.C. 1991) for the proposition that “the validity of [DCI data requirements] may not be challenged” at a hearing. Order at 4, 27. But *Atochem* addressed a situation, unlike here, in which the registrant asserted that EPA had no legal right to request the data it was seeking in that case.³⁵ The Plaintiff there was arguing (also not in the context of a suspension hearing) that the mere request for data was not permissible under FIFRA, or was issued without proper notice and comment procedures, or was arbitrary and capricious. *Atochem*, 759 F. Supp. at 866. AMVAC raises no such challenges – it does not assert that EPA may not validly ask for the data. Rather, AMVAC has asserted scientific bases for why the data is not needed to confirm that DCPA meets the FIFRA registration standard, following a waiver process explicitly sanctioned in EPA

³⁴ It does not matter if deference will resolve the issue in EPA’s favor following a hearing. The hearing may reveal that there is in fact no “bona fide difference” of opinion (or no relevant difference); or EPA’s expert’s opinion may be revealed to be inapplicable or not credible. Additionally, the hearing may clarify the precise bounds of what is a legal question about which no deference is due, and what is a “technical issue” about which some deference may be due. Granting the accelerated decision cuts off this important exercise.

³⁵ At issue in the case was a complex monitoring program that the registrants deemed to be economically prohibitive.

regulations. *See* 40 C.F.R. § 158.45. This distinguishes a waiver request – which are routine responses to DCIs – from the course taken by the plaintiff in *Atochem* (*i.e.*, denial that EPA was acting lawfully in making the request in the first instance), and the dicta in *Atochem* refers to the latter type of claim. The Order also cites *In re Bayer Cropscience LP*, 17 E.A.D. 228 (EAB 2016), to support its extremely narrow view of what may be addressed in a hearing under the Suspension Provision. But *Bayer* is also distinguishable, as it was addressing a Section 6(e) conditional registration cancellation hearing. The discussion in *Bayer* of what “matters” were beyond the scope of the hearing related to *Bayer’s* challenge to the lawfulness of a condition on *Bayer’s* registration; AMVAC presents no such challenge.

B. The Order Failed to Resolve Genuinely Disputed Facts in AMVAC’s Favor and Obscures Which Facts Were Material to its Analysis

The first step in considering a Motion for Accelerated Decision is to determine what factual disputes are *material* – that is, which disputes, under the governing law, affect the outcome of the proceeding. *In re Clarksburg Casket Co.*, 8 E.A.D. 496, 501-02 (EAB 1999). Then the tribunal must determine which factual disputes are *genuine*. A factual dispute is genuine if the evidence is such that a reasonable factfinder *could* find for the nonmoving party after a hearing. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The factfinder must construe the evidence available in the light most favorable to the nonmoving party and make all reasonable inferences in that party’s favor when determining if a dispute is genuine. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

The Order frequently is not clear in stating what issues the ALJ concluded are *material*. There is some ambiguity as to whether certain observations are dicta (because they concern a factual dispute that is not material) or whether those observations in fact supported the conclusions of law made. To the extent the latter occurs, it is improper, because the Court’s

observations frequently adopt EPA's contentions, even though they are contested, and thus reflect a failure to acknowledge a genuinely disputed issue. Occasionally the Order expressly states that a particular finding is made in the alternative – *i.e.*, it is not material under the improperly narrow legal standard the Order applies. In these instances as well, the Order frequently denies the existence of a genuine factual dispute (which would be material under the correct facts-and-circumstances inquiry) where one exists.

