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.	)	

INITIAL DECISION AND ORDER

Dated: May 16, 2023

Presiding Officer: Susan L. Biro
Chief Administrative Law Judge, EPA

Appearances:

For the U.S. Environmental Protection Agency:

Forrest Pittman, Esq.
Erin S. Koch, Esq.
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
Mail Code 2310A
1200 Pennsylvania Avenue NW
Washington, DC 20460

For Petitioner AMVAC:

David B. Weinberg, Esq.
Tracy A. Heinzman, Esq.
Keith A. Matthews, Esq.
Hume M. Ross, Esq.
Mark B. Sweet, Esq.
WILEY REIN LLP
2050 M Street NW
Washington, DC 20036

Timothy J. Donnelly, Esq.
AMVAC Chemical Corporation
4695 MacArthur Ct, Suite 1200
Newport Beach, CA 92660

For Petitioners Grower-Shipper Association of Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms:

Cristen S. Rose, Esq.
HAYNES BOONE
800 17th Street NW
Washington, DC 20006

I. Procedural History

The U.S. Environmental Protection Agency's ("EPA," "the Agency," or "Respondent") Office of Pesticide Programs ("OPP") initiated this matter in April 2022 when it issued a Notice of Intent to Suspend ("NOITS") pesticide product[1] Technical Chlorthal Dimethyl ("DCPA"), registration number 5481-495, under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). JX 1. *See also* Notice of Intent To Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration, 87 Fed. Reg. 25,262 (Apr. 28, 2022) (EPA's publication of the NOITS in the Federal Register). The NOITS is premised on Petitioner AMVAC Chemical Corporation's ("AMVAC") failure to provide to the Agency certain data about DCPA during a review of the pesticide's registration.

On May 27, 2022, AMVAC timely objected to the NOITS and requested a hearing. *See* Req. for Hr'g and Statement of Objections by AMVAC Chemical Corporation (May 27, 2022) ("AMVAC Hearing Request"). That same day, petitioners Grower-Shipper Association of Central California, Sunheaven Farms, LLC, J&D Produce, Ratto Bros. Inc., and Huntington Farms ("Growers Group") also filed collective objections and a hearing request. *See* Objection and Req. for Hr'g by Grower-Shipper Association of Central California, Sunheaven Farms, LLC, J&D Produce, Ratto Bros. Inc., and Huntington Farms (May 27, 2022).

On June 3, 2022, I issued an Order Scheduling Hearing and Prehearing Procedures that set an expedited schedule for the exchange of documents, motions practice, and an evidentiary hearing. The Agency subsequently moved for accelerated decision. I granted the Agency's motion on July 1, 2022 and canceled the scheduled hearing. *See* Order on Resp't's Mot. for Accelerated Decision. Petitioners appealed the accelerated decision order to the Environmental Appeals Board ("EAB"). On September 28, 2022, the EAB remanded the case to this Tribunal with instructions to hold a hearing. *See AMVAC Chem. Corp.*, 18 E.A.D. 769, 2022 WL 4968470 (EAB 2022).

Following remand, a new hearing was scheduled. The parties engaged in limited additional discovery and document exchange and, following AMVAC's submission of additional data, the Agency withdrew 11 of the 20 bases for which it issued the NOITS. At my direction, EPA filed a prehearing brief ("EPA PHB") on January 6, 2023, and AMVAC filed a prehearing brief ("AMVAC PHB") on January 13, 2023.

The hearing was held January 24-25, 2023, in Washington, D.C.[2] The following exhibits were admitted into evidence: Joint Exhibits ("JX") 1-48 and 50-93; Agency Exhibits ("RX") 1-18, 20-21, and 24-27; AMVAC exhibits ("PAX") 1-43, 45-57, 63-82, 84-85, 87, 89, and 91-97; Growers Group exhibits ("PGX") 1-7, 7A, and 8; and Court Exhibits ("CE") 1-4. Three

[1] FIFRA regulations define "pesticide" as a substance intended to prevent, destroy, repel, or mitigate a pest, whereas a "pesticide product" is a pesticide in the particular form in which it is distributed or sold. 40 C.F.R. § 152.3. In this Initial Decision, the term "pesticide" is used generally to refer to both a pesticide and a pesticide product.

[2] Parties and witnesses participated both in person and remotely by videoconference.

witnesses testified on behalf of EPA: Christina Wendel, Steven Wente, and Jill Bloom.[3] AMVAC presented five witnesses: Niamh McMahon, Richard S. Freedlander, Ann Jonynas, Suneet Ranganath, and Ephraim Gur.[4] By order of this Tribunal, witnesses for EPA and AMVAC submitted their direct testimony through verified written statements in advance of the hearing and then appeared at hearing for cross examination by the opposing parties. The Growers Group submitted verified written statements of three witnesses—Christopher Valdez, Stephen A. Fennimore, and Richard Smith—who by agreement among the parties did not appear for cross examination.

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[3] Christina Wendel is a biologist in EFED and has served as an ecological risk assessor there since 2009. Wendel Statement at 1. Among other tasks, she reviewed various waiver requests submitted by AMVAC in response to the DCI. *See, e.g.*, JX 66; JX 69.

Stephen Wente, Ph.D., is a biologist and senior fate scientist in EFED, where he has worked since 2007. Wente Statement at 1, 10. He has been involved in the DCPA registration review since 2017-2018. Tr. 96.

Jill Bloom is a lead environmental protection specialist in PRD and has worked on approximately 50 registration review cases. Bloom Statement at 1-2. She was involved with the development of the DCPA DCI as a CRM before she was promoted to her current role as a team leader who assists other CRMs, including those working on the DCPA registration review. Tr. 144, 147-48, 150-53.

[4] Niamh McMahon, Ph.D., is a chemist and product regulatory manager for AMVAC. McMahon Statement ¶¶ 1-2. Dr. McMahon took over responsibility for the DCPA registration from her predecessor at AMVAC in April 2022. McMahon Statement ¶ 7; Tr. 287-88.

Richard S. Freedlander, Ph.D., is a chemist and director of environmental science at AMVAC, where he has been involved in work and communications related to the DCPA DCI since 2013. Freedlander Statement ¶¶ 2, 4, 6-7.

Ann Jonynas is the director of toxicology for AMVAC, where she is responsible for all toxicological data development necessary to obtain and maintain the registration of AMVAC's global portfolio of pesticides.

Suneet Ranganath is the vice president of global supply chain and operations for AMVAC. His responsibilities include planning, sourcing, logistics, formulation, and packaging for all of AMVAC's products, including DCPA. Ranganath Statement ¶¶ 4-5.

Ephraim Gur, a zoologist, provides regulatory consulting services to agrochemical companies that make and sell pesticides regulated under FIFRA. He is also chief scientist at Gowan Co. LLC. Gur Statement ¶¶ 3-4, 6. Mr. Gur testified as an expert witness in the areas of pesticide registration, reregistration, and registration review under FIFRA, including (1) responding to data call-ins; (2) data development; and (3) interfacing with EPA and other regulatory agencies regarding these topics. CE 4 at 2-3.

On February 6, 2023, I transmitted to the parties an electronic copy of the initial draft of the transcript and ordered them to submit a joint motion to conform the transcript to the actual testimony at hearing. *See* Order for Joint Mot. to Conform the Tr. The parties on February 17, 2023 jointly moved for various transcript revisions and for the admission of additional exhibits. *See* Joint Mot. to Conform Tr.; *see also* Joint Status Report Concerning Expert Qualifications & Exs. (Jan. 31, 2023).

On March 17, 2023, after the parties' requested transcript corrections had been made, I certified the transcript pursuant to 40 C.F.R. § 164.82 and admitted additional exhibits into evidence as jointly requested by the parties. *See* Order Conforming Tr. and Evidence. With this taking of the last evidence, I set a post-hearing briefing schedule for the parties pursuant to 40 C.F.R. § 164.90. *See* Post Hr'g Scheduling Order (March 17, 2023).

AMVAC and the Growers Group timely filed their Initial Post-Hearing Briefs (respectively "AMVAC Br." and "GG Br.") on April 7, 2023. The Agency was granted leave to file out of time[5] and submitted its Initial Post-Hearing Brief ("EPA Br.") on April 8, 2023. The parties submitted Post-Hearing Reply Briefs ("EPA Reply," "AMVAC Reply," and "GG Reply") on April 21, 2023. With these filings, the record closed.

II. Legal Background

FIFRA, codified at 7 U.S.C. §§ 136-136y, "is a 'comprehensive regulatory statute' governing the sale, distribution, and use of pesticides for the purpose of protecting both human health and the environment." *Bayer CropScience L.P.*, 17 E.A.D. 228, 235, 2016 WL 4125892, *7 (EAB 2016) (quoting *Ruckelshaus v. Monsanto*, 467 U.S. 986, 991-92 (1984)). No person may sell or distribute a pesticide that is not registered under FIFRA. FIFRA § 3(a), (c)(3), 7 U.S.C. § 136a(a), (c)(3). To that end, "[t]he primary mechanism through which FIFRA protects human health and the environment is by requiring that EPA review the safety of a pesticide and register the pesticide prior to its sale or distribution in the United States." *AMVAC Chem. Corp.*, 18 E.A.D. 769, 771, 2022 WL 4968470, *3 (EAB 2022).

a. Registration Requirement

To apply for registration, an applicant must submit "information about the applicant, a copy of the labeling with claims made for the pesticide and directions for use, and, if requested by the Administrator, data supporting the claims made about the pesticide." *AMVAC Chem. Corp.*, 18 E.A.D. at 772, 2022 WL 4968470, *3 (citing FIFRA § 3(c)(1), 7 U.S.C. § 136a(c)(1)). "EPA shall register the pesticide if the Agency determines that:

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

[5] *See* Order on Resp't's Mot. for Leave to File Out of Time (April 11, 2023).

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

AMVAC Chem. Corp., 18 E.A.D. at 772, 2022 WL 4968470, *3 (quoting FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5)). "The phrase 'unreasonable adverse effects on the environment' is defined, in relevant part, as '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.'" *Bayer*, 17 E.A.D. at 235, 2016 WL 4125892, *7 (quoting FIFRA § 2(bb), 7 U.S.C. § 136(bb)).

b. Registration Review

EPA must review the registration of each registered pesticide every 15 years under regulatory procedures outlined at 40 C.F.R. Part 155 Subpart C.[6] FIFRA § 3(g)(1)(A)(i)-(iv), 7 U.S.C. § 136a(g)(1)(A)(i)-(iv). The purpose of registration review is "to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration" and 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." 40 C.F.R. § 155.40(a)(1). A pesticide that no longer meets FIFRA's general registration standard of not causing unreasonable adverse effects on the environment "may be subject to cancellation or other remedies under FIFRA." 40 C.F.R. § 155.40(a)(2).

FIFRA further empowers EPA "to require the submission of data when such data are necessary for a registration review," i.e., when the Agency "determines that additional data are required to maintain in effect an existing registration of a pesticide." FIFRA § 3(c)(2)(B)(i), (g)(2), 7 U.S.C. § 136a(c)(2)(B)(i), (g)(2). The Agency's request for additional data is made in the form of "a Data Call-In ("DCI") notice under FIFRA section 3(c)(2)(B)," and the Agency may issue a DCI "at any time if the Agency believes that the data are needed to conduct the registration review." 40 C.F.R. § 155.48. Further, within 90 days of receiving the DCI, the registrant "shall provide evidence . . . that it is taking appropriate steps to secure the additional data that are required." FIFRA § 3(c)(2)(B)(ii), 7 U.S.C. § 136a(c)(2)(B)(ii).

The Agency initiates a pesticide's registration review by publishing a notice in the Federal Register, establishing a public docket with information about the pesticide, and describing data it does not have that its needs to conduct its review. A 60-day public comment period then allows "interested persons [to] identify any additional information they believe the Agency should consider in the course of the registration review." 40 C.F.R. § 155.50(a)-(c).

As part of the review, EPA "will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk

[6] Until a few months ago, the Agency was under a statutory deadline to complete all of its initial pesticide registration reviews by October 1, 2022. FIFRA § 3(g)(1)(A)(iv), 7 U.S.C. § 136a(g)(1)(A)(iv). In an omnibus bill passed on December 29, 2022, nearly eight months after the NOITS was issued, Congress extended EPA's deadline to complete an initial registration review of each registered pesticide to October 1, 2026. *See* Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 § 711, 136 Stat. 4459, 6083.

assessment procedures or methods, or data requirements." 40 C.F.R. § 155.53(a). If a new risk assessment is needed, the Agency may determine that "additional data are required to conduct the review" and issue a DCI under FIFRA § 3(c)(2)(B). 40 C.F.R. § 155.53(b). The Agency will then conduct the new risk assessment and make a draft available for public review and comment. 40 C.F.R. § 155.53(c).

Registration review culminates in a registration review decision, which is "the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA." 40 C.F.R. § 155.57. However, when appropriate, the Agency may first issue an "interim registration review decision" that will "require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review." 40 C.F.R. § 155.56. Before either type of decision is issued, EPA will publish a notice in the Federal Register of a proposed registration review decision or a proposed interim registration review decision and open a 60-day public comment period. 40 C.F.R. § 155.58(a). In its proposed decision or proposed interim decision, EPA will:

> (1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.
> (2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.
> (3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.
> (4) Specify proposed labeling changes; and
> (5) Identify deadlines that it intends to set for completing any required actions.

40 C.F.R. § 155.58(b). EPA will issue a registration review decision or interim registration review decision after considering any comments on the proposed decision, and the registration review docket will remain open "until all actions required in the final decision on the registration review case have been completed." 40 C.F.R. § 155.58(c). "If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA." 40 C.F.R. § 155.58(d).

c. Suspension Procedures

The Agency may issue a DCI "at any time" during the registration review process. 40 C.F.R. § 155.48. Under FIFRA § 3(c)(2)(B)(iv), if EPA "determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required [by the DCI]. . ., the Administrator may issue a notice of intent to suspend [NOITS] such registrant's registration of the pesticide for which additional data is required." 7 U.S.C. § 136a(c)(2)(B)(iv). The NOITS may include "such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide." *Id.* Any

proposed suspension shall become final and effective 30 days after the registrant receives the NOITS, "unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend." *Id.*

A hearing on the NOITS is conducted under FIFRA § 6(d), 7 U.S.C. § 136d(d). *Id.* "The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA]." *Id.* A final decision on suspension is issued after completion of the hearing, and "[a]ny registration suspended . . . shall be reinstated by [EPA] if [EPA] determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration." *Id.*

In this case, the EAB has determined that the legal standard for imposing a suspension in accordance with FIFRA § 3(c)(2)(B)(iv) following a hearing "is whether, within the time required by the Administrator, AMVAC failed to take appropriate steps to secure the data required by the Data Call-in Notice." *AMVAC Chem. Corp.*, 18 E.A.D. at 787, 2022 WL 4968470, *16.

d. Provisions for Existing Stocks

It is unlawful to distribute or sell any pesticide whose registration has been suspended, except as otherwise authorized by EPA. FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A). EPA may include in the NOITS "provisions . . . the Administrator deems appropriate concerning the continued sale and use of existing stocks of" the pesticide to be suspended, and the hearing shall resolve "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with" FIFRA. FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). *See also* FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1) (Following suspension for failure to comply with a DCI, EPA *may* permit the continued sale and use of existing stocks "to such extent, under such conditions, and for such uses as the [EPA] determines that such sale or use is not inconsistent with the purposes" of FIFRA). The Agency's policy on existing stocks further provides that "[w]here 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." *See* Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362, 29,367 (June 26, 1991) (Notice). Under this policy, "existing stocks are defined as 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 action." *Id.* at 29,362.

e. Hearing on Remand and Burdens of the Parties

The EAB remanded this case for a hearing conducted pursuant to 7 U.S.C. § 136d(d) to determine (1) whether AMVAC failed to take appropriate steps to secure the data to fulfill each of the outstanding data requirements cited in the NOITS, and (2) if there is a basis for suspension, whether the existing stocks provision of the DCPA NOITS is consistent with FIFRA.

AMVAC Chem. Corp., 18 E.A.D. at 796, 2022 WL 4968470 at *23. At the same time, the EAB accepted EPA's argument that "the necessity of the data in the Data Call-in Notice is not at issue," ruling that "the legality of the [DCI] and what it requested is not at issue in this proceeding." *Id.* at 791, 2022 WL 4968470 at *18.

In a suspension proceeding, the Agency "bears the initial burden of presenting an affirmative case for suspension of the registration," i.e., the burden of production. *Id.* at 774, 2022 WL 4968470, *5 (citing 40 C.F.R. § 164.80(a), (b)); *Bayer*, 17 E.A.D. at 259-260, 2016 WL 4125892, at *25. The registrant bears the ultimate burden of persuasion that its registration should continue. *AMVAC Chem. Corp.*, 18 E.A.D. at 774, 2022 WL 4968470, *5 (citing 40 C.F.R. § 164.80(a), (b)); *Bayer*, 17 E.A.D. at 260, 2016 WL 4125892, at *25. Thus, AMVAC and the Growers Group, as proponents of registration, must meet their burden by either rebutting EPA's prima facie case for suspension or demonstrating by a preponderance of the evidence that they took appropriate steps to secure the data required by the DCI, and that EPA's determination on existing stocks is not consistent with FIFRA. *See Bayer*, 2016 WL 4125892, at *25. This Tribunal's Initial Decision shall be based on "substantial evidence" in the hearing record, which equates to a "preponderance of the evidence standard." *See id.*; 7 U.S.C. § 136d(d).

III. Factual Background

a. Registration review by the Office of Pesticide Programs

Registration reviews at EPA are overseen by the Pesticide Reevaluation Division ("PRD"), Office of Pesticide Programs ("OPP"), Office of Chemical Safety and Pollution Prevention ("OCSPP"). *See* Verified Written Statement of Witness, Jill Bloom, in Support of Respondent's Notice of Intent to Suspend at 1-2 (June 17, 2022) (RX 27) ("Bloom Statement"). PRD is supported by OPP's science divisions, including the Health Effects Division ("HED") and the Environmental Fate and Effects Division ("EFED"). Tr. 99. While PRD manages the overall registration review process, the science divisions produce the risk assessments that ultimately inform PRD's registration decision, and they evaluate the data that registrants submit in response to a DCI or the requests they make to waive data required by a DCI.

With respect to risk assessments, HED prepares the human health risk assessment of a pesticide's use. Verified Written Statement of Witness, Stephen Wente, in Support of Respondent's Notice of Intent to Suspend at 2 (June 17, 2022) (RX 26) ("Wente Statement"). Similarly, EFED prepares the ecological risk assessment, which includes evaluating and validating environmental data submitted on pesticide properties related to environmental fate, exposure, and ecological effects. *See* Verified Written Statement of Witness, Christina Wendel, in Support of Respondent's Notice of Intent to Suspend at 2 (June 17, 2020) (RX 25) ("Wendel Statement"); Wente Statement at 2; Tr. 38. EFED also produces a drinking water assessment that provides drinking water estimates used by HED in its human health risk assessment. PRD relies on the human health and ecological risk assessments produced by HED and EFED to make risk management determinations and issue registration review decisions. Wente Statement at 2; Tr. 38, 99-100.

Regarding registrants' submitted data and waiver requests, the science divisions review the studies registrants present to determine whether they meet EPA guidelines and were conducted in a way such that the data can be used for risk assessments. They also review registrants' requests for waivers and recommend to PRD whether the requests be granted or denied. Tr. 97. Registrants do not communicate directly with the science divisions but rather with PRD. Tr. 38. They submit their documents to PRD via an electronic filing system, and after they are screened for administrative accuracy, the documents are assigned a document accession number called an MRID.[7] Tr. 39-40, 95, 219-221. Registrants then generally notify PRD of their submission, and the assigned Chemical Review Manager ("CRM") in PRD forwards the documents that require scientific review to HED or EFED. Tr. 39-40, 95, 219-220, 222-24. The CRM alerts the science division to the submission, and a timeline for review is negotiated between the offices. Tr. 41, 94-95, 176, 223-25. When the science division has finalized its review, it transmits its recommendation back to PRD and closes out the review request.[8] Tr. 52, 225-26. PRD then determines and communicates a final response to the registrant based on the science division's recommendation, although it does not necessarily do so through a formal document. Tr. 55-56. If PRD is dissatisfied with a submission or waiver request, it communicates its dissatisfaction to registrants by emailing its explicit rejection of the study or waiver request or by sending an email that includes as an attachment the science division's recommendation supporting rejection.[9] Tr. 185-86, 226-27.

CRMs keep track of registrants' submissions and maintain their own records. Tr. 230. There are no automated reminders of approaching deadlines, and registrants must obtain status updates on their submissions by contacting PRD. Tr. 231. Registrants are not otherwise aware of reviews completed by OPP until the CRM notifies them. Tr. 231. According to Ms. Bloom, it is "very common" for registrants to inquire about the status of their submissions, and PRD "usually . . . but not always" responds to those requests. Tr. 231-32. Mr. Gur testified that when a registrant submits a waiver request, it is good practice to inquire about its status after six months. Tr. 443.

Once EPA has collected enough data, it publishes the draft risk assessments and opens another public comment period during which registrants or users may ask that other factors be considered. Tr. 241. EPA addresses any substantive requests and, if they make a difference, adjusts the decision. Tr. 241. Mr. Gur also testified that on some occasions EPA might request additional data after issuing a draft risk assessment to refine that risk assessment. Tr. 400-01.

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[7] An MRID is the Master Record Identification Number that EPA uses to track documents. Wente Statement at 5; Tr. 220, 221, 223.

[8] Such transmissions may have occurred electronically or by paper copy during the DCPA review. Tr. 53.

[9] The science evaluations and other submissions from the registrant may be posted to the public docket available online at www.regulations.gov, but this does not always happen in a timely manner, if at all. Tr. 228.

Following risk assessment, EPA issues a *proposed* interim decision,[10] which forecasts how the Agency plans to mitigate a pesticide's risks by limiting its use. During the public comment period that follows, registrants who dislike the proposed decision often seek to provide more data to try and change the outcome, including data that was originally requested in the DCI but not previously submitted. Tr. 237-39. Similarly, growers who use the pesticide frequently submit public comments at this stage attempting to persuade the Agency to reassess its proposed mitigation requirements. Tr. 240. Whether EPA agrees to accept more data and reconsider its conclusions before entering the interim decision "is a judgment call," according to Ms. Bloom:

> If it's going to take five more years to get the data for the decision, we're going to go ahead and make the interim decision and then consider the [additional] data in the next [registration review], or if it's really, really critical, some other avenue . . . . If it's a matter of months or maybe even a year, we might be willing to hold off to get that data[.]"

