UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

ORDER ON RESPONDENT'S MOTION FOR ACCELERATED DECISION

I. Procedural History

Petitioners commenced this action on May 27, 2022 when they objected to the U.S. Environmental Protection Agency's ("EPA," "the Agency," or "Respondent") proposal to suspend registration of the pesticide dimethyl tetrachloroterephthalate ("DCPA") and requested a hearing on the matter. *See* Notice of Intent To Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration, 87 Fed. Reg. 25262 (Apr. 28, 2022) ("NOITS"); Objection and Request for Hearing by Grower-Shipper Association of Central California, Sunheaven Farms, LLC, J&D Produce, Ratto Bros. Inc., and Huntington Farms (May 27, 2022); Request for Hearing and Statement of Objections by AMVAC Chemical Corporation (May 27, 2022) ("AMVAC Hearing Request").

On June 3, 2022, I issued an Order Scheduling Hearing and Prehearing Procedures that set an expedited schedule for this proceeding, which under Section 3(c)(2)(B)(iv) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136a(c)(2)(B)(iv), must be completed within 75 days after a hearing is requested.

In accordance with that order, Respondent filed a Motion for Accelerated Decision ("Motion") on June 13, 2022. Petitioner AMVAC filed a response brief ("Response") in opposition to the Motion on June 21, 2022.[1]

[1] Petitioners Grower-Shipper Association of Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms (collectively "Growers Group") filed a joint response to the Motion joining in the portion of AMVAC's Response concerning the existing stocks provision of the NOITS.

Petitioners also filed their prehearing exchange documents and proposed exhibits on June 17, 2022, and Respondent filed its prehearing exchange materials on June 21, 2022.[2]

For the following reasons, the Motion is **GRANTED**.

II. Relevant Statutory and Regulatory Provisions

The Federal Insecticide, Fungicide, and Rodenticide Act, codified at 7 U.S.C. §§ 136-136y, is "a comprehensive regulatory statute" that controls the use, sale, and labeling of pesticides.[3] *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005) (citing *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). Under FIFRA, no person may sell a pesticide in the United States unless it is registered with the EPA. FIFRA § 3(a), 7 U.S.C. § 136a(a). This registration requirement is FIFRA's "primary regulatory mechanism," providing "a product-specific license describing the terms and conditions under which [a pesticide] can be legally distributed, sold, and used." *Bayer CropScience LP*, 17 E.A.D. 228, 235, 2016 WL 4125892, at *7 (EAB 2016) (quoting *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010)). An applicant seeking to register a pesticide must provide to EPA extensive information about the product, including scientific data that demonstrates the pesticide's health and safety properties and potential adverse effects on the environment. FIFRA § 3(c)(1), (c)(2), 7 U.S.C. § 136a(c)(1), (c)(2); 40 C.F.R. Part 158. A pesticide will not be registered under FIFRA unless the Agency determines that it can be "used in accordance with widespread and commonly recognized practice" without causing "unreasonable adverse effects on the environment." FIFRA § 3(c)(5)(C)-(D), 7 U.S.C. § 136a(c)(5)(C)-(D). FIFRA defines "unreasonable adverse effects on the environment" to mean "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food[.]" 7 U.S.C. § 136(bb).

Once a pesticide has been registered,[4] FIFRA requires EPA to conduct periodic reviews of the registrations. FIFRA § 3(g), 7 U.S.C. § 136a(g). In 2007, FIFRA was amended to mandate that EPA complete an initial registration review for then-existing registrations no later

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[2] The AMVAC Hearing Request was accompanied by 80 serially numbered exhibits. In its Prehearing Exchange Statement ("PHE"), AMVAC indicated that the parties had conferred and stipulated to all but one of those exhibits (Ex. 49), as well as six additional exhibits, being marked as joint exhibits ("JX") for the purposes of this proceeding. AMVAC PHE at 2-3. In addition, with its PHE AMVAC filed a series of six sworn statements by its current and/or former employees and two expert witnesses. AMVAC PHE at 2. The Grower Group filed with their PHE an additional five exhibits ("PGX") and three witness statements. Grower Group PHE at 1-3. EPA's PHE included nine additional exhibits ("RX") as well as sworn statements from its five witnesses. EPA also requested that pursuant to 40 C.F.R. § 164.81(e), this Tribunal take official notice of two publicly available records. Witness statements are cited herein as "[witness's last name] Statement."

[3] Pesticides are defined as "substances intended for preventing, destroying, repelling, or mitigating any pest . . . ." 7 U.S.C. § 136.

[4] To address certain long-established pesticides, Congress amended FIFRA in 1998 to require the re-registration or renewed registration of pesticides that had first been registered before November 1, 1984. Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1998, Pub. L. No. 100-532 (S 659), Pub. L. No. 100-532, 102 Stat. 2654; FIFRA § 4, 7 U.S.C. § 136a-1; H.R. Rep. No. 100-939, pt. 1, 100 Cong. 2d Sess. (1988).

than October 1, 2022. *See* Pesticide Registration Improvement Renewal Act, Pub. L. No. 110-94, 121 Stat. 1000 (as codified at 7 U.S.C. § 136a (g)(1)(A)(iii), (iv)). Following this initial registration review, the Agency must conduct subsequent periodic registration reviews every 15 years thereafter. *Id.*

The review procedures are set forth in 40 C.F.R. Part 155, Subpart C. "Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment," and concludes with "the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA." 40 C.F.R. §§ 155.40(a)(1), 155.57. That is, using up-to-date scientific data, the registration review must ensure the pesticide continues to satisfy FIFRA's requirement that it "generally will not cause unreasonable adverse effects on the environment." 40 C.F.R. § 155.40(a)(1). A pesticide registration review is published in a docket maintained by the Federal Register and is open to public participation and comment. 40 C.F.R. §§ 155.42, 155.50. During the registration review, the Agency will:

- assess any changes that may have occurred since the last registration decision to determine the significance of such changes and whether the pesticide still satisfies FIFRA's registration standard
- consider whether to conduct a new risk assessment to take into account any changes
- consider whether any new data or information on the pesticide warrant conducting a new risk assessment or a new risk/benefit assessment

40 C.F.R. § 155.53(a). If EPA determines that additional data are required to maintain the registration, it may at any time send a Data Call-In notice ("DCI") to the registrant to supply more information. FIFRA § 3(c)(2)(B)(i), 7 U.S.C. § 136a(c)(2)(B)(i); 40 C.F.R. § 155.48.

When issuing a DCI, the Agency must "permit sufficient time for applicants to obtain such additional information." FIFRA § 3(c)(2)(A), (B), 7 U.S.C. § 136a(c)(2)(A), (B). The minimum data and information that EPA typically requires to support the maintenance of a pesticide registration by means of the DCI process is described in 40 C.F.R. Part 158. 40 C.F.R. § 158.1(b)(1). In addition to specifying the kinds of data and information that EPA needs to make regulatory judgments under FIFRA about a pesticide's risks and benefits, Part 158 specifies that the statute

> provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process.

40 C.F.R. § 158.30. Registrants may also ask the Agency to waive certain data requirements. 40

C.F.R. § 158.45. The Agency may do so for data requirements it finds inappropriate, "either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product." 40 C.F.R. § 158.45(a). Nevertheless, EPA "will ensure that sufficient data are available to make the determinations required by the applicable statutory standards." 40 C.F.R. § 158.45(a). Once a DCI is issued, the registrant has 90 days to provide to EPA evidence "that it is taking appropriate steps to secure the additional data that are required." FIFRA § 3(c)(2)(B)(i), (ii), 7 U.S.C. § 136a(c)(2)(B)(i), (ii); 40 C.F.R. § 155.48.

"If the registrant fails to take appropriate steps within the designated time frame, the EPA may issue a notice of intent to suspend the registration" and include any provisions the Agency "deems appropriate concerning the continued sale and use of existing stocks of such pesticide." *Atochem N.A. v. EPA*, 759 F. Supp. 861, 863 (D.D.C. March 12, 1991); FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). The suspension takes effect 30 days after the registrant receives the notice unless the registrant or any other adversely affected person requests a hearing to contest the proposed suspension. FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). The hearing is conducted under FIFRA § 6, 7 U.S.C. § 136d, and is governed by procedural rules outlined in 40 C.F.R. Part 164. *Id.* At hearing, the *only* matters that can be considered are "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." *Id.* That is, "the validity of the additional data requirement may not be challenged." *Atochem*, 759 F. Supp. at 864; *see also Bayer*, 17 E.A.D. at 233, 2016 WL 4125892, at *5 (finding that similar language addressing the "only" questions to be considered in a cancellation proceeding for conditional registrations under FIFRA § 6(e) placed a "strict limitation on the scope" of the proceeding that precludes collateral attacks on the lawfulness of a registration or any of its conditions). With or without a hearing, any registration that is suspended under FIFRA § 3(c)(2)(B)(iv) will be reinstated once EPA "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).

III. Factual Background

DCPA, known commercially as "Dacthal," is a chlorinated benzoic acid herbicide[5] used to control annual grasses and broadleaf weeds for various agricultural crops, including collards and onions. AMVAC Hearing Request ¶¶ 6, 19, 25. It was first registered in 1958, and in 1998 it was re-registered pursuant to FIFRA § 4, 7 U.S.C. § 136a-1. AMVAC Hearing Request ¶ 21.[6] Petitioner AMVAC is the only registrant of DCPA. AMVAC Hearing Request ¶ 24.

On June 29, 2011, EPA initiated its initial registration review of DCPA under FIFRA § 3(g), 7 U.S.C. § 136a(g), and opened a public docket for that purpose. *See* Registration Review:

[5] Although the term "herbicide" commonly refers to chemicals used to control vegetation, herbicides are defined as pesticides under FIFRA. *See* 7 U.S.C. § 136(t), (u).

[6] *See also* R.E.D. Facts DCPA, EPA-738-F-98-002 (Nov. 1998), *available online at* https://archive.epa.gov/pesticides/reregistration/web/pdf/0270fact.pdf.

Pesticide Dockets Opened for Review and Comment and Other Docket Actions, 76 Fed. Reg. 38166 (Notice). Registration reviews are conducted by the Office of Pesticide Programs ("OPP") in the Agency's Office of Chemical Safety and Pollution Prevention ("OCSPP"). Within OPP, the Pesticide Reevaluation Division ("PRD") is responsible for developing EPA's regulatory position regarding the re-evaluation of conventional pesticides that are currently registered under FIFRA. Bloom Statement at 2.[7] The Health Effects Division ("HED") is responsible for assessing pesticide hazard, exposure, and risks to humans, which is part of the re-evaluation required for conventional pesticides that are currently registered under FIFRA. Mendez Statement at 1;[8] Drew Statement at 1.[9] The Environmental Fate and Effects Division ("EFED") evaluates and validates environmental data submitted on pesticide properties related to environmental fate, exposure, and ecological effects, and the data are used to inform a variety of pesticide registration and re-evaluation decisions. Wendel Statement at 2.[10]

In its preliminary work plan regarding the review, which was electronically published in the Federal Register, the Agency noted its expectation to require additional data to update and refine its ecological risk and human health risk assessments for DCPA. *See* DCPA Summary Document Registration Review: Initial Docket June 2011, EPA-HQ-OPP-0374-0002, at 3, 7, *available online at* www.regulations.gov. 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. *See* DCPA Final Work Plan Registration Review November 2011, EPA-HQ-OPP-0374-0008, at 3; Bloom Statement at 3.

