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, **Petitioners.**	)	**Docket No. FIFRA-HQ-2022-0002**

VERIFIED WRITTEN STATEMENT OF AMVAC FACT WITNESS RICHARD S. FREEDLANDER

I, Richard S. Freedlander, declare and state as follows:

1. The following statements are true and correct to the best of my knowledge and belief and are based on my personal knowledge.

Background and Curriculum Vitae

2. I received a Bachelor of Science in Chemistry in 1975 from the University of Miami and a Doctor of Philosophy in Chemistry in 1980 from the University of South Carolina.

3. Prior to working for AMVAC Chemical Corp ("AMVAC"), from 1980 to 1987, I served as a Formulation Chemistry Group Leader and then a Senior Residue Chemistry Group Leader for ICI America. From 1987 to 1988, I worked as a Manager of Regulatory Chemistry for Pennwalt/Elf Atochem. From 1988 to 2007, I served as the Director for Research & Development Laboratories for Elf Atochem/Cerexagri. From 2007 to 2012, I served as the President and Laboratory Director of JRF America.

4. I am currently the Director of Environmental Science at AMVAC. I have worked for AMVAC in this role since 2012.

5. In these roles, I have amassed over 40 years' experience in the agrochemical industry with technical and regulatory expertise at local, federal, and global levels.

6. In my position as AMVAC's Director of Environmental Science, I have been directly involved in AMVAC's response to the Data-Call In ("DCI") that is the subject of the Notice of Intent to Suspend ("NOITS") AMVAC's Dimethyl Tetrachloroterephthalate ("DCPA") Technical Registration received by AMVAC on April 27, 2022 that is the subject of the proceeding.

7. Specifically, from 2013 onward, I have been directly involved in work and communications relating to the various data requirements from the DCI discussed below.

The DCPA Fish Early Life Stage Studies

8. In the DCI, EPA requested data for Guideline No. 850.1400 "Fish Early Life-Cycle Toxicity Test" for DCPA. The footnotes associated with this requirement indicated that the preferred test species are Rainbow Trout, bluegill, and sheepshead minnow. Joint Exhibit ("JX") 4.

9. AMVAC indicated in its initial response to the DCI on April 29, 2013, (the "Initial Response") that it would submit existing data for the Fish Life-Cycle Toxicity Tests for DCPA and request a waiver for the requirement to do the Fish Life-Cycle Toxicity Tests with TPA. JX 5. The Fish Life-Cycle Toxicity Tests with TPA are discussed separately in below.

10. On January 30, 2014, AMVAC submitted existing study Chlorthal-dimethyl (DCPA): Prolonged Toxicity Test to Juveniles [Rainbow Trout] Under Semi-Static Conditions: Final Report. Project Number: 1708/034, 1708/034/D2149, identified by MRID No. 49307520.

11. On October 16, 2020, EPA sent a letter to AMVAC summarizing the outstanding data requirements from the DCI. JX 21. The letter included a chart entitled "Status of DCPA GDCI-078701-1140 with Current Due Dates (as of October 16, 2020)." For Guideline 850.1400, three separate data requirements are listed for DCPA – Fish Early Life-Cycle (Rainbow Trout), Fish Early Life-Cycle (bluegill sunfish), and Fish Early Life-Cycle (sheepshead minnow). EPA indicates that the status as "supplemental; additional data not required" for rainbow trout, and "outstanding" for the bluegill and sheepshead minnow. The chart references two EPA data evaluation records dated February 17, 2019, (JX 51), and February 26, 2019, (JX 52). The data evaluation records were first provided with EPA's October 16, 2020, letter. JX 21.

12. The first DER referenced in EPA's chart shows that EPA did not complete its review of the Rainbow Trout study (MRID No. 49307520) submitted by AMVAC on January

30, 2014, until February 17, 2019, (5 years after it was submitted). This review would have been informative if received earlier to support the conduct of the remaining two DCPA fish studies. JX 51.

13. The second document referenced in the EPA chart is a memo dated February 26, 2019, from EPA's Environmental Fate and Effect Division ("EFED") to the Pesticide Re-Evaluation Division ("PRD") transmitting the February 17, 2019, data review. JX 52.

14. AMVAC has no record of ever receiving the memo, (JX 52), or the DER reviewing the 2014 Rainbow Trout study, (JX 51), prior to receiving EPA's October 16, 2020, letter. The Rainbow Trout DCPA 850.1400 Guideline study was not listed as outstanding in the NOITS.

15. Shortly after receiving EPA's data review in October 2020, AMVAC took steps to conduct the Fish Life-Cycle Toxicity studies for bluegill and sheepshead minnow with DCPA.