Tr. 239-240. Ultimately, PRD makes the final call with respect to whether more data is needed, whether a pesticide should be registered, or whether mitigation efforts are needed to reduce a pesticide's risk. Tr. 101-02.

b. Registration review of DCPA

The Agency began its registration review of DCPA in 2011. Petitioner AMVAC is the current and only registrant for DCPA, a chlorinated benzoic acid or phthalate pre-emergence herbicide used to control annual grasses and certain annual broadleaf weeds. DCPA works by inhibiting cell division of root tips in target plants. *See* Verified Written Statement of AMVAC Fact Witness Niamh McMahon ¶ 9 (Jan. 9, 2023) (PAX 93) ("McMahon Statement"); RX 2 at 4. It is registered for use on a variety of crop and non-crop sites, including cole crops, cucurbits, peppers, herbs, and non-residential turf and ornamentals. The pesticide was first registered in the United States in 1958. A Reregistration Eligibility Decision was issued for DCPA in 1998, and tolerances for DCPA residues on certain food and feed crops were reassessed in 2005.[11] McMahon Statement ¶ 11; RX 2 at 4; JX 93. DCPA was previously the subject of EPA data collection requirements in 1987, 1992, and 1995. McMahon Statement ¶ 13; Tr. 242-43. DCPA's major degradate is tetrachloroterephthalic acid ("TPA"). JX 65 at 1.

On June 29, 2011, EPA established a public docket for the registration review of DCPA, opening a 60-day public comment period and contemporaneously publishing in the Federal Register preliminary work plans and anticipated data needs. Bloom Statement at 3; RX 1-RX 2;

[10] Because registration review is a cyclical process, most decisions are interim rather than final, because every chemical has to be evaluated every 15 years and sometimes there are issues that EPA cannot make judgments on. Tr. 238. Indeed, the data EPA sought from AMVAC in this registration review of DCPA included some of the same data that the Agency asked for in advance of DCPA's 1998 re-registration. That data had never been submitted and was still outstanding, although a NOITS was never issued. Tr. 243-44.

[11] *See* 40 C.F.R. § 180.185 (DCPA residue tolerances).

RX 4; *see also* DCPA (dacthal), PC Code 078701; Registration Review, Docket No. EPA-HQ-OPP-2011-0374, https://www.regulations.gov/docket/EPA-HQ-OPP-2011-0374 ("Registration Review Docket"). In the Preliminary Work Plan, EPA stated its intent to update and refine the pesticide's (1) ecological risk assessment (including an endangered species risk assessment) and (2) human health risk assessment. RX 2 at 4. The Preliminary Work Plan summarizes the Agency's position going into the registration review and is based largely on the Preliminary Problem Formulation for the Ecological Risk Assessment of DCPA, a document produced by EFED, and the Human Health Assessment Scoping Document, produced by HED. RX 2; Tr. 168. These initial filings discuss in detail the scope and types of data required to complete these risk assessments and why EPA believed further investigation of various aspects of DCPA was warranted. *See, e.g.*, RX 2; RX 4; JX 65.

For example, EFED's Preliminary Problem Formulation outlines the plan to be used in the ecological risk assessment of DCPA. JX 65. It advises what EFED knows about DCPA already, what data is needed, and what assessments will be required. Tr. 169. In particular, the Preliminary Problem Formulation describes the Agency's intent to include TPA in the risk assessment because it "has up to a 100% conversion rate and forms as a major degradate in aerobic and anaerobic metabolism studies." JX 65 at 1. A brief paragraph near the beginning of the 81-page document summarizes the data gaps for TPA:

> No data have been submitted on the major degradate, TPA. TPA forms at high levels relative to parent chemical, it is expected to be more mobile than DCPA, and is expected to be somewhat persistent. Therefore, availability of a relatively comprehensive dataset on the toxicity and environmental fate of TPA is needed. However, a more limited testing strategy will be considered *in lieu* of a comprehensive data submission if one is proposed.

JX 65 at 2 ("TPA Data Gap Summary"). Because it lacks significant data on TPA, the Agency has in past reviews assumed that TPA is stable in the environment, i.e., that it does not breakdown, based on observations from DCPA parent molecule studies. Tr. 110-12; PAX 80 at 79; JX 65 at 25. The Preliminary Problem Formulation also observes that the Agency in the past had completed risk assessments by "bridg[ing] the data gap" using data from structurally similar pesticides. JX 65 at 25. But the Preliminary Problem Formulation states that for this registration review, "in the absence of toxicity data for the degradate TPA, EFED will make highly conservative assumptions when evaluating the toxicity of TPA." JX 65 at 25; Tr. 169.

Preliminary filings available for comment in the public docket also list the specific data EPA expected to request according to its relevant OCSPP Final Test Guideline for Pesticides and Toxic Substances Number ("Test Guideline"). *See, e.g.*, RX 2; RX 4; JX 65. 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.[12]

[12] The Test Guidelines are publicly available on the Agency's website. *See* Test Guidelines for Pesticides and Toxic Substances, *accessible at* www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic; *see also* 40 C.F.R. § 158.70(c).

During this initial phase of the review, "more times than not . . . people will comment on the data requirement part of the preliminary work plan and other things." Tr. 160. About 25 percent of the time, "the data requirements change because of comments on the preliminary work plan[.]" Tr. 161. But even though it is common for people to submit comments on the proposed workplan and data collection, in this case, neither AMVAC nor any other person did so. Bloom Statement at 3; RX 5 at 3; Tr. 241. Dr. Freedlander agreed that it is beneficial for companies "to respond early on" to the Preliminary Work Plan, but said that at the time, AMVAC was "not exactly geared up" to do so. Tr. 338. Correspondingly, Dr. McMahon, who is responsible for eight to ten other chemicals produced by AMVAC, said that the company has never responded to the Agency's preliminary work plans for any of the cases she has personally worked on. Tr. 289-90. Mr. Gur testified that in his experience, some registrants will comment regardless of what is proposed in the work plans, some will address specific requirements of the workplan, and others will "simply ignore [the public comment period] if they either don't want to or don't need to comment." Tr. 430. In his opinion, the Agency would prefer not to address specific data requirements until the DCI is issued and the registrant has submitted a waiver "because that's easier for them just to follow the process and not start having things jump in the middle on one hand." Tr. 433. Thus, EPA hears the comments, Mr. Gur argued, but it "won't address a specific attempt to . . . waive a requirement or tell [EPA] that you think this requirement is redundant or won't inform your risk assessment[.]" Tr. 441. After the DCPA registration review comment period closed without word from AMVAC or any other party, EPA in December 2011 posted to the registration review docket its final work plan listing the data it would seek. RX 5; Registration Review Docket, EPA-HQ-OPP-2011-0374-0008.

On January 31, 2013, PRD issued a Generic Data Call-In Notice ID# GDCI-078701-1140 ("DCI") for DCPA that requires AMVAC to submit data necessary for EPA to complete its registration review and for AMVAC to maintain the continued registration of DCPA under FIFRA. JX 4; Bloom Statement at 2-3; Tr. 186. In terms of its scope and data requested, the DCI is typical of most DCIs issued by EPA during that time. Verified Witness Statement of AMVAC Expert Witness Ephraim Gur ¶ 16 (Jan. 9, 2023) (PAX 97) ("Gur Statement"). The DCI requires more than 60 individual studies for DCPA or its degradate TPA, most categorized by relevant Test Guideline. JX 4; Joint Set of Stipulated Facts ¶ 1 (Jan. 6, 2023) ("Second Jt. Stips."). Five of the studies are non-guideline special studies with the designation "ss." They involve data requirements so new that they do not yet have established testing guidelines or standardized protocols. JX 4 at 31-32; Gur Statement ¶¶ 18-19. The DCI sets deadlines for AMVAC to submit data responsive to each requirement, in most cases one to two years after receipt of the DCI, and in one case, three years. JX 4; Bloom Statement at 3; Gur Statement ¶ 21. The data submission deadlines in the DCI are standard EPA deadlines for a registration review and calculated based on the number of months EPA expects a given study to take to complete. Bloom Statement at 3-4.

In accordance with FIFRA § 3(c)(2)(B)(ii), 7 U.S.C. § 136a(c)(2)(B)(ii), the DCI gave AMVAC 90 days to respond stating how it intended to comply with the DCI requirements, why it believed it was exempt from any of the DCI requirements, or why it believed EPA should not require submission of data in the manner specified by the DCI. JX 4 at 1; Bloom Statement at 3; Gur Statement ¶ 40. The DCI offers instructions for responding to data requirements. It states, among various options, that AMVAC could "agree to satisfy the data requirements" of the DCI

or request a data waiver "based on [AMVAC's] belief that the data requirement(s) are inapplicable and do not apply to [DCPA]." JX 4 at 6-16; Bloom Statement at 3; Gur Statement ¶ 40. If agreeing to satisfy the data requirements, the DCI indicates that AMVAC could choose to do so by (1) generating and submitting data within the specified timeframe; (2) submitting an existing study that had not previously been submitted to EPA by anyone else; (3) submitting or citing data to "upgrade" a study classified by EPA as partially acceptable and upgradeable; or (4) citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency. JX 4 at 7; Bloom Statement at 3; Gur Statement ¶ 40. If AMVAC requested a waiver, the DCI states that AMVAC must submit a rationale explaining why it believed the data requirement should not apply. JX 4 at 15; Bloom Statement at 3. Regarding waiver requests, the DCI further advises that:

> If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of [the DCI] within the time frame provided by [the DCI]. Within 30 days of your receipt of the Agency's written decision, you must submit a revised [response to the DCI] indicating the option chosen.

JX 4 at 15-16. It required that AMVAC acknowledge its understanding "that, unless modified by the Agency in writing, the data requirement as stated in this [DCI] governs." JX 4 at 38. The DCI also warns that "[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 [NOITS] . . . ." JX 4 at 17. Grounds for suspension may include AMVAC's failure to meet EPA requirements specified in the DCI regarding the design, conduct and reporting of required studies; requirements regarding submission of protocols; or requirements regarding the reporting of data. JX 4 at 17-18. When registrants request that certain data requirements be waived or that EPA rely on previously submitted data, they typically make these requests within the 90-day period after issuance of the DCI, but occasionally after that time. Bloom Statement at 4. EPA generally accommodates 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 submitted its initial 90-day response ("90 Day Response") identifying how it intended to satisfy each of the data requirements in the DCI. Second Jt. Stips. ¶ 9; JX 5. It proposed to generate new data for some studies, request waivers for others, and remove certain uses from DCPA labels. JX 5. As outlined below, over the next several years, AMVAC and EPA engaged in substantial discussion about submitting data responsive to the DCI, and AMVAC satisfied some of the data requirements during that time while seeking additional waivers for other requirements. Bloom Statement at 4.

By October 16, 2020, around 40 of the DCI data requirements were still incomplete, prompting EPA to send AMVAC a letter ("Data Delay Letter") notifying the company which data requirements the Agency considered outstanding and requesting their submission. Bloom Statement at 4; JX 21; Tr. 80. The Data Delay Letter indicated that EPA intended to complete an Interim Decision for DCPA's registration review by October 1, 2022, which required it to complete DCPA's draft risk assessments by June 2021. JX 21 at 1. It reminded AMVAC that

"[a] substantial portion of the data required in the [DCI] has not yet been submitted and is outstanding." JX 21 at 1. The Agency stated that it would "rely upon data available at the time when the risk assessments are being developed. Where the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments." JX 21 at 1; Tr. 82-83, 169-170. The Data Delay Letter then instructed AMVAC to "[p]lease arrange for the generation and submission of any data which is not waived," and referred to an attached table listing each DCI requirement and indicating whether it was waived. JX 21 at 1. The letter added that

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

JX 21 at 2 (emphasis added).

Dr. Wente described the Agency's assertions that it would use "conservative assumptions" where data is lacking as "kind of a carrot and stick thing."

> So, if you give us the data, we'll use your half-life. That would be much better for your chemical in terms of the risk assessment. If you don't give us the data then we say that we can assume – we'll assume stability which is kind of saying that bad things are going to happen with your chemical because it's not going to do very well in a risk assessment.

Tr. 113. Ms. Bloom also described OPP's statements that it was willing to make conservative assumptions in the absence of data as "the only avenue open to us" to prompt AMVAC to submit the data requested. Tr. 232. The Agency was not looking for and did not need AMVAC's agreement to make conservative assumptions instead of using actual data, and it did not have a timeframe for going forward without the data. Tr. 232-33. According to Ms. Bloom, OPP viewed the Data Delay Letter as providing "reasonable" and "definitive[ ]" notice that "[w]e really need these data," and "we were still hoping to get the data[.]" Tr. 212, 233. The expectation was that AMVAC would provide it within a year or two, the amount of time originally established for many of the studies. Tr. 211-12.

AMVAC responded to the Data Delay Letter in December 2020, generally reasserting prior waiver requests or making new waiver requests. *See* JX 22.

Around June 2021, OPP began officials began meeting to determine the next course of action as it became apparent that HED would be unable to complete its human health risk assessment because of missing data. Tr. 105-07. This was initially triggered by AMVAC's submission in May 2021 of a range-finding study that was a preliminary part of a comparative thyroid analysis ("CTA") called for by the DCI. Tr. 233-34; Verified Written Statement of AMVAC Fact Witness Ann Jonynas ¶ 124 (Jan. 9, 2023); JX 4 at 32. But EFED's ability to perform an ecological risk assessment was also disrupted by the lack of data. Tr. 107-08. In

particular, the Agency did not have the data it needed to accurately calculate pesticide exposure levels or toxicity endpoints, the comparison of which is needed to determine risk. Tr. 107-08. If EPA simply input numbers based on making conservative assumptions, the risk calculation "would have been based on two numbers that were completely uncertain and so it wouldn't have made any sense," Dr. Wente testified. Tr. 108. "It wouldn't have been of value . . . ." Tr. 108. Eventually, EPA concluded that because "a number of data requirements had not been satisfied and [ ] we didn't have data or expectations for when they would be satisfied," it could not fully evaluate the risks associated with DCPA. Tr. 181-82.

OPP issued the NOITS to AMVAC on April 27, 2022. JX 1; JX 92. The stated basis for the NOITS was that AMVAC had "failed to comply with the terms of the Data Call-In (DCI)," because "multiple data requirements from the DCI remain outstanding" despite AVMAC's provision of updates and status reports regarding that data. JX 1 at 1. The NOITS cites a total of 20 outstanding data requirements leading to its issuance and describes their status in attached tables. JX 1 at 1-2, 7-29. Nine of those data requirements remain at issue. According to the NOITS, AMVAC's failure to provide the missing data[13] means "the Agency is not able to complete a human health risk assessment." JX 1 at 1. By the time the NOITS was issued, the Agency had considered and rejected 10-20 waiver requests or studies that AMVAC had submitted in response to the DCI. Tr. 184-85, 218-19.

Despite the Agency's previously stated intent to complete DCPA's draft risk assessment by June 2021, it had not done so as of the hearing in this matter. Tr. 83-84. EFED is still able to complete a risk assessment using conservative assumptions where data is missing, but that risk assessment cannot be refined without additional data. Tr. 48, 84.

c. Outstanding grounds for suspension

Although the NOITS refers to 20 outstanding data requirements, AMVAC continued to submit data after receiving notice of the proposed suspension. Consequently, the Agency has withdrawn eleven of the original bases for the NOITS, including the CTA. *See* Respondent's Prehearing Brief at 26 (Jan. 6, 2023); Respondent's Status Report (Jan. 18, 2023). Nine data requirements, most involving DCPA's degradate, TPA, remain outstanding and are discussed below.

i. TPA Ecotoxicology studies

The DCI sought data on the toxicity of DCPA and TPA for various plant and animal species. JX 4 at 27-34; Wendel Statement at 3. Five of those requirements pertaining to TPA ("TPA Ecotoxicology Studies") are bases for the NOITS and are currently outstanding:

- Test Guideline No. 850.1350, Aquatic invertebrate life-cycle, estuarine/marine mysid, TPA
- Test Guideline No. 850.1400, Fish early life-stage (freshwater fish: rainbow trout), TPA

[13] The NOITS states that this included, but was not limited to, missing CTA data. JX 1 at 1.

- Test Guideline No. 850.1400, Fish early life-stage (bluegill sunfish), TPA
- Test Guideline No. 850.1400, Fish early life-stage (sheepshead minnow), TPA
- Test Guideline No. 850.4500 (f/k/a .5400), Algal toxicity test, Tier I/II (marine diatom), TPA

The Agency required this TPA data to identify toxicity endpoints for adverse effects to aquatic invertebrates, fish, and aquatic plants. The endpoints are used for assessing risk to these organisms, "with chronic data being particularly important for evaluating persistent chemicals." Wendel Statement at 3, 5, 7. The DCI gave AMVAC 12 months to complete each of the studies. JX 4 at 29, 30. AMVAC's Dr. McMahon testified that she would generally expect this type of study to take 11-14 months between the time AMVAC first contacts a contract research laboratory and a final report is ready for submission. Tr. 299-301.

In its 90 Day Response submitted in April 2013, AMVAC sought a waiver of the TPA data requirements, proposing that EPA wait until the corresponding DCPA studies were complete "and then . . . perform an ecological risk assessment of the metabolite TPA using the endpoint[s] determined for DCPA." JX 5 at 22-24; Verified Written Statement of AMVAC Fact Witness Richard S. Freelander ¶ 8 (Jan. 9, 2023) (PAX 94) ("Freedlander Statement"); Wendel Statement at 3, 6, 8; Tr. 49, 54. AMVAC justified its request by specifically citing the TPA Data Gap Summary in the Preliminary Problem Formulation and suggested that using DCPA toxicity endpoints for TPA was akin to EPA making conservative assumptions in its ecological risk assessment. JX 5 at 24; Freedlander Statement ¶ 9.

Nothing further transpired with respect to the TPA Ecotoxicology Studies before the 12-month deadline expired on January 31, 2014. About two months later, EFED recommended that AMVAC's waiver requests be denied and issued its response in an internal memorandum to PRD dated March 21, 2014 ("2014 Waiver Denial"). JX 4 at 29, 30; JX 66; Tr. 54-55. Further, although EFED completed its recommendation in March 2014, due to staff shortages and turnover in PRD, the Agency did not actually transmit the 2014 Waiver Denial to AMVAC until March 27, 2017. JX 36; JX 37; JX 66; Second Jt. Stips. ¶ 8; Tr. 190, 229; Freedlander Statement ¶ 15; Tr. 51-52, 263.

In the 2014 Waiver Denial, issued to AMVAC in 2017, EFED stated:

> TPA, a major degradate, has up to a 100% conversion rate and forms as a major degradate in aerobic and anaerobic metabolism studies. As stated in the problem formulation, TPA will be included as a residue of concern with the parent DCPA for the ecological risk assessment, and to conduct a risk assessment without these data would result in a highly uncertain risk assessment. EFED indicated in the problem formulation if a limited testing strategy was proposed it would be considered in lieu of a comprehensive data submission. EPA would still consider a more limited testing strategy if proposed by the registrant. However, deferring all toxicity testing of the

> degradate TPA until DCPA studies are completed, is not an acceptable alternative strategy; therefore, EFED recommends that PRD ***denies request 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 7; Tr. 55, 58. Dr. Freedlander testified that he understood this document to deny AMVAC's waiver requests. Tr. 312.

A chronic daphnid study using TPA was one of the studies called for in the DCI under Test Guideline No. 850.1300, and AMVAC had in the 90 Day Response also requested a waiver for it based on the same grounds as the currently outstanding TPA Ecotoxicology Studies.[14] JX 4 at 30; JX 5 at 22-23. On September 8, 2017, nearly six months after it received the 2014 Waiver Denial, AMVAC hired a laboratory to conduct a chronic TPA toxicity study in daphnids. The study itself did not begin for another eight months.[15] Freedlander Statement ¶ 24.

On February 22, 2018, almost one year after it received the 2014 Waiver Denial, AMVAC submitted a response that it styled as a "rebuttal" to the 2014 Waiver Denial.[16] JX 67. In its response, AMVAC stated 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." JX 67 at 9-10, 12; Tr. 57-58. AMVAC's contracted laboratory finally initiated the chronic daphnid study on May 23, 2018 and completed it on January 23, 2019. Freedlander Statement ¶ 24. AMVAC did not submit the chronic daphnid study until August 2020. *See* AMVAC Br. at 7 n.8 (citing PAX 91).

EPA issued the Data Delay Letter in mid-October 2020, a couple of months after AMVAC's submission of the chronic toxicity study in daphnids and more than 20 months after the study's completion, notifying AMVAC that the status of the TPA Ecotoxicology data was "[w]aiver request denied; outstanding." JX 21 at 4-5. The Data Delay Letter cited the 2014 Waiver Denial but not AMVAC's February 2018 response, and EPA does not know if it reviewed that response before sending the Data Delay Letter. JX 21; Second Jt. Stips. ¶¶ 23-24. Ms. Wendel testified that she did not recall seeing AMVAC's February 2018 response "until at

[14] AMVAC also compiled the results of a 2003 acute TPA study in daphnids that had previously been conducted to satisfy European regulators and submitted to EPA in connection with the DCPA DCI in January 2014. Freedlander Statement ¶¶ 22-23.

[15] The laboratory was initially delayed in obtaining TPA for the study from a third party. The delay was resolved in February 2018. Freedlander Statement ¶ 24.

[16] OPP does not treat this "rebuttal" as a separate waiver request. EPA PHB at 24 n.18.

least 2020." Tr. 57. In the Data Delay Letter, the status of the chronic toxicity study in daphnids was listed as "[i]n review." JX 21 at 4.