As forecast, on January 31, 2013, EPA issued to AMVAC a "Generic Data Call-In Notice" ("DCI") under FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B), for technical grade DCPA.[11] JX 4. The DCI requested what AMVAC characterizes as 89 different types of data. AMVAC Hearing Request ¶ 5; JX 4. The DCI required a response from AMVAC within 90 days setting forth how it intended to comply with each data requirement. AMVAC Hearing Request ¶ 54; JX 4. The DCI also established timeframes for submitting the data itself, ranging from 9 months to 36 months after AMVAC received the DCI.[12] 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 Statement at 3-4. According to Agency testimony:

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[7] Jill Bloom is a lead environmental protection specialist in the Pesticide Reevaluation Division. Bloom Statement at 1.

[8] Elizabeth Mendez, Ph.D., is a senior scientist in the Health Effects Division. Mendez Statement at 1.

[9] Danette Drew is a chemist in the Health Effects Division. Drew Statement at 1.

[10] Christina Wendel is a biologist in the Environmental Fate and Effects Division. Wendel Statement at 1.

[11] According to the Agency, technical grade pesticides "are high-concentration forms of pesticides that are used to formulate end-use pesticide products." Mot. at 11 n.9.

[12] Before it was issued, the DCI was reviewed and approved by the Office of Management and Budget. Bloom Statement at 3.

> It is common for registrants to request extensions of time for responding to individual data requirements when they believe they will be unable to meet the original deadlines imposed by the DCI. Registrants may request that certain data requirements be waived or request that EPA rely on previously submitted data, typically making these requests within the 90-day period after issuance of the DCI, but occasionally after that period. EPA is generally accommodating of unexpected delays in conducting required studies, or new waivers or substitute studies submitted even after the 90 days, if accompanied by a rationale the Agency deems valid.

Bloom Statement at 4.

On April 29, 2013, AMVAC timely provided its initial response to EPA's DCI, indicating that it planned to comply with the request by developing data, submitting existing data, upgrading existing studies, deleting uses for which data are required, and requesting waivers of certain data requirements. AMVAC Hearing Request ¶ 56; JX 5.

On October 26, 2020, EPA by letter ("Outstanding Data Letter") formally notified AMVAC that it intended to complete all registration review interim decisions for previously registered pesticides, including DCPA, by October 1, 2022 (the statutory deadline). To meet this deadline, the Agency stated its expectation to complete draft risk assessments in June 2021, and it observed that a substantial portion of the data requested by the 2013 DCI needed to complete such an assessment had not been submitted and remained outstanding. The Agency requested that AMVAC generate and submit all the outstanding data. JX 21. The Agency further stated its intent to move forward with the review of DCPA, and observed that without the required data it would be required to "make conservative assumptions in place of such data in order to complete the necessary risk assessments." Bloom Statement at 4; JX 21. These assumptions could "take the form of extrapolating from related studies or databases or adding safety factors to account for uncertainties resulting from the lack of data." Bloom Statement at 4.

In its April 28, 2022 NOITS, the Agency contends that 18 months later, more than 9 years after the DCI issued, and nearly 11 years after EPA began its review of DCPA's registration, AMVAC still has not met 20 of the data requirements originally called for in the 2013 DCI. NOITS; Mot. at 11-12; Bloom Statement at 4. "While it is not unusual for registrants to fail to meet some deadlines for registration review DCIs, these as-yet unfulfilled DCPA data requirements represent an abnormally high ratio of non-submissions and waiver requests and an abnormally long time for data to remain outstanding after they are required," according to testimony from Jill Bloom, a lead environmental protection specialist in OPP's Pesticide Reevaluation Division. Bloom Statement at 1, 4-5.

Each outstanding data requirement is referenced in the NOITS according to its relevant OCSPP Final Test Guideline for Pesticides and Toxic Substances Number ("Test Guideline"),[13]

[13] EPA's Test Guidelines are organized by series number and contain standards for conducting acceptable tests, guidance on the evaluation and reporting of data, definition of terms, and suggested study protocols. They are publicly available on the Agency's website. *See* Test Guidelines for Pesticides and Toxic Substances, *accessible at*

and they are divided into categories of "Fate Data," "Ecological Effects Data," and "Human Health Data." NOITS at 7; Mot. at 11-12.

With respect to the Environmental Fate and Ecological Effects Data requirements, Ms. Bloom stated that

> [t]he absence of data from these required studies would impart excessive uncertainty into the ecological risk assessment and/or the drinking water exposure assessment, particularly related to testing with the primary degradate of DCPA, tetrachloroterephthalic acid (TPA). Without these data, the Agency would need to rely on assumptions about the persistence of TPA in the environment and/or the toxicity of TPA to certain species. The available data suggest that TPA is persistent in the aquatic environment, but without the required data, EPA is unable to definitively characterize the half-life of TPA in water and would need to assume that it is stable (having a long and indeterminate half-life). EPA could potentially develop an ecological risk assessment built on the assumption that TPA is stable and use DCPA endpoints as surrogates for the missing TPA endpoints. However, in such a situation, risk estimates would be very high, and EPA would not be able to refine the estimates with any certainty. The missing environmental fate and ecological effects data are particularly critical because of the magnitude of expected TPA concentrations in the water column and limitations in the ecological toxicity database for DCPA chronic data. Chronic testing with DCPA has shown effects in estuarine/marine invertebrates at all test doses, so that the Agency knows only that the lowest dose tested resulted in adverse effects, and it is possible that adverse effects could have occurred at an even lower dose. Without a precise endpoint, the registration review decision would be based on considerable uncertainty in the science, and the proposed risk mitigation developed to address the risks to man and the environment may be overly restrictive. For example, an assumption that TPA does not degrade in water or degrades more slowly than can be estimated by existing data, coupled with the Agency's policy of making conservative (protective) assumptions when data are lacking, could result in onerous restrictions affecting the users of DCPA and the production of some agricultural commodities.

Bloom Statement at 5-6.

Although there are 20 outstanding data requirements cited in the DCI, any single one can form a basis for issuing a notice of suspension. As such, I need not review each one of the 20

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www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic; 40 C.F.R. § 158.70(c).

identified in the NOITS. Accordingly, only a few representative examples of the outstanding DCI data requirements, which the undisputed facts show AMVAC has not fulfilled, are discussed in greater detail below.

a. Fish toxicity data

In the 2013 DCI, the Agency requested data identified as "Fish early life-stage toxicity test" in both freshwater and estuarine/marine species under the Test Guideline requirement number 850.1400. AMVAC Hearing Request ¶ 238; JX 4 at 31; Freedlander Statement ¶ 8;[14] Wendel Statement at 5. The DCI requires that tests be conducted using both DCPA and its TPA[15] degradate, and provides 12 months to complete the studies. The DCI further indicates that the preferred test species are rainbow trout, bluegill sunfish, and sheepshead minnow. AMVAC Hearing Request ¶ 238; JX 4 at 35; Freedlander Statement ¶ 8. This data was required "to identify endpoints for adverse effects to fish throughout their early life-stages for both DCPA and TPA," according to testimony from Christina Wendel, a biologist in EFED. Wendel Statement at 4-5. "The endpoints are used in assessing risk to fish, with chronic data being particularly important for evaluating persistent chemicals . . . . Without these data the Agency is unable to confidently refine the chronic risks to fish." Wendel Statement at 5.

i. DCPA fish toxicity studies

In its April 2013 response, AMVAC informed EPA that it would submit what it referred to as existing data for the required fish toxicity tests with respect to DCPA. AMVAC Hearing Request ¶ 239; JX 5 at 9, 19, 24; Freedlander Statement ¶ 9; Wendel Statement at 5. On January 30, 2014, AMVAC submitted to EPA an existing study involving a prolonged toxicity test in rainbow trout using DCPA. AMVAC Hearing Request ¶ 240; Freedlander Statement ¶ 10.

However, AMVAC submitted nothing with respect to toxicity tests in bluegill sunfish or sheepshead minnow, and these data requirements remained unfulfilled when the Agency issued its Outstanding Data Letter in October 2020. AMVAC Hearing Request ¶ 241; JX 21; Wendel Statement at 4-5. In its December 17, 2020 response, AMVAC informed EPA that it would "initiate work to fulfill the Fish Early Life Stage study requirement for DCPA in early 2021." AMVAC Hearing Request ¶ 246; JX 22; Wendel Statement at 5.

Both studies began on March 21, 2021. AMVAC submitted the bluegill sunfish study using a different species than the DCI indicated, fathead minnow, to EPA on June 7, 2022, roughly six weeks after the NOITS was issued. It is currently being reviewed, inter alia, for sufficiency and compliance with the DCI by the Agency. The sheepshead minnow study has not

[14] Richard S. Freedlander, Ph.D., is the director of environmental science at AMVAC. Freedlander Statement ¶¶ 2-4.

[15] As described above, TPA is the primary degradate of DCPA and is one of the "three residues of concern for DCPA" that are considered in the Agency's ecological risk assessments and drinking water assessments. *See* Bloom Statement at 5; Wente Statement at 2-3. "[I]t is only when TPA finally degrades that environmental exposure to the 'residues of concern' actually decreases." Wente Statement at 3. Stephen Wente, Ph.D., is a senior fate scientist in the Environmental Fate and Effects Division. Wente Statement at 1.

been submitted and remains outstanding, although AMVAC states that it intends to submit that study for review on July 15, 2022. Freedlander Statement ¶ 17; Wendel Statement at 5.

ii. TPA fish toxicity studies

In its April 2013 response, AMVAC requested a waiver of the fish early life-stage toxicity data using TPA, proposing to wait to conduct any such tests until the Agency finished its review of corresponding data using DCPA. This apparently reflected AMVAC's hope that EPA would decide that "endpoints experimentally determined for DCPA may be utilized to waive the required TPA studies."[16] Freedlander Statement ¶ 46; JX 5.

EFED responded to the waiver request (as well as similar requests with respect to other data requirements in which AMVAC had proposed waiting for DCPA test results) in a March 21, 2014 memorandum ("First EFED Waiver Memo"). JX 66 at 8. EFED acknowledged its willingness to consider more limited testing strategies if proposed by a registrant, but said that deferring TPA testing until DCPA studies are completed "is not an acceptable alternative strategy."

> [T]herefore, EFED recommends that PRD ***denies request*** [sic] ***to defer the data collection of TPA until DCPA studies are completed with the intention of using DCPA toxicity data in lieu of TPA toxicity data. Toxicity data is needed for TPA, therefore one possible solution is conducting a limited set of toxicity tests initially for TPA (for example, an acute and chronic toxicity study in daphnids); and depending on the results of these initial studies, a full suite of studies may or may not be subsequently required.***

JX 66 at 8. Thus, the Agency recommended the waiver request be denied. JX 66 at 8.

According to Dr. Freedlander, the First EFED Waiver Memo was not communicated to AMVAC until March 27, 2017.[17] Freedlander Statement ¶ 53. After receiving the First EFED Waiver Memo, AMVAC responded on February 22, 2018, stating that it "agrees with the Agency's proposal for conducting acute and chronic TPA studies in daphnids and reviewing those results with the Agency in order to determine whether additional aquatic organism testing is warranted." Freedlander Statement ¶ 58; JX 67 at 9. AMVAC then "proceeded to collect and or conduct acute a chronic *Daphnia Magna* TPA toxicity test data that would permit a

[16] According to Dr. Freedlander, AMVAC had derived this hope from a 2011 EFED document outlining some of the Agency's registration review plans for DCPA, which stated that with respect to TPA, "a more limited testing strategy will be considered in lieu of a comprehensive data submission if one is proposed." Freedlander Statement ¶¶ 47-48; JX 65 at 3.

[17] EPA apparently maintains an electronic docketing system for registrants and the Agency to file and exchange, via upload and download, documents. This system has flaws, AMVAC asserts, resulting in unknown lengthy delays in receipt of documents by both parties. AMVAC Hearing Request ¶ 294.

comparison with DCPA data . . . ."[18] Freedlander Statement ¶ 59.

