IN RE AMVAC CHEMICAL CORPORATION

FIFRA Appeal Nos. 22-01 & 22-02

DECISION AND REMAND ORDER

Decided September 28, 2022

Syllabus

AMVAC Chemical Corporation ("AMVAC"), the Grower-Shipper Association of Central California, and several farm operators appeal from a July 2022 accelerated decision by Chief Administrative Law Judge ("ALJ") Susan L. Biro suspending without a hearing AMVAC's registration of a pesticide product containing dimethyl tetrachloroterephthalate ("DCPA") under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). The Environmental Protection Agency ("EPA") Office of Pesticide Programs ("Pesticide Program") issued a notice of intent to suspend the registration in April 2022 based on AMVAC's alleged failure to submit twenty data requirements or take other appropriate steps to secure data required for registration review of DCPA. The Pesticide Program issued the underlying Data Call-In Notice in 2013.

The issues raised on appeal are whether: (1) the ALJ correctly applied the statutory legal standard for a suspension under FIFRA section 3(c)(2)(B)(iv), (2) the ALJ properly applied the standard for an accelerated decision, (3) the ALJ is required to determine whether suspension is warranted with respect to each of the twenty data requirements listed in the notice of intent to suspend, and (4) the provisions of the notice of intent to suspend with respect to existing stocks of DCPA are consistent with FIFRA.

Held: The Environmental Appeals Board ("Board") finds that the ALJ misconstrued and misapplied the statutory standard for granting suspensions under FIFRA and failed to properly apply the standard for an accelerated decision. Accordingly, the Board remands the case to the ALJ for a hearing.

1. *Statutory Standard for Suspension of a Pesticide Registration*

The ALJ misconstrued the statutory standard for suspension by failing to give effect to a fundamental component of the statutory language—the "to take appropriate steps" language setting forth the statutory basis for the notice of intent to suspend. FIFRA section 3(c)(2)(B)(iv) provides three possible grounds for a notice of intent to suspend, and

the one applicable in this case is failure to "take appropriate steps to secure the data required." 7 U.S.C. § 136a(c)(2)(B)(iv). The statutory language limiting the scope of a hearing to "whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend" must relate back to the statutory grounds for the notice of intent to suspend and the "appropriate steps" language. *Id*. Instead of applying the plain statutory language, the ALJ relied on a misreading of the legislative history and statutory deadlines for conducting a hearing and completing registration review as a basis for narrowing the statutorily defined scope of the hearing. Because the ALJ limited the inquiry to whether AMVAC had submitted the required data, omitting analysis of whether AMVAC had taken appropriate steps to secure the data, the ALJ misconstrued the statute and failed to apply the correct legal standard.

2. *Accelerated Decision*

When considered under the correct legal standard, the record does not support the conclusion that the Pesticide Program is entitled to judgment as a matter of law. The ALJ relied on the Pesticide Program's verified written statements characterizing AMVAC's response to the data requirements as "abnormally dilatory" despite AMVAC's verified statement characterizing the response as typical. Other genuine issues of material fact exist concerning requests for extensions and AMVAC's requests for waivers of data requirements. A hearing is necessary to develop an adequate record to reach a conclusion as to whether AMVAC failed to take appropriate steps to secure the data within the meaning of FIFRA.

3. *Hearing on Remand*

FIFRA and its implementing regulations provide an opportunity for a hearing at which the ALJ is required to weigh the evidence and make findings of fact and conclusions of law based on the evidence presented. On remand, the ALJ must independently review the evidence relevant to whether AMVAC took appropriate steps without special deference to the Pesticide Program's conclusions. Furthermore, the ALJ must determine whether AMVAC failed to take appropriate steps with respect to each of the twenty data requirements listed in the notice of intent to suspend. If a suspension were to take effect based on a finding that AMVAC failed to take appropriate steps with respect to fewer than twenty requirements, there would be no legal basis for continuing the suspension after AMVAC complied with those requirements.

4. *Existing Stocks*

Because the Board concludes that the case must be remanded to the ALJ to apply the appropriate legal standard and hold a hearing, review of the existing stocks determination at this stage is premature. The Board therefore remands the case to the ALJ to first determine whether AMVAC failed to take appropriate steps to secure the data to fulfill each of the twenty listed requirements, and then, if the ALJ finds a basis for the

suspension, whether the existing stocks provision of the DCPA notice of intent to suspend is consistent with FIFRA.

Before Environmental Appeals Judges Aaron P. Avila, Mary Kay Lynch, and Kathie A. Stein.

Opinion of the Board by Judge Stein:

I. STATEMENT OF THE CASE

In April 2022, the Environmental Protection Agency ("EPA" or "Agency") Office of Pesticide Programs ("Pesticide Program") issued a notice of intent to suspend the registration of a pesticide product containing dimethyl tetrachloroterephthalate ("DCPA") under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). AMVAC Chemical Corporation ("AMVAC"), the only registrant of DCPA, filed objections to the notice of intent to suspend and requested a hearing before an Administrative Law Judge ("ALJ"). Additionally, the Grower-Shipper Association of Central California and several farm operators[1] filed objections and a hearing request. After the ALJ scheduled a hearing, the Pesticide Program filed a motion for an accelerated decision, asserting that the suspension was warranted as a matter of law. The ALJ granted the Pesticide Program's motion for accelerated decision and cancelled the hearing.

On July 21, 2022, AMVAC and a group consisting of the Grower-Shipper Association of Central California, J&D Produce, Ratto Bros., Inc., and Huntington Farms ("Grower Group") filed exceptions to the ALJ's Order with the Environmental Appeals Board ("Board"). The appeals raise four primary issues: (1) whether the ALJ correctly applied the statutory legal standard for a suspension under FIFRA section 3(c)(2)(B)(iv), (2) whether the ALJ properly applied the standard for an accelerated decision under 40 C.F.R. § 164.91(a)(7), (3) whether the ALJ is required to determine whether suspension is warranted with respect to each data requirement listed in the notice of intent to suspend, and (4) whether the provisions of the notice of intent to suspend with respect to existing stocks of DCPA

[1] The group of operators filing before the ALJ differs from the group that filed before the Board. The operators requesting a hearing before the ALJ included Sunheaven Farms, LLC, J&D Produce, Ratto Bros., Inc., and Huntington Farms. Filings before the Board include the same operators except for Sunheaven Farms, LLC. We use the term "Grower Group" herein to refer only to those included in the filings before the Board, i.e., Grower-Shipper Association of Central California, J&D Produce, Ratto Bros., Inc., and Huntington Farms.

are consistent with FIFRA. For the reasons discussed below, the Board finds that the ALJ misconstrued and misapplied the statutory standard for granting suspensions under FIFRA and failed to properly apply the standard for an accelerated decision. Accordingly, the Board remands the case to the ALJ for a hearing.[2]

II. STATUTORY AND REGULATORY HISTORY

FIFRA establishes a comprehensive regulatory scheme for the sale, distribution, and use of pesticides. The primary mechanism through which FIFRA protects human health and the environment is by requiring that EPA review the safety of a pesticide and register the pesticide prior to its sale or distribution in the United States. *See In re Bayer CropScience L.P.*, 17 E.A.D. 228, 235 (EAB 2016). The FIFRA provisions relevant to this case are discussed further below.