16. AMVAC informed EPA of its plan to initiate the studies in a December 17, 2020, letter to EPA. JX 22.

17. Both of these studies began on March 21, 2021. The bluegill study (conducted on allowed alternative species fathead minnow) has already been submitted on June 7, 2022 (MRID 51926601). The sheepshead minnow study is expected to be provided on July 15, 2022.

The DCPA Mysid Life-Cycle Chronic Toxicity Test

18. AMVAC has worked diligently to address the Guideline 850.1350 Chronic Toxicity Mysid – DCPA data requirement, for which it indicated in the Initial Response that it would develop new data. JX 5.

19. To address the Guideline No. 850.1350 Mysid Life-Cycle Chronic Toxicity Test, on January 30, 2014, AMVAC submitted "Dacthal: A flow-through life-cycle toxicity test with

the saltwater mysid (*Americamysis bahia*)," MRID Number 49307512. JX 56 (DER for that study).

20. The DER, JX 56, (which, based on reviewer signatures, was "approved" on December 1, 2021, but which had been initially "reviewed" by a staff scientist on October 10, 2016) assessed the Mysid Life-Cycle study as "scientifically sound" and classified the study as "supplemental, may be used for risk characterization." JX 56.

21. EPA did not inform AMVAC that EPA had determined that the Mysid Life-Cycle Test, OCSPP 850.1350, MRID No. 49307512, did not satisfy the corresponding GDCI requirements and that EPA would require additional data (by providing a copy of the December 2021 DER) until *after* the NOITS was issued. JX 57. (April 27 email from J. Douglass to N. McMahon). EPA's assessment of this data was critical in their subsequent conclusion that marine/estuarine species were more sensitive to DCPA than freshwater species.

22. AMVAC is timely responding to EPA's communication regarding the DCPA Guideline OCSPP 850.1350 study.

23. AMVAC has contacted the responsible contract laboratory and awaits its input concerning EPA's DER evaluation.

24. These questions could have been addressed (or even a new study run, if needed, or other appropriate action taken) in the intervening time frame between EPA's contractor's initial review (2016) and the date that AMVAC was made aware of EPA's conclusions (concurrent with the NOITS).

The DCPA Terrestrial Vascular Plant Seedling Emergence Study

25. AMVAC has worked diligently to address the Guideline 850.4100 Terrestrial Vascular Plant Seedling Emergence – DCPA ecological effects data requirement, for which it

indicated in the Initial Response that it would develop new data. JX 5.

26. To address the Guideline No. 850.4100 Terrestrial Vascular Plant Seedling Emergence data requirement, on January 30, 2014, (date noted as being uploaded in PDMS), AMVAC submitted the study "Dacthal: A Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Ten Species of Plants," MRID 49307513. JX 58 (DER for MRID 49307513).

27. The DER for this study, JX 58, having a last signature December 10, 2021 from and EFED reviewer but a last signature date of December 22, 2016 from EPA's contract reviewer (Dynamac) concluded that, of the ten crops tested, the study was acceptable for all except lettuce. The lettuce portion of the study is classified as "supplemental and may be used for risk characterization only". Further, EFED concluded that if application rates result in higher estimated exposure concentrations than the concentration tested in this study, additional data may be required for lettuce (only). JX 58.

28. In a January 6, 2022 Memorandum from EFED to PRD, EFED concluded that the Terrestrial Vascular Plant Seedling Emergence study, MRID 49307513, is acceptable for all tested crops, except lettuce and ryegrass. The study was graded as supplemental for lettuce and ryegrass and may be used (1) to calculate risk quotients for ryegrass and (2) for risk characterization for lettuce. The memorandum stated that only lettuce requires additional testing. JX 59 (an attachment to JX 57).

29. AMVAC has taken appropriate steps to determine if it should begin further testing for lettuce since receiving the January 6, 2022 Memorandum, which was not received by AMVAC until April 27, 2022, *after* receipt of the NOITS. JX 57.

30. After receiving and reviewing the January 6, 2022, Memorandum, JX 59,

AMVAC immediately contacted the responsible laboratory and requested that it review the Agency's assessment.

31. It appears that there may be a discrepancy relevant to lettuce between the dose range finding study and the definitive study. AMVAC has contacted the responsible contract laboratory and awaits its input concerning EPA's DER evaluation.

32. These questions could have been addressed (or even a new study run, if needed, or other appropriate action taken) in the intervening time frame between EPA's contractor's initial review (2016) and the date that AMVAC was made aware of EPA's conclusions (concurrent with the NOITS).

The DCPA Chronic Sediment Toxicity Chironomus Special Study

33. AMVAC has worked diligently to address the SS-1069 (non-guideline) Chronic Sediment Toxicity – *Chironomus dilutus* ecological effects data requirement, for which it indicated in the Initial Response to the DCI that it would develop new data. JX 5.