However, when the Agency issued its Outstanding Data Letter in October 2020, it noted that all of the fish early life-stage toxicity tests involving TPA remained outstanding and that AMVAC's waiver requests had been denied. JX 21 at 5-6. AMVAC responded to the Outstanding Data Letter on December 17, 2020 with another waiver request and provided "a table showing DCPA and TPA endpoints derived from various studies, including the two studies specified by EPA for assessing the relative ecotoxicology between DCPA and TPA, the acute and chronic daphnia studies[.]" Freedlander Statement ¶ 61; JX 22. AMVAC then argued to the Agency "that TPA demonstrated a lower toxicity than DCPA and therefore the data generated as of that time should be sufficient for EPA's risk assessment purposes and EPA should not require any further Guideline 850.1400 studies of TPA." Freedlander Statement ¶ 61; JX 22.

AMVAC did not hear further from EPA until the Agency issued the NOITS in April 2022 and included a response from EFED to AMVAC's December 2020 waiver request. Freedlander Statement ¶ 63. EFED again denied the waiver request after it "reconfirmed the need for chronic freshwater and estuarine/marine fish toxicity studies for TPA." Freedlander Statement ¶ 66; JX 69 at 12.

In light of this most recent denial of its request for a waiver, AMVAC states that it "is prepared to run the sheepshead minnow Guideline 850.1400 TPA study per EPA's instructions because the DCPA results have indicated that species to be the most sensitive. AMVAC expects these results will be available in 2023." Freedlander Statement ¶ 69. It is unclear whether AMVAC intends to generate TPA data using rainbow trout or bluegill sunfish.

b. Mysid data

In the 2013 DCI, the Agency also requested data identified as "Mysid chronic toxicity test" under Test Guideline number 850.1350. The DCI requires that this test be conducted using both DCPA and the TPA degradate, and it provides 12 months to complete the studies. JX 4 at 31, 34. Mysids are tiny, marine/estuarine shrimp-like invertebrates. JX 4; Mot. at 17. The Agency required this data "to identify endpoints for adverse effects to aquatic invertebrates throughout their life-cycle for both DCPA and TPA. The endpoints are used in assessing risk to

[18] The DCI already required four ecotoxicity tests in daphnids using DCPA and TPA under Test Guideline 850.1010 (acute toxicity) and Test Guideline 850.1300 (chronic toxicity). JX 4. In its response to the DCI, AMVAC pledged to submit existing data (developed for regulatory requirements outside of the U.S.) for the acute toxicity tests for both DCPA and TPA and to develop new data for the chronic toxicity tests for DCPA. JX 5 at 18-19, 23-24. AMVAC requested a waiver for chronic toxicity studies with TPA. JX 5 at 23-24. In 2014, AMVAC submitted new studies for acute and chronic toxicity testing with DCPA and existing data for the acute toxicity testing with TPA. JX 27. The waiver request for TPA chronic toxicity testing on daphnids was denied. JX 66 at 8. AMVAC completed chronic toxicity testing for both DCPA and TPA; these studies were submitted to EPA in 2020. AMVAC Hearing Request ¶ 314, JX 69 at 4 ("Specifically, the studies submitted in 2020 were: Chronic (Reproduction) Study with Freshwater invertebrates (*Daphnia magna*) (850.1300); TPA . . . and DCPA . . . ."). In the October 2020 Outstanding Data Letter, all four of the daphnid Test Guidelines were listed as "In review." JX 21. In the 2022 review of data submissions letter, the studies submitted for these four test items were deemed "Acceptable," and no further data were needed. JX 64.

aquatic invertebrates, with chronic data being particularly important for evaluating persistent chemicals." Wendel Statement at 3.

i. DCPA mysid studies

In its April 2013 response, AMVAC informed EPA that it would develop new data to satisfy the requirements for the chronic toxicity test in mysids using DCPA. Freedlander Statement ¶ 18; JX 5 at 9. On January 30, 2014, AMVAC submitted a study titled "Dacthal: A flow-through life-cycle toxicity test with the saltwater mysis (*Americanmysis bahia*)." Freedlander Statement ¶ 19; JX 27 at 3; JX 56.

The Agency reviewed AMVAC's submitted study in 2016 and in a Data Evaluation Record memorialized its determination that although the study could be classified as supplemental and used for risk characterization, it was deficient in that "[a] NOAEC[19] could not be determined . . . as dose-responsive effects on male weight and length were observed at all doses." JX 56 at 2-3. That is, "there were treatment-related effects at all concentrations tested." Wendel Statement at 4.

On April 27, 2022, EPA informed AMVAC of its conclusions in the Data Evaluation Record with respect to AMVAC's study and indicated that it would need additional data to satisfy the DCI request. Freedlander Statement ¶ 21; JX 57. AMVAC indicates that it "is timely responding to" this communication and that it "has contacted the responsible contract laboratory and awaits its input" concerning the Agency's evaluation. Freedlander Statement ¶¶ 22-23.

ii. TPA mysid study

In its April 2013 response, AMVAC requested a waiver for the chronic toxicity tests on mysids using TPA. Freedlander Statement ¶ 70; JX 5. For the same reasons it suggested delaying fish toxicity studies using TPA, i.e., its hope that EPA would adopt a more limited testing strategy, AMVAC proposed to wait to conduct any TPA tests on the mysid until the Agency finished its review of the DCPA mysid data. Freedlander Statement ¶¶ 70-72; JX 5.

The Agency denied AMVAC's waiver request via the First EFED Waiver Memo in March 2014 (which was received by AMVAC in March 2017). JX 66; Freedlander Statement ¶¶ 77-78. As with the fish toxicity study using TPA, AMVAC informed EPA in its February 2018 response that it "agrees with the Agency's proposal for conducting acute and chronic TPA studies in daphnids and reviewing those results with the Agency in order to determine whether additional aquatic organism testing is warranted," and it embarked on daphnia TPA toxicity testing. Freedlander Statement ¶¶ 80-81; JX 67 at 10.

When the Agency issued its Outstanding Data Letter in October 2020, it noted that the mysid chronic toxicity test involving TPA remained outstanding and that AMVAC's waiver requests had been denied. JX 21 at 5. In its December 2020 response, AMVAC, as it did with the fish toxicity studies, again requested a waiver supported by "a table showing DCPA and TPA

[19] NOAEC is an initialism for "No Observed Adverse Effect Concentration." It is the exposure level at which no adverse effects have been observed at or below. *Bayer v. Bayer A.G.*, 564 F. Supp. 2d 365, 373 (M.D. Pa. 2008).

endpoints derived from various studies and explained, in detail, why AMVAC concluded that TPA demonstrated a lower toxicity than DCPA and therefore the data generated as of that time should be sufficient for EPA's risk assessment purposes" such that no mysid chronic toxicity study for TPA was required. Freedlander Statement ¶ 82; JX 22.

AMVAC did not hear further from EPA until the Agency issued the NOITS in April 2022 and included a response from EFED to AMVAC's December 2020 waiver request. Freedlander Statement ¶ 83; JX 69. EFED again denied the waiver request, finding that "due to the lack of definitive acute and chronic endpoints," the approach AMVAC desired "cannot be used to quantify the chronic toxicity of TPA to mysids." JX 69 at 9. The Agency further observed:

> The data indicate that on a chronic basis, DCPA is at least an order of magnitude more toxic to daphnids than TPA. However, mysids appear to be more sensitive to DCPA than daphnids on a chronic exposure basis, with effects occurring even at the lowest test concentration. Furthermore, as noted above, TPA may be present in high concentrations in the water-column and concentrations may increase over time with repeated applications of DCPA. Therefore, EFED does not recommend granting the waiver request for ecological toxicity testing with TPA for the Mysid Chronic Toxicity Test (Guideline 850.1350) test.

JX 69 at 9.

In light of this denial of its waiver requests, "AMVAC representatives are contacting EPA to discuss an appropriate response" as it relates to the mysid chronic toxicity TPA study, and the data is not expected to be available until 2023. AMVAC Hearing Request ¶ 326; Freedlander Statement ¶ 90.

c. Marine diatom study

The DCI requested "algal toxicity" studies on four algal species, including marine diatom, under Test Guideline 850.5400 (currently 850.4500). JX 4 at 30, 35. Data were requested for both DCPA and TPA, and all studies were to be submitted within 12 months. JX 4 at 30, 34.

In its April 2013 response, AMVAC requested a waiver for the TPA algal studies, and, as it did with the fish and mysid toxicity studies, "proposed to defer these . . . TPA studies and perform the assessments for TPA using the endpoints determined in the corresponding DCPA studies." Freedlander Statement ¶¶ 70-71; JX 5. Likewise, the Agency denied AMVAC's waiver request via the First EFED Waiver Memo in March 2014 (received by AMVAC in March 2017), to which AMVAC responded in February 2018 with its "agreement" that it would use acute and chronic studies in daphnids to determine whether TPA testing of the algal species was warranted. JX 66; JX 67 at 13; Freedlander Statement ¶¶ 77-78, 80-81.

When the Agency issued its Outstanding Data Letter in October 2020, it noted that the

algal toxicity test involving TPA remained outstanding. JX 21 at 6. After receiving this letter, AMVAC again submitted waiver requests for the algal TPA studies. AMVAC Hearing Request ¶ 316, JX 22. AMVAC argued that "data generated as of that time [including the daphnid studies] should be sufficient for EPA's risk assessment purposes and EPA should therefore not require" an algal toxicity test involving TPA. Request ¶¶ 314, 317; Freedlander Statement ¶ 82; JX 22.

In its 2022 response, EPA granted the TPA waiver requests for all algal species except the marine diatom. AMVAC Hearing Request ¶ 321; JX 69 at 2; Freedlander Statement ¶ 86. EPA maintained that "[t]he marine diatom was the most sensitive species tested for DCPA" and that it would have to use endpoints from other studies in the absence of TPA marine diatom data, which could yield uncertain risk conclusions. AMVAC Hearing Request ¶ 322; JX 69 at 13.

Currently, AMVAC is conducting the marine diatom TPA study and expects to provide results in 2023. AMVAC Hearing Request ¶ 325.

d. Leptocheirus chronic sediment toxicity study

Under the heading "Toxicology Data Requirements (Conventional Chemical)," the DCI instructed AMVAC to submit "SS [Special Study]-1072 Chronic Sediment - Leptocheirus plumulosus" within 24 months. JX 4 at 31-32. Further, the DCI mandated that the study's "[p]rotocol must be submitted to the Agency for review and approval prior to study inception" and that "[t]he draft protocol must be submitted to the Agency within 90 days of receipt of this DCI." JX 4 at 33.

In its April 2013 response to the DCI, AMVAC represented that it would "provide a new study" and included a proposed protocol for a 28-day study to address chronic sediment toxicity testing of *Leptocheirus plumulosus*. JX 5 at 2, 10, 18. The Agency's EFED subsequently reviewed the proposed protocol, "DCPA (Chlorthal Dimethyl)-Protocol for Conducting a 28-Day Toxicity Test Exposing Estuarine Amphipods *(Leptocheirus plumulosus)* to a Test Substance Applied to Sediment Following EPA Test Methods by Smithers Viscient (DP 413319)" and on March 20, 2014, issued a Memorandum in regard thereto. JX 70 at 1-3. The 2014 EPA Memorandum recommended additional specified details be added to the protocol "to help ensure study acceptability," and assured AMVAC that with such "revisions" the protocol would be adequate. JX 70 at 2. Further, EPA instructed AMVAC that "[r]evised protocols are not required, but the final report should take into consideration EFED's comments and recommendations." JX 70 at 2.