A. *Registration of Pesticides Under FIFRA Section 3*

Before selling or distributing a pesticide, a person must apply to EPA for registration of the pesticide.[3] FIFRA § 3(a), (c)(3), 7 U.S.C. § 136a(a), (c)(3). The application must include information about the applicant, a copy of the labeling with claims made for the pesticide and directions for use, and, if requested by the Administrator, data supporting the claims made about the pesticide. *Id.* § 3(c)(1), 7 U.S.C. § 136a(c)(1). EPA shall register the pesticide if the Agency determines that:

> (A) its composition is such as to warrant the proposed claims for it;
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> (B) its labeling and other material required to be submitted comply with the requirements of [FIFRA];
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> (C) it will perform its intended function without unreasonable adverse effects on the environment; and

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[2] The Board finds that oral argument would not materially assist its deliberations at this stage of the proceedings and therefore denies AMVAC's request for argument.

[3] Under the FIFRA regulations, a pesticide is a substance intended to prevent, destroy, repel, or mitigate a pest, while a pesticide product is a pesticide in the particular form in which it is distributed or sold. 40 C.F.R. § 152.3. We use the term "pesticide" generally to refer to both a pesticide and a pesticide product.

> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

Id. § 3(c)(5), 7 U.S.C. § 136a(c)(5). The registration of a pesticide under FIFRA is "a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used." *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010).

B. *Registration Review Under FIFRA Section 3(g)*

Once a pesticide is registered with EPA, it is subject to periodic review. FIFRA § 3(g)(1)(A)(i), 7 U.S.C. § 136a(g)(1)(A)(i). The initial review is to be completed by October 1, 2022, or fifteen years after the registration of the first pesticide containing the active ingredient, whichever is later. *Id.* § 3(g)(1)(A)(iii), 7 U.S.C. § 136a(g)(1)(A)(iii). Subsequent reviews are required every fifteen years. *Id.* § 3(g)(1)(A)(iv), 7 U.S.C. § 136a(g)(1)(A)(iv).

The Agency may, at any time, issue a data call-in notice if it believes that additional data are needed to conduct the registration review. 40 C.F.R. § 155.48; *see* FIFRA §§ 3(c)(2)(B), 3(g)(2), 7 U.S.C. §§ 136a(3)(c)(2)(B), 3(g)(2). Within ninety days of receipt of the data call-in notice, the registrant is required to provide evidence "that it is taking appropriate steps to secure the additional data that are required." *Id*. § 3(c)(2)(B)(ii), 7 U.S.C. § 136a(c)(2)(B)(ii). If there is more than one registrant of a pesticide, the registrants may enter into agreements to share the cost of developing data and may initiate binding arbitration to set the terms of the data development arrangement. *Id.* § 3(c)(2)(B)(ii)-(iii), 7 U.S.C. § 136a(c)(2)(B)(ii)-(iii).

C. *Suspension Procedures Under FIFRA Section 3(c)(2)(B)(iv)*

The procedures for suspending a registration for failure to comply with a data call-in notice are set forth in FIFRA section 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). Specifically,

> [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, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to

> suspend such registrant's registration of the pesticide for which additional data is required.

Id. The notice of intent to suspend takes effect thirty days from receipt by the registrant unless a person adversely affected requests a hearing or the registrant "has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend." *Id.* Any hearing on the notice of intent to suspend is conducted pursuant to FIFRA section 6(d). *Id.* According to section 3(c)(2)(B)(iv):

> The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA].

Id. The Pesticide Program bears the initial burden of presenting an affirmative case for suspension of the registration. 40 C.F.R. § 164.80(a). The registrant bears the burden of persuasion that its registration should continue. *Id.* § 164.80(b).

III. FACTUAL AND PROCEDURAL HISTORY

A. *Background*

DCPA is an herbicide used to control grasses and broadleaf weeds for agricultural crops. U.S. EPA, *DCPA Summary Document Registration Review: Initial Docket*, Docket No. EPA-HQ-OPP-2011-0374, at 3 (June 2011) ("Registration Review Summary"). DCPA was first registered under FIFRA in 1958 and was reregistered in 1998. *Id.* Technical grade DCPA is used to formulate various end-use products, known commercially as "Dacthal." Memorandum from Christina Wendel, Biologist, & Wm. J. Shaughnessy, Ph.D., Envtl. Fate Scientist, Envtl. Fate & Effects Div., Office of Pesticide Programs, U.S. EPA, to Jill Bloom, Chem. Review Manager, Pesticide Re-evaluation Div., Office of Pesticide Programs, U.S. EPA 6, 8 (May 31, 2011) (Joint Ex. 65). AMVAC is the only registrant of technical grade DCPA. Registration Review Summary at 11.

B. *The Data Call-In Notice*

The Pesticide Program initiated registration review of DCPA in 2011. Registration Review; Pesticide Dockets Opened for Review and Comment and Other Docket Actions, 76 Fed. Reg. 38,166, 38,167 (June 29, 2011). On January 31, 2013, the Pesticide Program issued a data call-in notice requesting data necessary for the registration review. Letter from Richard P. Keigwin, Jr., Dir.,

Pesticide Re-evaluation Div., Office of Pesticide Programs, U.S. EPA, Re: *Generic Data Call-In Notice* 1 (Jan. 31, 2013) (Joint Ex. 4) ("Data Call-In Notice"). The Data Call-In Notice listed thirty-five data requirements for studies evaluating DCPA's environmental fate, impact on non-target plant species, residue on food, impact on terrestrial and aquatic organisms, and toxicology. *Id.* at attach. 3. Some of the studies were required to be performed with both DCPA and tetrachloroterephthalic acid ("TPA"), a metabolite of DCPA.[4] Request for Hearing and Statement of Objections by AMVAC Chemical Corporation, Docket No. FIFRA-HQ-2022-0002, at ii, 51 (May 27, 2022) ("AMVAC Request for Hearing"); Data Call-In Notice at attach. 3, n.2. Additionally, the Data Call-In Notice listed multiple "preferred test species" for some studies. Data Call-In Notice at attach. 3 nn.12-17, 20-21.

The Data Call-In Notice further provided AMVAC options for responding to each requirement, including: 1) requesting voluntary cancellation, 2) deleting uses, 3) claiming a generic data exemption, 4) agreeing to satisfy the data requirement, or 5) requesting a waiver. *Id*. at 4-6. To satisfy the data requirements, AMVAC could develop new data, submit an existing study, upgrade an existing study, or cite an existing study previously submitted to EPA. *Id.* at 6-7. On April 29, 2013, AMVAC responded to the Data Call-In Notice and indicated which option it had selected for each data requirement. Letter from Julie Porter, Regulatory Product Manager, AMVAC, to Jill Bloom, Office of Pesticide Programs, U.S. EPA (Apr. 29, 2013) (Joint Ex. 5). In its response, AMVAC requested data waivers for several studies, mainly relating to TPA. *Id*. at attach. 2, 3; *see also* Data Call-In at attach. 3 (providing instructions and codes for response). A brief summary of the eight-year correspondence from 2013 to 2020 between the Pesticide Program and AMVAC concerning the Data Call-In Notice follows.

On March 21, 2014, EPA issued an internal memorandum stating that the Agency had evaluated AMVAC's waiver requests and found that no additional data were needed for three requirements and that additional data were still needed with respect to the other requirements for which AMVAC had requested waivers. Memorandum from Christina Wendel, Biologist, & James Lin, Envtl. Engineer, Envtl. Fate & Effects Div., Office of Pesticide Programs, to Jill Bloom, Chem. Risk Manager, & Kevin Costello, Branch Chief, Pesticide Re-evaluation Div., Office of Pesticide Programs (Mar. 21, 2014) (Joint Ex. 66) ("Waiver Response

[4] A metabolite is a residue chemical that results from the biological breakdown of a pesticide. *See* 40 C.F.R. § 158.1400.