34. The designation "SS" means a "special study" for which there are no established EPA data requirements under 40 C.F.R. Part 158, no OSCPP Testing Guidelines, and no standardized protocols for use in conducting the study.

35. AMVAC's April 29, 2013, Initial Response to the DCI included three proposed protocols to address chronic sediment toxicity testing of *Chironomus dilutus* (ss-1069), *Hyalella azteca* (ss-1066), and *Leptocheirus plumulosus* (ss-1072). JX 5.

36. On October 20, 2014, EPA provided AMVAC with the Agency's response to these protocols, "DCPA (Chlorthal-dimethyl): Review of Study Protocols for Determining Chronic Toxicity to Sediment-Dwelling Estuarine/Marine and Freshwater Organisms." JX 60 at 1.

37. EPA's protocols review was dated March 20, 2014, but was not provided to AMVAC until October 20, 2014. JX 60 (Attachment I).

38. On December 15, 2014, AMVAC submitted detailed responses to EPA's protocols review and submitted updated full protocols for Agency review that addressed the Agency's comments. JX 60.[1]

39. On March 19, 2015, EPA confirmed approval of the revised protocols, including for the SS-1069 data requirement. JX 61.

40. AMVAC submitted "Sediment Chronic Toxicity Testing – ss-1069, Life Cycle Chronic Toxicity Test, *Chironomus dilutus*, MRID No. 49865802" on March 15, 2016. JX 62.

41. An EFED DER, last signed December 1, 2021, "Data Evaluation Record, Life-Cycle Sediment *Chironomus dilutus* Toxicity Test, MRID No. 49865802," assessed MRID 49865802 as "scientifically sound" and classified it as "supplemental" because of potential solvent control issues. This document had a last signature date of January 6, 2017 from EPA's contract reviewer (CDM Smith/CSS-Dynamac JV). JX 63.

42. On April 27, 2022, EPA transmitted the EFED DER referenced above to AMVAC (after issuing the NOITS). JX 57. (April 27 email from J. Douglass to N. McMahon); JX 63 (attachment to JX 57).

43. AMVAC is reviewing the DER and is working with the performing lab to investigate the solvent control issue and compile additional information/data regarding the conduct of the study.

44. These questions could have been addressed (or even a new study run, if needed,

[1] This is incorrectly characterized in the NOITS as a notification by AMVAC that the final protocol report for SS-1069 would be submitted by June 15, 2016. AMVAC submitted the protocol on December 15, 2014, and in that protocol proposed the final study date would be June 15, 2016, provided the EPA approved the protocol in a timely manner.

or other appropriate action taken) in the intervening time frame between EPA's contractor's initial review (2017) and the date that AMVAC was made aware of EPA's conclusions (concurrent with the NOITS)

The TPA Fish Early Life Stage Studies

45. As discussed above, AMVAC advised EPA in its Initial Response to the DCI that it would submit existing data to satisfy the Fish Early Life Stage studies for the TGAI, DCPA. JX 5.

46. With regard to the metabolite, TPA, AMVAC proposed to defer performance of the Fish Early Life Stage Studies until EPA's review of the DCPA study was complete, after which EPA could determine if endpoints experimentally determined for DCPA may be utilized to waive the required TPA studies. JX 5.

47. AMVAC's proposal to sequence the testing in this manner was made after a specific invitation from EPA (made in EPA's May 31, 2011, document titled, "Registration Review – Preliminary Problem Formulation for the Ecological risk Assessment of Dimethyl 2,3,5,6-Tetrachlorophthalate (DCPA)") (the "DCPA Preliminary Problem Formulation") (JX 65), to consider such a strategy.

48. The DCPA Preliminary Problem Formulation specifically stated that "a more limited testing strategy [for the metabolite TPA] will be considered *in lieu* of a comprehensive data submission if one is proposed." JX 65.

49. EPA has, in several documents, accepted the contention that certain data for DCPA can be applied to TPA, and that risk assessment can proceed in the absence of TPA-specific data, even if this leads to conservative results for purposes of risk assessment, as discussed in more detail in the sections concerning each data requirement, below. EPA has

nonetheless refused to grant waivers for certain of the TPA ecological effects studies referenced in the NOITS.

50. EPA also stated in the DCPA Preliminary Problem Formulation that it could complete a risk assessment for DCPA even without the TPA-specific data, though it would have to "make highly conservative assumptions when evaluating the toxicity of TPA." JX 65.

51. In view of EPA's statements in the DCPA Preliminary Problem Formulation, AMVAC's request to defer the TPA fish early life-stage toxicity tests pending completion of the DCPA analysis was reasonable and an appropriate step.