By letter dated December 15, 2014,[20] AMVAC advised EPA that its lab, Smithers Viscient, had notified the company that it needed "additional method development time for establishing a rugged *Leptocheirus plumulosus* study." JX 60 at 1. The lab explained that it had been working since late 2013 to "develop formulated sediment that is suitable for use in this testing" because the "locally collected natural sediment used historically" had not been

[20] As indicated above, AMVAC asserts that it did not receive EPA's March 24, 2014 Memorandum (JX 70) until October 20, 2014. JX 60 at 1.

producing useable test results. JX 60 at 49. This sediment suitability testing issue had resulted in a backlog of *Leptocheirus* studies. JX 60 at 51-52. The lab noted, however, that it anticipated being able to begin clearing the backlog in early 2015. JX 60 at 51-52. AMVAC indicated that it would update the Agency by March 31, 2015, concerning the progress at the lab. JX 60 at 1. EPA was made aware of this issue as early as 2013. JX 60 at 49.

The 24 months for performing the *Leptocheirus* testing expired at the end of January 2015, with no study being produced.

On March 19, 2015, EPA emailed AMVAC advising that it was "aware of the issues with the delay in conducting the Leptocheirus study (DP 424921) and would like for you to check back in with us in April to determine a path forward." JX 61. On March 30, 2015, AMVAC responded providing an update from its lab. JX 61; JX 71. The lab explained that pilot testing was ongoing, but that it anticipated being able to begin clearing the backlog in the third quarter of 2015. JX 71. Based thereon, AMVAC requested permission to provide another status update in six months. JX 61.

On September 22, 2015, AMVAC provided EPA with another update from its lab on its progress in conducting sediment suitability and *Leptocheirus* testing. JX 61; JX 72. In this update, the lab advised that it had addressed the testing issues with EPA directly and that "EPA ha[d] reviewed the revised protocol and approved of the changes made to the test method." JX 72 at 4-5. As such, the lab stated it anticipated being able to begin clearing its testing backlog in quarter 4 of 2015 using the updated protocol. JX 72 at 5. Based upon this report, AMVAC stated it would like the opportunity to provide another update in six months to permit the next phase of effort by the lab to be completed. JX 61.

However, in six months AMVAC *did not* provide an update on its lab and the studies. Rather, on March 15, 2016, AMVAC submitted to EPA a request to waive the *Leptocheirus* chronic sediment study. JX 62. As the basis for the request, "AMVAC explained that, in light of testing then completed on other aquatic invertebrates, further testing of *Leptocheirus* should not be needed because, [among other things]: DCPA concentrations were unlikely to reach levels demonstrated to affect aquatic invertebrates and sediment dwelling amphipods (like *Leptocheirus*) had demonstrated less sensitivity to DCPA than other aquatic invertebrates." AMVAC Hearing Request ¶ 335.

EPA responded to the waiver request in a document dated June 27, 2016. JX 74.[21] In its response, it stated –

> EFED is aware of the challenges some laboratories have experienced running the chronic sediment toxicity test with L. plumulosus. As an alternative, the Agency will allow Amvac [sic] to conduct an OCSPP 850.1740 study, (10-day Whole Sediment Acute Toxicity Invertebrates, Marine*) in the interim*. *EPA encourages the registrant to conduct the study as expeditiously as possible* so the results can be considered in the forthcoming

[21] AMVAC asserts it did not receive this document until July 18, 2016. JX 75.

> ecological risk assessment for Registration Review. Allowing a registrant to conduct the 10-day 850.1740 study instead of the 28-day study *does not* constitute a change in the EPA's policy or data requirements. *The 28-day study will remain an outstanding DCI requirement since it includes effects on growth and reproduction which are not part of the 10-d study*. This memo does not constitute a waiver of the estuarine/marine chronic sediment toxicity data requirement. A waiver may be considered at a later date pending the results of the 10-d study and any other supporting data. This approach is also described in EFED's 2014 *Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates* guidance document.

JX 74 at 2-3 (emphasis added).

The record indicates that contrary to EPA's suggestion, AMVAC did not proceed to "expeditiously" conduct the 10-day study which could support its request for a waiver of the 28-day study. Rather, in November 2016, AMVAC submitted a supplementary waiver request as to the 28-day *Leptocheirus* study. JX 76. In the supplementary request, AMVAC argued that neither the 28-day nor the 10-day *Leptocheirus* study would be useful for risk assessment. JX 76 at 6.

On March 17, 2017, EPA held a telephonic "DCPA (078701) Registration Review Registrant Check-In Meeting" with AMVAC, which it memorialized in an email sent to the company regarding the discussed "Action Items." JX 33; JX 34. As to the *Leptocheirus* data requirement, the only action item identified in the email was EPA's, which was to "confirm with EFED whether a clean/negative 10-day study negates the need for the 21-day [sic] study." JX 33. At this point, it was four years from the DCI establishing the 28-day chronic study requirement.

Ten days later, on March 27, 2017, EPA followed up with AMVAC by email regarding the "action items" discussed during the prior phone meeting. JX 35; JX 36. It noted that with regard to "SS-1072 (Chronic Sediment - *Leptocheirus plumulosus* study) Amvac [sic] want[ed] assurance that if 10-day study yields no adverse effects, then the 28-day data requirement would be waived." JX 35 at 1. In response, the email indicated that EPA's "June 27, 2016 memo 'DCPA: Response to Waiver Request for the Chronic Sediment Toxicity Study with Leptocheirus plumulosus,' June 27, 2016, D432677 indicates that the 28-day study is not waived even when the registrant submits report from the 10-day study." JX 35 at 1-2.

On February 22, 2018, now five years after the DCI was issued, AMVAC again submitted a waiver request to EPA with regard to the 28-day Chronic Sediment (*Leptocheirus plumulosus*) study. JX 67 at 1. In support, AMVAC provided a document entitled "Rebuttal to EPA's March 21, 2014 memorandum, 'Response to registrant's data waiver requests for environmental fate and ecological effects related to data for the parent DCPA and degradate TPA.'" JX 67 at 4. In its Rebuttal, AMVAC stated in part:

> Within our March 17 teleconference with the EPA, AMVAC discussed the outstanding chronic *Leptocheirus plumulosus* data requirement. We were informed that EFED continues to seek an interim 10-day sub-chronic study. In response, we affirmed our view that such a study would not be useful in the Agency's determination of the chronic toxicity potential of Dacthal for reasons that are documented in our two previous submissions. Although we disagree with EFED on this point, we explained that AMVAC remains committed to conducting the chronic study once the performance guidelines are established.
>
> The basis for our position was discussed. It remains our view that the sub-chronic study is really only useful as a measure of survival toxicity. We understand from discussions with CRO [contract research organization] experts who are managing these types of laboratory studies that the sub-chronic study is limited in scope as assessing other effects such as the impact of exposure on growth is typically not well defined due to the shortened study period. Based on the established aquatic profile of Dacthal, which includes two chronic studies on sediment-dwelling organisms, there is already substantial evidence for predicting that acute effects will not emerge within the study's 10-day window.
>
> Thus far, our view that the sub-chronic study is not a true indicator of chronic toxicity does not appear to be shared by EFED. For that reason, we discussed the possibility of AMVAC conducting the sub-chronic study as a part of a tiered approach. Under these circumstances, should the sub-chronic study be conducted and found not to reveal any sign of toxicity, we would expect EFED to recommend that the chronic study requirement was fulfilled. It is our understanding that the attending EPA staff on the conference call believed that there was merit in this proposal and that they would seek a response from EFED. We are currently awaiting that response.

JX 67 at 4.

Approximately twenty months later, on October 16, 2020, EPA sent AMVAC the Outstanding Data Letter. JX 21. Citing to EPA's June 27, 2016 document (JX 74), EPA advised AMVAC that, with regard to the Chronic Sediment *Leptocheirus* data requirement, the "[w]aiver request [was] denied; [study] outstanding; Guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates) *may* proceed in the interim and results *may* allow EPA to reconsider waiver request for SS-1072." JX 21 (emphasis added).

On December 17, 2020, AMVAC responded to EPA's October 16, 2020, correspondence. JX 22. In its response, the company advised EPA that it intended to "await a specific DCI requirement for [the *Leptocheirus* 10-day] acute study or will wait for confirmation

that the chronic [28-day] study guideline has been validated." JX 22 at 2. AMVAC further stated its belief that, "[c]onsidering the very low toxicity associated with DCPA to aquatic organisms, AMVAC believes that this delay will not impact the Agency's conclusions concerning sediment dwelling organisms that can be made based on the available studies." JX 22 at 2.

It appears from the record that neither party took any further action regarding the *Leptocheirus* sediment study until just recently. Specifically, on April 27, 2022, along with the NOITS, AMVAC was provided with EPA's 2022 EPA Ecological Effects Waiver Response. JX 57; JX 69 (dated Apr. 19, 2022). Unsurprisingly, the 2022 Waiver Response did not grant AMVAC's request for a waiver of the 28-day *Leptocheirus* study, which remains outstanding. JX 69 at 16-19.

In the AMVAC Hearing Request initiating this matter, the company represents as to the *Leptocheirus* Chronic Sediment Toxicity Study that –

> AMVAC intends to proceed with the Guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates) and, as requested will provide a protocol for EPA review. AMVAC anticipates that results from this study will be *available in 2023* subject to a timely protocol review by EPA and swift initiation of that study. AMVAC understands the EPA will "reconsider [its] waiver request for SS-1072" in view of these results, as stated in EPA's October 16, 2020, correspondence ([JX] 21), given that EPA did not specifically state that it would not so reconsider in the 2022 EPA Ecological Effects Waiver Response ([JX] 69).

AMVAC Hearing Request ¶ 349 (emphasis added).

e. Other data

As previously discussed, the NOITS cites many other data requests from the DCI that allegedly remain outstanding. I find it unnecessary to discuss them in detail, because the lack of fish toxicity data, mysid data, marine diatom data, and *Leptocheirus* chronic sediment toxicity study are sufficient evidence on their own to independently support suspension of DCPA's registration.

IV. Standard for Accelerated Decision and Burden of Proof

Under the rules governing this proceeding, this Tribunal may "render an accelerated decision in favor of Respondent as to all or any portion of the proceeding, including dismissal without further hearing or upon such limited additional evidence . . . as he may receive" when "there is no genuine issue of any material fact and . . . the respondent is entitled to judgment as a matter of law." 40 C.F.R. § 164.91(a)(7). An accelerated decision has "the same force and effect as an initial decision" issued after a hearing. 40 C.F.R. § 164.91(b). Although the Federal Rules of Civil Procedure do not specifically apply to consideration of the Motion, the summary

judgment standard in Rule 56 and associated jurisprudence provide guidance in addressing a motion for accelerated decision. *See, e.g.*, *BWX Technologies*, 9 E.A.D. 61, 74 (EAB 2000).

In this proceeding, the Agency "has the burden of going forward to present an affirmative case for the cancellation or change in classification of the registration." 40 C.F.R. § 164.80(a). However, "the ultimate burden of persuasion shall rest with the proponent of the registration." 40 C.F.R. § 164.80(b); *Bayer*, 17 E.A.D. at 260, 2016 WL 4125892, at *25. Therefore, AMVAC, as the proponent of DCPA's registration, must meet its burden by either rebutting the Agency's prima facie case for suspension, or demonstrating by a preponderance of the evidence that it has not failed to take the action that served as the basis for the notice of intent to suspend DCPA's registration and that the Agency's determination on existing stocks is not consistent with FIFRA. *Bayer*, 17 E.A.D. at 260, 2016 WL 4125892, at *25.

V. Discussion

a. The scope of this proceeding is limited

Although the parties in large measure agree on the facts leading to issuance of the NOITS, they disagree somewhat on the legal standard that applies in this proceeding, particularly as to breadth of issues that should be considered. I find that the scope of the proceeding in this case is limited.

i. EPA's Argument

The Agency contends there are just two questions to consider: "(1) whether AMVAC has, within the timeframes required by the Agency, failed to take appropriate steps to secure the data required by the DCI and (2) whether the terms of the NOITS concerning existing stocks of AMVAC's product are consistent with FIFRA." Mot. at 39. In this regard, the Agency urges a strict reading of the statute: "[T]he only matters for resolution [] shall be whether [AMVAC] 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 [EPA's] determination with respect to the disposition of existing stocks is consistent with [FIFRA]." Mot. at 42 (quoting 7 U.S.C. § 136a(c)(2)(B)(iv)).