Memorandum"). AMVAC asserts that it did not receive a copy of EPA's Waiver Response Memorandum until March 27, 2017, three years after it was dated. AMVAC Request for Hearing at 63. On February 22, 2018, AMVAC responded with renewed waiver requests and responses to EPA's evaluation. Letter from Jon C. Wood, Sr. Regulatory Manager, AMVAC, to Jordan Page, Pesticide Re-evaluation Div., Office of Pesticide Programs, U.S. EPA (Feb. 22, 2018) (Joint Ex. 67).

In October 2020, the Pesticide Program notified AMVAC that it intended to complete registration review interim decisions by October 1, 2022, and that portions of data required in the Data Call-In Notice remained outstanding.[5] Letter from Elissa Reaves, Ph.D., Acting Div. Dir., Pesticide Re-evaluation Div., Office of Pesticide Programs, to Jon C. Wood, AMVAC 1 (Joint Ex. 21).[6] The letter requested a response within thirty days indicating how AMVAC planned to satisfy the remaining requirements. *Id.* at 2.

On December 17, 2020, AMVAC responded, again renewing its request for waivers of several studies. Letter from Jon C. Wood, Sr. Regulatory Manager, AMVAC, to James Douglass, Pesticide Re-evaluation Div., Office of Pesticide Programs, U.S. EPA (Dec. 17, 2020) (Joint Ex. 22). Additionally, AMVAC indicated it would begin certain fish studies, was continuing a thyroid study, and was seeking clarification of the scope of the requirements for a sediment study. *Id.* at 2.

Although AMVAC and EPA continued to correspond regarding the status of studies, the Pesticide Program did not make a final determination on the waiver requests until EPA issued the notice of intent to suspend in April 2022.

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[5] Under the regulations, EPA may issue an interim review decision before completing a registration review. 40 C.F.R. § 155.56. The interim decision may include risk mitigation measures, identify data required to complete the review, and include schedules for completing the review. *Id.*

[6] Although not dated, the letter indicates it was providing the status of the Data Call-In Notice as of October 16, 2020.

C. *The Registration Suspension Proceedings*

On April 21, 2022, the Pesticide Program issued a letter notifying AMVAC that the Agency intended to suspend the registration of Technical Chlorthal Dimethyl ("technical DCPA"), which contains the active ingredient DCPA. Letter from Mary Elissa Reaves, Ph.D., Dir., Pesticide Re-evaluation Div., Office of Pesticide Programs, to Jon C. Wood, AMVAC (Apr. 21, 2022) (Ex. 1) ("Notice Letter"). The letter stated that the suspension would take effect thirty days from receipt of the letter unless AMVAC took certain steps before then to prevent the notice from becoming final. *Id*. at 1. EPA published the suspension notice in the *Federal Register* one week later. Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration, 87 Fed. Reg. 25,262 (Apr. 28, 2022) ("DCPA NOITS"). The DCPA NOITS states that AMVAC "failed to submit the data or information required by the Data-Call-In Notice * * * or to take other appropriate steps to secure the required data" associated with twenty of the data requirements.[7] *Id*. at 25,263-64. The DCPA NOITS further provides that once the suspension becomes final, any sale or distribution by AMVAC of technical DCPA, or use of technical DCPA to formulate another product, would be unlawful. *Id.* at 25,265. The DCPA NOITS provides that persons other than AMVAC may lawfully continue to sell, distribute, or use existing stocks of technical DCPA. *Id.*

On May 27, 2022, AMVAC and the Grower-Shipper Association of Central California, Sunheaven Farms, LLC, J&D Produce, Ratto Bros., Inc., and Huntington Farms filed objections and requested a hearing on the DCPA NOITS. AMVAC Request for Hearing; Objection and Request for Hearing by Grower-Shipper Association of Central California, Sunheaven Farms, LLC, J&D Produce, Ratto Bros., Inc., and Huntington Farms, Docket No. FIFRA-HQ-2022-0002 (May 27, 2022). On June 3, 2022, the ALJ issued an order scheduling a hearing to begin on July 6, 2022, and continuing as necessary through July 8, 2022. Order Scheduling Hearing and Prehearing Procedures 2 (ALJ June 3, 2022).

On June 13, 2022, the Pesticide Program filed a motion for an accelerated decision, arguing that there was no genuine issue of material fact with respect to AMVAC's failure to take appropriate steps to secure the data required by the Data Call-In Notice and with respect to the DCPA NOITS's determination as to existing stocks. Respondent's Motion for Acclerated [sic] Decision 1-2 (June 13, 2022) ("Motion"). AMVAC opposed the Motion, arguing that FIFRA requires a "facts

[7] Other requirements of the Data Call-In Notice were waived or satisfied by AMVAC. *See* Notice Letter at 1.

and circumstances inquiry" and that genuine issues of material fact exist that require a hearing. Petitioner AMVAC's Opposition to Respondent's Motion for Accelerated Decision 1, 17 (June 21, 2022).

On July 1, 2022, the ALJ granted the Pesticide Program's Motion, finding that "'the *only* matters for resolution in this proceeding' are (a) whether AMVAC has submitted the data required by the 2013 [Data Call-In Notice]; and (b) whether the Agency's determination with respect to the disposition of existing stocks of DCPA is consistent with FIFRA." Order on Respondent's Motion for Accelerated Decision 23 (ALJ July 1, 2022) ("Order"). The Order explained that the ALJ had reviewed the correspondence between the Pesticide Program and AMVAC with respect to nine of the twenty requirements listed in the DCPA NOITS and, based on that review, had concluded the Pesticide Program was entitled to judgment as a matter of law for each. *Id.* at 23-30. The ALJ reasoned that it was not necessary to review the remaining outstanding data requirements because "AMVAC's failure to comply with any *one* of [the data requirements] is sufficient cause for suspension." *Id.* at 31. Finally, the ALJ concluded that the DCPA NOITS's determination regarding existing stocks was "appropriate and consistent with FIFRA." *Id*. at 34. The ALJ therefore dismissed AMVAC's objections and cancelled the scheduled hearing. *Id.* at 34-35. This appeal followed.[8]

IV. STANDARD OF REVIEW

In a FIFRA suspension proceeding, the ALJ may issue an accelerated decision if "there is no genuine issue of any material fact and [] the respondent [EPA] is entitled to judgment as a matter of law." 40 C.F.R. § 164.91(a)(7). "The Board has construed an accelerated decision to be in the nature of summary judgment, and has adopted the formulation of the Supreme Court in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), and *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), construing Federal Rule of Civil Procedure 56." *Rogers Corp. v. EPA.*, 275 F.3d 1096, 1103 (D.C. Cir. 2002) (parallel citations omitted); *see also Martex Farms, S.E. v. EPA*, 559 F.3d 29, 32 (1st Cir. 2009) (finding an EPA ALJ's accelerated decision to be "the equivalent of a summary judgment ruling"). Thus, in resolving a motion for an accelerated decision, the evidence "must be viewed in

[8] AMVAC and the Grower Group each filed a Notice of Exceptions and Appeal Brief, which were entered on the Board's docket as FIFRA Appeal Numbers 22-01 and 22-02, respectively. Upon a joint motion of the parties, the Board consolidated the two appeals. Order Granting Leave to File Reply Brief and Consolidating Cases (EAB Aug. 10, 2022).

the light most favorable to the party opposing the motion." *Rogers*, 275 F.3d at 1103 (citing *Anderson*, 477 U.S. at 251, 255).

An accelerated decision by an ALJ has the same effect as an initial decision under 40 C.F.R. § 164.90. 40 C.F.R. § 164.91(b). The Board therefore reviews the ALJ's Order *de novo* and will consider AMVAC's and the Grower Group's exceptions to the Order on that basis. *Bayer CropScience*, 17 E.A.D. at 259 (stating that Board reviews an initial decision on a *de novo* basis).