As explained *supra*, Section IV.A, pp. 12-31, the Order's overriding – but erroneous – legal conclusion is that a registrant may be suspended if there is any DCI study it has not submitted (or which EPA has not accepted) at the time EPA issues a NOITS. Period. Circumstances are irrelevant. Order at 23, 26. AMVAC does not contest that studies for most of the 20 data requirements referenced in the NOITS still have not been submitted, so if the ALJ's improper interpretation of the law is correct, there are no unresolved material facts concerning those studies.³⁶

But the Order goes on at length about numerous facts – some specific to individual studies or groups of studies, and some applicable to AMVAC's conduct as a general matter – as though they are material without clearly stating otherwise. For instance, the Order appears to accept EPA's controverted testimony that AMVAC's conduct was “abnormal[],” Order at 23. This could signify that the ALJ's legal holding really is that a registrant may be suspended on the basis of any study it has not submitted (or which EPA has not accepted) at the time EPA issues a NOITS, *but only if that registrant took an “abnormal” amount of time to complete one or more*

³⁶ Three studies were submitted after the notice was issued (two for DCPA Guideline 850.1400, and the SS-1069 CTA Study). And for four studies, AMVAC is alleged to be out of compliance with the Suspension Provision based on the content of submitted studies rather than non-submittal of those studies. (DCPA Guidelines 850.2100, 850.4100, SS-1069, and 850.1350).

data requirements. The text of the Order makes it impossible to be sure, but if this was the legal principle the ALJ was adopting, she also was erroneously denying the existence of a genuine factual dispute about whether AMVAC's conduct was abnormal, as discussed in more detail in the first bulleted section below.

In sum, the Order should be reversed and remanded either because the ALJ failed to recognize a *genuine* dispute where one exists and such dispute is material either because: (1) it may have contributed to a conclusion of law reached in the Order; or (2) would be material under a properly conducted "appropriate steps" inquiry. Even a lack of clarity in the Order concerning whether a particular dispute was treated as material may be independent grounds for remand. *BWX Technologies*, 9 E.A.D. at 68-69 (orders granting accelerated decisions may be remanded if they do not sufficiently specify the basis for central legal conclusions and allow a determination of whether summary judgment principles were properly applied).

Five examples of the Order's failures to acknowledge the existence of genuine factual disputes, and/or to make clear what disputes were material to its analysis or outcome, are set forth in the bulleted sections below.³⁷

- References to EPA Witness Bloom's testimony that even though "it is not unusual for registrants to fail to meet some deadlines for registration review DCIs," AMVAC's

³⁷ There are many other similar instances in the Order where the ALJ failed to recognize the existence of genuine disputes of fact or committed other errors. AMVAC takes exception to the Order's failure to acknowledge the existence of genuine disputes of fact when discussing individual data requirements at pp. 24-31 of the Order. All of these factual disputes are identified in AMVAC's Opposition to the Motion for Accelerated Decision (Sections III.C.1, 2, 5, 9 and 10 for the data requirements discussed in the Order). Exhibit 1 is intended to summarize, for ease of reference, the Order's treatment of these issues. AMVAC separately objects to the Order's failure to assess other data requirements discussed in Sections III.C.3, 4, and 6-8 of its Opposition below, as discussed *infra* Section IV.A.C, pp. 38-39. In accordance with the EAB's recent July 8, 2022, Standing Order regarding brief length limitations, Exhibit 1 is not included in the word count certified below. If the EAB considers this to be inconsistent with the Standing Order, AMVAC requests an opportunity to be heard.

conduct was “abnormal” as compared to other registrants in terms of the “high ratio of non-submissions and waiver requests,” the “time for data to remain outstanding after they are required,” and the degree to which it was “dilatory and repetitive.” Order at 6, 23, referring to the Verified Written Statement of EPA Witness Julie Bloom (“Bloom (EPA) Statement”) at 1, 4-6.

The Order can be read in several places to find it material that AMVAC’s conduct in response to the DCI was “abnormal,” or “dilatory and repetitive.”³⁸ A reference to Bloom’s testimony on this point features prominently under the heading “AMVAC failed to take the action that served as the basis of the NOITS ... ” of the Order at 23. The Order appears to treat this as a factual finding. *Id.* But this is a genuinely disputed fact. AMVAC’s fact witnesses describe how they responded to each data requirement. *See* Statements of Freedlander, Porter, Jonynas, and Wood (AMVAC). AMVAC’s expert, Mr. Gur, provided testimony that the back-and-forth iterations of the precise nature encountered in this case are typical of DCIs. Gur (AMVAC) Statement ¶¶ 17-19, 25-27, 37. Ms. Bloom’s assertions also are contradicted by the fact that many of the data evaluation reports presented to the ALJ show that EPA itself was responsible for years of delay. *See* n.18, *supra*. This evidence (even just Mr. Gur’s expert testimony) clearly establishes a genuine factual dispute. Cross-examination of, and rebuttal evidence from, Mr. Gur and Ms. Bloom, and others, are clearly required to resolve the issue if it is material to the outcome.