According to EPA, this serves congressional intent that through FIFRA, the Agency use current data and scientific knowledge to protect human health and the environment from unreasonable adverse effects of pesticide use. Mot. at 42. Because Congress recognized that a lack of data "thwarts EPA's ability to determine if [a] pesticide continues to meet the standard for registration," it authorized EPA to suspend registrations when a registrant does not respond to the Agency's data requests, the Agency states. And it "expressly limited" the scope of matters to be considered when a registrant facing suspension requests a hearing, the Agency observes, as well as the timeframe in which the hearing must take place. Mot. at 42. Consequently, according to EPA, this proceeding should not be broadened to include other matters, "such as the technical sufficiency of its data submissions, the time taken by EPA to review and respond to said submissions, the fact that certain data may be submitted while this hearing is pending, or EPA's rationale for requiring the submission of certain data[.]" Mot. at 43. Rather, the Agency

states, the only question is whether AMVAC submitted data that EPA requested in the timeframe that EPA requested, and the undisputed facts demonstrate that it did not. Mot. at 44-47.

ii. AMVAC's Argument

AMVAC asserts a more expansive view of this proceeding: "In short, [7 U.S.C. § 136a(c)(2)(B)(iv)] requires a decision-maker to determine at least three things: (1) what EPA's actual time requirement was, (2) whether the 'steps' a registrant took 'to secure the data' EPA requested within the time allowed by the Administrator was 'appropriate,' and (3) facts relevant to whether EPA's existing stocks provision is consistent with FIFRA." Response at 5. Further, AMVAC contends, the inquiry is not limited by the portion of the statute "providing that the 'only matters for resolution [at a hearing] shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend.'" Response at 5 (quoting 7 U.S.C. § 136a(c)(2)(B)(iv)). AMVAC argues that its interpretation of the standard is supported by the plain language of the statute, legislative history, and a comparison to other provisions of FIFRA, and it further alleges that EPA's issuance of the NOITS is inconsistent with its past practices and that its view of this proceeding is "incompatible with the statute." Response at 6-17.

iii. Analysis

Based on the plain language of the statute, I generally agree with EPA's formulation of the scope of this particular proceeding involving DCPA's initial registration review. With respect to statutory interpretation, the Environmental Appeals Board has stated that:

> When interpreting the language of a statute, the starting point is always the language of the statute itself. If the statute is clear and unambiguous, that is the end of the matter, for the court * * * must give effect to the unambiguously expressed intent of Congress. In addition, 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. A statute is ambiguous if it is capable of being understood in two or more possible senses or ways. As the Supreme Court has emphasized, the meaning—or ambiguity—of certain words or phrases may only become evident when placed in context. Thus, it is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme. In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.

U.S. Army, Fort Wainwright Cent. Heating & Power Plant, 11 E.A.D. 126, 141 (EAB 2003) (Remand Order on Interlocutory Appeal) (citations omitted) (quotation marks omitted).

FIFRA states in relevant part that: "[T]he only matters for resolution [here] shall be whether [AMVAC] has failed to take the action that served *as the basis for* the [NOITS.]" 7

U.S.C. § 136a(c)(2)(B)(iv)) (emphasis added). In this case, as to the "action" on which it is based, the NOITS states:

> The Notice of Intent to Suspend was issued following the Agency's January 21, 2013, issuance of a Data Call-In Notice (DCI), which required the registrant of the affected pesticide product containing DCPA to take appropriate steps to secure certain data. *Following the registrant's failure to submit these data* or to take other appropriate steps to secure the required data, *the agency is unable to fully evaluate the risks associated with DCPA.* Data for DCPA were determined to be required to maintain the existing registration of the affected product . . . . *The failure of the registrant to comply with* the thyroid toxicity and *other data requirements of the DCPA DCI is a basis for suspension of the affected registration under FIFRA.*

NOITS, 87 Fed. Reg. at 25262-25263 (emphasis added). Thus, in this case the "action" AMVAC is alleged to have "failed to take" is to submit, *at all*, *to date*, certain data requested in the 2013 DCI.[22] AMVAC was the only party legally responsible for producing the data and it has not claimed that any extraordinary circumstances caused the submission failure. Therefore, the issue is a simple binary question.

Further, there is no need in this case to consider the issue of what limits were imposed upon AMVAC by EPA in regard to data production. EPA is not seeking a suspension merely based upon AMVAC's late filing or partial filing of data, and AMVAC has not alleged that any deadline for data production was unfeasible or remains outstanding, all within the confines of the statutory period provided for review. To the contrary, the company has acknowledged that it cannot submit the requisite data even before the final October 1, 2022 statutory deadline imposed upon EPA to "complete" its registration review of DCPA.

As such, I find no merit to AMVAC's argument that I am obliged to consider either what EPA's various time requirements for each missing study were and whether the steps AMVAC took to secure the data within each of those time limits were "appropriate." I note undertaking such considerations might well involve a wide variety of collateral matters that ultimately are not the basis of the NOITS, such as a detailed analysis of the technical data requirements and AMVAC's opinion thereon as to validity or usefulness; what the Agency's role should be in reviewing and responding to a registrant's communications or submissions; and/or the workings of the Agency's document tracking system, et cetera.

Aside from abiding by the plain language of the statute, limiting the scope of this proceeding in this manner is consistent with the 75-day time limit on this proceeding. *See* FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). If Congress intended a more in-depth assessment of the "appropriateness" of a registrant's actions as to dozens of data requests over a period of almost a decade, it would not have required that this whole proceeding begin and end

[22] The statute provides other bases upon which a NOITS may issue, such as failing to participate in a procedure for reaching a joint data development arrangement or an arbitration proceeding or to comply with the terms of an agreement or arbitration decision, none of which are relevant here. 7 U.S.C. § 136a(c)(2)(B)(iv).

in less than three months.

In addition, narrowing the issues supports the overall statutory intent to efficiently complete the registration review process to ensure that DCPA "continues to meet the FIFRA statutory standard for registration based on the science, policies, and regulations current at the time of the review." *See* Pesticides; Procedural Regulations for Registration Review, 65 Fed. Reg. 24586, 24588 (Apr. 26, 2000) (Advanced Notice of Proposed Rulemaking). In reviewing DCPA's registration, scientific advancements or experience of use allow the Agency to determine if DCPA poses significant new risks not previously known or considered. Completion of the process, within the statutory time limits, "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."[23] *Nat'l Family Farm Coalition v. U.S. EPA*, 966 F.3d 893, 918 (9th Cir. 2020). In DCPA's case, there are various data gaps that prevent EPA from conducting a complete analysis of the pesticide's risks and complying with FIFRA's initial registration review requirements. EPA sought to fill those gaps by issuing the 2013 DCI, but AMVAC has not produced the required data in the time required by the Agency.[24]

On the other hand, to adopt AMVAC's reading of FIFRA § 3(c)(2)(B)(iv) – that to avoid suspension a registrant need only prove that it took "appropriate steps" *towards providing* the required data before the deadline – is akin to inviting registrants to spend an interminable amount of time *attempting* to provide data without actually providing it. Even if AMVAC were taking *only* appropriate steps toward producing required data and acting entirely in good faith, but continually failing to actually provide the data, it would undermine FIFRA's mandate that a pesticide not remain registered unless the Agency determines that it can be used without causing "any unreasonable risk to man or the environment." *See* FIFRA § 3(c)(5)(C)-(D), 7 U.S.C. § 136a(c)(5)(C)-(D); 7 U.S.C. § 136(bb). It would also shift to EPA the company's burden of maintaining its registration, because AMVAC's proposed standard suggests that DCPA is *entitled* to continuous registration even if the data necessary to support its registration are not

[23] It is noted that 24 years have passed since the RED of DCPA was issued in 1998. R.E.D. Facts DCPA, EPA-738-F-98-002 (Nov. 1998), *available online at* https://archive.epa.gov/pesticides/reregistration/web/pdf/0270fact.pdf. This is one and a half times the quindecinnial period which Congress determined was a generally appropriate interval for periodic registration review. 7 U.S.C. § 136a(g).

[24] In any event, such evaluations and determinations are better made by officials in OPP conducting DCPA's FIFRA-mandated registration review. The statute grants them (through delegation by the Administrator) discretion to assess the appropriateness of a registrant's actions prior to issuing a NOITS. This makes sense, given their management of such tasks as setting deadlines for data submission, determining whether requested data was in fact submitted, and evaluating whether gaps in the data have been sufficiently filled. This Tribunal, which issues initial decisions that in some circumstances become the final decision of the Agency, does not formally defer to OPP in the same sense that a federal court gives legal deference to agency decisionmaking. *See Consent Agreements and Proposed Final Orders for Animal Feeding Operations*, 2006 WL 478143, at *9 n.21 (EAB 2006) (noting that *Chevron* deference does not apply to EAB decisions because the Board serves as the final decision maker for the Agency). However, I recognize as a general principle that "'[t]he rationale for deference is particularly strong when the [EPA] is evaluating scientific data within its technical expertise[.]'" *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1000 (D.C. Cir. 2008) (quoting *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992)). To that extent, it is more suitable for the science and technical experts within OPP 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.

actually available to EPA for review.

Additionally, allowing for interminable but nevertheless "appropriate" steps ignores the fact that in this case, FIFRA imposes on EPA an October 2022 deadline to complete its review of DCPA.[25] *See* 7 U.S.C. § 136a(g)(1)(A)(iii); AMVAC Hearing Request ¶ 21. AMVAC has had notice of this statutory deadline since it was imposed by Congress in 2007 as well as notice since June 2011 of the type of information it would need to provide EPA to maintain its registration of DCPA. *See* Pesticide Registration Improvement Renewal Act, Pub. L. No. 110-94, 121 Stat. 1000 (Oct. 9, 2007); Registration Review; Pesticide Dockets Opened for Review and Comment and Other Docket Actions, 76 Fed. Reg. 38166 (June 29, 2011) (Notice); DCPA Summary Document Registration Review: Initial Docket June 2011, Docket No. EPA-HQ-OPP-2011-0374-0002 (June 29, 2011), *available online at* www.regulations.gov. 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. Bloom Statement at 2-3.

I further note that legislative history supports my conclusion that the only question for this Tribunal with respect to the additional data requested is whether AMVAC did or did not submit what the 2013 DCI required. Congress amended FIFRA in 1978 to add provisions regarding use of additional data to support existing registrations in Section § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). *See* Pub. L. No. 95-396, 92 Stat. 819 (1978). The Senate's initial version of the bill, S. 1678, required the Administrator to cancel a pesticide's registration without further hearing if the Administrator determined a registrant had failed to take appropriate steps to secure the data required within the time the Administrator required. *See* 123 Cong. Rec. S13087-13103, 13100 (daily ed. July 29, 1977); S. Rep. No. 95-334, at 18, 131 (1977). Under those same conditions, corresponding House bills, H.R. 8681 and 7073, required the Administrator to cancel the pesticide's registration in accordance with FIFRA § 6(b), which permits a registrant to request a hearing under FIFRA § 6(d) when the Agency issues a notice of intent to *cancel* a pesticide. *See* H.R. Rep. No. 95-663, at 4, 83 (1977). In its reconciliation of these bills, the conference committee added the hearing process that was ultimately codified, providing that a registrant could request that a hearing be conducted under FIFRA § 6(d) and spelling out that "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]." *See* S. Rep. No. 95-1188, 5-6, 32-33 (1978); H.R. Rep. 95-1560, at 5-6, 32-33 (1978) (Conf. Rep.), *as reprinted in* 1978 U.S.C.C.A.N. 2043, 2048. The conference committee described its substitute bill as "authoriz[ing] the Administrator *to enforce a defensive data requirement* . . . by instituting a procedure to suspend the registrant's registration until such time as *the data are received or compliance obtained*." *See* S. Rep. No. 95-1188, at 5-6, 32-33 (1978); H.R. Rep. 95-1560, at 5-6, 32-33 (1978) (Conf. Rep.), *as reprinted in* 1978 U.S.C.C.A.N. 2043, 2048.