In response to the Data Delay Letter, AMVAC submitted a new waiver request on December 17, 2020, and included a report titled "Tetrachlorophthalic Acid (TPA): Selected Ecological Study Waiver Request." That report reviewed results from the acute and chronic TPA studies in daphnids along with other previously submitted data. JX 22; PAX 45; Second Jt. Stips. ¶¶ 25-26; Tr. 59. The document's stated purpose was "to review the ecotoxicological data that AMVAC has provided to the Agency and compare derived study endpoints with that developed in comparable studies with the parent compound DCPA." PAX 45 at 6. It argued AMVAC's belief "that the great distinction in toxicological effects between the parent compound and its degradates provides EPA with the information it is seeking and demonstrates that TPA is not of risk to terrestrial and aquatic species and as such the focus of ecological risk assessments should focus solely on DCPA." PAX 45 at 6.

The Agency denied AMVAC's December 2020 waiver request concurrent with its issuance of the NOITS in April 2022.[17] JX 69; Second Jt. Stips. ¶ 27; Tr. 60-61. EPA reconfirmed that TPA was "an ecological residue of concern," because its documented and assumed stability in the environment would result in increased accumulation over time with repeated applications of DCPA. JX 69 at 5. The waiver denial, based on EFED's further scientific review of all of the available literature, reiterated the Agency's 2014 assertion that it could not use DCPA data to accurately describe TPA risks:

> While EFED could use DCPA endpoints (generally at the limit of solubility) to represent the toxicity of TPA itself, doing so could overestimate the potential hazard. The stability of TPA (and assumptions about stability of TPA due to a lack of data) suggest the potential for this degradate to accumulate to high concentrations in water bodies although not likely at concentrations that would result in acute risk . . . . Because of these two potentially offsetting factors, TPA toxicity data are still needed in some cases (especially chronic toxicity data) to improve our understanding of the potential risks to aquatic organisms and reduce the uncertainty in the risk assessment.

JX 69 at 5; *see also* Tr. 47-48, 63. It was EFED's belief that the lack of TPA data would force it to make "very conservative" assumptions for the risk assessment. Tr. 62. Dr. Freedlander testified that he understood this document to deny AMVAC's waiver requests. Tr. 314.

With respect to Test Guideline No. 850.1350, the aquatic invertebrate life-cycle, estuarine/marine mysid toxicity test, EFED evaluated all of the available chronic aquatic toxicity data for DCPA and TPA. This included a study on DCPA toxicity to mysid, marked for identification as MRID 49307512 ("the 7512 Study"), that AMVAC had submitted in January 2014 in response to the DCI. JX 27 at 2; JX 82; Tr. 66-68. The 7512 Study was first reviewed

[17] At the same time, the Agency granted other data waivers that AMVAC had requested. JX 69; Tr. 63.

by an EPA contractor in the fall of 2016 and afterward returned to EFED in 2016 or 2017. JX 82 at 1; Tr. 66-69. EFED completed its review in December 2021. JX 82 at 1; Tr. 69-70. In denying AMVAC's third waiver request in April 2022, EFED concluded that estuarine/marine mysid chronic toxicity TPA data was still needed:

> 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, . . . TPA may be present in high concentrations in the water-column and concentrations may increase over time with repeated applications of DCPA.

JX 69 at 8; Tr. 64, 69. For that reason, EPA denied AMVAC's third waiver request for this Test Guideline. EFED further observed that because no definitive acute and chronic endpoints were available from existing data, EPA could not use an acute to chronic ratio approach to predict chronic toxicity of TPA to mysids. JX 69 at 8. The Agency could rely on submitted DCPA data to characterize the potential chronic risk to estuarine/marine invertebrates from TPA, EFED noted, but it may overestimate TPA toxicity and the potential risk. JX 69 at 8. On the other hand, the risk could also be underestimated because the DCPA data shows toxic effects at all concentrations tested. JX 69 at 8; Wendel Statement at 4. And further uncertainties arise given TPA's potential to accumulate in water over time when stability is assumed. JX 69 at 8; *see also* Wendel Statement at 4 (observing that in the absence of chronic TPA data for estuarine/marine aquatic invertebrates, EPA could assume TPA's stability "and use the DCPA chronic toxicity endpoints as a surrogate for the missing estuarine/marine aquatic invertebrate ecotoxicity chronic TPA endpoints. However, in such a situation, estimated risks would be extremely high, and EPA would not be able to refine the estimates with any certainty within the risk assessment."). Therefore, "[t]hese data are critical because of TPA's potentially high concentrations in the water column and the limited DCPA chronic data showing effects to estuarine/marine invertebrates at all concentrations tested." Wendel Statement at 4. If the data are not provided, the Agency assumes "that TPA presents high chronic risks to aquatic invertebrates, that it persists for a long time, and the Agency has no way to confidently refine this conclusion further." Wendel Statement at 4.

Regarding Test Guideline No. 850.1400, the fish early life stage toxicity tests in various freshwater and estuarine/marine species, EFED considered all of the available chronic fish and aquatic vertebrate toxicity data for DCPA. JX 69 at 11. This included a study on DCPA toxicity to rainbow trout, marked for identification as MRID 49307520 ("the 7520 Study"), that AMVAC had submitted in January 2014 in response to the DCI.[18] JX 69 at 11-12; JX 51; Tr. 64-66. The 7520 Study was first reviewed by an EPA contractor in July 2016 and afterward returned to EFED in 2016 or 2017. JX 51 at 1; Tr. 70-71. EFED completed its review in February 2019. JX 51 at 1. In denying AMVAC's third waiver request in April 2022, EFED concluded there were no chronic fish data—either freshwater or estuarine/marine—available for TPA. JX 69 at 11. Based on the observed effects of DCPA on the aquatic species in those studies and the total

[18] The study was classified as "supplemental" because it did not include all of the measurement endpoints required under the OCSPP guidelines. JX 69 at 11; JX 51.

lack of chronic aquatic vertebrate data for TPA, EFED "reconfirmed the need for chronic freshwater and estuarine/marine fish toxicity studies for TPA" and the Agency denied AMVAC's third waiver request for this Test Guideline. JX 69 at 11. In the absence of this data, "EPA could assume stability of TPA based on the limited dataset available for the environmental fate, persistence, and accumulation of TPA in aquatic systems which do suggest stability, and potentially use the newly submitted DCPA chronic fish endpoints as a surrogate for the missing chronic TPA endpoints." Wendel Statement at 6. But if EPA did this, the "estimated risks would likely be high, and EPA would not be able to refine the estimates with any certainty within the risk assessment." Wendel at 6. Consequently, without fish early life stage toxicity data for TPA, "the Agency assumes that TPA presents high chronic risks to fish that persists for a long time and the Agency has no way to refine this conclusion further." Wendel at 6.

As for Test Guideline No. 850.4500 (f/k/a 850.5400), the algal toxicity test in the marine diatom, EFED reviewed all of the available aquatic plant toxicity data for both DCPA and TPA. JX 69 at 12. This included a study on the acute toxicity of DCPA to the marine diatom, marked for identification as MRID 49307504 ("the 7504 Study"), that AMVAC had submitted in 2014 in response to the DCI. PAX 79; Wendel at 8; Tr. 65-66. The 7504 Study was first reviewed by an EPA contractor in September 2016 and afterward returned to EFED in 2020. PAX 79 at 1; Tr. 71-72. EFED completed its review in November 2021. PAX 79 at 1; Tr. 72. In denying AMVAC's third waiver request in April 2022, EFED noted that the 7504 Study had technical issues that resulted in reduced confidence in its endpoints, and there are no marine diatom data available for TPA. JX 69 at 13. Without TPA data, EFED would have to use the uncertain endpoints from the 7504 Study for both DCPA and TPA in the risk assessment, which "may overestimate the toxicity of TPA to aquatic plants and yield uncertain risk conclusions." JX 69 at 13. Accordingly, EPA denied AMVAC's third waiver request for this Test Guideline in the marine diatom. Until it acquires TPA toxicity data for the marine diatom, "the Agency is unable to fully assess the risks of TPA exposure to sensitive aquatic plants, impacting confidence in the aquatic risk assessment overall." Wendell Statement at 8.

AMVAC is currently proceeding to conduct a Guideline 850.1400 TPA study with sheepshead minnow and a Guideline 850.1350 TPA mysid study and anticipates submitting their final reports by November 2023. It is also conducting a Guideline 850.4500 TPA study assessing the marine diatom which it anticipated providing no later than April 2023. McMahon Statement ¶¶ 37-39.

ii. TPA Environmental Fate studies

The DCI also sought data on the environmental fate of DCPA and its degradate TPA under various conditions. JX 4 at 28; Wente Statement at 3-5. Three of those study requirements pertaining to TPA are bases for the NOITS and are currently outstanding:

- Test Guideline No. 835.4200, Anaerobic soil metabolism, TPA
- Test Guideline No. 835.4300, Aerobic aquatic metabolism, TPA
- Test Guideline No. 835.4400, Anaerobic aquatic metabolism, TPA

The Agency required this data to evaluate how long residue of TPA persists in the

environment under the specific study conditions. Wente Statement at 3. In this case, the "anaerobic soil study simulates conditions in soils that become saturated with oxygen-depleted water," the "aerobic aquatic study simulates conditions in the upper portions or near the surface of a waterbody where oxygen is abundant," and the "anaerobic aquatic study simulates conditions in or near the bottom sediment in a waterbody where oxygen is limited."[19] Wente Statement at 3 n.1. The longer a residue persists "typically results in more potential for ecological and human health exposures," and in the case of DCPA, "it is only when TPA finally degrades that environmental exposure to the 'residues of concern' actually decreases." Wente Statement at 3. The DCI gave AMVAC 24 months to complete each of the studies. JX 4 at 28.

In its 90 Day Response submitted in April 2013, AMVAC asserted there was no need to conduct new studies to satisfy the three outstanding TPA environmental fate data requirements. JX 5 at 19-21. In general, AMVAC contended that further TPA studies were unnecessary because "much can be inferred about TPA based on an assessment of [DCPA] and studies that have been conducted with [DCPA]." JX 5 at 21. The inferences AMVAC drew were that TPA is stable in the environment and not easily degraded by light or chemical processes. The company further maintained that microbial degradation of TPA may occur over time in the environment but that testing under EPA guidelines did not provide enough time to observe this in the laboratory. AMVAC concluded "that TPA is relatively persistent and can leach into groundwater" but that this risk was mitigated by what AMVAC argued was the chemical's "low toxicity." JX 5 at 21.

To that end, AMVAC attempted to satisfy Test Guideline No. 835.4200, Anaerobic soil metabolism, by submitting an existing study on DCPA from 1976, "Anaerobic Soil Metabolism of Dacthal," marked for identification as MRID 114651 ("the 4651 Study"). JX 5 at 20-21; Wente Statement at 5; Second Jt. Stips. ¶ 46; Freedlander Statement ¶ 64; JX 78 at 13. In doing so, AMVAC argued that EPA could infer the TPA data that it sought using results of prior studies conducted with DCPA. JX 5 at 21.

AMVAC sought a waiver for Test Guideline No. 835.4300, Aerobic aquatic metabolism, proposing to defer the TPA data requirement until the corresponding DCPA study was complete so that EPA could "perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA." JX 5 at 20; Wente Statement at 6; Freedlander Statement ¶ 50; Second Jt. Stips. ¶ 41.

AMVAC also requested a waiver for Test Guideline No. 835.4400, Anaerobic aquatic metabolism, proposing to meet that requirement in the same manner that the Agency concluded the corresponding requirement for DCPA was fulfilled by relying on EFED's "Guidance for Chemistry and Management Practice Input Parameters for Use in Modeling the Environmental Fate and Transport of Pesticides" dated February 28, 2002. JX 5 at 20; Freedlander Statement ¶ 65; Second Jt. Stips. ¶ 45. That is, AMVAC argued "that EPA could estimate anaerobic *aquatic* metabolism as two times the anaerobic *soil* metabolism half-life." Wente Statement at 7 (emphasis added).

[19] The presence or absence of oxygen affects the rate of chemical transformations. Wente Statement at 3 n.1.

The DCI deadline for AMVAC to fulfill the three environmental fate data requirements passed on January 31, 2015. As outlined below, AMVAC did not receive EPA's responses to its waiver requests concerning these data until 2017 and 2020.

In March 2017, AMVAC received the 2014 Waiver Denial in which EPA rejected AMVAC's request for waivers of Test Guideline No. 835.4300, Aerobic aquatic metabolism, and Test Guideline No. 835.4400, Anaerobic aquatic metabolism. JX 66; Second Jt. Stips. ¶¶ 42, 47; Wente Statement at 7; Tr. 135-36. The Agency's reasoning, as stated here for Test Guideline No. 835.4400, was essentially the same for both data points:

> TPA, a major degradate, has up to a 100% conversion rate and forms as a major degradate in aerobic and anaerobic metabolism studies. As stated in the problem formulation, TPA will be included with the parent DCPA for the ecological risk assessment. Given the high conversion rate, understanding the dissipation of TPA is a critical risk assessment question. Therefore, **EFED recommends that PRD *deny the waiver request to defer the data collection of TPA until DCPA studies are completed.***

JX 66 at 6; *see also* JX 66 at 5 (substantially the same response for Test Guideline No. 835.4300); Wente Statement at 6, 7 (noting that waiver denial was based on the fact that "TPA is a major degradate of DCPA, that DCPA has up to a 100% conversion rate to TPA in the environment, and that the required data are critical to understand the degradation pathway of DCPA."). Dr. Freedlander and Dr. McMahon testified that they understood this document to deny AMVAC's waiver requests. Tr. Tr. 265-67, 269, 312.

AMVAC waited nearly one year to follow up on this waiver denial, submitting in its February 22, 2018, "rebuttal" new waiver requests for Test Guideline No. 835.4300, Aerobic aquatic metabolism, and Test Guideline No. 835.4400, Anaerobic aquatic metabolism. JX 67; Wente Statement at 7. Regarding Test Guideline No. 835.4300, Aerobic aquatic metabolism, AMVAC stated:

> The EPA has indicated that based on their recognition of the aerobic soil degradation pathway leading to the formation of TPA, it is important for the Agency to develop data on the aquatic dissipation pathway for DCPA. In a recent response to EPA, we have informed the Agency that we intend to submit a study report that addresses this requirement by providing appropriate fate data for both DCPA and TPA.

JX 67 at 15. With respect to Test Guideline No. 835.4400, Anaerobic aquatic metabolism, "AMVAC requested that EPA reconsider its data waiver request after the Agency reviewed data from studies of DCPA metabolism in aerobic soil either previously submitted or planned to be submitted in response to other DCI requirements." Wente Statement at 7. AMVAC asserted:

> The EPA has indicated that based on their recognition of the

> anaerobic degradation pathway leading to the formation of TPA in soil, that it is important for the Agency to develop data on the fate of TPA under anaerobic conditions in an aquatic environment. AMVAC believes that previous studies have already demonstrated that microbial processes are not effective in degrading this compound. We propose that the Agency review the combined data set for the aerobic soil metabolism study, the anaerobic soil metabolism study, and the pending submission on the aerobic aquatic metabolism study to assess our contention. It is worth noting that in the anaerobic soil metabolism study (MRID 114651), TPA residues that are quickly formed remain stable throughout the duration of the study. This has been demonstrated in a sandy loam, a sandy clay loam, and a clay soil. There is also data demonstrating that TPA is fully stable to hydrolysis. Therefore, it is reasonable to assume full stability of TPA under anaerobic aquatic metabolism conditions with the expectation that a short-lived laboratory study would demonstrate no evidence of any degradation. The additional data that is forthcoming from the aerobic aquatic metabolism study will provide further evidence concerning the stability of TPA to microorganisms.
>
> Therefore, we would request that the EPA defers their decision on the need of an anaerobic aquatic metabolism study until it has had the opportunity to consider the finding of all three studies in the context that is herein presented.

JX 67 at 14; *see also* Freedlander Statement ¶ 73. On cross-examination at hearing, Dr. McMahon agreed with the proposition posed by Agency counsel that "AMVAC is again requesting that OPP consider the results of other studies before OPP would require AMVAC to submit this TPA study." Tr. 268. "So they discuss some studies, . . . and they want data to be looked at before they submit this" TPA study, she added. Tr. 268.

In October 2020, EPA issued the Data Delay Letter notifying AMVAC that the status of AMVAC's waiver requests for the three TPA Environmental Fate studies was "[w]aiver request denied; outstanding." JX 21 at 3; Wente Statement at 6, 7; *see also* Tr. 271-72 (Dr. McMahon agreeing that EPA's position had not changed between 2017, when AMVAC received the 2014 Waiver Denial, and 2020, when the Data Delay Letter was issued).

Concurrent with the Data Delay Letter, the Agency provided its first response to AMVAC's 2013 proposal to submit existing data—the 4651 Study—for Test Guideline No. 835.4200, Anaerobic soil metabolism. JX 77. In an internal memorandum ("Anaerobic Soil Memo") to PRD dated February 7, 2017, but not supplied to AMVAC until October 2020,[20] EFED declared AMVAC's proposal insufficient, rejecting its plan to use the findings of the

[20] As with the 2014 Waiver Denial, it is presumed that staff shortages and turnover in PRD contributed to the lag time between when the Anaerobic Soil Memo was produced and when it was transmitted to AMVAC. Tr. 119, 190, 229.

existing DCPA anaerobic soil metabolism study to fulfill the TPA requirement:

> Previously, the DCPA anaerobic soil metabolism study has been classified as supplemental due to the limited data with only three data points, EFED does not believe that the results can be applied to TPA; therefore, EFED believes that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment, but will assume stability in the absence of a study.

JX 4 at 28; JX 77 at 3; Second Jt. Stips. ¶ 48; Freedlander Statement ¶ 70; Wente Statement at 5; Tr. 116-17.

In response to the Data Delay Letter, on December 17, 2020, AMVAC submitted a new waiver request for the two TPA anaerobic metabolism studies under Guideline Nos. 835.4200 and 835.4400, "Tetrachlorophthalic Acid (TPA) Anaerobic Terrestrial and Aquatic Metabolism Waiver Request," marked for identification as MRID No. 51398102. JX 22 at 1; JX 78; Wente Statement at 7. The document aimed "to present [previously submitted] information again but with additional lines of evidence that can be used by the Agency in fulfilling this requirement." JX 78 at 7. The request relied in part on the 4651 Study that EFED had deemed inapplicable in the 2017 Anaerobic Soil Memo and partly on "[t]he general scientific literature" discussing chemical compounds similar to TPA. JX 78 at 8-11; Wente Statement at 5. It repeated AMVAC's claim that TPA was "innocuous" but "has been shown to be highly persistent" and would not degrade under the Agency's testing conditions, concluding that "there would be no value in conducting new anaerobic soil metabolism or anerobic aquatic metabolism studies for this compound." JX 78 at 4-5; *see also* Wente Statement at 5 (describing AMVAC's 835.4200 waiver submission as "arguing that compounds similar to TPA are initially stable in anaerobic environments but do degrade after a lag period and that, because 'TPA is relatively innocuous to mammalian and aquatic life,' no data responsive to Guideline No. 835.4200 are necessary for EPA to complete registration review of DCPA."); Wente Statement at 7 (describing AMVAC's 835.4400 waiver submission as "arguing that TPA is stable until DCPA has been used in a given area over a period of several years, as populations of microorganisms capable of breaking down TPA would be likely to increase after repeated exposure."). At hearing, Dr. Wente resisted characterizing AMVAC's waiver request as scientific analysis, testifying that he "didn't really think of it as a scientific evaluation." Tr. 119.

As for the aerobic metabolism study under Guideline No. 835.4300, AMVAC provided only a two-sentence statement in its December 2020 response: "The Agency's rationale for not requiring further studies for DCPA also applies to TPA. Further, evidence has been provided that TPA is very stable and would not degrade during the course of a laboratory-based study." JX 22 at 1; *see also* Wente Statement at 6 ("AMVAC disputed EPA's reasons for denying the data waiver request [in the 2014 Waiver Denial] but did not submit the required data or provide any new or additional evidence supporting its data waiver request."); Tr. 136. At hearing, when AMVAC counsel pointed him to the fact that during the course of the DCI AMVAC had submitted an aerobic metabolism study under Guideline No. 835.4300 using DCPA, Dr. Wente acknowledged that the company may have been citing that study as a basis for waiving the outstanding TPA study. Tr. 137-38.

In April 2022, concurrent with issuance of the NOITS, EPA denied AMVAC's December 2020 waiver request for Guideline Nos. 835.4200 and 835.4400, the anaerobic soil and water studies. JX 79; Second Jt. Stips. ¶ 51; Wente Statement at 5, 7; Tr. 283. Pointing to AMVAC's contention that, "over time," microbes could begin to degrade accumulating TPA through aerobic and anaerobic processes, EFED recommended the data requirements be satisfied by studies "of sufficient duration to reliably derive a half-life for TPA." JX 79 at 4-6; Wente Statement at 5-6, 7. EFED noted it "has routinely received metabolism studies with one year study durations." JX 79 at 4. Dr. Wente further testified that "[w]hile the guidance for developing anaerobic soil metabolism data indicates that test duration typically should not exceed 120 days, it indicates that a study of longer duration may be needed to characterize the decline of the test substance and formation and decline of major transformation products." Wente Statement at 5-6; Tr. 127.[21] For anaerobic soil studies, No. 835.4200, the Test Guideline states that "[w]hen necessary to characterize the decline of the test substance and the formation and decline of major transformation products, studies can be continued for longer periods (e.g., 6 or 12 months)," and for additional information references guidance published by the Society of Environmental Toxicology and Chemistry in Europe ("SETAC"). PAX 82 at 13, 16; PAX 85. The SETAC guidance suggests greater caution must be taken with longer studies than EPA's Test Guidelines do, but Dr. Wente testified that the Agency applies only the Test Guidelines and that SETAC has no jurisdiction over pesticide registration in the United States. Tr. 130-35, 138-39. Further, he said, "EFED has a lot of studies that have gone on six months to a year, and they appear to be perfectly good studies." Tr. 127.

If AMVAC did not submit the anaerobic soil and water data, the waiver denial states that the Agency would continue to assume TPA's stability in the environment, which "may overestimate TPA's actual persistence and reduce confidence in the risk assessment conclusions." JX 79 at 5. Further, EFED noted its modeling of the effect of the assumed stability of TPA in water showed a linearly increasing accumulation pattern in the water column and benthic region of receiving water bodies. This continual increase could result in concentrations that exceed chronic aquatic toxicity endpoints, generating further uncertainty in the drinking water and ecological risk assessments, according to EFED. JX 79 at 5-6. In that regard, "the Agency does not have sufficient information on the toxicity of TPA to conclude that it is 'innocuous' in the environment." Wente Statement at 6.