V. ANALYSIS

A. *The ALJ Misconstrued and Misapplied the FIFRA Statutory Standard for Suspension*

1. *The Plain Language of FIFRA Requires Analysis of Whether AMVAC Took Appropriate Steps to Comply with the Data Call-In Notice*

AMVAC takes issue with the ALJ's determination that the scope of the hearing should have been limited to whether AMVAC submitted the data required by the Data Call-In Notice, arguing that the ALJ "wrongly interpret[ed]" the statutory language as "creating an all or nothing inquiry." AMVAC Appeal Br. at 13. We examine AMVAC's argument by starting with a close reading of section 3(c)(2)(B)(iv) of FIFRA, 7 U.S.C. § 136a(c)(2)(B)(iv), which we refer to as the "Suspension Provision." For ease of reference, we have numbered and listed separately below each sentence in the Suspension Provision:

> [1] Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required.
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> [2] The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide.
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> [3] Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the

> registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend.
>
> [4] If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title.
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> [5] The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter.
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> [6] If a hearing is held, a decision after completion of such hearing shall be final.
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> [7] Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.
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> [8] Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

FIFRA § 3(c)(2)(B)(iv); 7 U.S.C. § 136a(c)(2)(B)(iv).

We note at the outset that "[t]he starting point for interpreting any statute is the language of the statute itself." *In re Arcelormittal Cleveland Inc.*, 15 E.A.D. 611, 621 (EAB 2012). Each word of the statute should be given effect. *See In re San Pedro Forklift, Inc.*, 15 E.A.D. 838, 856 (EAB 2013). Furthermore, "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *In re Shell Gulf of Mexico, Inc.*, 15 E.A.D. 103, 122 (EAB 2010) (*quoting Wilderness Soc'y v. U.S. Fish & Wildlife Serv.*, 353 F.3d 1051, 1060 (9th Cir. 2003)).

The first sentence of the Suspension Provision provides three possible grounds for a notice of intent to suspend a pesticide registration following a data call-in notice: 1) failure to "take appropriate steps to secure the data required"; 2) failure to participate in a procedure for reaching a joint data development arrangement or in an arbitration; or 3) failure to comply with the terms of an

agreement or arbitration decision concerning a joint data development arrangement. FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv).

The fifth sentence of the Suspension Provision limits the scope of a suspension hearing by providing that "[t]he only matters for resolution * * * shall be whether the registrant has failed to take *the action that served as the basis for the notice of intent to suspend* the registration * * * and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter." *Id*. § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv) (emphasis added). AMVAC asserts that the "basis for the notice of intent to suspend" language in the fifth sentence must be read in conjunction with the statutory language in the first sentence that authorizes a notice of intent to suspend "if the Administrator determines that the registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required." *Id.*; *see* AMVAC Appeal Br. at 16. AMVAC contends that the ALJ improperly construed the statutory language to mean that a suspension hearing must focus *only* on whether the requested data were submitted and on the disposition of existing stocks, thereby effectively reading "appropriate steps" out of the statute. AMVAC Appeal Br. at 13, 15.

We agree with AMVAC. In this case, the "to take appropriate steps" phrase is a fundamental component of the statutory language to which we must give effect. The reference in the fifth sentence to the "action that served as the basis" for the notice of intent to suspend must refer back to one of the three actions identified in the first sentence whereby the Administrator, or the Administrator's delegate, is authorized to issue a notice of intent to suspend. Otherwise, the notice would not be authorized.

Here, the only possible basis the Pesticide Program could have for issuing the notice of intent to suspend technical DCPA is the first one—AMVAC's failure to take appropriate steps to secure the data. The other two bases for suspension relate to cost-sharing among multiple registrants and are not relevant to this matter because AMVAC is the only registrant of technical DCPA. Thus, the statutory basis for the DCPA NOITS must be that AMVAC "within the time required by the Administrator, has failed to take appropriate steps to secure the data required." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv).

The DCPA NOITS itself confirms this reading. Under the heading "Basis for Issuance of Notice of Intent to Suspend; Requirement List," the notice states: "[t]he registrant failed to submit the data or information required by the Data-Call-In Notice * * *, *or to take other appropriate steps to secure the required data* for

their pesticide product." DCPA NOITS at 25,263 (emphasis added). The inclusion of "or to take other appropriate steps to secure the required data" was necessary to conform the DCPA NOITS to the statutory standard for its issuance and is clearly the "basis" for issuing the DCPA NOITS.

The ALJ's interpretation that the "only matters for resolution" clause in the fifth sentence of the Suspension Provision limits the scope of the hearing to whether AMVAC failed to submit the required data runs counter to the statutory language. Significantly, by failing to consider whether AMVAC took "appropriate steps to secure the required data," the ALJ did not give effect to all the words of the statute. *See San Pedro Forklift*, 15 E.A.D. at 856-57. Rather, the ALJ assumed, without explaining, that the only possible "appropriate steps" consisted of submitting the data.

Other language elsewhere in the Suspension Provision that links back to the first sentence further supports our determination that the ALJ read the limiting language in the fifth sentence too narrowly. The third sentence provides that a proposed suspension shall become final and effective after thirty days unless either a hearing has been requested or "the registrant has complied fully with the requirements that *served as a basis for* the notice of intent to suspend." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv)(emphasis added). And the eighth sentence provides that a suspended registration shall be reinstated "if the Administrator determines that the registrant has complied fully with the requirements that *served as a basis* for the suspension of the registration." *Id*. (emphasis added). On the facts of this case, both of those clauses must refer back to the "appropriate steps" language in the first sentence. Together, these aspects of the Suspension Provision demonstrate the centrality of the "appropriate steps" language in the first sentence, which the ALJ failed to analyze.

In its brief, the Pesticide Program acknowledges that a "permissible interpretation is that suspension may only be granted after * * * examination of the steps taken to comply with each data requirement." Response Brief of Respondent 6 (July 28, 2022) ("Resp. Br."). Not only is this interpretation permissible, it is required by the plain language and structure of the statute.

2. *The Timeframe for Conducting a Suspension Hearing Is Not a Basis for Narrowing the Scope of the Hearing*

Next we turn to the ALJ's observation that the statute establishes a seventy-five-day deadline for conducting a hearing and that "[i]f Congress intended a more in-depth assessment of the 'appropriateness' of a registrant's actions * * * it would not have required that this whole proceeding begin and end in less than three

months." Order at 20; *see* FIFRA § 3(c)(2)(B)(iv),7 U.S.C. § 136(a)(c)(2)(B)(iv) ("a hearing shall be held and a determination made within seventy-five days after receipt of a request for such a hearing"). We find nothing in the statutory language or overall framework of FIFRA that provides a basis for concluding that the seventy-five-day timeframe should narrow the scope of a suspension hearing.[9]

At the same time that Congress enacted the Suspension Provision set forth in FIFRA section 3(c)(2)(B)(iv), it also enacted FIFRA section 6(e), codified at 7 U.S.C. § 136d(e), which governs the cancellation of conditional registrations of pesticides. The timeframe for holding a hearing and issuing a determination for the cancellation of a conditional registration under section 6(e) is also seventy-five days. 7 U.S.C. § 136d(e)(2). In that circumstance, the seventy-five-day timeframe is used to determine whether "the registrant has initiated and pursued *appropriate action* to comply with the condition or conditions" of registration.[10] *Id.* (emphasis added). The fact that Congress simultaneously concluded that seventy-five days is a sufficient amount of time to determine whether a conditional registrant took "appropriate action" to satisfy the conditions of its registration undermines the reasoning that Congress thought the same timeframe insufficient to consider "appropriate steps" under the Suspension Provision. A hearing on appropriate steps may prove to be more complicated than Congress anticipated decades ago, but the ALJ cannot base a decision on the scope of the hearing on a disagreement with or view of the difficulty of adhering to a specific statutory timeframe.