[25] It is against this backdrop of completing FIFRA's mandated periodic registration review of DCPA that the Agency issued the 2013 DCI in the first place. As set forth above, when additional data are needed to complete a registration review, FIFRA *mandates* that the Agency exercise its authority in 7 U.S.C. § 136a(c)(2)(B) to require the submission of data and to use and apply the provisions of that subsection to any data requests the Agency makes. 7 U.S.C. § 136a(g)(2).

The conference committee's changes are notable, because they focus the inquiry in this proceeding on whether data have in fact been timely produced. Most significantly, the committee could have kept the House bill's proposal for a hearing in accordance with FIFRA § 6(b), which contains no specification as to "the only matters" that are to be considered at that hearing. But instead, the committee inserted express language that strictly limits what the hearing is intended to resolve, which is whether the registrant did or did not fail to provide the required data. Likewise, the committee amendment undermines AMVAC's argument that the "action that served as the basis for the [NOITS]" language is a reference to the "appropriate steps" language that precedes it: the "action that served as the basis for the [NOITS]" language was added by later amendment, when the committee could have repeated the "appropriate steps" language but chose not to do so. *See* Response at 16. Additionally, the committee reported that its revisions were intended to authorize EPA "to enforce a defensive data requirement" by enabling it to suspend a registration until the requested "data are received or compliance obtained." This demonstrates congressional intent that AMVAC bear the burden of *actually delivering* the data necessary to maintain DCPA's registration. AMVAC is not permitted to take indefinite steps *toward* securing the data before the Agency moves to suspend the registration. The fact that AMVAC has attempted but failed to provide the data to EPA is by definition not "appropriate." In this sense, AMVAC "failed to take appropriate steps to secure the data required" because EPA has not actually received the outstanding data and AMVAC has not complied with the DCI.

For these reasons I find that "the *only* matters for resolution in this proceeding" are (a) whether AMVAC has submitted the data required by the 2013 DCI; and (b) whether the Agency's determination with respect to the disposition of existing stocks of DCPA is consistent with FIFRA.

b. AMVAC failed to take the action that served as the basis for the NOITS because it failed to submit data required by the 2013 DCI

The undisputed material facts demonstrate that AMVAC failed to take the action that served as the basis for the NOITS because, despite several years of back-and-forth communications with the Agency, as of this Order's date, "multiple data requirements from the DCI remain outstanding." *See* NOITS. In her testimony, Ms. Bloom discusses this failure generally, describing AMVAC's actions with respect to the DCI as "abnormally dilatory and repetitive."

> Following EPA's denial of AMVAC's requests to waive certain data requirements, AMVAC followed up with additional waiver requests, which usually provided rationales similar to the originals, often with only minor or insignificant changes. In some cases, AMVAC simply opposed the Agency's denials and did not offer any additional, substantive rationale. During this cycle of waiver requests and denials, AMVAC did not initiate attempts to satisfy the subject data requirements. In my experience, this cycle of repeated waiver requests is not common for other registrants and registration review cases. Additionally, explicit statements like AMVAC's that

> it did not intend to submit certain data required by the DCI are not typical of registrants in general.

Bloom Statement at 6. As previously noted, there are 20 categories of data set forth in the DCI for which EPA alleges AMVAC did not submit sufficient acceptable data when the NOITS was issued. Each of these data categories present bases for issuing the NOITS, and AMVAC's failure to comply with any *one* of these bases is sufficient cause for suspension regardless of AMVAC's compliance with any other data requirement.

i. DCPA fish toxicity data

AMVAC admits that it did not provide any data concerning bluegill sunfish or sheepshead minnow before the NOITS was issued, some eight years after the deadline imposed by the DCI. Response at 30-31; Freedland Statement ¶ 17. But AMVAC argues that this Tribunal "could reasonably conclude that AMVAC acted appropriately because it provided a timeline initial response and initiated work on the two additional species studies shortly after EPA's October 2020 communication." Response at 31. AMVAC further contends that because it submitted one of the missing studies on June 7, 2022, I should find as a matter of law that the missing fish toxicity studies cannot be a basis for suspension. Response at 31.

I am not persuaded by AMVAC's arguments. There is no question that AMVAC did not fully comply with the data request within the 12-month timeframe set by the DCI. Data related to bluegill sunfish and sheepshead minnow had not been submitted when EPA issued the Outstanding Data Letter nearly eight years after the DCI, it was still missing when EPA issued the NOITS more than nine years after the DCI, and to this date, no sheepshead minnow data has been provided. AMVAC clearly did not take the action that served as the basis for the NOITS. Moreover, even if I were to consider the appropriateness of AMVAC's actions under the circumstances, I reject the notion that it acted appropriately. Yes, it provided *a* response to the DCI and produced an existing study with regard to rainbow trout within 12 months. But this was not the response called for, and waiting until it received the Agency's Outstanding Data Letter in 2020 to begin studies involving the other necessary fish species is not appropriate. It is unclear whether AMVAC is suggesting that, prior to receiving the Outstanding Data Letter, it believed the rainbow trout study fully satisfied the fish toxicity data requirement or whether AMVAC just plain forgot about or decided not to complete the bluegill sunfish and sheepshead minnow studies. But either way, the burden falls on AMVAC, not EPA, to produce the data requested.

Further, AMVAC's June 2022 submission of a study in response to the bluegill sunfish requirement (using, again, a different species) does not negate a suspension based on the missing fish toxicity data. The data were not submitted until after the NOITS was issued and a hearing requested, it is unclear whether it will prove acceptable to EPA, and more significantly, the sheepshead minnow data remain outstanding. To the extent the suspension of DCPA is based on missing fish toxicity data, the Agency will reinstate the registration if it determines AMVAC has complied fully with this data requirement. But at this time, there is no evidence in the record that the Agency has found that AMVAC has complied fully with this data requirement.

Consequently, the undisputed facts demonstrate that AMVAC did not produce the fish

toxicity data requested by the DCI within the time required by the Agency, and EPA is entitled to judgment as a matter of law.

ii. TPA fish toxicity data

It is undisputed that AMVAC has not submitted any of the studies called for in the 2013 DCI with respect to early life fish toxicity studies using TPA, and it concedes that it will not do so until 2023. Freedlander Statement ¶ 69. AMVAC's argument instead is that it "acted reasonably" by requesting waivers based on its reading of EFED's 2011 document discussing plans for conducting DCPA's registration review in which it stated that with respect to TPA, "a more limited testing strategy will be considered in lieu of a comprehensive data submission if one is proposed." Response at 24; Freedlander Statement ¶ 47-48; JX 65 at 3.

As discussed above, whether 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 DCI within the time the Agency required it. There is no dispute that AMVAC did not.

Regardless, AMVAC's "reasonableness" argument has no merit. AMVAC elected at the outset to pursue a waiver rather than generate the required data. It apparently made this choice based on a statement in a general planning document describing what the Agency would "consider" doing, not what the Agency said it would necessarily do. AMVAC bore the risk that the Agency would consider, and reject, any proposal it made for a more limited testing strategy. Then, when AMVAC learned the Agency had in fact found its proposal unacceptable and rejected it, AMVAC doubled down on its goal of obtaining a waiver by pursuing TPA data involving daphnids. It did so despite EPA's express caveat that "*depending on the results* of these initial studies, a full suite of studies *may or may not* be subsequently required." JX 66 at 8. After that, in the October 2020 Outstanding Data Letter, EPA formally advised AMVAC that its TPA fish toxicity data requirements still had not been met. AMVAC responded with a waiver request based on TPA daphnid data, knowing that it may or may not be found acceptable to EPA, and then did nothing until the NOITS was issued. This is not a reasonable course of action, and the result is that no data were produced within the time the Agency required.

Consequently, the undisputed facts demonstrate that AMVAC did not produce the TPA fish toxicity data requested by the DCI within the time required by the Agency, and EPA is entitled to judgment as a matter of law.

iii. DCPA mysid data

It is undisputed that AMVAC did not produce acceptable data from DCPA chronic toxicity tests on mysids. As EPA made clear in the DCI, "[t]he Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend or an order revoking or modifying a tolerance or tolerance exemption." JX 4 at 17. The DCI further specifies that suspension may be based on a failure to satisfy EPA requirements regarding the design and conduct of studies and requirements regarding the reporting of data, including "the completeness of results." JX 4 at 17-18. In the

case of AMVAC's 2014 DCPA chronic toxicity mysid study, EPA determined that it lacked data at low enough doses to allow the establishment of a definitive NOAEC, and it declined to characterize the study as fully acceptable. JX 27; JX 56; JX 59; JX 64. To that end, AMVAC failed to take the action that served as the basis for the NOITS because it has failed to produce the data required by the DCI in the time required by the Agency.[26]

AMVAC argues that the Agency provided it belated notification that more data were required to satisfy the DCI. Response at 35-36. AMVAC suggests that EPA first reviewed the 2014 study in 2016, finalized that review in December 2021, but did not inform AMVAC of its evaluation until April 2022, concurrently with the issuance of the NOITS. Response at 35. Dr. Freedlander testified on behalf of AMVAC that "[t]hese questions could have been addressed (or even a new study run, if needed, or other appropriate action taken) in the intervening time frame between EPA's contractor's initial review (2016) and the date that AMVAC was made aware of EPA's conclusions (concurrent with the NOITS)." Freedlander Statement ¶¶ 4, 24. Moreover, AMVAC argues that "it would be plainly inconsistent with the statute to rule that EPA may suspend a registration based on limitations of a study that EPA had under review for years, did not find to be unacceptable and for which EPA did not share its review until concurrent with a NOITS." Response at 35-36. Whether the six years between the initial EPA review and the notice provided to AMVAC is a lost opportunity to have corrected the study's deficiencies is neither here nor there. The undisputed fact is that, although a study was submitted on-time, EPA determined the study was lacking necessary data points. This finding, whenever it was shared with AMVAC, was a sufficient basis for issuing the NOITS.

AMVAC additionally argues that "a reasonable decision maker could conclude that AMVAC took appropriate steps to run and submit the study based on the protocol." Response at 35. As discussed above, the only matter for resolution in this proceeding is whether AMVAC failed to take the action that served as the basis for the NOITS. The Agency, through OPP, determined that AMVAC did not take appropriate steps to run and submit the study because it failed to submit *acceptable* data for DCPA chronic toxicity tests on mysids. The fact that these data were not submitted is undisputed, and it demonstrates AMVAC's failure to take the action that served as the basis for the NOITS, i.e., its failure to produce data required by the DCI.

Consequently, the undisputed facts demonstrate that AMVAC has failed to submit a DCPA chronic toxicity study in mysids as requested by the DCI within the time required by the Agency, and EPA is entitled to judgment as a matter of law.

iv. TPA mysid data

It is also undisputed that AMVAC performed no chronic toxicity study using the mysid model for TPA. AMVAC requested waivers for this study twice, in 2013 and 2018. *See* JX 5; JX 22; JX 67. Both waiver requests were denied, in 2014 and 2022, respectively. JX 37; JX 69. AMVAC states that it is now undertaking a TPA chronic toxicity mysid study and will submit results in 2023. AMVAC Hearing Request ¶ 326. Consequently, there is no dispute that AMVAC failed to submit a TPA chronic toxicity study utilizing the mysid model in accordance with the DCI in the time required by EPA.