As for Guideline No. 835.4300, the aerobic aquatic metabolism study, the Agency "did not consider AMVAC's [December 2020] contestation of the waiver request denial to constitute a second waiver request." Wente Statement at 6.

AMVAC is currently proceeding with the Guideline 835.4200, 835.4300, and 835.4400 metabolism studies. It expects to be able to provide interim final reports no later than November 2023 based on the guideline study timeframe of 100 days (aquatic) and 120 days (soil), and it will continue to generate data for up to 200 days (aquatic) and 365 days (soil) for a final report if the Agency desires it. McMahon Statement ¶ 41.

[21] Dr. McMahon testified that EFED's April 2022 waiver denial was the first time that EPA had proposed AMVAC conduct a longer-than-usual study for these Test Guidelines. Tr. 285.

iii. Leptocheirus study

The DCI sought data on the chronic sediment toxicity of DCPA for estuarine/marine species using the sediment-dwelling organism *Leptocheirus plumulosus*. This "Special Study," designated "SS-1072" in the DCI, had no established Test Guidelines. JX 4 at 32; Wendel Statement at 9; Second Jt. Stips. ¶¶ 28-29. The Agency "required these data to identify endpoints for adverse effects to sediment-dwelling aquatic invertebrates throughout their life-cycle for DCPA. The endpoints are used in assessing risk to sediment-dwelling aquatic invertebrates." Wendel Statement at 9. The DCI gave AMVAC 90 days to submit a study protocol to EPA for review and 24 months to submit the final data from the study. JX 4 at 32; Second Jt. Stips. ¶ 30.

In its 90 Day Response submitted in April 2013, AMVAC stated it would develop new data and timely submitted its proposed study protocol. JX 5 at 17-18; Freedlander Statement ¶¶ 86-87; Wendel Statement at 9; Second Jt. Stips. ¶ 30; Tr. 73.

EFED reviewed and recommended revisions to AMVAC's proposed protocol in a document dated March 20, 2014. JX 70; Second Jt. Stips. ¶ 31; Wendel Statement at 9. The Agency did not provide EFED's protocol review to AMVAC until October 20, 2014. Second Jt. Stips. ¶ 31. On December 15, 2014, AMVAC informed EPA its contracted laboratory was encountering technical challenges following the protocol revisions and needed more time to develop the study. JX 60; Second Jt. Stips. ¶ 32; Wendel Statement at 9.

Shortly thereafter, on January 31, 2015, the DCI deadline for the Leptocheirus study expired. JX 4 at 32.

On March 30, 2015, and again on September 22, 2015, AMVAC forwarded to EPA status updates from its contracted laboratory outlining the lab's difficulties in developing an appropriate test protocol. JX 71; JX 72; Second Jt. Stips. ¶ 33; Freedlander Statement ¶¶ 91-93; Wendel Statement at 9; Tr. 74.

Against the background of its protocol difficulties, on March 15, 2016, more than three years after the DCI issued, AMVAC requested a waiver for SS-1072. JX 62; JX 73; Second Jt. Stips. ¶ 34; Wendel Statement at 9; Tr. 73. AMVAC argued that based on the results of other tests "completed on other aquatic sediment-dwelling 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." Freedlander Statement ¶ 94; JX 73.

In a memorandum dated June 27, 2016 and transmitted to AMVAC on July 18, 2016, EFED recommended AMVAC's waiver request be denied. JX 74; JX 75; Freedlander Statement ¶ 95; Wendel Statement at 9; Tr. 74. EFED acknowledged that recently submitted testing of other sediment-dwelling organisms suggested low sensitivity to DCPA, but disagreed with the assumption that Leptocheirus "would not be impacted at concentrations of DCPA expected to occur in the environment." JX 74 at 2. In addition, EFED 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 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 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 ("Lepto Waiver Denial"); Wendel Statement at 9. At hearing, Dr. Freedlander testified that the Lepto Waiver Denial made "clear statements" that it did not waive the 28-day study for SS-1072, that it encouraged AMVAC to conduct the 10-day study as expeditiously as possible, and that OPP may consider a waiver request in the future depending on the results from the 10-day study. Tr. 315-16.

Four months later, on November 22, 2016, AMVAC again proposed that EPA waive the SS-1072 requirement. JX 76; Freedlander Statement ¶ 99; Second Jt. Stips. ¶ 35. This request mostly repeated the initial waiver request but added a page highlighting "case studies" that AMVAC argued supported its claim that DCPA concentrations were unlikely to reach levels in the environment that would affect sediment dwelling invertebrates. JX 73; JX 76; Freedlander Statement ¶ 99. AMVAC's restated waiver request also argued that a 10-day study "will provide no information of merit as Dacthal has only been found to be 'slightly toxic' in certain early studies with no acute effects in later studies for more sensitive invertebrates" and the shorter study did not allow "for assessing more sensitive effects associated with reproduction . . . ." JX 76 at 6; Freedlander Statement ¶ 100; Tr. 350. Testimony at hearing suggests that EFED did not review this document, JX 76, until December 2020 and that it was not considered when the Agency issued its final waiver denial in April 2022. Tr. 75-79.

Six months after submitting its second waiver request, AMVAC and EPA held a teleconference on March 17, 2017. Second Jt. Stips. ¶ 36; JX 33-JX 36. Agency notes from the meeting state that AMVAC requested assurance that if a 10-day Leptocheirus study yielded no adverse effects, then EPA would waive the 28-day Special Study called for in the DCI. JX 35 at 1. The notes indicate that the Agency's response to this request was "pending," but there is no further record of what that response was, if any. JX 35 at 2; Second Jt. Stips. ¶ 38; Tr. 293-95. Dr. McMahon conceded that if the Agency had actually agreed that AMVAC could substitute the 10-day study for the DCI's 28-day study to satisfy SS-1072, there would be some documentation

of this agreement. Tr. 295.

Nearly one year later, on February 22, 2018, in its response to the 2014 Waiver Denial, AMVAC again asked for a waiver of SS-1072. JX 67 at 4. AMVAC reiterated its position that a 10-day study was not useful but that it would be willing to conduct one if EPA would allow the results—presuming they did not reveal any sign of toxicity—to satisfy the DCI's SS-1072 requirement. JX 67 at 4. AMVAC stated that it was still awaiting EPA's response to this proposal based on the March 2017 teleconference. JX 67 at 4; Freedlander Statement ¶ 103.

More than two years passed. In October 2020, EPA issued the Data Delay Letter to AMVAC, describing the study status for SS-1072 as "[w]aiver request denied; 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; Tr. 272-73. The Data Delay Letter cited the 2016 Lepto Waiver Denial. JX 21 at 6 n.10; JX 74; Freedlander Statement ¶ 104. Dr. Freedlander agreed that in the Data Delay Letter, the Agency "made . . . clear" what it had previously said in the Lepto Waiver Denial: that the DCI's SS-1072 data requirement was not waived but that EPA would in the future consider AMVAC's request to waive the requirement based on the outcome of the 10-day study. Tr. 317-18.

AMVAC responded to the Data Delay Letter on December 17, 2020, stating that it had learned that EFED would not accept its request to use the 10-day study to satisfy the DCI's SS-1072 data requirement "and insisted on retaining the requirement for the [28-day] chronic study." JX 22 at 2. Therefore, AMVAC declared, rather than generate the required data it would wait for EPA to either issue a new DCI requirement specifically for the 10-day study or confirm that a guideline for the 28-day SS-1072 study has been validated. It claimed its decision would "not impact the Agency's conclusions concerning sediment dwelling organisms that can be made based on the available studies." JX 22 at 2; Freedlander Statement ¶ 106; Wendel Statement at 9; Tr. 280, 349-350.

At hearing, Dr. Freedlander testified that this response conditioned AMVAC's moving forward with either the 10-day or 28-day study on EPA first taking certain steps, particularly with respect to validating the 28-day study guideline. Tr. 319-320. "[I]t needed to be demonstrated that multiple laboratories could perform the study and meet the specifications that it normally set for an appropriate study . . . . And if that can be shown repeatedly within several different laboratories, then it would be considered a validated bit with respect to that particular requirement," he said. Tr. 320-21. Thus, AMVAC would have completed the 28-day study if EPA provided more guidance for how to do so, Dr. Freedlander stated. Tr. 321. And even though AMVAC was hesitant to undertake the 10-day study, it would have done so if EPA formally asked for it by amending the DCI, a step that Dr. Freedlander argued was necessary for AMVAC to be compensated if other parties used the data in the future.[22] Tr. 323, 348-350. As for the claim that not providing the data would not impact EPA's conclusions for sediment

[22] FIFRA contemplates that multiple registrants of a pesticide may share the cost of data development. *See* 7 U.S.C. § 136a(c)(2)(B). Dr. Freedlander contends AMVAC would be unable to obtain this compensation from another registrant that started selling DCPA in the future without evidence that EPA required AMVAC to conduct the study. Tr. 348-49.

dwelling organisms, AMVAC "felt that the [A]gency could move forward in an appropriate manner with regard to the risk assessment" anyway, because it had other "data that pointed to this type of study," Dr. Freedlander said. Tr. 321-22.

Additionally, Dr. McMahon testified that AMVAC may have been confused as to whether the 10-day study was to be done instead of the 28-day study or whether it was to be used to build to a waiver. Tr. 281. "And I think it took AMVAC a little while to understand that it was to build towards a waiver and not a direct swap of studies from one to the other," she added. Tr. 281. Ultimately, she said, AMVAC wanted the DCI amended to provide clarity and more formal definition of what was being asked and proposed for the SS-1072 data requirement, because "how [the proposed 10-day interim study] would connect in with the formal DCI was not clear." Tr. 282.

Regardless, AMVAC took no further action on this requirement, and in April 2022, when it issued the NOITS, the Agency again asserted that the SS-1072 Leptocheirus requirement was not waived. JX 69 at 16-19; Freedlander Statement ¶¶ 107-08. In particular, EFED disagreed with AMVAC's argument that the concentration of DCPA in the environment would not reach levels high enough to impact aquatic invertebrates, and it also pointed to data suggesting increased sensitivity to DCPA in estuarine/marine sediment dwelling species that distinguish them from less-sensitive freshwater species. JX 69 at 18. Further, in response to AMVAC's complaints that there was no validated study protocol, EFED noted that it was "aware that several studies conducted pursuant to EPA Test Method 600/R-01/020[23] were found to be acceptable and were used in other risk assessments. These efforts should limit the previously identified issues associated with the conducting of the L. plumulosus studies." JX 69 at 18-19; Tr. 286-87.

Without data from the SS-1072 study, "the Agency is unable to fully assess the risks [to] sediment dwelling estuarine/marine aquatic invertebrates, reducing confidence, and increasing uncertainty in the ecological risk assessment overall." Wendel Statement at 10. At hearing, Ms. Wendel testified that she was aware of at least 16 other Leptocheirus SS-1072 studies in other registration review cases that have been successfully completed since 2017. Tr. 86. This includes studies conducted by Smithers, the laboratory that AMVAC had initially hired before it began pursuing a data waiver. Tr. 74, 86-87. No guideline has been validated because it is a non-guideline special study "that utilizes other EPA methods that after consultation with protocol the lab was able to successfully complete the studies. There were highlighted issues that were discussed and talked about that since 2017 and onward they've been able to successfully complete studies." Tr. 88. Dr. Freedlander testified that he did not learn that SS-1072 studies had been successfully completed until he was preparing for the hearing in this proceeding. Tr. 356-58.

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[23] This is an apparent reference to a technical guidance document titled "Methods for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod *Leptocheirus plumulosus*," published by EPA and the U.S. Army Corps of Engineers more than 20 years ago. *See* Notice of Availability of Methods for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod *Leptocheirus plumulosus*—First Edition, 66 Fed. Reg. 37,961 (July 20, 2001) (Notice).

AMVAC has never initiated the 28-day SS-1072. Tr. 318. But Dr. McMahon testified in June 2022 that, based on EPA's statement in the Data Delay Letter, AMVAC intended to proceed with a 10-day Leptocheirus study with the understanding that the Agency will reconsider its waiver request for the 28-day study required by the DCI. RX 21 at 5; JX 21 at 6; Tr. 274-76. AMVAC decided after the NOITS was issued that it did not want to risk technical difficulties with the 28-day study or spend further time on protocol review. AMVAC has since commenced the 10-day study and anticipates providing a final report no later than October 2023.[24] Tr. 277; McMahon Statement ¶ 40.

d. AMVAC's approach to DCPA's registration review

At hearing, Dr. Freedlander testified how AMVAC's general perspective of DCPA's registration review has informed its specific responses to the DCI, particularly as it relates to TPA's stability and the data that remain outstanding.

AMVAC recognized that "there were some very legitimate questions with regard to" DCPA, because it is "an older product" with persistency characteristics that make it riskier than other pesticides. Tr. 331, 336. "These days, you don't tend to see many persistent products being put on the market," Dr. Freedlander observed. Tr. 331. AMVAC also believed the Agency recognized that TPA was persistent based on OPP's statements in the preliminary work plans, and the DCI was merely "[a]sking for more data to be more confirmatory" of this fact. Tr. 336.

Consequently, AMVAC hoped to demonstrate that DCPA's degradate, TPA, would not persist forever and would eventually break down "to a manageable level," even if such degradation took several years. Tr. 333-34, 336, 342. But AMVAC did not believe it could make its case by simply generating the data called for under the Test Guidelines of the DCI. In the company's view, the studies would not last long enough, and the laboratory setting lacked what AMVAC argues are real-world conditions of acclimated soils in which microbes degrade the pesticide. Tr. 331-34, 337. "The studies we were being asked to perform were just not going to . . . provide the compound in a sophisticated light. It was going to suggest what the agency suspected[,] that under these conditions in a laboratory, the chemical is persistent," Dr. Freedlander testified. Tr. 344. He viewed this as a waste of time and resources. Tr. 330. AMVAC wanted EPA to go ahead and issue its draft risk assessment, regardless of what conservative assumptions it made. Tr. 327, 329-330, 341. At that point, with the benefit of having seen the Agency's "thinking" and how it modeled certain risks, AMVAC believed it could then engage the "more complicated issues" of the chemical's persistence in the environment. Tr. 342-43. Dr. Freedlander saw this period after the draft risk assessment was published as an opportunity for AMVAC to discuss the persistence issue at a higher level of complexity. Tr. 331.

Many of AMVAC's waiver requests and supporting information were intended to provide information that AMVAC thought would prompt EPA to move forward with the risk

[24] Dr. McMahon acknowledged at hearing that AMVAC now views the 10-day study as "an interim step," and depending on the outcome, it may or may not satisfy the SS-1072 data requirement. Tr. 285-86.

assessment so that they could reach "the real questions" about persistency, Dr. Freedlander averred. Tr. 325-29, 332, 334.

> That information I tried to put forward to the agency so they could—so they could look at it and see that the pathway they had indicated to me, 'we're going to do the risk assessment,' that's really step 1. That should have been done.
>
> And then after that, there would have been questions that would have required a more higher-tiered level of thinking, important questions for the agency to answer. And that's what I was preparing to deal with. I wanted to move forward to the risk assessment and try to get both what I saw as the, the issues of concern, to get the agency scientists thinking along with me so we could address that.

Tr. 334 (Freedlander).

AMVAC never told OPP that it wished to proceed straight to a risk assessment without providing data requested by the DCI because "it wouldn't have set the right tone" and "wasn't an appropriate way to respond to the agency." Tr. 329, 347. The company did not want to appear unresponsive. Tr. 330. Instead, AMVAC hoped its many submissions would "fill in what gaps the EPA had in terms of a point we were trying to make . . . . so they could arrive at the conclusion." Tr. 329. The goal was to "bring the agency . . . up to the technical understanding we had as to why it made sense" to go forward with the risk assessment in the absence of requested data "rather than tell them, 'just go forward.'" Tr. 347-48. "[W]e weren't trying not to do data. We were trying to give all the data . . . *we believed that was necessary* for the agency to conduct their business." Tr. 340 (emphasis added).

AMVAC viewed the Agency's various statements about making conservative assumptions in the absence of data not as a carrot or stick to promote data submission but rather as "indicating paths [EPA] would follow if [AMVAC] didn't meet the [DCI's data] requirements." Tr. 326. Further, while recognizing EPA's concern that the risk assessments would not accurately reflect the chemical's characteristics if such assumptions were made, AMVAC actually preferred this outcome over submitting new data:

> We were trying to basically maintain [to the Agency that] you're correct and . . . whether you waive the requirement or not, you've said that you're going to go forward in your assessment and assume it's stable. We thought that was an appropriate path. *We didn't believe that we needed a waiver to be satisfied.* We saw that direction the agency was warning us they were going to take and, and we thought actually it was appropriate to move forward in that way. We appreciated the fact the agency was trying to alert us that there could be concerns if they conducted the risk assessment in a certain manner. And we were trying to respond and say we understand what you're saying, but we think that you can proceed

> forward.

Tr. 326 (emphasis added). In short, Dr. Freedlander explained that AMVAC did not believe it needed to provide all of the data the DCI requested, because it expected the Agency to complete the risk assessment with or without the data, stating: "They do it all the time. I think the agency's job is to make sure that the assessment is protective. And if we're not going to take certain steps in terms of providing them certain data that they believe would help to refine it, then we do [so] at our own risk," Dr. Freedlander testified. Tr. 327. "[A]lthough they put these studies out requesting them in the data call-in, they had their own clear pathway anyway if they didn't get the data," he added. Tr. 328. Until the NOITS was issued, AMVAC's strategy was one of "trying to convince the Agency that they don't need these studies." Tr. 358.

Despite this approach, Dr. Freedlander, as well as other AMVAC witnesses conceded that EPA, not the registrant, ultimately decides what data must be submitted. "I think EPA makes [the final judgment], . . . absolutely[,] in terms of what's needed," he said. Tr. 346. Likewise, when it comes to the back-and-forth discussion between a registrant and the Agency about waivers and data requirements, Dr. McMahon testified that "as a regulating agency, the EPA has that last word." Tr. 303.

> The Tribunal: Okay. So if they come back and say you know we understand, Dr. McMahon, everything you said, but we want this study.
> Dr. McMahon: Yes.
> The Tribunal: That's it, right?
> Dr. McMahon: Yeah. Yes.

Tr. 303-04. And Mr. Gur, when asked who, between a registrant and the Agency, had the last word on whether a study needed to be done or not, he replied, "obviously, EPA." Tr. 410.

From Dr. Wente's perspective, AMVAC through its waiver requests and related submissions was promoting two contradictory propositions. One the one hand, its responses suggest "it would be appropriate for EPA to go ahead and assume stability" of TPA, but on the other hand, the company argues "the chemical would break down, but it breaks down after a lag phase and therefore it wouldn't be measurable in OPP's study design." Tr. 122. In short, "they're hedging their bets" by both encouraging EPA to complete the risk assessment using conservative assumptions about stability and then "saying that even though you should make that assumption, it would be wrong essentially—they're arguing that essentially it will break down at some point. Therefore, whatever you assume, if you assumed stability then obviously, you're wrong because what they're saying . . . is it degrades." Tr. 122-23. EPA also suspects that TPA may not be stable, but if it were to assume stability, that would introduce so much uncertainty into the risk calculations as to render them "meaningless." Tr. 123-24. Consequently, it would then be "kind of preordained" that DCPA would fail the risk assessment:

> So, we prepare [the] risk assessment making . . . conservative assumptions, knowing the chemical is going to fail[,] and we would be right back at that same place where it would be like, well, do we

> believe those numbers[?] Do we need a study to go ahead and tell us what . . . those numbers are going to show[?] It's not so much that -- the study could actually come back and say, yes, it is stable but the question is -- what's the uncertainty in the assumption[?] So, in other words, nobody's going to believe it until you've got a study that backs it up[.]

Tr. 125.

IV. Whether AMVAC failed to take appropriate steps to secure the outstanding data within the time required by EPA

It has been more than 10 years since EPA issued the DCI in this case, and nine of the DCI's data requirements remain outstanding. In most cases, data would be submitted within three to four years of a DCI's issuance, Ms. Bloom testified, and as AMVAC's Dr. McMahon observed, a registration review that lasts more than seven years "is starting to get to the long side[.]" Tr. 237, 291. For the reasons discussed below, I conclude that AMVAC failed to take appropriate steps to secure these data within the time required by EPA.

a. Applying the relevant legal standard to the DCPA DCI

It is first necessary to delineate the legal standard that applies to this proceeding. I am tasked with determining "whether AMVAC failed to take appropriate steps to secure the data listed in Table 2 of the DCPA NOITS" within the time required by EPA "and, if so, whether the provisions of the DCPA NOITS concerning existing stocks are consistent with FIFRA." *AMVAC Chem. Corp.*, 18 E.A.D. at 796, 2022 WL 4968470 at *23.

i. Appropriate Steps

Given that there is no statutory definition, the phrase "appropriate steps" is defined by its "'ordinary, contemporary, common meaning,'" and constitutes "an action, proceeding, or measure" that occurs "as one in a series" and is "specially suitable," "fit," or "proper." *AMVAC Chem. Corp.*, 18 E.A.D. at 790, 2022 WL 4968470, *17 (dictionary citation omitted). The terms "suitable," "fit," and "proper" can be further defined as "adapted to a use or purpose," "adapted to an end or design," and "marked by suitability, rightness, or appropriateness." Merriam-Webster.com Dictionary, www.merriam-webster.com/dictionary/suitable; www.merriam-webster.com/dictionary/fit; www.merriam-webster.com/dictionary/proper (last accessed May 15, 2023); *see also* AMVAC PHB at 5-6. These are concepts that denote adherence to a certain end, design, or purpose. In the context of registration review and responding to a DCI, the end, design, or purpose of the appropriate steps is "to secure the data required" by the DCI within the time required by EPA. FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). Securing this data itself serves the broader purpose of enabling EPA to determine whether a pesticide continues to satisfy the FIFRA registration standard.