52. EPA addresses AMVAC's request to defer the TPA fish early life-stage toxicity tests pending completion of the DCPA analysis in a memorandum dated March 21, 2014. JX 66.

53. EPA's March 21, 2014, response was not provided to AMVAC by EPA until March 27, 2017, three years after it was dated.[2] JX 36 (email); JX 66 attachment). So as to provide the proper context for AMVAC's subsequent actions in response, the March 21, 2014, response, (JX 66), will be referred to as the March 2017 Waiver Response.

54. Thus, EPA did not even internally conclude its consideration of AMVAC's timely submitted waiver request (submitted with AMVAC's 90-day Initial Response, JX 5) until after the nominal 12-month timeframe EPA had provided for in the DCI had elapsed. EPA then failed to provide evidence of its internal conclusion on the timely submitted waiver until more than three years after the DCI timeframe had elapsed. This sequence of events contributed to AMVAC's understanding that there was no need to seek formal extensions of EPA's nominal time frames for study completion in the DCI.

55. The March 2017 Waiver Response denied AMVAC's request to completely defer

[2] AMVAC does not have an explanation for EPA's delay in providing these materials, although the provision of the 2014 documents in 2017 coincided with a change in Chemical Review Managers at EPA.

the TPA fish early life-stage toxicity tests until the DCPA studies were completed, contrary to direction given in the preliminary work plan. JX 66.

56. However, instead of simply insisting that AMVAC proceed with the Guideline 850.1400 studies for the three species that EPA now lists in the NOITS (rainbow trout, bluegill sunfish, and sheepshead minnow), EFED raised an alternative ("one possible solution is conducting a limited set of toxicity tests … for TPA (for example, an acute and chronic toxicity study in daphnids); and depending on the results of these initial studies, a full suite … may or may not be subsequently required.") JX 66.

57. The proposed condition on using DCPA study data for TPA referenced had not previously been proposed by EPA.

58. On February 22, 2018, AMVAC provided a response to the March 2017 Waiver Response (the "February 2018 Waiver Correspondence"). JX 67. 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."

59. AMVAC proceeded to collect and or conduct acute a chronic *Daphnia Magna* TPA toxicity test data that would permit a comparison with DCPA data as it understood the Agency to have proposed.

60. Given that AMVAC was at this time proceeding down an *alternate* path suggested for it by EPA, AMVAC would have had no reason to believe it was not taking appropriate steps, within a timeline dictated and understood by EPA, to comply with the DCI requirements.

61. On December 17, 2020, AMVAC submitted to EPA a document entitled

Tetrachloroterephthalic Acid (TPA): Selected Ecological Study Waiver Request ("The December 2020 Waiver Analysis"). JX 22. The December 2020 Waiver Analysis provided a table showing DCPA and TPA endpoints derived from various studies, including the two studies specified by EPA for assessing the relative ecotoxicology between DCPA and TPA, the acute and chronic daphnia studies, and explained, in detail, why AMVAC concluded that TPA demonstrated a lower toxicity than DCPA and therefore the data generated as of that time should be sufficient for EPA's risk assessment purposes and EPA should not require any further Guideline 850.1400 studies of TPA.

62. This was precisely the approach that EPA had laid out in the DCPA Preliminary Problem Formulation in 2011, (JX 65), and again in the March 2017 Waiver Response (JX 66).

63. AMVAC did not receive any response from EPA concerning AMVAC's December 2020 Waiver Analysis until it received EPA's "Response to Data Waiver Requests for Ecological Effects Related Data for Dimethyl 2,3,5,6-Tetrachloroterephthalate (DCPA) and Its Degradate Tetrachlorophthalic Acid (TPA)," (JX 69, dated April 19, 2022), which was not sent to AMVAC by EPA until April 27, 2022 (concurrent with the NOITS). JX 57.

64. Because the 2022 EPA Ecological Effects Waiver Response, (JX 69), was not received by AMVAC until the same day AMVAC received the NOITS, AMVAC therefore did not have any opportunity to discuss EPA's conclusions in the 2022 EPA Ecological Effects Waiver Response with EPA personnel prior to the issuance of the NOITS.

65. The 2022 EPA Ecological Effects Waiver Response, (JX 69), granted AMVAC's requests for waivers in connection with six Guideline requirements, demonstrating that EPA was still actively reviewing and approving waiver requests.