[26] It is not the role of this Tribunal to evaluate EPA's conclusion regarding the study.

AMVAC's contention that EPA "failed to timely respond to AMVAC's request for conditional waivers, thereby leading AMVAC to believe that studies would likely not be required based on the results of other studies" is unavailing. AMVAC Hearing Request ¶ 11. If AMVAC was uncertain about the necessity of some of the TPA ecotoxicity studies, it was incumbent upon AMVAC to clarify with the Agency, not make an erroneous assumption based on silence. Equally unpersuasive is AMVAC's veiled assertion that these data are not needed by EPA. *See* AMVAC Hearing Request ¶¶ 324 ("EPA thus does not state in the 2022 Waiver Response that its ability to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects standard will be compromised as a result of lacking . . . the Guideline 850.1350 Mysid Chronic Toxicity, only that it will have to use a conservative endpoint that might overestimate toxicity (i.e., yield a conservative risk analysis)."). The utility to the Agency of certain data is not for AMVAC to resolve; moreover, as indicated above, "the validity of the additional data requirement may not be challenged." *Atochem*, 759 F. Supp. at 864. AMVAC additionally argues that

> in the light most favorable to AMVAC it appears that AMVAC submitted timely waivers in 2013, did not hear back until 2017, submitted additional information in 2018 (in part based on new studies at EPA's suggestion), and did not receive a substantive response from EPA until the NOITS had already been issued in 2022.
>
> At the very least, this presents a triable issue of fact as to whether AMVAC acted reasonably under the circumstances and whether EPA's conduct reasonably led AMVAC to believe that the original deadlines were no longer applicable (as to these and the other studies discussed below), and that it was not until the issuance of the NOITS that EPA made its position concerning the passage of deadlines clear.

Response at 22. This too is unavailing. As stated above, the factual issue is whether AMVAC failed to complete the submissions required by the DCI, not whether it acted reasonably or appropriately under the circumstances. There is no dispute as to whether AMVAC submitted the chronic TPA mysid report: It did not, and AMVAC admits this study will not be completed until 2023. AMVAC Hearing Request ¶ 326. Therefore, accelerated decision is warranted.

Finally, even if this proceeding were to assess whether AMVAC acted reasonably or appropriately, it is clear the company has not. As part of the February 2018 round of waiver requests, AMVAC stated that it "agree[d] with the Agency's proposal for conducting acute and chronic TPA studies in daphnids and reviewing those results with the Agency in order to determine whether additional aquatic organism testing is warranted." JX 67. The acute and chronic TPA daphnid studies were submitted to the Agency in 2014 and 2020, respectively. JX 27, 69. AMVAC argues that "[a] factfinder could determine that AMVAC was acting reasonably in attempting to follow the path EPA laid out for it [the daphnid studies] in connection with these studies." Response at 24. However, even after it received the 2020 Outstanding Data Letter that informed AMVAC that EPA needed the missing studies to complete a draft risk assessment in June 2021 (*see* JX 21), there is no evidence that AMVAC

followed up with the Agency between December 2020 (JX 22) and April 2022 (JX 69) to confirm that the daphnid studies provided the information the Agency needed to complete its work. When seven studies are contingent on the suitability of the daphnid results, and EPA has informed AMVAC of its approaching June 2021 deadline, it is not appropriate to do nothing.

Consequently, the undisputed facts demonstrate that AMVAC has failed to submit a TPA chronic toxicity study in mysids as requested by the DCI within the time required by the Agency, and EPA is entitled to judgment as a matter of law.

v. Diatom TPA data

It is undisputed that AMVAC did not perform TPA toxicity testing using marine diatoms. Waivers for this study were requested in 2013 and 2018. *See* JX 5; JX 22; JX 67. These waivers were denied in 2014 and 2022. JX 66; JX 69. AMVAC states that it has commenced a TPA toxicity study using the marine diatom, and that the results will become available in 2023. AMVAC Hearing Request ¶ 325.

As with the fish toxicity and mysid studies, I am not convinced by AMVAC's arguments concerning the amount of time it took EPA to respond to waivers; whether these data are actually needed for EPA's risk assessments; or whether AMVAC acted reasonably and appropriately. AMVAC Hearing Request ¶¶ 11, 324; Response at 22. The question I am considering is whether AMVAC failed to submit data required by the 2013 DCI. I find that it did.

Consequently, the undisputed facts demonstrate that AMVAC has failed to submit a TPA toxicity study in the marine diatom model as requested by the DCI within the time required by the Agency, and EPA is entitled to judgment as a matter of law.

vi. *Leptocheirus* chronic sediment toxicity data

AMVAC does not dispute that, despite the passage of nine years since the DCI was issued, it has, to date, not completed the SS-1072 - *Leptocheirus* Chronic Sediment Toxicity Study, required of it by EPA as part of the review process to maintain its registration. Response at 36-38. Further, it acknowledges that "testimony concerning the Leptocheirus Chronic Sediment Toxicity Study, Special Study 'SS' 1072 is largely consistent between the parties through 2016." Response at 36 (citing Porter Statement at 6-8, Wendel Statement at 9). Such consistency includes the fact that EPA refused to waive the study requirement despite the lab difficulties and even though EPA agreed that AMVAC's assertions "that DCPA showed only 'minor toxicological effects' in relevant comparable species for which data was available and that sediment dwelling organisms such as Leptocheirus 'display[ed] a much lower level of sensitivity' to other organisms for which data was available were 'consistent with . . . study reports' EFED was reviewing." Response at 36-37 (citing JX 39 at 2).

Nevertheless, AMVAC argues that suspension for failing to produce the study is unwarranted because after the DCI was issued in 2013 it took "appropriate steps" towards fulfilling the DCI request. Response at 36-38. Among the steps it identifies taking are its

submission of "substantive" additional data (JX 76) in support of its waiver request on November 22, 2016, and its seeking assurance from EPA that if it conducted the 10-day study, the 28-day study would not be required. Response at 36-37. As to the November 2016 submission, AMVAC suggests that its lack of inclusion in the testimony of EPA's witnesses "raises the inference that EPA has not reviewed [it]." Response at 37.

Petitioner further insists that it was reasonable for it to ask EPA to formally amend the DCI to add the additional Guideline 850.1740 requirement for the 10-day *Leptocheirus* study, and not to act until it did, declaring that "[o]therwise there would be no meaningful restriction on EPA's ability to 'move the goalposts' on what the scope of the DCI even is." Response at 38. In support it argues that this Tribunal

> should not find that EPA may support a suspension order on the basis of non-performance of a study that was not included in the DCI in the first instance without formal amendment of the DCI. Even if the Presiding Officer determines that suspensions based on data requirements not formally added to the DCI are legally possible, it is still the case that, resolving all inferences in AMVAC's favor, AMVAC acted appropriately.[27]

Response at 38.

The undisputed factual record indicates that the January 2013 DCI required AMVAC to submit "SS [Special Study]-1072 Chronic Sediment - *Leptocheirus plumulosus*" within "24" months. JX 4 at 32. AMVAC initially represented to EPA it could and would do so and presented a proposed protocol which EPA approved, with minor tweaks. JX 5; JX 70. Issues cropped up thereafter with AMVAC's lab, and EPA exercised its discretion and amicably accepted the delays past the initial 24-month deadline without initiating any punitive action against the company. When Petitioner's chosen lab was finally caught up and capable of timely conducting the study, AMVAC apparently declined to have the study done. Rather, at that point, in March of 2016, it requested a waiver of the study, which EPA timely denied in writing within three months, in June of 2016. JX 62; JX 74. It is clear and unequivocal from the language of the denial of the waiver request, that in mentioning a 10-day study, EPA was generously merely suggesting to AMVAC a path by which it might obtain evidence in support of its waiver request. JX 74 at 2-3. It was explicitly not adding the 10-day test to its list of required studies, nor agreeing at that point to removing the 28-day required study.[28] JX 74 at 2-3.

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[27] As AMVAC seems to implicitly recognize here, FIFRA does not clearly mandate that EPA request information through issuance of a DCI only, but that it "notify" the registrant of the data it wants produced. 7 U.S.C. § 136a(c)(2)(B)(i); *see also* 40 C.F.R. § 155.50(c) (EPA may at any time identify data or information which may be useful for consideration of registration review); 40 C.F.R. § 155.53 (the Agency will review the data submitted in response to § 155.50(c) "*or*" submitted in response to a Data Call-in notice); 40 C.F.R. § 155.48 (providing EPA "may" issue a "Data Call-In notice").

[28] Denial of a waiver constitutes "a final Agency action." 40 C.F.R. § 152.91(c). As such, following denial, "the applicant *must* choose another method of satisfying the data requirement." *Id*. (emphasis added); *see also* JX 4 at 15-16 (within 30 days after a denial of waiver, the registrant must submit a statement documenting the method chosen to comply with the DCI requirements).

Apparently, at that point, even undertaking this abbreviated study was not to AMVAC's liking, so instead of "expeditiously" initiating either study, five months later, in November 2016, it submitted instead a supplementary request for a waiver arguing neither test would be useful. JX 76. While the testimony of EPA's witnesses may not discuss this supplementary waiver request, it is clear that EPA was not altering its position. Specifically, the record shows that a few months thereafter, in March of 2017, when the parties held a telephonic meeting, EPA made it clear to AMVAC that the *Leptocheirus* sediment study was still outstanding and not waived, referring in regard thereto to the June 2016 EPA Memo, and that it intended such declination to stand "even when the registrant submits report from the 10-day study." JX 35 at 1-2.

In October 2020, EPA reiterated its position when it sent AMVAC the Outstanding Data Letter. JX 21. Citing to EPA's June 27, 2016 document (JX 74), EPA advised AMVAC that, with regard to the Chronic Sediment *Leptocheirus* data requirement, the "[w]aiver request [was] denied; [study] outstanding; Guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates) *may* proceed in the interim and results *may* allow EPA to reconsider waiver request for SS-1072." JX 21 at 6 (emphasis added). Still having not received the study for review, EPA included it as an outstanding item in its NOITS filed in April 2022 and again issued another waiver denial. JX 57; JX 69 at 16-19. To date, AMVAC has not submitted the Chronic Sediment *Leptocheirus* study required by the 2013 DCI.

Rather, in its Request for Hearing, AMVAC now states it "intends to proceed" with the required 10-day study, after getting EPA's approval of a protocol, and anticipates the results in 2023. AMVAC Hearing Request ¶ 349. On this basis, it seeks to avoid a suspension based upon its previous failure to submit a study in compliance with the DCI. Response at 36-38. This Tribunal is unpersuaded by AMVAC's arguments for leniency. AMVAC had nine years to undertake the Chronic Sediment *Leptocheirus* study and failed to do so. While its lab had difficulties initially, the failure to conduct the test over the years is overwhelmingly attributable solely to the choices and decisions AMVAC alone made; completing the study was never beyond its control. Moreover, by its own admission, AMVAC cannot complete the study and submit the report until sometime in 2023, which is after expiration of the October 2022 statutory deadline imposed on EPA for conducting the registration review. FIFRA's statutory deadline is intended to ensure that pesticide registrations are periodically reviewed to determine if they still meet the statutory criteria based upon current scientific knowledge. AMVAC was on notice of the deadline and its actions thwarted EPA's attempt to meet it. It should bear responsibility for that failure.