Therefore, whether a step is "appropriate" depends on whether that step is "specially suitable," "fit," or "proper" for the purpose of timely submitting to OPP data required by the

DCI. As the EAB observed, this "is a factual inquiry." *AMVAC Chem. Corp.*, 18 E.A.D. at 790, 2022 WL 4968470, *17. Relevant factors to consider in this inquiry may include the directions for response set forth in the DCI; directions for response subsequently communicated by EPA; associated time periods provided for response; the Agency's determinations made with respect to waivers requested by the registrant; the parties' course of performance; and relevant regulatory and statutory purposes and requirements. *See* EPA PHB at 6-7; AMVAC PHB at 6-7.

AMVAC contends the EAB has instructed "that the 'course of performance' between OPP and AMVAC on this DCI is 'highly significant' to determining whether AMVAC's conduct was appropriate." AMVAC PHB at 6 (quoting *AMVAC Chem. Corp.*, 18 E.A.D. at 790, 2022 WL 4968470, *17). Although the EAB does suggest course of performance may be a factor, it is not an overriding one.

The EAB cited *Alabama v. North Carolina*, 560 U.S. 330 (2010), in support of its determination that a factual inquiry is needed to decide whether an action was appropriate. *AMVAC Chem. Corp.*, 18 E.A.D. at 790, 2022 WL 4968470, *17. It then parenthetically described that case as "(finding parties' course of performance 'highly significant' to whether State failed to take 'appropriate steps' to obtain license in accordance with interstate compact.)." *Id.* (quoting 560 U.S. at 346). However, *Alabama* is distinguishable from this proceeding. That case involved what amounts to a contractual relationship among eight states who were equal parties to a congressionally authorized interstate compact. To interpret that agreement and determine the states' obligations under it, the Supreme Court cited the Restatement (Second) of Contracts for its proposition that "the parties' course of performance under the Compact is highly significant." 560 U.S. at 346. But here, AMVAC and EPA are not equal parties to some sort of contract or bargain-based agreement. As the regulating Agency under FIFRA, EPA is charged with implementing specific statutory and regulatory requirements with respect to the registration of pesticides, and it is empowered by law to do so. AMVAC, as a pesticide registrant, is a regulated entity required to abide by these laws to maintain DCPA's registration. So their course of performance during DCPA's registration review goes only so far in determining the appropriateness of AMVAC's actions. More important to that question is the extent to which AMVAC's steps complied with the express terms of the DCI and the authorities under which it was issued. *See Riethman v. Berry*, 287 F.3d 274, 277 (3d Cir. 2002) ("Although courts use course of performance and course of dealing in interpreting contract terms, 'express terms are given greater weight than course of performance [and] course of dealing.'"); *CGS-ASP Security, JV, LLC v. United States*, 162 Fed. Cl. 783, 810, 813 (2022) (rejecting plaintiff bidder's argument that government's course of conduct with respect to rejection of its bid should be considered, finding that plaintiff "would have to show a clear violation of the [Federal Acquisition Regulations] because there is no other requirement of course of performance"); *Meckley v. United States*, 2018 WL 10667306, at *7-*8 (N.D. W. Va. July 26, 2018), adopted by *Meckley v. United States*, 2020 WL 598332 (N.D. W. Va. Feb. 7, 2020) (rejecting habeas petitioner's "course of performance" argument that federal prosecutors should have sought downward departure from sentencing guidelines in her case because the government had done so in other equivalent cases, observing that "course of performance" refers to conduct of two parties to a contract, and petitioner had no bargain-based expectation that the government would provide the relief she sought).

AMVAC also argues that evidence of "typicality" is material "to help *confirm* that the conduct in the course of performance between AMVAC and OPP was 'suitable' and 'acceptable' (*i.e.*, appropriate, per the definitions) in the broader context of how OPP administered data call-in responses at the time." AMVAC PHB at 8. At the same time, AMVAC rightly acknowledges "that its own conduct is central" and "[e]vidence that AMVAC's conduct was consistent with that of other registrants would not be *dispositive* that AMVAC's conduct was appropriate." AMVAC PHB at 8; *see also* AMVAC PHB at 10 ("though [this Initial Decision] may consider typicality, [it] will turn primarily on the course of conduct as between OPP and AMVAC"). As this Tribunal has previously stated,

> The "typicality" of AMVAC's conduct relative to other registrants may be *a* factor in this factual inquiry, but it is not necessarily a significant one. Registrants widely differ from one another. Pesticides widely differ from one another. The state of the established science surrounding each pesticide may vary widely. It only follows that EPA DCIs and registrant responses to DCIs will play out differently depending on the pesticide and registrant involved. In that regard, whether AMVAC's actions were typical of how registrants address data call-ins is less material to whether AMVAC took "appropriate steps" than is the *parties'* course of performance during the specific registration review of DCPA. Conceivably, many or all registrants could engage in the same inappropriate act. That AMVAC engaged in the same inappropriate conduct might make it typical, but it would not make it "appropriate." On the other hand, AMVAC may have established a "typical" procedure with EPA for responding to DCIs that no other registrant had and, as a result, its steps *were appropriate*, albeit in its own unique way. Thus, although the typicality of AMVAC's conduct in relation to other registrants may not be totally meaningless, it carries less weight than the steps AMVAC actually did or did not take to respond to the DCI in this specific registration review of DCPA.

Order on Mots. for Add'l Disc. at 3 (Nov. 4, 2022). Accordingly, the typicality of AMVAC's conduct may or may not shed light on the appropriateness of its conduct, and the import of such evidence depends on its context within the broader factual inquiry.

ii. Within the Time Required by the Administrator

In its remand order, the EAB did not specifically address the meaning of the phrase "within the time required by the Administrator." *See* FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). But it is clear the plain language of the statute vests the Agency with discretion in the matter: The time within which appropriate steps must be taken to secure DCI data is "the time *required by the Administrator.*" *Id.* Further, when EPA issues a DCI to obtain additional data under FIFRA § 3(c)(2)(B), "*the Administrator shall permit* sufficient time for applicants to obtain such additional information." FIFRA § 3(c)(2)(A), 7 U.S.C. § 136a(c)(2)(A)

(emphasis added). That is, EPA controls the amount of time—which still must be "sufficient"—that registrants are afforded to obtain the additional information that EPA is requesting.

Perhaps because the statute broadly grants EPA discretion with respect to time, when the Agency began implementing the registration review process it determined "that it is not necessary to develop new procedures for calling in data for registration review because FIFRA section 3(g) requires the Agency to use section 3(c)(2)(B) to collect the data, and that section provides EPA with sufficient authority to obtain any necessary data." Pesticides; Procedural Regulations for Registration Review, 71 Fed. Reg. 45,720, 45,723 (Aug. 9, 2006) (Final Rule). The Agency had concluded that if it needed new data for risk assessments or to complete a registration review, it would issue a DCI under existing FIFRA section 3(c)(2)(B) authority, and that "such notices would establish deadlines for submitting the data." Pesticides; Procedural Regulations for Registration Review, 70 Fed. Reg. 40,251, 40,268 (July 13, 2005) (Proposed Rule). EPA "explained that early acquisition of data or information that could be useful in refining a pesticide's risk assessment would reduce the time and effort needed to complete the review of a pesticide." 71 Fed. Reg. at 45,727. Further, during the rulemaking process, the Agency consulted a committee of stakeholders that included pesticide manufacturers and trade associations as well as user and commodity groups. 70 Fed. Reg. at 40,256. EPA and the stakeholder committee agreed "that the Agency should have all the data and information it needs to conduct a registration review before it performs any new risk assessments or other analyses." *Id.* EPA further addressed the "[t]imely submission of data or information" as follows:

> The Agency must receive pertinent data or information early in the registration review process to assure that any risk assessment conducted in registration review is based on the best data and information available. The Agency is particularly concerned that registrants and other stakeholders might not submit relevant data or information until the Agency releases a draft risk assessment. The Agency could then find that it needs to redo the risk assessments to take into account the new data or information. Such rework delays completion of the pesticide's review and ties up scarce resources.

Id. at 40,266. EPA continued that it "would use data and information available (or employ appropriate assumptions) in its risk assessments" in the event that data were not submitted within the time it required. *Id.* Given that a risk assessment must be completed to carry out the registration review process, and in the context of the preceding paragraph, this is a statement of how the Agency would by necessity *have to proceed*, not an open invitation to registrants to withhold data so that conservative assumptions are employed. [25]

[25] EPA later responded to an industry trade group's comment that it is "inevitable" that a registrant will want to submit new data in response to a preliminary risk assessment. The Agency acknowledged that "some iteration may be inevitable," but pointed out that it "publishes its risk assessment methods including its approach for interpreting data. So it may be possible for registrants to anticipate the Agency's information or data needs in a forthcoming registration review and to reduce the degree of iteration in the risk assessment process." 71 Fed. Reg. at 45,727.

In this proceeding, EPA argues "that 'the time required by the Administrator' should be read . . . as referring to the time periods set out in the DCPA DCI." EPA PHB at 2. As mentioned above, the DCI expressly informed AMVAC that it was "required to submit the data or otherwise satisfy the data requirements specified . . . within the time frames provided." JX 4 at 3. The DCI then provided specific deadlines for the completion of each study required, ranging from 9 to 36 months. *See* JX 4 at 28-32. It also instructed that if a waiver were requested and denied, AMVAC "must choose a method of meeting the requirements of [the DCI] within the time frame provided by [the DCI]." JX 4 at 15-16. EPA acknowledges "that for some requirements of the DCPA DCI, by the time OPP had responded to AMVAC's waiver requests, the 'time frame provided' in the DCPA DCI had been completely or mostly exhausted." EPA PHB at 3-4. For that reason, it argues that upon receiving a denied waiver request, "AMVAC, at the very latest, should have provided data within a period equivalent to the original time specified in the DCPA DCI." EPA PHB at 5. For example, where the DCI gave AMVAC 24 months to complete SS-1072, and the Agency denied AMVAC's initial waiver request in June 2016, "AMVAC should reasonably have submitted data, or taken other appropriate steps to secure the data required" for that study by July 2018. EPA PHB at 5.

In contrast, AMVAC declares the EAB "rejected a rigid approach whereby only the timeframes in the DCI control," and contends that the analysis should instead favor "course of performance" and "typicality." AMVAC PHB at 8. The company argues EPA's formulation rests on several faulty premises: "that any further attempt to justify a waiver request 'should not be considered' an appropriate step"; that "there is a clear point in time at which a waiver is 'denied'"; and "that it ignores the potential that other statements by OPP might, within the 'course of performance,' indicate that the registration review process would proceed to a further phase with the data then available, after which waivers would be reconsidered." AMVAC PHB at 9-10. AMVAC also asserts that EPA's interpretation is inconsistent with the statutory standard "because it proceeds by ignoring rather than examining the broader course of conduct of the parties," inconsistent with EPA's past practice of engaging in several rounds of scientific discussion, and inconsistent with an internal EPA guidance document that refers to suspending registrants who "refuse[ ] to submit data or make a good faith effort to comply." AMVAC Br. at 34-35; RX 13 at 4.

I find aspects of both parties' interpretations of "the time required by the Administrator" to be applicable here. The statutory language clearly places EPA in control of the amount of time to be provided to registrants to produce required data. Although EPA must provide registrants "sufficient" time to respond, it has the discretion to decide what constitutes "sufficient." The Agency does this by establishing specific timeframes in the DCI within which a registrant is required to take appropriate steps to secure the specified data. The DCI also provides ample notice of the times for submission as well as how those timelines would be impacted if a waiver was requested and denied. The notion that, upon denial of a waiver, a registrant should provide data within a period equal to the original time specified in the DCI is entirely reasonable.[26] This standard need not be applied rigidly. It incorporates course of

[26] I note also that FIFRA applies this concept with respect to "minor use" waivers:

> If a registrant makes a request for a minor use waiver, regarding data required by the Administrator . . . and if the Administrator denies in

performance to the extent that a registrant cannot take certain steps until the Agency has itself completed particular actions, such as responding to a waiver request or approving a proposed study protocol. For example, EPA allows registrants to request waivers, and in this case, the time the Agency took to respond to *relevant* waiver requests from AMVAC must be accounted for. Similarly, a registrant's conduct with respect to the time it takes to perform certain steps, such as initiating a study or following up on its submissions to EPA, may also inform the analysis of whether those steps are "appropriate." It is in this manner that the parties' conduct has some bearing on the question of time.

b. AMVAC's failure to take appropriate steps cannot be excused by its general course of performance arguments

AMVAC argues that the "course of performance of this DCI amply establishes that OPP was engaged in an ongoing dialog with AMVAC in connection with this DCI" and that the waiver request denials it received "were part of an ongoing discussion rather than indications that OPP as a whole, or EFED or PRD specifically, would not engage in further dialog and review of additional information." AMVAC Br. at 6. According to AMVAC, "it is not important if an AMVAC employee should have or did understand a particular document to be a 'denial,' or an EFED recommendation that PRD deny: what is important . . . is whether or not a document would have alerted AMVAC that any further scientific dialog was being foreclosed." AMVAC Br. at 6-7. The existence of this ongoing dialogue "is demonstrated by the fact that EFED recommended granting seven waivers concurrently with the NOITS in the very same documents in which it recommended denying those remaining at issue," AMVAC declares. AMVAC Br. at 7 (citing JX 69; JX 79). The only distinction between the waivers granted and the waivers denied "is whether EFED concurred, as a scientific matter, with AMVAC's assertion that the data would not be useful for risk assessment," the company states, but that decision does not mean that the request itself was not an appropriate step. AMVAC Br. at 7-8. Further, the parties' conduct demonstrates that extension requests were not required, because AMVAC never received a response to the single extension request it submitted early in the DCI process, AMVAC alleges. AMVAC Br. at 8. In short, AMVAC declares, it was engaged in a scientific dialogue that is typical of the DCI process, and "PRD could have advised AMVAC at any time that, in view of a recommendation from EFED, it was finally denying a waiver and would entertain no further attempts to justify one. But PRD **never** did." AMVAC Br. at 8-9. This is true even though, as AMVAC's witnesses testified, scientific dialogue of this nature is typical. AMVAC Br. at 9.

EPA contends that AMVAC is making a "late-arising argument—that OPP was required to 'foreclose' any further scientific discussion in order to deny a waiver request"—in place of its initial argument "that OPP never actually denied the company's waiver requests." EPA Reply at

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> whole or in part such data waiver request, the registrant shall have a full-time period for providing such data . . . . [T]he term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

FIFRA § 3(c)(3)(D), 7 U.S.C.A. § 136a(c)(3)(D).

10-11. The Agency describes AMVAC as claiming that "absent a communication from OPP 'that no further waiver requests would be considered,' the 'existence of [an] ongoing dialogue' precludes any finding that a registrant failed take appropriate steps to comply with a DCI." EPA Reply at 11. No such requirement exists in FIFRA § 3(c)(2)(B), the Agency points out. EPA Reply at 11.

The Agency is correct. There is no statutory requirement for EPA to provide advance notice to a registrant that additional waiver requests will not be considered. AMVAC cannot graft such a requirement onto Section 3(c)(2)(B) through the parties' course of performance. When EFED recommended that OPP deny AMVAC's waivers, and OPP transmitted those recommendations to AMVAC, AMVAC understood its waivers were being denied. *See, e.g.*, Tr. 265, 317. While the request for a waiver, and EFED's response, included a scientific dialogue, there was no indication that such a dialogue could or would proceed indefinitely. It is not as if the Agency had adopted some course of performance whereby it generally "alerted AMVAC that any further scientific dialog was being foreclosed," but then dispensed with doing so for the particular waivers at issue here. Indeed, the opposite is true: the DCI imposed clearly defined deadlines for satisfying its data requirements, and it reiterated that those deadlines continued to apply in the event a waiver was denied. Moreover, the Data Delay Letter issued in October 2020 further underscored that there should be no expectation on AMVAC's part for incessant scientific debate. The Data Delay Letter reminded the company that "[a] substantial portion of the data required in the [DCI] has not yet been submitted and is outstanding" and instructed it to "arrange for the *generation* and *submission* of any data which is not waived." *See* JX 21 at 1 (emphasis added). The attached table of outstanding data cited all of the requirements for which waivers had been denied. In other words, the Data Delay Letter specifically asked AMVAC to generate and submit data with respect to DCI requirements that had not been waived at that point, and it said nothing to suggest it was equally permissible to submit new waiver requests or continue to argue for the acceptance of previously submitted waiver requests.

It is also not necessarily significant that in April 2022, OPP granted some waivers at the same time and in the same document that it denied waivers for the data at issue here. *See* JX 69; JX 79. The fact that EPA agreed with AMVAC's scientific rationale for some data requirements and not others reflects the fact that different data requirement have different inherent characteristics. It does not speak to the appropriateness of AMVAC's conduct in making the request to waive the data still at issue.

That Dr. Freedlander, Dr. McMahon, and Mr. Gur testified to their view of the waiver request process as a scientific dialogue in which EPA "almost always will entertain further attempts to justify a waiver request" does not mean that the Agency is bound to do so indefinitely, that it is bound to do so in one registration review because it did so in a different registration review, or that it is necessarily bound by its prior actions in the same registration review. *See* AMVAC Br. at 9 (citing Gur Statement ¶¶ 48-49; Freedlander Statement ¶ 117; Tr. 305, 410). There was no bargained for agreement between AMVAC and EPA that EPA would accept requests for waivers beyond what FIFRA and the DCI permitted. As the Agency notes, "FIFRA Section 3(c)(2)(B) does not provide for a cycle of back-and-forth discussion between the Agency and registrant as to whether the required data are in fact needed," and anything EPA permits in this regard is "an exercise of the Agency's discretion." EPA PHB at 9.

Relatedly, AMVAC argues that it expected OPP to complete risk assessments for DCPA prior to making final decisions on waivers. AMVAC Br. at 9-10. It bases this expectation on statements in the Data Delay Letter that

> EPA expects to complete the draft risk assessments in June 2021. A substantial portion of the data required in the Data Call-In (DCI) (see below) has not yet been submitted and is outstanding. The Agency will rely upon data available at the time when the risk assessments are being developed. Where the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments.

JX 21 at 1; AMVAC Br. at 10-11. From this, AMVAC claims that it "reasonably would have expected OPP to conduct these assessments, after which OPP would reach final decisions on pending waivers, consistent with typical OPP practice." AMVAC Br. at 10.

AMVAC's asserted expectation is unreasonable. The company's obligation to respond to the DCI under Sections 3(c)(2)(B) and 3(g) does not depend on how and when the Agency proceeds with the risk assessments. When the Agency issues a DCI for registration review, it does so because the data requested by the DCI is necessary for that review. *See* FIFRA § 3(g)(2), 7 U.S.C. § 136a(g)(2). EPA builds risk assessments from the data submitted, and completion of those risk assessments are necessary to complete registration review. Clearly there are times when EPA must complete a risk assessment in the absence of data—either because the Agency chooses to do so or because it is impractical to wait for a recalcitrant registrant to produce the data. The Agency must take some action in the face of missing or withheld data, and one way the Agency completes the risk assessment in these scenarios is by making conservative assumptions about what the data would show if provided "or adding safety factors to account for uncertainties resulting from the lack of data." *See* Bloom Statement at 4. But neither the Agency's ability to rely on conservative assumptions, nor that it informs the registrant that it *may* do this, relieves the registrant of the fundamental requirement to produce the data in a timely manner. Indeed, EPA has an obligation to act diligently and in good faith to comply with its statutory duties and deadlines in conducting registration reviews. *See Sierra Club v. Johnson*, 444 F. Supp. 2d 46, 53 (D.D.C. 2006) ("When an agency has failed to meet a mandatory statutory deadline, it is insufficient for the agency to demonstrate only that it has proceeded in good faith; it also must demonstrate that it has exercised 'utmost diligence' in its efforts to comply with the statute."). It follows that registrants, who have the burden of maintaining their registration, must also act diligently and in good faith to produce the data that EPA requires. *See Indus. Union Dept. v. Am. Petroleum Inst.*, 448 U.S. 607, 653 n. 61 (1980); *Envtl. Def. Fund v. Envtl. Prot. Agency*, 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1975); *Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324 (8th Cir. 1973).

Consequently, in the context of this proceeding, the Data Delay Letter serves as a description of how the Agency may have to compose the risk assessments required to complete DCPA's registration review if AMVAC declined to provide the required data. As Dr. Wente observed, this is a "carrot and stick" strategy designed to prompt registrants to produce data that presumably would reflect more favorably on their pesticide than would the Agency's

conservative assumptions. Nothing about this strategy suggests that data requirements were being waived. Indeed, the Data Delay Letter expressly states the opposite—informing AMVAC what data is outstanding and instructing it to generate and submit any data that has not been waived and specifying the many data requirements whose status was "waiver request denied; outstanding." JX 21 at 1, 3-6. The Data Delay Letter also observes that "completion and submission of required studies will not necessarily lead to changes in the risk estimates or safety factors used in the Draft Risk Assessment," because "*[t]hese data are required by the DCI* and . . . EPA expects to use them in Registration Review to assess the risks of the chemical." JX 21 at 2 (emphasis added). This reflects AMVAC's independent obligation under the DCI to submit the data irrespective of EPA's decision to make conservative assumptions if no data is provided. In other words, EPA has a legal obligation to the public, established by Congress under FIFRA, to timely review pesticide registrations. Likewise, AMVAC as a registrant has its own legal obligation to provide to EPA the data necessary for this review. If a registrant like AMVAC does not satisfy this obligation, EPA is not relieved from completing the registration review. But how the Agency intends to carry out its obligation—such as by relying on conservative assumptions where no data has been provided—is simply irrelevant to the registrant's responsibility to provide the data. Further, the Data Delay Letter makes no suggestion that EPA is surrendering its statutory authority to issue a NOITS, nor did it even need to reference the NOITS as an alternative enforcement mechanism: AMVAC had fair notice that EPA may issue a NOITS to compel the submission of necessary data, because this ability is codified in FIFRA and restated in the DCI. *See* JX 4 at 16. That EPA has the option to make conservative assumptions instead does not negate its ability to suspend a registration for lack of data.