66. The 2022 EPA Ecological Effects Waiver Response, (JX 69), denied AMVAC's

request for a waiver based on the TPA/DCPA endpoint comparison approach EPA had previously suggested. EPA stated that EFED had "reconfirmed the need for chronic freshwater and estuarine/marine fish toxicity studies for TPA" based on a review of three MRIDs (49307520, 48670304, and 48670303). JX 69.[3]

67. EPA thus did not advise AMVAC until 2022, the same day as the NOITS was transmitted, that the path EPA had set AMVAC upon for the Guideline 850.1400 TPA data from the outset would not satisfy EPA in view of DCPA studies that EPA had been in possession of since 2012 and 2014 (that is, the three MRIDs noted in the previous paragraph).

68. The 2022 EPA Ecological Effects Waiver Response, JX 69, states that EPA is able to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects in the absence of the Guideline 850.1400 TPA data so long as the Guideline 850.1400 DCPA data is available. As stated in Paragraph 17, one of these studies has already been submitted and the other will be submitted in mid-July.

69. Based on the 2022 EPA Ecological Effects Waiver Response, JX 69, received the same day as the NOITS, and despite the fact that EPA has indicated that additional data is not needed to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects standard, AMVAC is prepared to run the sheepshead minnow Guideline 850.1400 TPA study per EPA's instructions because the DCPA results have indicated that species to be the most sensitive. AMVAC expects these results will be available in 2023. AMVAC's response to the DCI was appropriate in view of the circumstances and its decision to proceed with this study reflects information not received from EPA until concurrent with the NOITS.

[3] EPA provided no technical justification for this position in JX 69. The position is also contrary to EPA's conclusion that marine/estuarine species would likely be more sensitive to TPA than would freshwater species. That strategy though adopted for algal species that permitted certain waivers, was not adopted for the fish. This decision is therefore counterintuitive to the strategy design originally promoted by EPA.

The TPA Tier I/II Algal Toxicity Test and Mysid Chronic Toxicity Study

70. AMVAC advised EPA in its April 29, 2013, Initial Response that it would develop new data to satisfy the Algal Toxicity Test, Tier I/II data requirement under OSCPP Guideline 850.5400 and the Mysid Chronic Toxicity data requirement under OSCPP Guideline 850.1350 for the TGAI, DCPA, but it requested a waiver for corresponding data requirements for DCPA's primary metabolite, TPA. JX 5.

71. AMVAC specifically proposed to defer these two TPA studies and perform the assessments for TPA using the endpoints determined in the corresponding DCPA studies. JX 5.

72. AMVAC's proposal to sequence the testing in this manner was made in view of a specific invitation from EPA in the DCPA Preliminary Problem Formulation, (JX 65), to propose such a strategy.

73. The DCPA Preliminary Problem Formulation specifically stated that "a more limited testing strategy [for the metabolite TPA] will be considered *in lieu* of a comprehensive data submission if one is proposed." JX 65.

74. EPA has, in several documents, accepted the contention that certain data for DCPA can be applied to TPA, and that risk assessment can proceed in the absence of TPA-specific data, even if this leads to conservative results for purposes of risk assessment, as discussed in more detail in the sections concerning each data requirement, below. EPA has nonetheless refused to grant waivers for certain of the TPA ecological effects studies referenced in the NOITS.

75. EPA also stated in the DCPA Preliminary Problem Formulation that it could complete a risk assessment for DCPA even without the TPA-specific data, though it would have to "make highly conservative assumptions when evaluating the toxicity of TPA." JX 65.

76. In view of EPA's statements in the DCPA Preliminary Problem Formulation, JX 65, AMVAC's request to defer the TPA Tier I/II Algal Toxicity test and the Mysid Chronic Toxicity test pending completion of the DCPA analysis was reasonable and appropriate.

77. EPA first responded to AMVAC's request to defer the TPA Tier I/II Algal Toxicity test and the Mysid Chronic Toxicity test pending completion of the DCPA analysis in the March 2017 Waiver Response, JX 66, which AMVAC received on March 27, 2017.

78. EPA did not even internally conclude its consideration of AMVAC's timely submitted waiver request (submitted with AMVAC's 90-day Initial Response, JX 5) until after the nominal 12-month timeframe EPA had provided for in the DCI had elapsed. EPA then failed to provide evidence of its internal conclusion on the timely submitted waiver until more than three years after the DCI timeframe had elapsed. As noted above, this sequence of events contributed to AMVAC's understanding that there was no need to seek formal extensions of EPA's nominal time frames for study completion in the DCI.

79. The March 2017 Waiver Response denied AMVAC's request to completely defer the TPA Tier I/II Algal Toxicity test and the Mysid Chronic Toxicity until the DCPA study was completed. However, instead of simply insisting that AMVAC proceed with these studies, EFED raised an alternative ("one possible solution is conducting a limited set of toxicity tests … for TPA (for example, an acute and chronic toxicity study in daphnids); and depending on the results of these initial studies, a full suite … may or may not be subsequently required.") JX 66.