Consequently, the undisputed facts demonstrate that AMVAC has failed to submit a *Leptocheirus* chronic sediment toxicity study as requested by the DCI within the time required by the Agency, and EPA is entitled to judgment as a matter of law.

vii. Other data

As previously indicated, the data points considered in the above analysis reflect only a fraction of the outstanding information that the Agency alleges has not been submitted. However, because I have found with respect to the examples cited herein that AMVAC did not

submit what the Agency required in the DCI, it is not necessary for me to conduct similar reviews of the remaining outstanding data points. Each of the datasets requested in the DCI present potential bases for the NOITS. The Agency alleges that 20 of those datasets remain outstanding and formed bases for the NOITS in this matter. Under FIFRA, AMVAC's failure to comply with any *one* of these bases is sufficient cause for suspension regardless of its compliance with any other data requirement.

viii. Conclusion

In sum, to meet the October 2022 deadline for conducting its initial registration review of DCPA, the Agency judiciously issued a DCI to AMVAC in 2013, providing 36-months for completion of the most protracted study. AMVAC concedes that it cannot and will not submit a number of the scientific studies requested by the Agency to complete its registration review until 2023, due to their recent initiation. As such, if 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. *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2490 (2021) (our system does not permit agencies to act unlawfully even in pursuit of desirable ends); *Texas v. United States*, 555 F. Supp. 3d 351 (S.D. Tex. 2021), *appeal dismissed,* No. 21-40618, 2022 WL 517281 (5th Cir. Feb. 11, 2022) (agency's decreed result must be within scope of its lawful authority); *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 971 (N.D. Cal. 2013) (Agency failure to comply with statutory deadline constitutes 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, 1177-78 & n.11 (9th Cir. 2002) (where Congress has specifically provided a deadline for performance by an agency, "no balancing of factors is required or permitted"); *Am. Lung Ass'n v. Browner*, 884 F. Supp. 345 (D. Ariz. 1994) (Agency carries heavy burden to show that compliance with statutorily mandated deadlines is impossible or infeasible, and excuses for delay must go beyond general proposition that further study and analysis of materials will make final agency action better). *Cf. Nat'l Urb. League v. Ross*, 489 F. Supp. 3d 939, 994 (N.D. Cal.), *order clarified,* 491 F. Supp. 3d 572 (N.D. Cal. 2020) (Agency single-mindedly sacrificing statutory objectives to meet a statutory or judicial deadline can itself violate the APA). 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.

Accordingly, I find that the undisputed material facts outlined above show that AMVAC has failed to take the action that served as the basis for the NOITS.

c. EPA's determination with respect to the disposition of existing DCPA stocks is consistent with FIFRA

When proposing to suspend a pesticide for a registrant's failure to provide required data, the Agency may include in the NOITS "such provisions as the Administrator deems appropriate

concerning the continued sale and use of existing stocks of such pesticide."[29] FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv).

The NOITS in this case declares that after the suspension becomes final and effective, AMVAC "may not legally distribute, sell, use (including use to formulate another pesticide product), offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person," Technical DCPA, but other entities may do so. NOITS at 4-5. That is, at the point in time the suspension takes effect, anyone other than AMVAC who has existing stocks of Technical DCPA may continue to use it, and anyone, including AMVAC, may continue to use and sell end-use products formulated from Technical DCPA (except that AMVAC may not formulate additional end-use products from Technical DCPA after the suspension date). *See* Mot. at 48. Ms. Bloom testifies that these provisions "are typical for products suspended under FIFRA Section 3(c)(2)(B)" and "similar to provisions from most prior" such suspensions. Bloom Statement at 6-7.

Additionally, the existing stocks provision in this case reflects EPA's publicly stated policy governing the disposition of existing stocks:

> 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. Registrants who sell or distribute a pesticide which has been suspended under FIFRA section 3(c)(2)(B) will be in violation of FIFRA section 12(a)(2)(J). 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.

56 Fed. Reg. at 29367; *see also* Bloom Statement at 7 (observing that provisions in the NOITS "are consistent with EPA's longstanding existing stocks policy, which generally does not allow registrants to sell or distribute existing stocks during the pendency of the suspension, as allowing such action would diminish the incentive for registrants to comply with the DCI in a timely manner").

EPA has broad statutory discretion in deciding how existing stocks of a suspended pesticide can be used: "*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." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv); Bloom Statement at 7. The only question for this Tribunal is whether the Agency's determination with respect to existing stocks is consistent with FIFRA. FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. §

[29] Existing stocks are "those stocks of a registered pesticide product which are currently in the United States, and which have been packaged, labeled, and released for shipment prior to the effective date of the [suspension] action." Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29362, 29362 (June 26, 1991) (Notice).

136a(c)(2)(B)(iv). I find that it is.

Pesticides are chemical substances specifically intended for "preventing, destroying, repelling, or mitigating any pest . . . ." 7 U.S.C. § 136(u). They are used to many beneficial purposes, particularly in agriculture. Nevertheless, FIFRA recognizes that even when used as intended, they can have negative consequences on human health and the environment, particularly with long term exposure. 7 U.S.C. § 136a(c)(5)(C), (D). As a result, as discussed above, FIFRA charges EPA with periodically reviewing previously registered pesticides to determine whether they can continue to be used safely without causing "unreasonable adverse effects on the environment," i.e., "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or . . . a human dietary risk from residues that result from a use of a pesticide in or on any food[.]" FIFRA § 3(c)(5)(C)-(D), 7 U.S.C. § 136a(c)(5)(C)-(D), 7 U.S.C. § 136(bb); Bloom Statement at 7. This determination necessarily rests on EPA's ability to acquire and consider extensive information about the pesticide, including new and advancing scientific data that demonstrates the pesticide's health and safety properties and potential adverse effects on the environment. FIFRA § 3(c)(1), (c)(2), 7 U.S.C. § 136a(c)(1), (c)(2); 40 C.F.R. Part 158; Bloom Statement at 7. The Agency cannot carry out this task when it is missing key data, nor can it accurately complete its registration review process. Ms. Bloom's testimony bears these points out:

> Meeting the standard of no unreasonable adverse effects is the burden of registrants, and almost always requires registrants to submit necessary data so that risks can be assessed . . . . EPA is unable to assess DCPA's risks to man and the environment, due to AMVAC's failure to submit necessary data years after the deadlines for submission imposed by the DCI. Accordingly, EPA would not be able to assess whether the risks are unreasonable and thus whether allowing the sale of the suspended product under an existing stocks provision would meet the standard under FIFRA.

Bloom Statement at 7. Ms. Bloom goes on to explain how the existing stocks provision proposed in the NOITS is consistent with FIFRA: "Where the risk picture is so uncertain that EPA cannot even make conservative estimates, not allowing existing stocks to continue to be sold or used by the registrant after issuance of a NOITS is fully consistent with FIFRA's goals to protect humans and the environment from unreasonable adverse effects." Bloom Statement at 7.

Petitioners argue that because AMVAC is the sole producer of DCPA, i.e., the sole formulator of end-use products, the NOITS's existing stocks provision "may harm growers in a manner that would not have occurred if AMVAC was not the sole producer of DCPA available to them. The fact that a market impact will occur solely because of the structure of the supply chain is illogical." Response at 39. Petitioners also assert that "the exact impact of the suspension on availability of end use products for 2022 and beyond" is unknown, but "that any expected shortage resulting from the suspension could be alleviated if AMVAC were permitted to formulate end-use products from available existing stocks of technical DCPA at the time a potential suspension goes into effect." Response at 41. Finally, Petitioners contend that EPA's decision on existing stocks "was directly impacted by the fact that it lacked information . . . that

would be provided by the CTA study" because the Agency claimed it was unable to make an accurate human health risk assessment, but that study is now in EPA's hands and should not be used to justify the existing stocks provision. Response at 39-40.

Petitioners' arguments miss the significance of AMVAC's failure to provide the requisite information to EPA for registration review within the lengthy statutory period provided. If the Agency cannot periodically assess a pesticide's current and/or cumulative risk to human health and the environment, then it cannot balance that against whatever economic, social, or environmental benefits the pesticide's current and future use might provide. Thus, Petitioners' claims about disruption to the market due to AMVAC's inability to formulate end-use DCPA products and that such disruption will adversely affect growers of agricultural commodities may be valid, but it is impossible to weigh the impact of such disruption against the harm, if any, its cumulative use over time may be causing as determined using current scientific data.

Moreover, the existing stocks provision gives teeth to EPA's ability to enforce FIFRA's data requirements and effect to the statutory deadline for review. A dilatory registrant has a much greater incentive to comply with the Agency's data requests when doing so can lift a suspension order on its product, including any determinations as to existing stocks. In this case, the fastest and surest way to limit the economic harm that AMVAC and the growers may suffer from the suspension is for AMVAC to submit *all* of the data to EPA that it has requested so that the Agency may most efficiently complete its review of DCPA's registration. Without such a suspension order the record suggests that AMVAC may continue to unhurriedly, if at all, provide the requisite studies even though the statutory deadline for review has passed. As such, I am persuaded that the Agency's decision to remove existing stocks of DCPA from the market to the extent described in the NOITS is appropriate and consistent with FIFRA.

Accordingly, I find that the undisputed material facts show that EPA's determination with respect to the disposition of existing DCPA stocks is consistent with FIFRA.

VI. Conclusion and Order

For the reasons discussed above, I find that there is no genuine dispute of material fact concerning (1) whether AMVAC has failed to take the action that served as the basis for the notice of intent to suspend the registration of DCPA Technical, or (2) whether the Agency's determination with respect to the disposition of existing stocks of DCPA is consistent with FIFRA. Accordingly, the Agency is entitled to judgment as a matter of law as to these facts, and its Motion for Accelerated Decision is **GRANTED**. The hearing in this matter previously scheduled for July 6-8, 2022 is **CANCELED**.

Regarding the registered pesticide products containing Technical Chlorthal Dimethyl (DCPA), EPA Reg. No. 5481-495, I find, for the reasons set forth above:

(1) Petitioner AMVAC has failed to comply fully with the data requirements of the data call-in GDCI-078701-1140 and has thereby failed to take the action that served as the basis for the notice of intent to suspend the registration of Technical Chlorthal Dimethyl (DCPA); and

(2) The Administrator's determination with respect to the disposition of existing stocks of Technical Chlorthal Dimethyl (DCPA) is consistent with FIFRA.

This Order renders accelerated decision in favor of Respondent and has the same force and effect as an initial decision entered under 40 C.F.R. § 164.90. 40 C.F.R. § 164.91(b). Accordingly, Petitioners' objections to the NOITS are **dismissed**, the Agency's NOITS is approved, and suspension of the registration for Technical Chlorthal Dimethyl shall immediately become effective when this decision becomes a final order under 40 C.F.R. § 164.90 and 7 U.S.C. § 136a(c)(2)(B)(iv).

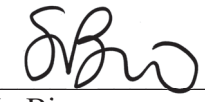
Any party may file an appeal of this Order with the Environmental Appeals Board pursuant to 40 C.F.R. Part 164:

"Within **20 days** after filing of an accelerated decision by the Administrative Law Judge, any party may file exceptions and a supporting brief with the hearing clerk, stating with particularity the grounds upon which he asserts that the decision is incorrect." 40 C.F.R. § 164.102(a).

"Within **7 days** of the service of exceptions and brief under paragraph (a) of this section, any other party or amicus curiae may file and serve a brief responding thereto, with appropriate page references to the relevant portions of the record, if applicable." 40 C.F.R. § 164.102(b).

"Within 90 days . . . from the filing of an accelerated decision, unless otherwise stipulated by the parties, the Environmental Appeals Board shall, on appeal or review from an . . . accelerated order of the Administrative Law Judge, issue its final decision and order, including its rulings on any exceptions filed by the parties; such final order may accept or reject all or part of the . . . accelerated decision of the Administrative Law Judge even if acceptable to the parties." 40 C.F.R. § 164.103.

SO ORDERED.



Susan L. Biro
Chief Administrative Law Judge

Dated: July 1, 2022
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.
Docket No. FIFRA-HQ-2022-0002

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Order on Respondent's Motion for Accelerated Decision**, dated July 1, 2022, and issued by Chief Administrative Law Judge Susan L. Biro, was sent this day to the following parties in the manner indicated below.

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Dated: July 1, 2022
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