Additionally, AMVAC alleges that OPP meant what it said in the Data Delay Letter—that it could proceed to conduct risk assessments—but that it changed its mind after the company submitted preliminary data from a CTA range finding study that raised new concerns. AMVAC Br. at 11-12. "OPP could easily have informed AMVAC of its newfound concern, but failed to do so," AMVAC argues. AMVAC Br. at 12. But again, to whatever extent submission of the CTA study altered the Agency's calculus, EPA had no obligation to inform AMVAC that it would be issuing a NOITS, as no such requirement exists under FIFRA. Nor did the Data Delay Letter preclude the Agency from seeking DCPA's suspension. Further, AMVAC had already taken the steps it was going to take—appropriate or otherwise—by the time it submitted the preliminary CTA study in May 2021.

Likewise, two years before the DCI was ever issued, the Agency formally provided AMVAC the opportunity to comment on the data that would be required and the general timeline proposed for its submission. *See, e.g.*, RX 2 at 5-8. AMVAC passed on this opportunity. In doing so, AMVAC surrendered its chance to challenge the legality of the DCI and the necessity of the data it requested. *AMVAC Chem. Corp.*, 18 E.A.D. at 791, 2022 WL 4968470 at *18. But many of AMVAC's successive waiver requests in this case amount to such a challenge, thereby needlessly extending the registration review process. Likewise, AMVAC generally argued for subsequent waivers based on substantially similar grounds as the initial denied waivers and ignored clear statements in Agency responses that specific data is needed, particularly with respect to TPA. Dr. Freedlander admitted at hearing that AMVAC believed that many of the data requirements at issue were unnecessary or kept the registration review on a path that AMVAC did not desire, so it tried to avoid securing this data by submitting successive waiver

requests to persuade the Agency to adopt its point of view.

c. AMVAC's additional arguments regarding OPP legal theories lack merit

AMVAC first contends the NOITS is deficient "for its failure to adequately apprise AMVAC, the public, or other registrants of the specific grounds on which OPP is seeking suspension" because it "failed to provide anything beyond a recitation of facts and the two suggestions as to further OPP motivation"—missing thyroid data and the prior October 2022 statutory deadline for registration review. AMVAC Br. at 1-2, 32. I disagree. The NOITS clearly states it is seeking to suspend DCPA's registration based on AMVAC's failure "to comply with the terms of the Data Call-In (DCI)," in that "multiple data requirements from the DCI remain outstanding" despite AVMAC's provision of updates and status reports regarding that data, and that the "action is being taken pursuant to the Agency's authority under Section 3(c)(2)(B)(iv) of [FIFRA]." JX 1 at 1. The NOITS cites the 20 then outstanding data requirements leading to its issuance and describes their status in attached tables. JX 1 at 1-2, 7-29. According to the NOITS, AMVAC's failure to provide the missing data means "the Agency is not able to complete a human health risk assessment." JX 1 at 1. The NOITS observes that EPA had previously reminded AMVAC of the October 2022 deadline in the Data Delay Letter and states that the missing data *includes, but is not limited to*, the CTA. JX 1 at 1. That is, reference to the statutory deadline was part of a brief background recitation of events leading to the NOITS, and the CTA study was just one of the 20 categories of missing data on which the NOITS was based. Whatever additional discussion the NOITS provides regarding these topics is of a contextual nature and has no bearing on the basis of the NOITS. The NOITS further informs AMVAC that it may avoid suspension if EPA "determines that you have taken appropriate steps to comply" with the DCI. JX 1 at 3-4. This fairly apprises AMVAC of the allegations it is facing.

AMVAC then complains that after the EAB rejected OPP's argument that suspension was appropriate because AMVAC did not submit data within the initial DCI time frames, EPA should have amended the NOITS to reflect its argument that the denial of a waiver request triggers the start of a new "time required" clock based on the original DCI data deadline. AMVAC Br. at 33-34. But again, the factual and statutory basis for the NOITS was clear when it was issued, and those bases have not changed. The EAB provided *some* additional direction in its remand order, but its partial interpretation of Section 3(c)(2)(B)(iv) did not change the bases of the NOITS or the nature of this proceeding. Following remand, this Tribunal requested that the parties brief their interpretation of the statutory phrase "within the time required by the Administrator," and the Agency submitted the argument discussed above. *See* Order on Resp't's Mot. to Amend Hrg. and Scheduling Order (Oct. 18, 2022); EPA's PHB at 2-6. I do not view the Agency's argument as establishing new "policy" that necessitates amending the NOITS or implicates requirements of the Administrative Procedure Act. *See* AMVAC Br. at 32-34 & n.23. It is simply EPA's preferred reading of a statutory phrase that does not appear to have been previously interpreted by other courts or tribunals. How the statute actually applies in this case is a determination that will be made either by this Tribunal or by the EAB, not OPP.

Finally, AMVAC argues that properly authorized waiver denials were never issued because they were not made by OPP but were in fact only recommendations from EFED.

AMVAC Br. at 36-37. I do not find this claim compelling. All of the waiver denials recommended by EFED were transmitted to AMVAC by OPP, which sometimes included explicit statements that they were the formal response of OPP and sometimes did not. *Compare* JX 74 & JX 75 *with* JX 36 & JX 66. Where OPP did not expressly state its denial, I find that the denial was readily implied by its transmission of EFED's memoranda to AMVAC. Moreover, prior to the NOITS, AMVAC never suggested it believed EFED's memoranda to be anything other than a denial issued by OPP. And at hearing, AMVAC's witnesses testified that they understood EFED's memoranda to contain waiver denials. *See, e.g.*, Tr. 271-72 (Dr. McMahon testifying that she understood JX 21, the Data Delay Letter, and JX 66, the 2014 Waiver Denial, as stating that AMVAC's waiver requests were denied); Tr. 312-316 (Dr. Freedlander testifying that he understood JX 66 and JX 74 to be the Agency's waiver denials). Consequently, for purposes of this proceeding, the EFED memoranda recommending denials of waiver requests constituted the Agency's denials of AMVAC's waiver requests when transmitted to AMVAC by OPP.[27]

d. AMVAC's conduct is colored by its effort to steer the registration review process

Dr. Freedlander's testimony at hearing suggested that through its successive waiver requests, AMVAC was not always taking steps to secure data required by the DCI but instead was taking steps to secure a more favorable registration review for DCPA. In particular, his testimony spoke to the company's quiet resistance to producing certain data, because it knew there were "some very legitimate questions" about the pesticide's stability and persistency characteristics and that the DCI studies were going to confirm this. *See* Tr. 331, 336. AMVAC believed it could mount a more robust defense of its pesticide by waiting until after EPA published draft risk assessments revealing the Agency's determinations, and it was not concerned that those draft assessments would rely on conservative assumptions.

In that light, the fact that AMVAC made successive waiver requests for the outstanding data even though "[it] didn't believe that [it] needed a waiver to be satisfied" begins to take on more dilatory overtones. *See* Tr. 326. Submitting multiple waiver requests that AMVAC did not genuinely believe it needed because its preference was to contest the draft risk assessments wasted Agency time and resources and unnecessarily extended the DCI process. AMVAC never informed EPA of the course it truly desired. In this context, AMVAC's waiver requests cannot be seen as steps that were suitable, fit, or proper for the purpose of "secur[ing] the data required" by the DCI. Rather, they appear more like affirmative steps taken to manipulate and distort the efficient and orderly registration review process to suit AMVAC's own interests and "to convince the Agency that they don't need these studies." *See* Tr. 358. Such actions cannot be "appropriate" steps if they are taken to meet AMVAC's own ends rather than to produce data. As observed above, when crafting the registration review regulations, the Agency was particularly concerned about registrants that "might not submit relevant data or information until the Agency releases a draft risk assessment. The Agency could then find that it needs to redo the risk assessments to take into account the new data or information. Such rework delays

[27] The same would be true for EFED memoranda recommending that a waiver request be granted. Despite its position on waiver denials, AMVAC has not argued that EFED memoranda granting its requests for waivers transmitted to it by OPP were improper or ineffective.

completion of the pesticide's review and ties up scarce resources." 70 Fed. Reg. at 40,266. Yet this appears to be precisely what AMVAC aimed to do.

AMVAC also contends that it expected EPA to proceed without certain data and to issue a draft risk assessment that relied on conservative assumptions, because "[t]hey do it all the time." Tr. 327. This suggests AMVAC had no intent to secure the data. And this passivity was more calculated risk than appropriate step on the part of AMVAC, which did not anticipate the issuance of a NOITS. *See* Tr. 358. As evident from this proceeding, EPA does not frequently issue suspension notices, and when it does so, it is a resource-intensive effort. But the fact that EPA "typically" relies on the "carrot and stick" of conservative assumptions to enforce compliance with DCIs does not negate its ability to issue a NOITS as well. It cannot be that this statutory enforcement authority is taken off the table just because EPA also raises the prospect of making conservative assumptions in this and other registration reviews to fulfill its own legal obligations. None of EPA's actions or communications suggest that issuing a NOITS was *not* a measure it could or would take. It was simply unreasonable for AMVAC to presume it could continue to submit waiver requests in place of data and never face a NOITS.

Dr. Freedlander testified that AMVAC was not trying to "snub" the Agency or withhold data. But more insightful was his comment that "[w]e were trying to give all the data [ ] *we believed* that was necessary for the agency to conduct their business." Tr. 340. This expresses a view that it was AMVAC's prerogative to determine what data the Agency required. Likewise, he said at hearing, at this point "we're not even thinking about whether the data is required or not. We're just doing it." Tr. 341. This too suggests a mindset prior to the NOITS in which data requested by a DCI may or may not be required, and that it is AMVAC's role to make that determination. That is incorrect.

e. Credibility of AMVAC's expert witness

The Agency argues that testimony by AMVAC's expert witness, Mr. Gur, should be generally discounted. EPA Br. at 10. EPA offers several grounds in support of this assertion:

- His written testimony as to whether EFED memoranda were waiver denials or recommendations is inconsistent between his June 2022 and January 2023 verified statements. EPA Br. at 10-12
- His hearing testimony with respect to typical timelines for a registrant to complete a DCI is contradicted by the hearing testimony of other witnesses. EPA Br. at 12.
- His hearing testimony with respect to successive waiver requests was contradicted by Agency witnesses and Dr. McMahon. EPA Br. at 12-13
- His testimony that AMVAC was unaware that OPP may assume an increase in TPA's environmental concentration is inconsistent with testimony from Dr. Wente and Dr. Freedlander that assuming stability would result in DCPA not faring well in a risk assessment. EPA Br. at 13.

In his June 2022 statement, Mr. Gur testified that "[o]ften, when *a waiver is denied by EPA*, the reviewer denying the waiver will indicate the basis for the denial, which might be an issue that could be answered with additional information." RX 20 at 10 (emphasis added). In

his revised January 2023 statement, Mr. Gur testified that "[o]ften, *when EFED or HED recommends denying a waiver*, the reviewer will indicate the basis for the recommendation. This explanation may identify an issue that could be answered with additional information." Gur Statement ¶ 49 (emphasis added). At hearing, Mr. Gur testified it was his idea to change his testimony because he had more time to read the documents, and he realized that the EFED memoranda "basically do say that EFED recommends." Tr. 399. EPA contends Mr. Gur made this change for litigation purposes. I agree that seems likely. Prior to remand, AMVAC had not specifically argued that EFED's memoranda did not constitute actual waivers. That changed when this matter was sent back for hearing. *See* AMVAC Br. at 36-37. This does not constitute a change in fact, as Mr. Gur is describing what EFED's memoranda literally say. But the extent to which Mr. Gur changed his testimony to better reflect AMVAC's legal argument undermines the credibility of that testimony.

Regarding general DCI timelines, Mr. Gur testified at hearing that it is "very rare to see a DCI finalized in 3 years" and that he has "had ones that are even more than 10 years." Tr. 434-35. Ms. Bloom testified that the longest studies that would be requested are between three and four years, and that EPA would expect to receive all of the data within that time frame. Taking ten years to respond would be "very long." Tr. 236-37. Similarly, Dr. McMahon testified that the process can "take somewhere between 3 ½ to 7 years." Tr. 291. Again, I see less factual inconsistency here and more inconsistency in presentation. Mr. Gur's testimony, perhaps guided by AMVAC counsel's examination, lends the impression that a three-year-long DCI process is unusual and a 10-year process is not. This again reflects argument as much as fact, and should be treated as such.

With respect to waiver requests, Mr. Gur testified in his written statement that "EPA consistently entertained further dialogue with AMVAC in this case and never indicated that no further waiver requests would be considered. This is consistent with the Agency's typical practice that it will consider multiple waiver requests as to the same data requirement." Gur Statement ¶ 66. In contrast, Ms. Bloom testified that "multiple waiver requests for the same data requirement . . . didn't happen that often." Tr. 205. Similarly, Ms. Wendel testified she was familiar with only one other study in one other registration review case in which a registrant submitted a second waiver request. Tr. 85. Ms. McMahon's testimony is less clear. She initially states that she does not "have any examples where I've done waivers, and submitted" two or three requests for waivers in a row.[28] Tr. 301. She then goes on to describe the process as "a conversation where you're discussing a position," and suggests that in this case, "a position is being taken and then [ ] you work towards, does the EPA agree with your position." Tr. 301. In this instance, the weight of the testimony goes against Mr. Gur's opinion. As a general matter, Ms. Bloom and Ms. Wendel are more credible sources as to the Agency's typical conduct during the DCI process, because they are the ones implementing it. Mr. Gur is expressing the viewpoint of his client, AMVAC. Additionally, Mr. Gur does not testify that it is common for registrants to make multiple waiver requests, only that if one is made, EPA "typically" considers it. Even if EPA were to typically consider successive waiver requests but only rarely receives them, that does not imply that their submission is an acceptable practice or that the Agency has

[28] Ms. McMahon trailed off her initial thought after "submitted." But the question immediately preceding that thought was whether "in other pesticides, have you submitted two or three requests for waiver[s] in a row?" Tr. 301.

established a particular course of conduct with respect to successive waiver requests. Ms. McMahon seems to suggest both that she finds it unusual to submit successive waiver requests and that she conceives of the Agency as being willing to engage in "a technical discussion where you come to an agreement." Tr. 302. But how *she* thinks about the process does not necessarily describe the Agency's general conduct. Accordingly, I give little weight to Mr. Gur's claim that EPA's "typical practice" is to consider multiple waiver requests as to the same data requirement.

As for the effects of assuming TPA's stability, Mr. Gur stated in his written testimony that when the Agency denied waivers in JX 69 concurrent with the NOITS, "EPA for the first time presented modeling indicating a concern that assuming stability would lead to a gradual increase in environmental concentrations. EPA had never articulated this concern in the past, even when it stated that it could and would assume stability." Gur Statement ¶ 64. This testimony was not included in his June 2022 statement. *See* RX 20. The Agency points out that both Dr. Freedlander and Dr. Wente testified to a common understanding that AMVAC would fair poorly in a risk assessment that relied on assumed stability. EPA Br. at 13 (citing Tr. 109-13, 325-28). Mr. Gur's statement points to an issue of relevance as much as credibility. Given that AVMAC desired EPA to assume stability and understood the consequences of doing so, it cannot claim to be surprised that such an assumption would lead to projections of an increase in environmental TPA concentrations. Mr. Gur's statement should be afforded little weight to whatever extent it is intended to suggest AMVAC was taken off guard by waiver denials that included these projections.

For the reasons discussed above, Mr. Gur's testimony has weaknesses to the extent he attempts to speak to EPA's "typical conduct" and/or is in conflict with the testimony of Agency witnesses with far more personal knowledge, training and experience as to actual Agency practices. Accordingly, I find it deserving of less weight on that basis.

f. AMVAC did not take appropriate steps to secure the TPA Ecotoxicology Data within the time required by EPA

AMVAC has not submitted data responsive to the DCI's five outstanding TPA Ecotoxicology Data requirements, and AMVAC failed to take appropriate steps to secure this data within the time required by the Agency.

In accordance with the options made available to it in the DCI, it was appropriate for AMVAC to request in its 90 Day Response a waiver for the five outstanding TPA Ecotoxicology Data requirements. Further, at the time the request was made, there was no impropriety in basing the waiver on a proposal that EPA complete the TPA risk assessment using DCPA endpoints. *See* JX 5 at 22-24; Freedlander Statement ¶ 8; Wendel Statement at 3, 6, 8; Tr. 49, 54.

AMVAC argues that OPP was then responsible for the nearly four years that passed between the 90 Day Response and the company's receipt of the 2014 Waiver Denial in March 2017. AMVAC Br. at 17. But AMVAC is not a blameless party in this scenario. AMVAC's missteps actually began when it did not follow up on its initial waiver request in a timely manner. As Ms. Bloom testified, it is "very common" for registrants to inquire about the status

of their submissions, and PRD "usually . . . but not always" responds to those requests. Tr. 231-32. Similarly, Mr. Gur testified that it was good practice for registrants to inquire about the status of a waiver request after six months and that the entire industry is aware of EPA's limitations in communicating with registrants. Tr. 443, 445. But despite facing a 12-month deadline for submitting data to satisfy the five TPA Ecotoxicology requirements, AMVAC sat on its hands and allowed years to pass without making a meaningful inquiry as to the status of its waiver request with respect to these particular data.[29] This is a departure from what Ms. Bloom and Mr. Gur described as typical and appropriate registrant conduct. Given the 12-month timeframe for data submission, the appropriate step in this context would have been for AMVAC to inquire about the status of its initial waiver request at the very least before the submission deadline expired and to continue its inquiry consistently thereafter until a response was provided. This is a de minimis obligation, particularly for a sophisticated industry operator like AMVAC. And it is the appropriate step to take independent of any other general contact AMVAC may have had with EPA regarding other DCI data. AMVAC's failure to pursue a timely response from OPP opened the door to significant delay of the entire review of DCPA's registration. Notably, the burden to demonstrate that a pesticide product satisfies the criteria for registration is at all times on the proponents of initial or continued registration. *Indus. Union Dept.*, 448 U.S. at 653 n.61; *Envtl. Def. Fund*, 510 F.2d at 1297, 1302; *Dow Chem. Co.*, 477 F.2d at 1324. Even though EPA did not transmit its response to the waiver request until well after its response was complete—whether because it was understaffed, experiencing turnover in personnel, occupied with the management of other pesticide registrations, or some other reason—AMVAC is not relieved of its burden to take appropriate steps to secure the data necessary to maintain DCPA's registration.

Setting aside AMVAC's failure to follow up on its initial waiver request, it then failed to timely respond to EPA after it received the 2014 Waiver Denial in March 2017. As set forth above, the DCI stated unambiguously that if a waiver request were denied, AMVAC must meet the requirements of the DCI "within the time frame provided by [the DCI]," and further, "[w]ithin 30 days . . . must submit a revised [response to the DCI] indicating the option chosen." JX 4 at 15-16. In the case of the five outstanding TPA Ecotoxicology Data requirements, the time frame provided by the DCI was 12 months. Even so, AMVAC waited six months, until September 2017, to hire a laboratory to conduct the study (a chronic TPA toxicity study in daphnids) that would serve as its chosen response for the TPA Ecotoxicology Data requirements. *See* Freedlander Statement ¶ 24. And then it did not inform EPA of its intent until late February 2018, nearly one year after receiving the 2014 Waiver Denial. *See* JX 67 at 9-10, 12; Tr. 57-58. Furthermore, AMVAC's contracted laboratory did not initiate the chronic daphnid study until the end of May 2018 and did not complete the study until the end of January 2019. Freedlander Statement ¶ 24. At that point, nearly 24 months, twice the amount of time provided by the DCI,

[29] A March 2016 letter from AMVAC submitting three chronic sediment studies also included an attached table reflecting the company's internal understanding of the status of each of the data guidelines requested by the DCI. *See* JX 62. It shows a current status for the TPA Ecotoxicology Data as "waiting for response from EPA." JX 62 at 9. I do not find this passing reference to be a meaningful or appropriate inquiry as to the status of AMVAC's waiver request for the TPA Ecotoxicology Data. Nothing stopped AMVAC from picking up the phone and/or emailing the assigned CRM on a regular basis to ask about the waiver response.

had elapsed since AMVAC learned that its waiver request was denied. Had AMVAC taken appropriate steps to secure this data within the time required by EPA, it would not have waited for half of the DCI-alloted study time to expire before hiring a laboratory to conduct the daphnid study, nor would it have waited until the end of that time frame to submit to EPA its revised plan for responding to the DCI.

AMVAC's failure to take appropriate steps within the time required by EPA is further illustrated by the fact that, after its laboratory finished the chronic daphnid study in January 2019, AMVAC allowed nearly two more years to pass before submitting its December 2020 response seeking another waiver of the DCI's TPA Ecotoxicology Data requirements based on the results.[30] *See* JX 22; PAX 45; Second Jt. Stips. ¶¶ 25-26; Tr. 59. And this submission came only after the Data Delay Letter notified AMVAC that the TPA Ecotoxicology data remained outstanding. Thus, nearly four years elapsed between the time AMVAC learned in March 2017 that its initial waiver request was denied and its submission in December 2020 of data it contended should waive further DCI requirements. This is four times the study duration time provided by the DCI. AMVAC has provided no satisfactory explanation for its failure to act more promptly.

Beyond the timing of AMVAC's various submissions, the substance of AMVAC's responses to the TPA Ecotoxicology Data requirements following its receipt of the 2014 Waiver Denial reflect a failure to take appropriate steps to secure that data. In the 2014 Waiver Denial, the Agency was clear that using DCPA toxicity data in lieu of TPA toxicity data "***is not an acceptable . . . strategy***" because "***[t]oxicity data is needed for TPA***" specifically. JX 66 at 7. The Agency then cited the acute and chronic toxicity studies in daphnids as an "***example***" of "***one possible***" means of conducting a more limited testing strategy as alluded to in the Preliminary Problem Formulation. JX 65 at 2; JX 66 at 7. And "***depending on the results***" of those studies, the "***full suite of studies may or may not be subsequently required.***" JX 66 at 7. AMVAC contends that when it decided to conduct acute and chronic daphnia studies using TPA, it "undertook a specific limited testing plan suggested by EFED" that "EFED stated would enable it to reconsider granting waivers for the data requirements in this group," and at the time the NOITS was issued "AMVAC was proceeding reasonably along a course laid out for it by OPP." AMVAC Br. at 15-16. But AMVAC overstates the reasonability of its asserted reliance on the 2014 Waiver Denial. The Agency was clear that (a) TPA toxicity data is necessary for DCPA's registration review and (b) even after completion of more limited TPA testing, such as in daphnids, further studies may still be required. That is, the DCI's baseline requirement for

[30] AMVAC alleges that it submitted the chronic daphnia study itself "prior to receiving the so-called Data Delay Letter and followed up with a full report and additional analysis shortly thereafter." AMVAC PHB at 13; AMVAC Br. at 15. It appears the study was submitted in August 2020. *See* AMVAC Br. at 7 n.8 (citing PAX 91). The Agency completed its initial review of the study on January 4, 2021, after AMVAC responded to the Data Delay Letter. *See* JX 88. Relatedly, the Agency states that AMVAC submitted the chronic daphnia study in 2018, but that appears to be a briefing error. *See* EPA Br. at 8 n.7. Based on the evidence and context for this statement, including that the chronic daphnia study was not completed until 2019, this Tribunal believes EPA may be referring to AMVAC's February 22, 2018 rebuttal to the 2014 Waiver Denial.