80. On February 22, 2018, AMVAC provided the February 2018 Waiver Correspondence, JX 67, in which 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."

81. AMVAC proceeded to collect and or conduct acute and chronic *Daphnia Magna* TPA toxicity test data that would permit a comparison with DCPA data as it understood the Agency to have proposed.

82. The December 2020 Waiver Analysis provided a table showing DCPA and TPA endpoints derived from various studies and explained, in detail, why AMVAC concluded that TPA demonstrated a lower toxicity than DCPA and therefore the data generated as of that time should be sufficient for EPA's risk assessment purposes and EPA should therefore not require a Guideline 850.5400 (now known as 850.4500) Tier I/II Algal Toxicity study, or a Mysid Chronic Toxicity study (Guideline 850.1350) for TPA. JX 22.[4]

83. AMVAC did not receive any response from EPA concerning the December 2020 Waiver Analysis until it received the 2022 EPA Ecological Effects Waiver Response. JX 69.

84. The 2022 EPA Ecological Effects Waiver Response was received by AMVAC the same day as the NOITS, and AMVAC therefore did not have any opportunity to discuss EPA's conclusions in the 2022 EPA Ecological Effects Waiver Response with EPA personnel prior to the issuance of the NOITS.

85. The 2022 EPA Ecological Effects Waiver Response granted AMVAC's requests for waivers in connection with six Guideline requirements, demonstrating that EPA was still

[4] The record of AMVAC's waiver requests demonstrates that the waiver requests did provide updated information responsive to developments in data availability and AMVAC's understanding of EPA's concerns. For example, the February 22, 2018 waiver requests modified AMVAC's position in response to EPA's proposal for conducting acute and chronic studies on daphnia. The December 17, 2020 waiver requests provided a comparative assessment of DCPA and TPA ecotoxicological studies including the two studies specified by EPA for assessing the relative ecotoxicology between DCPA and TPA, the acute and chronic daphnia studies. In 2022, EPA agreed with some of the positions advanced in prior waiver requests regarding certain algal studies. The focus of the NOITS on the studies for which EPA has ultimately not been persuaded by AMVAC's arguments obscures that EPA has accepted many waiver requests, even after some back and forth. For example, in the case of the DCPA terrestrial dissipation study requirement 835.6100, when the initial request for waiver was initially denied and EPA provided some detail relating to their concerns, a more comprehensive response to these points was provided in AMVAC's 2020 renewed waiver response (MRID 51398101) and the agency ultimately granted the waiver. AMVAC's requests were always scientifically justified and intended to prevent needless waste of company and Agency resources.

actively reviewing and approving waiver requests. JX 69.

86. The 2022 EPA Ecological Effects Waiver Response, JX 69, partially denied (with regard to tests on marine diatoms) and partially granted (with respect to all other species) AMVAC's request for a waiver of Tier I/II Algal Toxicity and Mysid Chronic Toxicity data requirements based on the TPA/DCPA endpoint comparison approach EPA had previously suggested.

87. With regard to the Tier I/II Algal Toxicity and Mysid Chronic Toxicity data requirement, EPA stated in the 2022 EPA Ecological Effects Waiver Response, JX 69, that, because "[t]he marine diatom was the most sensitive species tested for DCPA," using the "endpoint from MRID 49307504 for both DCPA and TPA … may overestimate the toxicity of TPA to aquatic plants and yield uncertain risk conclusions[.]" JX 69.

88. With regard to the Mysid Chronic Toxicity data requirement, EPA stated in the 2022 EPA Ecological Effects Waiver Response, JX 69, that, "in the absence of TPA chronic mysid toxicity data, the Agency will rely on the submitted data for DCPA" which may "overestimate the toxicity of TPA and therefore, the potential risks." JX 69.

89. EPA thus does not state in the 2022 EPA Ecological Effects Waiver Response, JX 69, that its ability to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects standard will be compromised as a result of lacking the Guideline 850.4500 TPA marine diatom data or the Guideline 850.1350 Mysid Chronic Toxicity, only that it will have to use a conservative endpoint that might overestimate toxicity (that is, yield a conservative risk analysis).

90. I understand that AMVAC representatives are contacting EPA to discuss an appropriate response to the 2022 EPA Ecological Effects Waiver Response, JX 69, as it relates to

the Guideline 850.4500 marine diatom TPA study and the Guideline 850.1350 Mysid Chronic Toxicity TPA study.

The TPA Environmental Fate Data Requirements

91. The following two sections discuss an Aerobic Aquatic Metabolism Study (Guideline 835.4300) and two Anaerobic Metabolism Studies (Guidelines 835.4200 and .4400) that are listed as outstanding in the NOITS.