Further, hearings authorized by the FIFRA section 3(c)(2)(B)(iv) Suspension Provision and the FIFRA section 6(e) cancellation of conditional registrations provision are more limited in scope compared to broader cancellation hearings authorized by FIFRA section 6(b). Section 6(b) authorizes the

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[9] We do not resolve the parties' arguments, made in relation to a Motion for Leave to File a Reply Brief and for Oral Argument, regarding the effect of the seventy-five-day timeframe on the Board's decision. *See* Respondent's Opposition to Motion for Leave 1 (Aug. 3, 2022); Reply to Opposition to Motion for Leave 1 (Aug. 4, 2022). As those arguments were not raised in the appeal briefs and we did not address them in our ruling on the Motion for Leave, *see* Order Granting Leave to File Reply Brief and Consolidating Cases (Aug. 10, 2022), we need not address them here.

[10] FIFRA section 3(c)(7) allows conditional registration of pesticides in certain situations where the data required for complete registration are not yet available. A conditional registration requires the registrant to submit any missing data according to an approved schedule and to comply with other conditions imposed by the Administrator. *Bayer CropScience*,17 E.A.D. at 236-37.

cancellation of a pesticide determined to cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b). Cancellation hearings pursuant to section 6(b) are highly technical, and a party may request referral of questions of scientific fact to the Committee of the National Academy of Sciences.[11] *Id.* § 136d(d). A hearing on whether a registrant took "appropriate steps" to secure data is not as broad in scope by comparison.

We therefore reject the argument that the timeframe for conducting a FIFRA section 3(c)(2)(B)(iv) suspension hearing is a reason for narrowing the scope of the hearing to simply whether the required data was submitted and not whether the registrant took appropriate steps to secure the data.

3. *The Legislative History Supports the Plain Meaning of the Suspension Provision*

When considering questions of statutory interpretation, "the plain meaning of legislation should be conclusive, except in the rare cases in which the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters." *In re U.S. Army, Fort Wainwright Cent. Heating & Power Plant*, 11 E.A.D. 126, 141 (EAB 2003) (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 242 (1989)) (internal quotation marks and brackets omitted). As discussed above, we conclude that the plain language of the Suspension Provision controls and, thus, there is no need to examine its legislative history to resolve this issue. However, because the ALJ relied on the legislative history, we address it here.

The ALJ reasoned that the legislative history of the Suspension Provision demonstrates a Congressional intent to focus the inquiry on whether the data were timely produced. Order at 22-23. AMVAC, on the other hand, argues that the legislative history "confirms that Congress intended a factual inquiry into the registrant's 'appropriate steps.'" AMVAC Appeal Br. at 16.

The suspension provision was added to FIFRA in 1978 through reconciliation of differing House and Senate bills. H.R. Rep. No. 95-1560, at 32 (1978) (Conf. Rep.) ("Conference Report"), *as reprinted in* 1978 U.S.C.C.A.N. 2043. Both the House and Senate bills provided for cancellation of a registration if the registrant failed to take appropriate steps to secure additional data as required

[11] There is no statutory deadline in FIFRA section 6(d) for conducting the hearing and the agency has ninety days after completion of the hearing to issue an order. 7 U.S.C. § 136d(d).

by a data call-in notice. *Id.* However, the Senate bill provided for cancellation without a hearing, while the House bill provided for a hearing to be conducted in accordance with FIFRA section 6(b). *Id.* The conference substitute provided for suspension of registration until such time as the data are received or compliance is obtained. *Id*. Registrants of a pesticide subject to suspension were to be given the opportunity to request a hearing pursuant to FIFRA section 6(d), but the scope of the hearing would be limited to the "only matters" language at issue here. *Id.* Thus, the compromise struck in the final version provides registrants with the opportunity for a hearing but the scope of the hearing is limited. The Conference Report does not expressly address the reason for the limitation on scope and there is nothing in the Conference Report that demonstrates a Congressional intent to limit the scope of a suspension hearing to something less than the statutory basis for the notice of intent to suspend. To the contrary, we must give effect to all of the words of the statute and cannot assume that some are mere surplusage. *See San Pedro Forklift*, 15 E.A.D. at 856.

The ALJ relies on language in the Conference Report indicating the reconciled bill authorizes the Administrator to "enforce a defensive data requirement." Order at 22 (quoting Conference Report at 32). That paragraph in full states:

> The conference substitute authorizes the Administrator to enforce a defensive data requirement, or compliance with the terms of an agreement or arbitration decision concerning a joint data development arrangement, by instituting a procedure to suspend the registrant's registration until such time as the data are received or compliance obtained.

Conference Report at 32. While this language indicates that a suspension will continue until data are received or compliance is obtained, it does not address the scope of a hearing. The report goes on to describe the scope of the hearing using the same language as the statute: "[t]he only matters for resolution at that hearing will be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend concerning the pesticide for which additional data is required." *Id.* at 32-33. The Pesticide Program can enforce a defensive data requirement by demonstrating that the registrant failed to take appropriate steps to secure the data, as expressly provided by statute.

We find nothing in the legislative history to indicate that Congress had an intent "demonstrably at odds" with the plain language of the statute. *Fort Wainwright*, 11 E.A.D. at 141 (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 242 (1989)). The statutory language is clear that the action that

served as the basis for the notice of intent to suspend, as relevant here, must be a failure to take appropriate steps. That plain language controls.

4. *The Statutory Deadline for Registration Review is Not a Basis for Narrowing the Scope of a Suspension Hearing*

FIFRA section 3(g) provides "[t]he Administrator shall complete the registration review of each pesticide or pesticide case * * * not later than * * * October 1, 2022."[12] 7 U.S.C. § 136a(g)(1)(A)(iii). In the Order, the ALJ notes that AMVAC has conceded it will not submit some of the data until after the October 2022 deadline and reasons that, among other things, AMVAC's delay in submitting data would result in noncompliance by the Agency should the DCPA registration be allowed to continue past the deadline. Order at 31. The Order states:

> [I]f DCPA's registration was permitted to remain active while the review process was on-going, it would inevitably result in the Agency being in violation of law. It 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. This Tribunal will simply not countenance providing its imprimatur to such an outcome.

Id. (internal citations omitted). AMVAC characterizes the deadline for registration review as "wholly an administrative target for EPA" and takes exception to the ALJ's reliance on it as a basis for limiting the scope of a suspension hearing. AMVAC Appeal Br. at 21.

The language in FIFRA section 3(g) only imposes a requirement on the Administrator to complete registration review; it does not provide a deadline for a registrant to submit data in response to a data call-in notice. Furthermore, there is no automatic suspension or cancellation associated with the review deadline. If the Pesticide Program determines based on its review that a pesticide no longer meets the requirements for registration, the Pesticide Program must initiate cancellation proceedings under FIFRA section 6(d). 7 U.S.C. § 136a(g)(1)(A)(v). As the Pesticide Program acknowledges in its brief, the statutory deadline for the Agency

[12] More specifically, the deadline is the latter of October 1, 2022, or fifteen years after the date on which the first pesticide containing a new active ingredient is registered. FIFRA § 3(g)(1)(A)(iii), 7 U.S.C. § 136a(g)(1)(A)(iii). Since DCPA has been registered since 1958, the October 1, 2022, deadline applies.

to complete registration review is separate from the suspension proceeding related to the Data Call-In Notice. Resp. Br. at 11.