AMVAC to submit the TPA Ecotoxicology Data is unchanged regardless of whether AMVAC completes and submits acute and chronic toxicity studies in daphnids. AMVAC could have taken steps to complete the TPA Ecotoxicology studies called for by the DCI and chose not to do so. Instead, it unilaterally determined that the 2014 Waiver Denial was instead *the Agency's* "proposal" that AMVAC conduct particular studies and then "review[ ] those results with the Agency in order to determine whether additional aquatic organism testing is warranted." JX 67 at 9-10, 12; Tr. 57-58. In reality, the 2014 Waiver Denial rejects AMVAC's request to estimate TPA toxicity using DCPA data and describes what "one possible" testing strategy might look like. The Agency did not *invite* AMVAC to set aside the DCI requirements, conduct the acute and chronic TPA toxicity studies in daphnids instead, and then *jointly* review and determine with OPP whether more data was needed. Ultimately, AMVAC charted its own course, and it bore the risk that the daphnid studies would be insufficient to timely or completely satisfy the DCI's TPA Ecotoxicology requirements.

Further, the Data Delay Letter informed AMVAC in October 2020 that the TPA Ecotoxicology requirements had not been satisfied, citing the 2014 Waiver Denial.[31] AMVAC could then have taken steps toward securing that data, but it did not. Rather, it submitted another waiver request in December 2020 premised on the argument that the Agency should "compare derived [TPA toxicity] study endpoints" from previously submitted data "with that developed in comparable studies with the parent compound DCPA" and then focus its ecological risk assessments "solely on DCPA." PAX 45 at 6. Although AMVAC produced new data in its chronic toxicity study in daphnia, the December 2020 waiver request essentially ignored the Agency's admonitions in the 2014 Waiver Denial that TPA was "a residue of concern . . . for the ecological risk assessment," that "to conduct a risk assessment without these data would result in a highly uncertain risk assessment," that DCPA toxicity data should not be used "in lieu of TPA toxicity data," and that "[t]oxicity data is needed for TPA." JX 66 at 7. In this context, the December 2020 waiver request cannot constitute an appropriate step toward securing data required by the DCI, because it is largely repetitive of the initial waiver request that had been denied.

Additionally, AMVAC argues that when EPA denied its December 2020 waiver requests concurrently with the NOITS, the Agency based its decision on information AMVAC submitted in 2014 in response to other data requirements. AMVAC Br. at 17-18 (citing, among others, the 7512 Study, 7504 Study, and 7520 Study). The company complains that EPA "could have, but did not" inform AMVAC that executing the daphnia studies mentioned in the 2014 Waiver Denial "would no longer potentially lead to a grant of waivers for the studies in this category[.]" AMVAC Br. at 18. I find this argument unpersuasive. EFED did not finalize its review of these studies until the end of 2021, a "not uncommon" length of time for the multi-level evaluations that involve EFED personnel as well as outside contractors. *See* JX 27; 51 at 1; JX 82 at 1; Tr. 69-70, 72. It was not unreasonable for EPA to deny AMVAC's waiver requests only a few months later based in part on its completed review of these studies. The Agency had no other

[31] At the time the Data Delay Letter was issued, it is not clear whether EPA had reviewed AMVAC's February 2018 rebuttal stating its intent regarding the daphnia studies. But this is neither here nor there. EPA did not construe this rebuttal as an independent waiver request. EPA PHB at 24 n.18. And AMVAC did not follow up before submitting its December 2020 response to the Data Delay Letter.

obligation to advise AMVAC that the daphnia studies would be insufficient prior to denying the waiver request.

The TPA Ecotoxicology Data remains outstanding, and for the reasons set forth above, when the NOITS was issued AMVAC had failed to take appropriate steps to secure that data within the time required by the EPA.

g. AMVAC did not take appropriate steps to secure the TPA Environmental Fate Data within the time required by EPA

AMVAC has not submitted data responsive to the DCI's three outstanding TPA Environmental Fate Data requirements, and AMVAC failed to take appropriate steps to secure this data within the time required by the Agency.

Regarding the 835.4200 TPA Anaerobic Soil Metabolism requirement, it was appropriate for AMVAC to request in its 90 Day Response a waiver based on the previously submitted 4651 Study of the anaerobic soil metabolism of DCPA. Further, at the time the request was made, there was no impropriety in asking the Agency to infer the TPA data using DCPA results. *See* JX 5 at 20-21; Wente Statement at 5; Second Jt. Stips. ¶ 46; Freedlander Statement ¶ 64; JX 78 at 13.

EFED responded to this waiver request in February 2017 (in the Anaerobic Soil Memo), but AMVAC did not receive that response until concurrent with the Data Delay Letter in October 2020. Notwithstanding EPA's obligations in this scenario, as with the TPA Ecotoxicology Data, AMVAC failed to take appropriate steps by not following up on its waiver request in a timely manner, even after the deadline for submitting the data passed in January 2015 and even after AMVAC received the 2014 Waiver Denial three years late in 2017. Both events should have prompted AMVAC to seek further status updates on its 835.4200 waiver request. AMVAC also did not take appropriate steps to secure this data when it responded to the Anaerobic Soil Memo and Data Delay Letter in 2020. PRD had denied the waiver request because the Agency did "not believe that the [DCPA] results can be applied to TPA" and it "believe[d] that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment," even as it noted that it would "assume stability in the absence of a study." See JX 4 at 28; JX 77 at 3; Second Jt. Stips. ¶ 48; Freedlander Statement ¶ 70; Wente Statement at 5; Tr. 116-17. But in the face of this denial, AMVAC made a second waiver request that largely ignored the Agency's reason for denying the first. That is, AMVAC submitted a request premised on previously submitted information such as the 4651 Study, which EPA had considered and rejected for this purpose, and the general scientific literature discussing compounds comparable to TPA for the purpose of applying their characteristics to TPA. Aside from the fact that is questionable whether this waiver request presented a meaningful scientific evaluation—Dr. Wente credibly testified that it did not—the request simply repeated AMVAC's argument that "there would be no value in conducting new anaerobic soil metabolism . . . studies for [TPA]." JX 78 at 4-5. However, EPA had clearly stated when rejecting the initial waiver request that "a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment." JX 77 at 3. AMVAC's second waiver request amounts to an outright dismissal of EPA's assertion about the data required under the DCI. Therefore, it cannot serve as an appropriate step to secure that data.

Similarly, regarding the 835.4400 TPA Anaerobic Aquatic Metabolism requirement, it was not inappropriate for AMVAC to request a waiver in its 90 Day Response based on an argument that the Agency could estimate data based on existing modeling parameters. *See* JX 5 at 20; Freedlander Statement ¶ 65; Second Jt. Stips. ¶ 45. But AMVAC failed to take appropriate steps when it did not follow up on its waiver request before receiving the 2014 Waiver Denial in 2017, despite the January 2015 data submission deadline. AMVAC then failed to take appropriate steps after it received the 2014 Waiver Denial. In that denial, the Agency was clear: TPA would "be included with the parent DCPA for the ecological risk assessment," and "[g]iven the high conversion rate, understanding the dissipation of TPA is a critical risk assessment question." JX 66 at 6. The Agency expressly declined AMVAC's "request to defer the data collection of TPA until DCPA studies are completed." JX 66 at 6. Even so, AMVAC in February 2018 again asked EPA to consider DCPA metabolism data previously submitted or planned to be submitted instead of generating new TPA metabolism data. *See* Wente Statement at 7; JX 67 at 14; Freedlander Statement ¶ 73; Tr. 268. AMVAC further failed to take appropriate steps to secure the TPA data when, after receiving the Data Delay Letter, it responded in December 2020 with the same new waiver request as it did for the 835.4200 TPA Anaerobic Soil Metabolism data requirement, likewise proclaiming that "there would be no value in conducting new . . . anerobic aquatic metabolism studies for [TPA]." JX 78 at 4-5. But the Agency had already foreclosed this option in the 2014 Waiver Denial when it reiterated that TPA data was required for the risk assessment. *See* JX 66 at 6. Because AMVAC's waiver requests subsequent to the 2014 Waiver Denial ignored this requirement, it did not take appropriate steps to secure this data within the time required by EPA.

With respect to the 835.4300 TPA Aerobic Aquatic Metabolism data, AMVAC appropriately (at that time) asked in its 90 Day Response to use DCPA endpoints in lieu of a TPA study. *See* JX 5 at 20; Wente Statement at 6; Freedlander Statement ¶ 50; Second Jt. Stips. ¶ 41. The 2014 Waiver Denial rejected this request for substantially the same reasons the Agency rejected a waiver for the 835.4400 TPA Anaerobic Aquatic Metabolism requirement. *See* JX 66 at 5-6. After waiting nearly one year, AMVAC stated in the February 2018 "rebuttal" that it had recently informed EPA "that we intend to submit a study report that addresses this requirement by providing appropriate fate data for both DCPA and TPA." JX 67 at 15. AMVAC then failed to submit any report, and after receiving the Data Delay Letter in December 2020, AMVAC provided only a two-sentence statement in its December 2020 response: "The Agency's rationale for not requiring further studies for DCPA also applies to TPA. Further, evidence has been provided that TPA is very stable and would not degrade during the course of a laboratory-based study." JX 22 at 1. Despite its stated intention in February 2018, by the time the NOITS was issued, AMVAC still had not submitted any study report to address this requirement.

AMVAC now argues that in its February 2018 response, it "believed that it had directed OPP to consider a Guideline 835.4300 study submitted for DCPA to satisfy the requirement for TPA." AMVAC Br. at 30; Freedlander Statement ¶¶ 54-59. That is, AMVAC's post-NOITS assertion is that it meant to point OPP to the study it had submitted to EPA in January 2014 to satisfy the 835.4300 DCPA requirement. Freedlander Statement ¶¶ 57-58. Dr. Freedlander concedes "that [AMVAC's] response . . . did not adequately convey its position and intent regarding this data requirement" and that he understands why OPP believed AMVAC would be

submitting a new aerobic aquatic study conducted for TPA. Freedlander Statement ¶ 55. *See also* Wente Statement at 6 ("AMVAC disputed EPA's reasons for denying the data waiver request [in the 2014 Waiver Denial] but did not submit the required data or provide any new or additional evidence supporting its data waiver request."). To that end, AMVAC failed to take appropriate steps to secure this data because it admittedly never provided an adequate response to the DCI. This is true regardless of AMVAC's intent.[32] But even if AMVAC intended in February 2018 and December 2020 to point EPA to a previously submitted study, it still does not constitute an appropriate step. The 2014 Waiver Denial refused AMVAC's proposal to "defer the data collection of TPA until DCPA studies are completed" because TPA was to "be included as a residue of concern . . . for the ecological risk assessment" and it was "critical to understand its dissipation pathways." JX 66 at 5. If AMVAC intended to respond to the 2014 Waiver Denial by again directing OPP to use the results of a DCPA study, then it again ignored the basis of the 2014 Waiver Denial.

The TPA Environmental Fate Data remains outstanding, and for the reasons set forth above, when the NOITS was issued AMVAC had failed to take appropriate steps to secure that data within the time required by the EPA.

h. AMVAC did not take appropriate steps to secure the SS-1072 Leptocheirus Data within the time required by EPA

AMVAC has not submitted data responsive to the DCI's SS-1072 Leptocheirus Data requirement, and AMVAC failed to take appropriate steps to secure this data within the time required by the Agency.

AMVAC appropriately planned to develop new data in response to this requirement and timely informed the Agency of its intent in the 90 Day Response. *See* JX 5 at 17-18; Freedlander

[32] I do not find it particularly significant that, during cross examination at hearing, Dr. Wente stated that he "believe[s] what you're saying is correct" when AMVAC counsel asserted that the December 2020 response "was asking EFED to take note of a DCPA guideline 835.4300 study" as "the basis for a waiver of the TPA study[.]" Tr. 137; AMVAC Br. at 31; AMVAC Reply at 9-10. There is no indication from this testimony that EFED understood *prior to the NOITS* that this was AMVAC's request. AMVAC attempts to buttress its argument by pointing to a footnote in EFED's April 2022 denial of AMVAC's December 2020 waiver request for 835.4400. AMVAC Br. at 31; AMVAC Reply at 9-10; JX 79 at 5 n.2. In that denial, EFED used the DCPA 835.4300 study to estimate a stable half-life for TPA so that it could model the effect of assumed stability of TPA in aquatic systems. *See* JX 79 at 5 & n.2; Tr. 137-38. This was for the purpose of showing why an 835.4400 Anaerobic Aquatic Metabolism of TPA study was needed to reliably derive a half-life for TPA—when DCPA data was used instead, it suggested "a linearly increasing accumulation pattern over time for TPA" in bodies of water and "may overestimate TPA's actual persistence and further reduce confidence in the risk assessment conclusions." JX 79 at 6. The fact that EFED used the *DCPA* 835.4300 study for this purpose is not evidence that EPA understood AMVAC intended the Agency use the *DCPA* 835.4300 study to satisfy the *TPA* 835.4300 data requirement or that EPA thought it would be appropriate to do so. It is simply an example of EFED demonstrating the problem posed when DCPA data is used to estimate outcomes for TPA.

Statement ¶¶ 86-87; Wendel Statement at 9; Second Jt. Stips. ¶ 30; Tr. 73. Although AMVAC initially attempted to complete the study, problems arose after it changed course in the face of protocol difficulties and decided in March 2016 to seek a waiver of the data requirement. When the Agency denied that request in the Lepto Waiver Denial, it provided AMVAC an additional option: as an alternative, the company could conduct an interim 10-day study under a different Test Guideline, and pending the results of that study, "[a] waiver may be considered at a later date[.]" JX 74 at 3. At the same time, the Agency clearly stated that allowing AMVAC to conduct this alternative 10-day study "does not constitute a change in the EPA's policy or data requirements," "[SS-1072] will remain an outstanding DCI requirement[,]" and "[t]his memo does not constitute a waiver of the estuarine/marine chronic sediment toxicity data requirement." JX 74 at 3. In other words, the Lepto Waiver Denial stated that AMVAC's request for a waiver was denied, the DCI still required AMVAC to satisfy the SS-1072 Leptocheirus Data requirement, but AMVAC had the option of completing a shorter study and *potentially* obtaining a waiver in the future *if* the Agency determined that the results of the shorter study permitted one.

Upon receiving the Lepto Waiver Denial in July 2016, AMVAC did not return to its effort to conduct the SS-1072 Leptocheirus study called for under the DCI, nor did it attempt to complete the shorter 10-day study. Instead, its initial response was to seek another waiver in November 2016, mostly repeating arguments it had made in the first waiver request and disputing the merits of performing a shorter 10-day study. *See* JX 76. AMVAC contends that its November 2016 waiver request was not repetitive of its March 2016 waiver request and cites certain additions to the November document. AMVAC Br. at 20 n.16; AMVAC Reply at 5. But these additions—a brief overview of DCPA's overall chemical and ecotoxicological properties; two sentences about the relative sensitivity of midges and amphipods to other AMVAC pesticides; and a short description of two cases where DCPA concentrations had been measured in sediment samples from estuarine watersheds—still sought to "provide[ ] information supporting AMVAC's contention that the 28-day Leptocheirus study would not produce useful endpoints for risk assessment based on the sensitivity of the subject species[.]" Freedlander Statement ¶ 100; JX 73; JX 76. That is, despite the additions, the underlying objection of both requests is substantively the same: AMVAC alleges a Leptocheirus study is not needed because data from other sediment-dwelling aquatic organisms with similar sensitivities to DCPA or other water column-dwelling aquatic organisms with greater sensitivities could be used in the risk assessment instead, and water concentrations of DCPA are unlikely to occur in the environment at a level that would have a toxicological effect on aquatic invertebrates like Leptocheirus. *See* JX 73; JX 76. Submitting repetitive waiver requests does not constitute an appropriate step toward securing the SS-1072 Leptocheirus Data. Additionally, AMVAC argues that the Agency never substantively evaluated the November 2016 waiver request and therefore cannot premise its claim that AMVAC failed to take appropriate steps on its "waiver requests being 'repetitive' or otherwise deficient." AMVAC Br. at 20-21. I disagree. The "appropriate steps" question focuses on AMVAC's conduct, not the Agency's. Regardless of whether EFED ever reviewed the November 2016 waiver request, its submission cannot constitute an appropriate step to secure the Leptocheirus data, because the step AMVAC took was essentially to dispute the same grounds on which the Agency had already denied its initial waiver.

Thereafter, AMVAC continued to state its opposition to both the SS-1072 Leptocheirus Data requirement and the 10-day study option that EPA had presented, first in its February 2018 rebuttal to the 2014 Waiver Denial, and again in its December 2020 response to the Data Delay Letter. The company made various entreaties to EPA—that it would complete the 10-day study if the Agency confirmed that it would allow the results to satisfy the SS-1072 DCI requirement; that it would complete the 10-day study if a new DCI were issued; that it would complete the DCI's SS-1072 Leptocheirus Data requirement if EPA confirmed "that the chronic study guideline has been validated"—but it never took steps to complete either study. *See* JX 22 at 2; JX 67 at 4.

AMVAC claims its proposal to complete the 10-day study on the condition that OPP first issue a formal DCI for the study was itself a "reasonable and appropriate" step. AMVAC Br. at 22; AMVAC Reply at 6. It was not. The 10-day study was not a requirement but rather an alternative interim path that AMVAC had the option of pursuing (or not). It was not necessary or appropriate for EPA to issue a separate DCI and presumably not a fitting use of scarce Agency resources. Additionally, in this proposal AMVAC sought to compel the Agency to take certain steps first *before* AMVAC would agree to secure data required by the DCI. But AMVAC's obligation to respond to the DCI is not contingent on the Agency agreeing to the company's conditions. Further, while it is understandable that AMVAC would be motivated to try to avoid a potential arbitration proceeding to obtain financial contribution from a speculative follow-on registrant, this self-serving business interest does not make its demand for a new DCI an appropriate step.

AMVAC also argues that it took appropriate steps when it told EPA in December 2020 "that it would begin the chronic *Leptocheirus* study if OPP 'confirm[ed] that the chronic study guideline has been validated.'" AMVAC Br. at 23 (quoting JX 22 at 2); AMVAC Reply at 6. But AMVAC cannot rely on this statement as an appropriate step. Most significantly, in this response AMVAC is declining to take any steps unless *EPA takes a step first* by "validat[ing]" the test guideline. This is not appropriate, because AMVAC's obligation to secure data required by the DCI is not dependent on EPA taking some affirmative step first, particularly the complex, years-long process that AMVAC's own witnesses testified is required to validate a study protocol. *See* Gur Statement ¶ 18; Tr. 319-321. AMVAC also complains that "OPP was clearly aware that there had been 'challenges some laboratories have experienced running the chronic sediment toxicity test'" with Leptocheirus, and that in its December 2020 response it "reasonably communicated to OPP that if OPP felt these challenges had been resolved, OPP could advise AMVAC of that and AMVAC would proceed with the chronic study." AMVAC Br. at 23 (quoting JX 74 at 2, as referenced in JX 21 at 6). Again, AMVAC was expecting EPA to take affirmative steps it had no obligation to take. Even if AMVAC was only asking EPA to inform it when other chronic Leptocheirus studies had been deemed acceptable by the Agency, this was an inappropriate expectation. There was no requirement for EPA to provide such notice. Further, AMVAC was entirely capable of discovering this for itself: as Ms. Wendel testified, at least 16 other Leptocheirus SS-1072 studies have been successfully completed since 2017, including studies from Smithers, the laboratory AMVAC had hired before it began pursuing a data waiver. *See* Tr. 74, 86-88.

The SS-1072 Leptocheirus Data remains outstanding, and for the reasons set forth above, when the NOITS was issued AMVAC had failed to take appropriate steps to secure that data within the time required by the EPA.

V. Whether the existing stocks provision of the NOITS is consistent with FIFRA

Because AMVAC has failed to take appropriate steps to secure the data discussed above within the time required by the EPA, it is necessary to determine "whether the provisions of the DCPA NOITS concerning existing stocks are consistent with FIFRA." *AMVAC Chem. Corp.*, 18 E.A.D. at 796, 2022 WL 4968470 at *23. As discussed below, I find the provisions consistent with FIFRA.

a. Background facts related to existing stocks of DCPA

AMVAC is the only registrant of Technical DCPA and DCPA end-use products ("EUPs") formulated with the Technical DCPA at issue in this proceeding. Consequently, it is the only source of DCPA EUPs for domestic growers. McMahon Statement ¶ 14. AMVAC formulates the EUP "Dacthal Flowable" at a facility in Marsing, Idaho and the EUP "Dacthal 75-W" wettable powder at a Columbus, Ohio facility. Neither location manufactures Technical DCPA. *See* Verified Written Statement of AMVAC Fact Witness Suneet Ranganath ¶ 6 (Jan. 9, 2023) (PAX 96) ("Ranganath Statement"). Rather, Technical DCPA is delivered to the production facilities where it is formulated into the respective EUP. Ranganath Statement ¶ 7.

AMVAC distributes and sells at a profit more than 100,000 gallons of DCPA EUPs domestically and internationally each year. Ranganath Statement ¶ 8; Tr. 387-88. At the time of hearing, AMVAC did not have precise data on the quantity of EUPs currently available from distributors or already purchased by growers, but it did not expect those amounts to satisfy demand through the end of 2023. It has not increased production of EUPs in the past year, but it is currently working to obtain more DCPA Technical from which it could formulate additional EUPs. Ranganath Statement ¶¶ 10-11; Tr. 385, 388. According to AVMAC, any EUP shortage that results from the suspension of Technical DCPA could be alleviated if AMVAC is permitted to formulate EUPs from the inventory of Technical DCPA available at the time the suspension goes into effect. Ranganath Statement ¶ 14.