- The deadlines were set “specific to the nature of the data requirements” and were “based on a number of months it is expected to take to conduct the studies . . . rather than for specific dates.” Bloom (EPA) Statement at 3-4; Order at 5-6.

This language could be read as material to the Order’s apparent conclusion that, at least after the nominal deadlines in the DCI pass, there is no inquiry into appropriate steps at all. The

³⁸ The Order’s assertion that AMVAC’s conduct was “interminable” and that failing to suspend AMVAC would invite other registrants to engage in “interminable” delays, Order at 21-22, suffers from the same defects discussed in this section; it is genuinely disputed by the same evidence cited in this section, and it is unclear the extent to which the Order relies on it.

Order appears to conclude that OPP made a specific determination regarding how long the studies in this DCI should take. Even EPA Witness Bloom’s statement, to which the Order cites, does not make this claim. AMVAC provided testimony that EPA’s default values are “usually grossly underestimated except for very routine, short-term studies, none of which are in the DCPA DCI.” Gur (AMVAC) Statement ¶ 22. There is therefore a genuine dispute as to whether the deadlines in the DCI were specifically tailored to AMVAC’s situation or were instead default values that may have been gross underestimates of the time actually required. To the extent the Order relies on, or finds probative, the nominal DCI deadlines, this issue is material.

- “Although it is common for registrants and other stakeholders to submit comments concerning anticipated data requirements, neither AMVAC nor any other entity or person did so.” Order at 4. “Notably, AMVAC did not respond to the 2011 notice and thereby surrendered an opportunity to help shape the content of the DCI before it was issued.” *Id.* at 22.

The second statement, denominated as “notable,” could be interpreted as a conclusion that certain of AMVAC’s objections after the DCI was issued were not “appropriate” specifically because AMVAC had not commented on “anticipated data requirements” in the “2011 notice.” Order at 5, 22. If this is material to the ALJ’s analysis (which is not clearly evident) the passage inappropriately resolves inferences in EPA’s favor. The passage implicitly concludes that there was a meaningful opportunity to “help shape the content of the DCI,” *id.* at 22, which is not even directly supported by the Bloom statement. AMVAC should have the opportunity to rebut the assertion that submitting comments is “common,” and the implication that the Agency is likely to alter a data requirement based on a registrant comment. In this case, AMVAC could not have known that whether it was “common” for registrants to comment on preliminary work plans would be a factual inference it would need to contest as the prehearing filings (in which EPA

first asserted this) were made simultaneously by EPA and AMVAC.³⁹

- “According to Agency testimony . . . [i]t is common for registrants to request extensions of time for responding to individual data requirements EPA is generally accommodating of unexpected delays in conducting required studies, or new waivers or substitute studies” Order at 5-6.

The inclusion of these statements suggests the ALJ may have felt that AMVAC acted inappropriately by failing to request extensions.⁴⁰ But such an inference is inconsistent with sworn testimony from AMVAC stating that EPA ignored the only extension request AMVAC ever made early in the response process here. Jonynas (AMVAC) Statement ¶¶ 148-150.⁴¹ A reasonable factfinder could conclude (based on the fact that AMVAC asked for an extension and EPA never responded, which EPA has not contested) that EPA signaled to AMVAC that extension requests were not needed or desired. This inference is further supported by testimony by one of AMVAC’s expert witnesses that EPA routinely ignores requests for extension and in some cases even discourages filing them because they add to the Agency’s workload. Gur (AMVAC) Statement ¶¶ 32-35.

- The Conclusion. Order at 31.