The cases cited by the ALJ do not support restricting the scope of the hearing in the suspension proceeding. *See* Order at 31. Some of the cited cases stand for the proposition that an agency must have legal authority for its actions. *See Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 141 S. Ct. 2485, 2490 (2021) (holding CDC could not impose an eviction moratorium without Congressional authorization); *Texas v. United States*, 555 F. Supp. 3d 351, 416 (S.D. Tex. 2021) (stating agency's result must be within its lawful authority), *appeal dismissed,* No. 21-40618, 2022 WL 517281 (5th Cir. Feb. 11, 2022). Others stand for the proposition that an agency must comply with statutory deadlines imposed on the agency. *See Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 970-71 (N.D. Cal. 2013) (finding FDA's failure to meet statutory deadline was a "failure to act" under the Administrative Procedures Act (citing *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1189-90 (10th Cir. 1999))); *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1176 (9th Cir. 2002) (finding Fish and Wildlife Services' failure to meet deadline for final determination violated Endangered Species Act); *Am. Lung Ass'n v. Browner*, 884 F. Supp. 345, 348 (D. Ariz. 1994) (finding EPA's failure to meet statutory deadline for review of National Ambient Air Quality Standards violated the Clean Air Act). None of the cases indicates that an agency may use a statutory deadline for agency action to narrow the scope of administrative review it applies to action undertaken by a regulated entity. To the contrary, in *National Urban League v. Ross,* a District Court found that the mandatory deadlines in the Census Act did not displace the Census Bureau's "duty to consider other express statutory and constitutional interests." *Nat'l Urban League v. Ross*, 489 F. Supp. 3d 939, 995 (N.D. Cal. 2020). The statutory deadline for registration review is therefore not a basis for narrowing the scope of a hearing.

The plain language of the statute and the DCPA NOITS demonstrate that the "action that served as the basis for the notice of intent to suspend" is the alleged failure by AMVAC to take appropriate steps to secure the required data. Neither the legislative history nor the statutory deadlines for the hearing or for registration review demonstrate an intent to narrow the scope of the hearing to whether the data were submitted. Accordingly, we find that the legal standard for determining whether the suspension should take effect is whether, within the time required by the Administrator, AMVAC failed to take appropriate steps to secure the data required by the Data Call-In Notice.

5. *The ALJ Misapplied the Statute and Did Not Address Whether AMVAC Failed to Take Appropriate Steps to Secure the Data*

Having concluded that the ALJ misconstrued the legal standard for the scope of a pesticide suspension hearing under FIFRA section 3(c)(2)(B)(iv), we next turn to whether the ALJ *applied* the correct legal standard to the facts in the proceeding. That is, we examine whether the ALJ's inquiry encompassed more than simply whether AMVAC had submitted the required data.

The Pesticide Program argues in its response brief that the ALJ considered whether AMVAC had taken appropriate steps "at least in a broad sense" and "consider[ed] appropriateness in an overarching sense." Resp. Br. at 6. We note, first, that considering the appropriate legal standard in a "broad" or "overarching" sense is not a sufficient basis on which to grant an accelerated decision, which, as discussed further below, requires a finding that no reasonable fact finder could rule for AMVAC. *See* Part V.B, below. Second, we disagree with the Pesticide Program's contention that the ALJ considered, even in a "broad" or "overarching" sense, whether AMVAC took appropriate steps to secure the data.

As discussed in Part V.A.1, above, the ALJ concluded that the appropriate inquiry was whether AMVAC had submitted the required data, rather than whether AMVAC had taken appropriate steps to secure the data. The ALJ's Order states, "I find that 'the *only* matters for resolution in this proceeding' are (a) whether AMVAC has submitted the data required by the 2013 [Data Call-In Notice]; and (b) whether the Agency's determination with respect to the disposition of existing stocks of DCPA is consistent with FIFRA." Order at 23.

Despite the Pesticide Program's argument to the contrary, it is clear that the ALJ applied that narrow standard to the analysis of the facts. As the Order indicates, the ALJ's sole focus was on AMVAC's failure to submit the requested data within the given timeframe. The Order states, "[W]hether AMVAC 'acted reasonably' is largely beside the point in this proceeding. The question is whether AMVAC submitted the TPA fish toxicity data requested by the [Data Call-In Notice] within the time the Agency required it." *Id*. at 25. Similarly, the Order finds "the factual issue is whether AMVAC failed to complete the submissions required by the [Data Call-In Notice], not whether it acted reasonably or appropriately under the circumstances." *Id*. at 27.

These statements demonstrate that the ALJ failed to apply the correct legal standard. Remand is therefore appropriate. We decline the Pesticide Program's invitation to undertake an after-the-fact correction of the ALJ's misapplication of the statute. When the correct legal standard is applied, AMVAC is entitled to a

hearing, and it would be inappropriate to deny AMVAC the statutorily provided opportunity it has invoked to attempt to show in a hearing that it took appropriate steps.

B. *The ALJ Improperly Granted an Accelerated Decision Where Genuine Issues of Material Fact Exist*

In addition to challenging the ALJ's interpretation of the legal standard for a pesticide suspension hearing under FIFRA section 3(c)(2)(B)(iv), AMVAC asserts that the ALJ failed to apply the correct standard for resolving a motion for an accelerated decision. AMVAC Appeal Br. at 31-38. The ALJ may grant an accelerated decision if "there is no genuine issue of any material fact and * * * the respondent [EPA] is entitled to judgment as a matter of law." 40 C.F.R § 164.91(a)(7). The Board has recognized that this standard is similar to the standard for summary judgment under Rule 56 of the Federal Rules of Civil Procedure and has been guided by case law interpreting Rule 56. *In re BWX Techs., Inc.*, 9 E.A.D. 61, 74-75 (EAB 2000); *In re Clarksburg Casket Co.*, 8 E.A.D. 496, 501-02 (EAB 1999).[13] Thus, to overcome a motion for accelerated decision, the nonmoving party "must demonstrate that an issue is both 'material' and 'genuine.'" *BWX Techs.*, 9 E.A.D. at 75 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1985)). "A factual dispute is material where, under the governing law, it might affect the outcome of the proceeding. * * * Whether an issue is 'genuine' hinges on whether, in the estimation of a court, a jury or other factfinder could reasonably find for the nonmoving party." *Id.*

As discussed above, the issue for resolution at the hearing in this case was supposed to have been whether AMVAC "within the time required by the Administrator, has failed to take appropriate steps to secure the data required." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). "Appropriate steps" is not defined in the statute. *See id*. § 2, 7 U.S.C. § 136. Where a term is not specifically

[13] *BWX Technologies* and *Clarksburg Casket* involved accelerated decisions under the Consolidated Rules of Practice, 40 C.F.R. § 22.20. The operative language is the same in the FIFRA regulations. *Compare* 40 C.F.R. § 22.20 ("The Presiding Officer may at any time render an accelerated decision in favor of a party as to any or all parts of the proceeding * * * if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law.") *with* 40 C.F.R. § 164.91(a) ("The Administrative Law Judge, in his discretion, may at any time render an accelerated decision in favor of Respondent as to all or any portion of the proceeding * * * under any of the following conditions: * * * [that] there is no genuine issue of any material fact and that the respondent is entitled to judgment as a matter of law * * *.").

defined in a statute or regulation, the Board looks to "the ordinary, contemporary, common meaning" of the term. *In re Chase,* 16 E.A.D. 469, 479 (EAB 2014) (quoting *In re Mayes*, 12 E.A.D. 54, 86 (EAB 2005)). "Appropriate" is defined as "specially suitable: fit, proper." Webster's Third New International Dictionary 106 (1993). "Step" is defined as "an action, proceeding, or measure often occurring as one in a series." *Id.* at 2236. Whether an action was appropriate is a factual inquiry. *See Michigan v. EPA*, 576 U.S. 743, 752 (2015) ("'[A]ppropriate' is 'the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors.'"); *Alabama v. North Carolina,* 560 U.S. 330, 346 (2010) (finding parties' course of performance "highly significant" to whether State failed to take "appropriate steps" to obtain license in accordance with interstate compact.).