Growers rely on DCPA to serve as "an essential foundational tool for effective and economical control of yield-robbing grasses and broadleaf weeds in onions and small acreage brassica crops . . . ." Direct Testimony of Steven A. Fennimore, Ph.D. ¶ 13 (Jan. 25, 2023) (PGX 7A) ("Fennimore Statement"). There are a limited number of alternative herbicides with similar selectivity and efficacy, and they "must be paired with greater use of mechanical and hand weeding." Fennimore Statement ¶¶ 15-16. But mechanical and hand weeding are less economically viable options because mechanical weeding technology is not fully mature and labor availability is sporadic and in short supply. Direct Testimony of Christopher Valadez ¶¶ 34-36 (June 16, 2022) (PGX 6) ("Valadez Statement"). Onion growers in particular will be put "in a precarious position for addressing weed control issues and safeguarding yields," because weed control in onions is already "challenging and complex due to the nature of onions' growth." Direct Testimony of Richard Smith ¶¶ 10, 14 (June 16, 2022) (PGX 8) ("Smith

Statement"). Consequently, the loss of DCPA to suspension "would have a significant, negative impact on the cost to produce crops and lower yields, both of which lead to higher prices." Fennimore Statement ¶ 30; *see also* Valadez Statement ¶ 42 ("The impact of the yield losses and increased costs from the loss of DCPA will not be limited to growers. The American consumer also will incur the increased costs for crops that rely on DCPA").

b. The existing stocks provision in the NOITS

FIFRA provides that the Agency "may include in the [NOITS] such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks" of the pesticide facing suspension. FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv). Agency policy defines existing stocks "as 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 action." Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362, 29,362 (June 26, 1991) (Notice) ("Stocks Policy"). With respect to existing stocks of DCPA, the NOITS provides:

> After the suspension becomes final and effective, [AMVAC], including all supplemental registrants of [Technical DCPA], cannot 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], except for the purpose of disposal . . . . Persons other than [AMVAC] may continue to distribute, sell, use, 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].

JX 1 at 4-5. These provisions in the DCPA NOITS are in accordance with the Agency's Stocks Policy concerning the disposition of existing stocks of a suspended pesticide:

> 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 29,367.

Ms. Bloom describes the existing stocks provisions in the NOITS as "similar to provisions from most prior FIFRA Section 3(c)(2)(B) suspensions where registrants have failed to submit data in response to EPA DCIs" and "consistent with EPA's longstanding existing stocks policy." Bloom Statement at 7. The Stocks Policy is premised on the notion that allowing registrants to sell or distribute existing stocks of a suspended pesticide "would diminish the incentive for registrants to comply with the DCI in a timely manner." Bloom Statement at 7. Ms. Bloom further notes that regarding FIFRA's purpose, "EPA is charged with determining if a pesticide 'will not generally cause unreasonable adverse effects on the environment.'" Bloom Statement at 7 (quoting 7 U.S.C. § 136a(c)(5)(D)). To make this determination, "EPA typically starts by considering whether the pesticide presents risks of concern and, if it does, EPA considers the economic benefits of the pesticide in order to determine whether those risks are unreasonable." Bloom Statement at 7. Registrants bear the burden of meeting this standard, and it "almost always requires registrants to submit necessary data so that risks can be assessed." Bloom Statement at 7.

For DCPA, the Agency is unable to assess the pesticide'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." Bloom Statement at 7. Because EPA cannot accurately measure these risks, it cannot "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 further notes that FIFRA does not require EPA to allow the sale of existing stocks and that such provisions are "discretionary to the extent" the Agency is acting consistent with FIFRA. Bloom Statement at 7. She adds: "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. In DCPA's case, "consideration of this uncertainty was the reason behind the existing stocks provisions the Agency put forward." Bloom Statement at 7.

c. AMVAC's existing stocks argument

AMVAC contests the existing stocks provision not in whole but in part: It "seeks elimination only of the limited prohibition on AMVAC's use of DCPA Technical in its possession as of the effective date of any suspension to formulate other pesticide products, *i.e.*, DCPA end-use products." AMVAC Br. at 37. Because AMVAC is the only registrant of Technical DCPA and its associated end-use products, it argues that not allowing it to formulate end-use products from existing stocks of Technical DCPA means that growers will face "more acute" impacts that would not occur if the market structure was different. AMVAC Br. at 38.

To that end, AMVAC first contends that FIFRA requires consideration of market impacts, because any person adversely affected by a NOITS may request a hearing that assesses whether the existing stocks provisions are consistent with FIFRA. AMVAC Br. at 38-39 (citing 7 U.S.C. § 136a(c)(2)(B)(iv)). AMVAC also alleges the Stocks Policy "recognizes that consideration of market impacts is a rational consideration when determining an existing stocks provision." AMVAC Br. at 39. Yet OPP did not consider market impacts, AMVAC asserts. AMVAC Br. at 40.

Second, AMVAC argues that data eliminating uncertainty in the risk assessment of DCPA was provided shortly after the NOITS was issued, when the company submitted final CTA data in June 2022 and then supplemented its submission in August 2022. AMVAC Br. at 41 (citing PAX 95 ¶¶ 143-149). Therefore, AMVAC believes it has addressed any uncertainty with respect to human health risks, and that "can no longer serve as a basis for the proposed existing stocks order." AMVAC Br. at 41.

Finally, AMVAC argues that "the correct inquiry is whether adverse impacts on growers and agriculture from the component of the existing stocks policy that AMVAC is challenging is warranted when those impacts are weighed against OPP's interest in ensuring the completion of the few studies currently underway." AMVAC Br. at 42. AMVAC concludes the answer is "no," because the company has already started generating data for the outstanding DCI requirements, and there is no evidence it would cease or slow down its data generation if permitted to continue formulating end-use products from existing Technical DCPA, because "AMVAC would remain subject to prohibitions on obtaining or manufacturing additional technical [DCPA]." AMVAC Br. at 42-43.

d. Growers Group's existing stocks argument

The Growers Group also "challenges the portion of the existing stocks provision that prohibits AMVAC from formulating stocks of DCPA technical in its possession at the time of a suspension into end use products following the effective date of the suspension." GG Br. at 1.

First, like AMVAC, the Growers Group contends that because FIFRA authorizes any person adversely affected by a suspension to request a hearing on whether the existing stocks provision of the NOITS is consistent with FIFRA, the statute necessarily requires consideration of the provision's impact on third parties. GG Br. at 10. Testimony from the Growers Group is relevant, it argues, because EPA based its existing stocks provisions on concerns of uncertain risks, and therefore the benefits of DCPA must also be considered to remain consistent with FIFRA. GG Br. at 11. Further, this testimony provides "evidence of the significant and adverse impacts that the existing stocks provision of [the] NOITS will create by prohibiting AMVAC from formulating technical DCPA in its possession of the suspension goes into effect." GG Br. at 12. Because the Agency has not disputed this evidence but instead argues it should be ignored, EPA "failed to consider the critical needs and benefits of DCPA and the impact the DCPA existing stocks provision would have" and failed to weigh these concerns against its allegations of uncertain risks. GG Br. at 15. This is inconsistent with EPA policy and FIFRA, the Growers Group argues. GG Br. at 15.

Second, the Growers Group contends that regardless of EPA's failure to engage in risk-benefit balancing, the evidence demonstrates that EPA's risk-based justification is without basis. GG Br. at 16. Specifically, the Growers Group argues, the Agency stated on several occasions that it did not believe the outstanding data would prevent it from conducting risk assessments but rather that it would have to base the assessments on conservative assumptions. GG Br. at 16 (citing JX 21 at 1; JX 32 at 1; JX 65 at 25; JX 79 at 2; Tr. 62, 83, 232). Only when the NOITS was issued did EPA reflect a change in its position by stating that the missing CTA data

prevented it from completing a human health risk assessment, the Growers Group states. GG Br. at 17. And once AMVAC submitted the data in June 2022, the Growers Group contends, the Agency's risk concerns were satisfied because it could use conservative assumptions for any other outstanding data. GG Br. at 18. Accordingly, the Growers Group concludes, "[b]ecause the Agency put forward 'this uncertainty [as] *the* reason behind the existing stocks provisions,' and the record establishes that any such 'uncertainty' has been resolved, the existing stocks provision is entirely unsupported by the record and cannot be sustained." GG Br. at 18 (quoting Bloom Statement at 6-8); *see also* GG Reply at 2-6.

Finally, the Growers Group asserts that the existing stocks provision is irrational, because the Agency has refused to reevaluate it now "that the sole justification the Agency offered for the existing stocks provision in the NOITS – the lack of a CTA study – no longer exists[.]" GG Br. at 18. But even if the CTA study had not been deemed satisfied by the Agency, the existing stocks policy still requires a fact-specific inquiry, and the only fact EPA considered was "uncertain risks." GG Br. at 19 (citing 56 Fed. Reg. 29,362). Yet after making this consideration, the Growers Group alleges, the Agency fashioned a provision that would permit third parties to formulate end-use products from existing stocks of Technical DCPA while prohibiting AMVAC from doing the same, and it would generally permit the continued sale and use of end-use products containing DCPA. GG Br. at 19. But the record provides no basis to conclude that there is a difference in the "uncertain risk" if AMVAC is the formulator of existing Technical DCPA into end-use product rather than a third party, AMVAC contends, or "if AMVAC formulates technical DCPA into end use products following suspension, but not if the formulated end use products are actually used." GG Br. at 18-19. "The Agency has discretion in its determinations of existing stocks," the Growers Group concludes, but "[b]ecause the terms and justification for the existing stocks provision in the NOITS are incongruous and cannot be harmonized in any rational way, the provision falls outside a reasonable exercise of the Agency's discretion." GG Br. at 20.

e. Analysis

Despite Petitioners' contentions, neither the NOITS nor the existing stocks provision is based *solely* on "uncertain risks" posed by DCPA due to missing CTA data. Rather, as Ms. Bloom explained, the existing stocks provision of the DCPA NOITS was fashioned so as to implement "EPA's longstanding existing stocks policy," which specifies that in the case of suspension the Agency will "generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension." *See* Bloom Statement at 7; 56 Fed. Reg. at 29,367. The reason for not allowing a registrant to sell or distribute existing stocks of its suspended pesticide is because that "would diminish the incentive for registrants to comply with the DCI in a timely manner." Bloom Statement at 7. Accordingly, the Agency determined that allowing AMVAC to formulate and sell additional end-use products from its existing stocks of Technical DCPA would subvert this compliance incentive. Even if concerns regarding CTA data drew greater scrutiny to AMVAC's conduct during the DCI process or first started the Agency down the path that led it to issue the NOITS, it is clear from the face of the document that AMVAC's failure to submit data required by the DCI is the basis for suspension. References to possible risk concerns related to CTA data by the NOITS or Agency witnesses provide additional context but do not change this essential fact, nor does their inclusion compel some broader

risk/benefit analysis.

For EPA to carry out its obligations under FIFRA, and for registrants like AMVAC to meet their burden of maintaining their registrations, timely compliance with the DCI is essential. The Agency issued the DCI in this case to obtain information required to complete its registration review of DCPA. The purpose of this registration review is to determine whether DCPA continues to satisfy the FIFRA standard for registration, i.e., whether, given current scientific and other knowledge regarding DCPA, it poses "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." *See* FIFRA § 2(bb), 7 U.S.C. § 136(bb). Making this determination necessarily requires EPA to produce risk assessments that weigh the "economic, social, and environmental costs and benefits" of using DCPA. In turn, developing accurate risk assessments requires EPA to obtain data from registrants in a timely manner through the DCI process. That the Agency at times must rely on conservative estimates when data is not produced does not negate its statutory authority to require registrants to submit data, nor does it invalidate the need for that data. If Congress expected EPA to simply fall back on conservative assumptions in the absence of data, it would not have provided the Agency with the statutory and regulatory tools to collect that data by issuing a DCI or an enforcement mechanism to suspend registrations when a registrant does not take appropriate steps to secure data within the time the Agency requires it: Suspension is the specific statutory remedy given to EPA to enforce compliance with its data collection efforts. Limiting AMVAC's ability to profit from its existing stocks of Technical DCPA by formulating end-use products is the only way to truly give teeth to this remedy, and it is a rational and appropriate means of incentivizing timely compliance with the DCI. To that end, it is consistent with FIFRA's specific requirements for registration review and its broader "purpose of protecting both human health and the environment." *Bayer*, 17 E.A.D. at 235, 2016 WL 4125892, *7.

To the extent that Ms. Bloom testified that "consideration of [the uncertain risk picture] was the reason behind the existing stocks provisions the Agency put forward," she is describing an underlying basis for the Agency compelling the submission of data in the first place. *See* Bloom Statement at 8. That is, the risk picture for DCPA is inherently uncertain until EPA has the data it requires through the DCI to complete registration review and evaluate the pesticide against FIFRA's standard. The existing stocks provision in the NOITS is designed to prompt the submission of data that will enable EPA to complete its review, including the risk-benefit analysis necessary to maintain DCPA's registration. In that regard, the uncertain risk picture that exists for DCPA can be made clear by AMVAC's submission of data, which is the reason behind EPA's inclusion of the existing stocks provision.

Petitioners argue that EPA was required to consider the economic, social, and environmental benefits of DCPA, i.e., weigh market impacts, when crafting the existing stocks provision in the NOITS. I do not believe this to be the case.

First, FIFRA's starting point upon suspension is that it is "unlawful for any person in any State to distribute or sell to any person any pesticide . . . whose registration has been canceled or suspended, *except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter[.]*" FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A)

(emphasis added). For suspensions based on the failure to submit required data, EPA "*may* include in the [NOITS] such provisions *as the Administrator deems appropriate* concerning the continued sale and use of existing stocks" of the suspended pesticide. FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv) (emphasis added). *See also* FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1) (providing that EPA "*may* permit the continued sale and use of existing stocks of a pesticide whose registration is suspended . . .under . . . section 136a . . . *to such extent, under such conditions, and for such uses as the Administrator determines* that such sale or use is not inconsistent with the purposes of this subchapter."). This is a broad grant of discretion to the Agency to *choose* to take additional steps that allow the sale or use of existing stocks of pesticides that would otherwise be forbidden by law. The statute says nothing about first balancing the pesticide's potential risks against the impact a suspension will have on third parties. The statutory presumption is that such conduct is unlawful due to the registrant's failure to submit required data, irrespective of the consideration of economic impact. Moreover, for cancellations of conditional registrations, FIFRA does not permit EPA to allow the continued sale and use of existing stocks unless the Agency first "determines that such sale or use is not inconsistent with the purposes of this subchapter *and* will not have unreasonable adverse effects on the environment." FIFRA § 6(e)(1), 7 U.S.C. 136d(e)(1) (emphasis added); *see also Bayer*, 17 E.A.D. at 301, 2016 WL 4125892, *58 (holding that FIFRA § 6(e)(1) permits EPA to allow the continued sale and use of existing stocks only if it first concludes that sale and use is not inconsistent with FIFRA and that it will not have unreasonable adverse effects on the environment). That is, in a scenario in which a registration is cancelled and a pesticide's distribution or sale *permanently* banned, EPA does not need to conduct a risk-benefit analysis *unless* it decides to allow *more* sale and use of a pesticide than would otherwise be available under FIFRA. In this case, where DCPA's suspension is temporary, Petitioners argue that AMVAC is entitled to more sale and use of its pesticide than FIFRA would otherwise allow because EPA did *not* conduct a risk-benefit analysis. That is backwards. Relatedly, if EPA seeks to permanently cancel a pesticide registration because the pesticide no longer complies with FIFRA or generally causes unreasonable adverse effects on the environment, FIFRA expressly requires that the Agency take into account the impact of cancellation "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." FIFRA § 6(b), 7 U.S.C. 136d(b). FIFRA states no such requirement with respect to suspensions under Section 3(c)(2)(B). *See* 7 U.S.C. § 136a(c)(2)(B).

Second, contrary to Petitioners' arguments, the Agency's Stocks Policy does not require consideration of market impacts for a suspension under FIFRA § 3(c)(2)(B). The Stocks Policy provides direction for the disposition of existing stocks based on whether a registration is being cancelled, suspended, or amended, and describes how each merits a different response. 56 Fed. Reg. at 29,362, 29364, 29367. For example, for cancellation of a pesticide that raises risk concerns, "the Agency *will not permit* continued distribution, sale, or use of existing stocks of the cancelled pesticide . . . *unless* it can be demonstrated that the social, economic, and environmental benefits associated with such distribution, sale, or use exceed the social, economic, and environmental risks." *Id.* at 29,364 (emphasis added). For cancellations due to FIFRA noncompliance but not involving risk concerns, "the Agency is not required to perform a risk/benefit analysis," and EPA will "generally prohibit a registrant from selling or distributing existing stocks more than 1 year from" the first date of noncompliance while allowing persons other than the registrant to distribute, sell, or use existing stocks until they are exhausted. *Id.* at

29,365-29,366. Suspension of pesticides posing "imminent hazards" under FIFRA § 6(c) are treated the same as cancellations with identified risk concerns—"the Agency is highly unlikely to allow significant sale, distribution, or use of pesticides suspended because of imminent hazard concerns." *Id.* at 29,367. And as set forth above, following suspensions under FIFRA § 3(c)(2)(B) for failure to comply with a DCI, "the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension," and "[r]egistrants 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)." *Id.* That the Agency responds one way to risk-based cancellations does not affect how it responds to suspensions for failure to submit required data. Further, as previously stated, the suspension of DCPA is not based on risk concerns but on AMVAC's failure to submit required data. The Stocks Policy simply does not require a balancing of risks and benefits in this case.

Third, Petitioners wrongly contend that because "a person adversely affected" by the NOITS—i.e., someone other than the registrant—can request a hearing under FIFRA § 3(c)(2)(B)(iv), the Agency is bound to weigh the impact of the existing stocks provision on persons other than the registrant. This argument reads into the statute a right that it plainly does not provide. While it might speak to the relevance of evidence non-registrants present as to how they would be adversely affected by a suspension, it does not impose on the Agency an obligation to balance either the risks of DCPA or the Agency's need to obtain necessary data against the pesticide's economic benefits and impact on growers. The existing stocks provision is consistent with FIFRA without this balancing, because it incentivizes the submission of data the Agency has determined to be necessary to maintain DCPA's registration.

Fourth, the existing stocks provision restricts only AMVAC's use of Technical DCPA, not third parties. Any harm that befalls growers results from the fact that AMVAC is the only registrant of DCPA and its end-use products. This cannot be justification for concluding that the existing stocks provision is inconsistent with FIFRA. If AMVAC were permitted to formulate and sell end-use products from Technical DCPA to alleviate third party harm, then the coercive effect of suspension is largely lost as the company continues to profit from its "suspended" product. Arguably this renders the existing stocks provision inconsistent with FIFRA, because it no longer serves the purpose of promoting the timely submission of data to maintain DCPA's pesticide registration. AMVAC claims coercion is no longer necessary because it has initiated the studies that will produce the remaining outstanding data, and most will be completed by November 2023. AMVAC Br. at 42 (citing McMahon Statement ¶¶ 37-42). I disagree. The course of the DCPA DCI does not suggest that just because AMVAC has initiated the requisite studies it will timely submit the data or that the Agency will find the data acceptable.

I also reject argument from the Growers Group that the existing stocks provision is irrational because it conceivably allows third-parties to use Technical DCPA but not AMVAC, despite there being no difference in risk. As set forth above, the existing stocks provision is not based on risk but on incentivizing AMVAC to submit data. There is no current need to limit third party use, because only AMVAC is responsible for generating the necessary data.

Accordingly, I find that the provisions of the DCPA NOITS concerning existing stocks are consistent with FIFRA.

VI. Conclusion and Order

AMVAC failed to take appropriate steps to secure the data to fulfill each of the nine remaining outstanding data requirements cited in the NOITS, and I find that the existing stocks provision of the DCPA NOITS is consistent with FIFRA.

Therefore, 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.

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).

Pursuant to the rules governing this proceeding, this "initial decision shall become the decision of the Environmental Appeals Board without further proceedings unless an appeal is taken from it or the Environmental Appeals Board orders review of it, pursuant to § 164.101." 40 C.F.R. § 164.90(b).

SO ORDERED.

Susan L. Biro
Chief Administrative Law Judge

Dated: May 16, 2023
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 **Initial Decision and Order**, dated May 16, 2023, and issued by Chief Administrative Law Judge Susan L. Biro, was sent this day to the following parties in the manner indicated below.

Matt Barnwell
Attorney-Advisor

Copy by OALJ E-Filing System to:
Mary Angeles, Headquarters Hearing Clerk
U.S. Environmental Protection Agency
Office of Administrative Law Judges
Ronald Reagan Building, Rm. M1200
1300 Pennsylvania Ave. NW
Washington, DC 20004

Copy by Electronic Mail to:
Forrest Pittman
Erin S. Koch
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
Mail Code 2310A
1200 Pennsylvania Avenue NW
Washington, DC 20460
Email: pittman.forrest@epa.gov
koch.erin@epa.gov
Attorneys for Respondent

Cristen S. Rose
HAYNES BOONE
800 17th Street NW
Washington, DC 20006
Email: cristen.rose@haynesboone.com
Attorney for Grower Group Petitioners

David B. Weinberg
Tracy A. Heinzman
Keith A. Matthews
Hume M. Ross
Mark B. Sweet
WILEY REIN LLP
2050 M Street NW
Washington, DC 20036
Email: dweinberg@wiley.law
Email: theinzman@wiley.law
Email: kmatthews@wiley.law
Email: hross@wiley.law
Email: msweet@wiley.law

Timothy J. Donnelly
AMVAC Chemical Corporation
4695 MacArthur Ct, Suite 1200
Newport Beach, CA 92660
Telephone: (949) 221-6115
timd@amvac.com
Attorneys for Petitioner AMVAC Chemical Corporation

Environmental Appeals Board
U.S. Environmental Protection Agency
Email: clerk_eab@epa.gov
cortes.emilio@epa.gov

Dated: May 16, 2023
Washington, D.C.