The legal irrelevance of the October 2022 deadline has already been discussed at length, *supra* Section IV.A.1.c, pp. 19-23. This section highlights only that the fact that, because such a large portion of the “Conclusion” of the Order is devoted to discussing the October 2022 deadline, and a string-cite concerning the general proposition that agencies must comply with

³⁹ The Order at 2 incorrectly states that EPA’s pre-hearing filing was made on June 21, 2022, after AMVAC provided its prehearing exchange on the 17th. All prehearing materials were exchanged on the same day, June 17.

⁴⁰ Because there is no formal findings of fact section, it is unclear when the Order uses phrases like “[a]ccording to Agency testimony . . .” whether it is signaling that it merely recounting EPA’s claim as a litigant, or whether it is making a factual finding in view of a perceived lack of testimony from AMVAC on the point.

⁴¹ Ms. Jonynas subsequently identified a missing “not” between “were” and “needed” in ¶ 150 of her statement.

statutory requirements applicable to those agencies, *see* Order at 31, it suggests that the ALJ found the existence of the October 2022 deadline material to the outcome. The dispute over whether the October 2022 deadline has any relevance is ultimately a legal one rather than a factual one. But the substantial reference to it in the Conclusion highlights the larger issue discussed in this section, that it is frequently difficult to determine what issues were material to the ALJ’s conclusion. The EAB should remand with instructions clarifying the legal standard and requiring the ALJ to clearly state the relevant considerations for any legal conclusions reached in a future decision.

The penultimate sentence of the Conclusion contains one legal error and two improperly resolved inferences.⁴² The sentence errs legally insofar as it asserts AMVAC would be “reward[ed]” if its registration remains in place after the registration review deadline. EPA’s registration review deadline is statutorily irrelevant to whether any registrations “remain active.” Order at 31. Any modifications following registration review require EPA to use other defined procedures under FIFRA (*i.e.*, a cancellation procedure). 7 U.S.C. § 136a(g)(1)(A)(v); *see also supra* n.29. The sentence errs on the facts by concluding that AMVAC would “obtain[] the benefit of delayed compliance costs” if it were given more time to complete data requirements. There is simply no basis for this conclusion in the record; there was no testimony concerning compliance costs of any type. Finally, the sentence errs in concluding that AMVAC has been given an amount of time to comply “beyond the period generally provided to others.” Order at 31. This is a variation on the improper acceptance of Ms. Bloom’s opinion of AMVAC’s

⁴² “[Permitting] DCPA’s registration ... to remain active while the review process was on-going . . . would also reward AMVAC by allowing it to maintain its registration in effect past the statutory deadline, having obtained the benefit of delayed compliance costs, beyond the period generally provided to others, including its competitors.” Order at 31.

conduct as fact despite the existence of a genuine dispute, as discussed in more detail above.⁴³

EAB must not approve the ALJ's analysis for the reasons stated above; more clarity is needed about what the Order considers to be material. And regardless, much more is material to a correctly performed "appropriate steps" inquiry than under the ALJ's unduly narrow legal standard.

C. AMVAC is Entitled to a Determination as to Whether it Took Appropriate Steps with Respect to Every Study That EPA Asserts is a "Basis for the Suspension"

AMVAC is entitled to a determination of whether it took appropriate steps for each of the 20 studies EPA discusses in the NOITS. This is important, because EPA may only suspend AMVAC's registration pending compliance by AMVAC for studies for which AMVAC did not take appropriate steps. The Order fails to recognize this and make the necessary determination. After reaching conclusions as to whether AMVAC's conduct met the statutory standard for only 6 of the 20 data requirements referenced by EPA in the NOITS, the Order asserts that "it is not necessary . . . to conduct similar reviews of the remaining outstanding data [requirements]" because "any single [study] can form a basis for issuing a notice of suspension." Order at 7, 31.