When considered under the correct legal standard, the record does not support the conclusion that the Pesticide Program is entitled to judgment as a matter of law. The ALJ relied on the Pesticide Program's verified written statement characterizing AMVAC's response to the Data Call-In Notice as "abnormally dilatory and repetitive." Order at 23 (citing Verified Written Statement of Witness, Jill Bloom, in Support of Respondent's Notice of Intent to Suspend 6 (June 17, 2022) ("Bloom Statement")). However, AMVAC provided a verified written statement characterizing AMVAC's response as "typical of how registrants address data call-ins." Verified Written Statement of AMVAC Expert Witness Ephraim Gur, M.S. 11 (June 17, 2022) ("Gur Statement"). These conflicting statements appear to be "material" in that they relate to whether the actions AMVAC took in response to the Data Call-In Notice were appropriate. The issue is genuine as both positions are supported by verified written statements.

Similarly, the ALJ relied on the Pesticide Program's verified written statement that "[i]t is common for registrants to request extensions of time for responding to individual data requirements." Order at 6 (quoting Bloom Statement at 4). AMVAC, however, submitted a verified written statement that some EPA staff do not want registrants to file extension requests and that "so long as communication between the registrant and EPA is on-going regarding the progress and status of completion of a study, and the EPA staff has not requested a formal extension request be filed" registrants understand that there is no need to ask for one. Gur Statement at 8. The parties' "course of performance" with respect to how they handled extension requests would appear to be material to whether AMVAC's submission of only one extension request was inappropriate. *See Alabama,* 560 U.S. at 346. The issue is genuine as a finder of fact could credit AMVAC's statement.

Furthermore, there is a genuine issue of material fact as to whether AMVAC's waiver requests satisfy, at least in part, the appropriate steps requirement. The Pesticide Program asserts that AMVAC had an opportunity to comment on the Data Call-In Notice and did not. Resp. Br. at 9. Thus, the Pesticide Program argues that the necessity of the data in the Data Call-In Notice is not at issue in this proceeding. We agree that the legality of the Data Call-In Notice and what it requested is not at issue in this proceeding. *See Atochem N. Am., Inc. v. EPA*, 759 F. Supp. 861, 864 (D.D.C. 1991) ("At the hearing, the validity of the additional data requirement may not be challenged * * *."); *see also In re Gen. Motors Corp.,* 7 E.A.D. 465, 474 (EAB 1997) (holding permittee who failed to challenge permit after issuance could not raise its validity in later enforcement proceeding), *pet. for review denied*, 168 F.3d 1377 (D.C. Cir. 1999). AMVAC had an opportunity to comment on the work plan for the registration review, including anticipated data needs, and could have challenged the Data Call-In Notice when it was issued but did not. *See* Registration Review Summary at 3-8; *see, e.g.*, *Atochem*, 759 F. Supp. at 863 (registrant of pesticide challenged lawfulness of data call-in notice in federal court).

However, AMVAC's waiver requests and the responses thereto may be relevant as to whether it took appropriate steps to secure the data required. Both the regulations and the Data Call-In Notice contemplate that registrants may make waiver requests in response to a data call-in notice. 40 C.F.R. § 158.45; Data Call-In Notice at 4. The Pesticide Program in fact granted some of AMVAC's waiver requests, suggesting that in at least some instances the Pesticide Program considered a waiver request to be appropriate. Waiver Response Memorandum at 2. The ALJ must on remand examine waiver requests as part of the determination on appropriate steps.

The Pesticide Program asserts that the Board can find AMVAC failed to take appropriate steps as a matter of law based on evidence in the record. Resp. Br. at 18-19. While the Board's review here is *de novo*, there remain genuine issues of material fact as described above. The parties have not yet had an opportunity to cross examine the witnesses who provided conflicting statements, and no fact finder has evaluated the credibility of those witnesses based on live testimony. And there are conflicting statements that the ALJ's Order does not address. *See* Petitioner AMVAC's Opposition to Respondent's Motion for Accelerated Decision, Docket No. FIFRA-HQ-2022-0002, at 26-28 (June 21, 2022) (describing conflicting statements about the reasonableness of time taken to conduct thyroid study). A hearing is necessary to develop an adequate record to reach a conclusion as to whether AMVAC failed to take appropriate steps to secure the data within the meaning of FIFRA, and a hearing before an ALJ is the appropriate forum for an

evidentiary hearing to develop the record. *See* 40 C.F.R. §§ 164.81, .90. The Board therefore remands to the ALJ to conduct a hearing.

C. *On Remand, the ALJ Must Determine Whether AMVAC Failed to Take Appropriate Steps with Respect to Each Requirement Listed in the DCPA NOITS*

Having determined that it is necessary to remand the case for a hearing, we turn to issues raised by AMVAC that will affect the conduct of the hearing on remand. First, AMVAC asserts that in resolving the motion for accelerated decision, the ALJ improperly deferred to the Pesticide Program. Second, AMVAC asserts that the ALJ was required to make a determination as to whether AMVAC took appropriate steps with respect to each data requirement listed in the DCPA NOITS. We address these issues below.

1. *The ALJ Must Independently Determine Whether AMVAC Took Appropriate Steps*

AMVAC takes exception to the ALJ's statement that the Pesticide Program is better suited to evaluate whether AMVAC took appropriate steps. AMVAC Appeal Br. at 27. The Order states that "such evaluations and determinations are better made by officials in [the Pesticide Program] conducting DCPA's FIFRA-mandated registration review. The statute grants the Pesticide Program (through delegation by the Administrator) discretion to assess the appropriateness of a registrant's actions prior to issuing a [notice of intent to suspend]." Order at 21 n.24. While the Order recognizes that the ALJ does not defer to the Pesticide Program in the same manner a court defers to a final agency decision, the ALJ nonetheless found "it is more suitable for the science and technical experts within [the Pesticide Program] than it is for this Tribunal to evaluate questions of whether AMVAC has taken appropriate interim steps to provide necessary data to support the continued registration of DCPA." *Id.*

Under the FIFRA regulations, the Pesticide Program bears the burden of going forward with evidence that AMVAC failed to take appropriate steps to secure the data. 40 C.F.R. § 164.80(a). AMVAC, as the registrant of technical DCPA, bears the burden of persuasion that its actions were appropriate. *Id.* § 164.80(b). After a hearing, the ALJ is required to issue an order "based only on substantial evidence of record of such hearing." FIFRA § 6(d), 7 U.S.C. § 136d(d). The Board has read this language as applying a preponderance of the evidence standard to hearings under FIFRA section 6(d). *Bayer CropScience*, 17 E.A.D. at 259. The ALJ must weigh the evidence presented based on its reliability and probative value, without giving special deference to the Pesticide Program. 40 C.F.R. § 164.81(a).