92. For all three studies, EPA has only recently conceded that a study longer than that called for in the guideline may be required, JX 69, as AMVAC has maintained for some time. JX 5, discussing MRID 49115401.

93. Based on this alone, EPA has conceded that the Guideline requirements it initially imposed do not apply.

94. Additionally, without these studies, the risk assessment will assume TPA to be fully stable, which is what the current data records already indicate; therefore, the assessment will not be overly conservative on this point as EPA asserts in its April 19, 2022, memorandum. JX 79.

95. If a risk assessment indicates a concern based on this assumption, the appropriate course is for EPA to require a higher tier study, not to attempt to re-write the previously referenced Guideline requirements into a higher tier study.

The TPA Aerobic Aquatic Metabolism Study

96. For TPA, AMVAC proposed in its Initial Response to the DCI to defer performance of the Aerobic Aquatic Metabolism Study until EPA's review of the DCPA study was complete, after which AMVAC would be able to use the data developed for TPA within that study for addressing the data requirement for TPA. JX 5.

97. EPA first responded to AMVAC's request to defer the Guideline 835.4300 data requirement in the March 2017 Waiver Response, JX 66, which AMVAC received on March 17, 2017. JX 36.

98. Thus, EPA did not even advise AMVAC that AMVAC's timely submitted waiver request (submitted with AMVAC's 90-day Initial Response in April of 2013, JX 5) was initially denied until after the nominal 24-month timeframe EPA had provided for in the DCI had elapsed.

99. EFED observed in the March 2017 Waiver Response that TPA was a residue of concern with a 100% conversion rate from DCPA and EFED recommended PRD deny the deferral request on that basis. JX 66.

100. In February of 2018, AMVAC responded that "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.

101. AMVAC now recognizes that its response, as set forth above, did not adequately convey its position and intent regarding this data requirement. Although the introduction to the language above states that it is a "*Rebuttal* to EPA's March 21, 2014 memorandum [received in March 2017]" (emphasis added), AMVAC understands why its response may have been construed by the Agency as an indication that a new aerobic aquatic study would be conducted and submitted for TPA.

102. AMVAC itself only realized that the wording of its response did not clearly

convey its intent during its technical staff's ongoing review of the communications implicated by the NOITS.

103. AMVAC's intent was to direct the agency to a previously submitted study, MRID 49307515, Nelson, T. (1984) An Aerobic Aquatic Soil Metabolism Study with (Carbon 14)-Dacthal. Unpublished study prepared by SDS Biotech Corporation. 44 p.

104. This was the same study that AMVAC submitted to EPA in January of 2014 to fulfil the DCPA Guideline 835.4300 requirement, which is no longer outstanding.

105. This study assesses the aerobic aquatic metabolism of DCPA also provides relevant data concerning the stability of TPA under aerobic aquatic conditions. It attests to the stability of TPA over the 90-day course of the study, thereby demonstrating the lack of value in conducting a separate study for the degradate.

106. AMVAC's February 2018 response reflected AMVAC's belief that the Agency had not realized that MRID 49307515 was intended to address both DCPA and TPA and AMVAC's intent. JX 66, received by AMVAC in March 2017, did not reference MRID 49307515 in the section discussing Guideline 835.4300 for TAP. AMVAC's intent in February 2018 was to clarify that the Agency should evaluate the satisfaction of Guideline 835.4300 for TPA in view of the MRID 49307515 that had already been submitted.

107. AMVAC now fully understands that its response not clearly convey this intent. AMVAC never intended to commit (in 2018) to conduct a new study for TPA. AMVAC had always intended to use the MRID 49307515 DCPA study for fulfilling this requirement and regrets that a clerical error led to a misunderstanding concerning its intent.

108. AMVAC is hopeful that the Agency will review MRID 49307515 and concur that a separate aerobic aquatic study for TPA is not required.

The TPA Anaerobic Metabolism Studies

109. AMVAC advised EPA in the April 29, 2013, Initial Response that it would cite existing data, specifically, "Anaerobic Soil Metabolism of Dacthal," Duane, W. C. (MRID 114651), to satisfy the Guideline 835.4200 Anaerobic Soil Metabolism data requirement. JX 5.

110. Also, in the Initial Response, AMVAC advised EPA that, just as EPA had concluded that the Guideline 835.4400 data requirement was satisfied for DCPA, data available from an existing study should be deemed sufficient for addressing Guideline 835.4400. JX 5.

111. EPA first responded to AMVAC's contention that the Guideline 835.4400 data requirement should be deemed satisfied in the March 2017 Waiver Response, JX 66, which AMVAC received on March 17, 2017.