As noted above, the *remedy* available to EPA based on the failure of a registrant to take appropriate steps is that it may suspend the registrant's registration until such time as "the registrant has complied fully with the requirements that served as a basis for the suspension of the registration." 7 U.S.C. § 136a(c)(2)(B)(iv). If it turns out that a registrant *did* take appropriate steps with respect to a particular data requirement, then that data requirement will

⁴³ An additional curiosity of the string-cite that dominates the Conclusion, which sets forth variations on the unremarkable proposition that agencies generally must/ought to operate within the bounds of the statutes they enforce, is that, as discussed *supra* Section IV.A.1.c, pp. 19-23, the requirement that EPA complete registration review is unrelated to whether DCPA is cancelled (or suspended) as of October 2022.

not form a *valid* “basis for the suspension of the registration.” *Id.*

The Order did not reach a legal conclusion concerning whether AMVAC’s conduct met the statutory standard with regard to any study other than the 6 it specifically discusses. Therefore, unless EPA is prepared to accept that its authority to maintain any suspension of AMVAC’s DCPA registration in effect relates only to compliance with those 6 data requirements, further analysis is required. Any other result would be illogical. If an ALJ could review only a sub-set of studies identified in a notice by EPA, but EPA were nonetheless permitted to continue a suspension in force until a registrant had met all requirements alleged to be outstanding, a registrant would be completely denied its opportunity for a hearing with respect to whichever studies the ALJ opted not to review.

D. OPP’s Existing Stocks Order is Inconsistent with FIFRA

AMVAC asserts that the Order’s conclusion that the existing stocks provisions of the NOITS were consistent with FIFRA was error. AMVAC incorporates the arguments in the Appeal Brief of the Grower Petitioners on this point.

V. CONCLUSION

For the reasons set forth above, the Order granting Respondent’s Motion for Accelerated Decision was improperly granted. The EAB should clarify the legal standard, consistent with the “appropriate steps” framework established by Congress and clarify that hearings under 7 U.S.C. § 136a(c)(2)(B)(iv) must properly consider all evidence of compliance with that standard. The EAB should also clarify that the deference afforded to OPP by the ALJ was improper (both regarding factual inferences and concerning the meaning of the statutory standard). Having so concluded, the EAB should remand this matter for a hearing on each of the data requirements EPA alleges continues to form a valid basis for the notice of intent to suspend, and for evaluation

of the existing stocks provision.

Date: July 21, 2022

Respectfully Submitted,

/s/ Hume M. Ross

David B. Weinberg

Tracy A. Heinzman

Keith A. Matthews

Hume M. Ross

WILEY REIN LLP

2050 M ST NW

Washington, DC 20036

Telephone: (202) 719-7000

dweinberg@wiley.law

theinzman@wiley.law

kmatthews@wiley.law

hross@wiley.law

Counsel for AMVAC Chemical Corp.

CERTIFICATION

I certify that this combined Notice of Exceptions and Appeal Brief contains 13,985 words, exclusive of the caption, table of contents, table of authorities, certifications, and Exhibit 1, based on the word count of the word-processing system used to prepare this document.

/s/ Hume M. Ross
Hume M. Ross

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Petitioner AMVAC Chemical Corporation's Notice of Exceptions and Appeal Brief**, and associated Exhibit 1, were sent on July 21, 2022, to the following parties in the manner indicated below.

/s/ Hume M. Ross

Hume M. Ross

Copy by EAB E-Filing System to:

U.S. Environmental Protection Agency
Environmental Appeals Board
1200 Pennsylvania Avenue, NW
Mail Code 1103M
Washington, D.C. 20460-0001

Copies by Electronic Mail to:

Forrest Pittman
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
Mail Code 2310A
1200 Pennsylvania Avenue NW
Washington, DC 20460
Email: pittman.forrest@epa.gov

Cristen S. Rose
Haynes Boone
800 17th Street NW
Washington, DC 20006
Email: cristen.rose@haynesboone.com

Counsel for Grower Petitioners

Counsel for Respondent

Emilio Cortes
Clerk of the Board
U.S. Environmental Protection Agency
Environmental Appeals Board
1200 Pennsylvania Avenue, NW
Mail Code 1103M
Washington, D.C. 20460-0001
Email: Clerk_EAB@epa.gov

Dated July 21, 2022