The preponderance of the evidence standard here is the same evidentiary standard as is applied by the ALJ under 40 C.F.R. § 22.24(b) in administrative enforcement cases. *See In re Taotao USA, Inc.*, 18 E.A.D. 40, 51 (EAB 2020), *aff'd* No. 20-cv-915 (D.D.C. March 31, 2022); *In re Elementis Chromium, Inc.*, 16 E.A.D. 649, 658 (EAB 2015). In such cases, the Board has considered whether the evidence presented at a hearing supports the ALJ's factual findings and legal conclusions. *See Elementis*, 16 E.A.D. at 708-714 (reversing the ALJ's finding of liability where ALJ failed to explain how evidence supported the conclusion that a study was required to be submitted to EPA); *see also In re John A. Biewer Co. of Toledo*, 15 E.A.D. 772, 782 (EAB 2013) (stating that, with respect to penalty calculation, "[a]n ALJ's role in the process is not to accept without question the Region's view of the case, but rather to determine an appropriate penalty").

Neither the case cited in the Order nor the Board's precedent support specially deferring to the Pesticide Program on whether AMVAC took appropriate steps. The Order cites a case from the Court of Appeals for the District of Columbia Circuit for the "general principle that '[t]he rationale for deference is particularly strong when the [EPA] is evaluating scientific data within its technical expertise[.]'" Order at 21 n.24 (quoting *American Wildlands v. Kempthorne*, 530 F.3d 991, 1000 (D.C. Cir. 2008) (internal quotation marks omitted)). Deference applied by a federal court to agency technical expertise is inapplicable here. As the final decisionmaker for the Agency, the Board performs its own "independent review and analysis of the issue." *In re Ocean State Asbestos Removal, Inc.*, 7 E.A.D. 522, 543 n.22 (EAB 1998) (quoting *In re Mobil Oil Corp.*, 5 E.A.D. 490, 508-09 & n.30 (EAB 1994)); *see also In re Lazarus, Inc.*, 7 E.A.D. 318, 351 n.55 (EAB 1997); *In re Mobil Oil Corp.*, 5 E.A.D. 490, 508-509 & n.30 (EAB 1994).

Furthermore, cases in which the Board has deferred to the agency's scientific or technical expertise involved appeals from permitting decisions on the administrative record following a notice and comment process. *See, e.g., In re Dominion Energy Brayton Point, L.L.C.*, 12 E.A.D. 490, 510 (EAB 2006) (appeal of permitting decision). Here, by contrast, the statute and applicable regulations specifically provide for an opportunity for a hearing at which the ALJ is required to weigh the evidence and make findings of fact and conclusions of law based on the evidence presented. FIFRA § 6(d), 7 U.S.C. § 136d(d); 40 C.F.R. §§ 164.2(k), .90. Accordingly, on remand, the ALJ must independently review the evidence relevant to whether AMVAC took appropriate steps without special deference to the Pesticide Program's conclusions. As part of that independent review, the ALJ should make credibility determinations based on the testimony and determine the weight to be applied to the evidence in rendering findings of fact.

2. *The ALJ Must Consider Whether AMVAC Took Appropriate Steps with Respect to Each Basis of the DCPA NOITS*

AMVAC also asserts that it is entitled to a determination as to whether it took appropriate steps to secure data with respect to each of the studies listed in the DCPA NOITS. AMVAC Appeal Br. at 38-39. The DCPA NOITS alleged that AMVAC "failed to submit the data or information required by the Data-Call-In Notice * * * or to take other appropriate steps to secure the required data for their pesticide product listed in Table 2." 87 Fed. Reg. at 25,263. Table 2 lists twenty requirements and the "[r]eason for notice of intent to suspend" for each as "[i]nadequate data received," "[i]nadequate 90-day response received," "[n]o data received," or a combination of those reasons. *Id.* at 25,264. In the Order, the ALJ stated, "I need not review each one of the [twenty outstanding data requirements] identified in the [DCPA] NOITS" because "any single one can form a basis for issuing a notice of suspension." Order at 7-8. The Order addresses nine of the twenty data requirements (two DCPA fish toxicity studies, three TPA fish toxicity studies, the DCPA mysid data study, the TPA mysid data study, the diatom TPA study, and the *Leptocheirus* chronic sediment toxicity study) and concludes that it is not necessary to review the remaining data requirements. *Id.* at 24-31.

While it is true that a registrant's failure to take appropriate steps with respect to a single data requirement may form the basis for *a* notice of intent to suspend, that is not the question here. The question here is "whether the registrant has failed to take the action that served as the basis for *the* notice of intent to suspend the registration of the pesticide for which additional data is required." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv) (emphasis added). The action that served as the basis for the specific notice of intent to suspend at issue in this case is AMVAC's alleged failure to submit data or take other appropriate steps to secure data to fulfill each of the twenty listed requirements as required by the first sentence of the FIFRA Suspension Provision. DCPA NOITS, 87 Fed. Reg. at 25,264.

Furthermore, as the eighth sentence of the Suspension Provision provides, a suspended registration must be reinstated "if the Administrator determines that the registrant has complied fully with the requirements that served as the basis for the suspension of the registration." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). Because the DCPA NOITS lists twenty requirements, the suspension, once final, would continue until AMVAC has "complied fully" with all twenty requirements. *Id.* The ALJ must therefore determine whether AMVAC has failed to take appropriate steps with respect to *each* requirement to avoid an unclear resolution. If the suspension were to take effect based only upon a finding

that AMVAC failed to take appropriate steps with respect to nine studies and AMVAC subsequently submitted and EPA approved those nine studies, AMVAC would not yet have "fully complied" with all twenty requirements that were the basis for the DCPA NOITS. Yet there would be no legal basis for continuing the suspension because there would be no finding that AMVAC failed to take appropriate steps with respect to the studies that remained outstanding. Accordingly, on remand, the ALJ must make findings of fact and draw legal conclusions as to whether AMVAC failed to take appropriate steps to secure all of the twenty required data listed as a basis for the DCPA NOITS.

D. *The ALJ Must Review the Existing Stocks Determination After Applying the Correct Legal Standard*

The other issue for resolution at the hearing on remand, as provided in the fifth sentence of the Suspension Provision, is "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA]." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). In order to determine whether the existing stocks determination is consistent with FIFRA, the Agency must first determine whether there is a basis for the suspension. The first sentence of the Suspension Provision authorizes the Administrator to issue a notice of intent to suspend if the Administrator determines a registrant has failed to take appropriate steps to secure data, and the second sentence authorizes the Administrator to include in the notice of intent to suspend "such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide." *Id*. EPA's policy on existing stocks provides:

> *Where a pesticide is suspended* because of failure to comply with the provisions of a data call-in or reregistration requirement, *the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension.* * * * Unlike imminent hazard suspensions, the Agency does not anticipate generally placing restrictions on the sale, distribution, or use of existing stocks by persons other than the registrant where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement unless risk concerns were identified.

Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362, 29,367 (June 26, 1991) (emphasis added).

The Board concludes above that the case must be remanded to the ALJ to apply the appropriate legal standard and hold a hearing in accordance with FIFRA section 3(c)(2)(B)(iv). The ALJ may find on review that there is not a basis for

imposing the suspension.[14] If that is the case, any review of the existing stocks clause will have been unnecessary. The Board therefore remands the case to the ALJ to first determine whether AMVAC failed to take appropriate steps to secure the data to fulfill each of the twenty listed requirements, based on the legal standard discussed above and then, if the ALJ finds a basis for the suspension, whether the existing stocks provision of the DCPA NOITS is consistent with FIFRA.

VI. CONCLUSION

For the reasons given above, the Board remands the July 1, 2022 Order to the ALJ. On remand, the ALJ must hold a hearing to determine whether AMVAC failed to take appropriate steps to secure the data listed in Table 2 of the DCPA NOITS and, if so, whether the provisions of the DCPA NOITS concerning existing stocks are consistent with FIFRA.

So ordered.

[14] We do not suggest that this will be the outcome of the hearing, only that it is one possible outcome. The Board takes no position in this order with respect to any ruling by the ALJ on any of these issues on remand.