112. Thus, EPA did not advise AMVAC that AMVAC's timely submitted waiver requests for the Guideline 835.4400 study for TPA (submitted with AMVAC's 90-day Initial Response in April of 2013, JX 5) was initially denied until after the nominal 24-month timeframe EPA had provided for in the DCI had elapsed.

113. The March 2017 Waiver Response denied AMVAC's request to waive the Guideline 835.4400 data requirement, stating that "understanding the dissipation of TPA is a critical risk assessment question." JX 66. However, there was no comment to the technical points that AMVAC had made previously concerning the availability of existing TPA data.

114. EPA addressed AMVAC's request to waive the Guideline 835.4200 data requirement in a separate document dated February 7, 2017 (the "February 2017 E-Fate Response"). JX 77.

115. Thus, as with the Guideline 835.4400 and others referenced above, EPA did not advise AMVAC that AMVAC's timely submitted waiver requests for the Guideline 835.4200

study for TPA (submitted with AMVAC's 90-day Initial Response in April of 2013, JX 5) was initially denied until after the nominal timeframe EPA had provided for in the DCI had elapsed.

116. In the February 2017 E-Fate Response, EPA stated that EFED "believe[d] that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment," but stated that EFED "will [conservatively] assume stability [for risk assessment purposes] in the absence of a [TPA Guideline 835.4200] study." JX 77.

117. In the February 2018 Waiver Correspondence, JX 67, AMVAC requested that EPA "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 substantiate AMVAC's contention that TPA would not be degraded under anaerobic conditions in any way that would be observed in a Guideline 835.4400 study. AMVAC requested that EPA reconsider its requirement for a Guideline 835.4400 study after reviewing these materials in light of AMVAC's further comments.

118. In December 2020, having received no formal response from EPA to the February 2018 Waiver Correspondence providing further information concerning why Guidelines 835.4200 and 835.4400 should be waived for TPA, AMVAC provided additional information in support of its waiver requests (the "December 2020 E-Fate Waiver Analysis"). JX 78.

119. AMVAC did not receive any response from EPA concerning the December 2020 E-Fate Waiver Analysis until it received the 2022 EPA E-Fate Waiver Response. JX 79 (dated April 19, 2022).

120. The 2022 EPA E-Fate Waiver Response, JX 79, was received by AMVAC the same day as the NOITS, and AMVAC therefore did not have any opportunity to discuss EPA's

conclusions therein with EPA personnel prior to the issuance of the NOITS.[5]

121. The 2022 EPA E-Fate Waiver Response, JX 79, granted AMVAC's requests for waivers in connection with the Terrestrial Field Dissipation requirements for DCPA and TPA, demonstrating that EPA was still actively reviewing and responding to waiver requests.

122. The 2022 EPA E-Fate Waiver Response denied AMVAC's request for a waiver of the Guideline 835.4200 and 835.4400 anaerobic soil and aquatic metabolism data requirements.

123. With regard to the Guideline 835.4200 anaerobic soil metabolism data requirement, EPA conceded that "a longer-than-standard study duration might be needed to quantify the potential anaerobic metabolism of TPA" in soil. EPA further stated that "EFED will continue to assume stability of TPA in [soil]," even though doing so "may overestimate TPA's actual persistence[.]" JX 79. Thus, EPA can proceed with its risk assessment, but the results will be conservative, as EPA had stated in the February 2017 E-Fate Response. JX 77.

124. For the Guideline 835.4400 anaerobic aquatic metabolism data requirement, EPA conceded that "a longer-than-standard study duration may be needed to quantify the potential anaerobic metabolism of TPA" in water. JX 79. EPA stated that even in the absence of Guideline 835.4400 anaerobic aquatic metabolism data, it could conservatively assume that TPA is stable for purposes of drinking water and ecological aquatic risk assessment purposes – a "conservative assumption may overestimate TPA's actual persistence[.]" JX 79.[6]

125. EPA's refusal to waive the data requirements given that it is able to proceed with

[5] Further, the EPA did not provide any comment on the technical points AMVAC has made in previous submissions concerning the availability of TPA data from the DCPA study reports and literature data that supported the contention that TPA would not degrade within the test systems required by EPA guidelines.

[6] EPA's response fails to consider the information submitted previously from AMVAC. An accurate half-life determination could not be made even when implementing a study extension such as the one EPA now discusses. Laboratory test systems may lose viability over time periods that extend past the guideline stated period.

risk analysis (despite having to employ conservative assumptions) is arbitrary. EPA has essentially accepted the initial premise of AMVAC's initial waiver requests, which was that the required studies would not demonstrate degradation of TPA in the respective media over the time horizon of the studies. EPA acknowledged that "longer-than-standard" studies might be needed only concurrently with the NOITS.

126. To summarize the overall time frames for the Guideline 835.4400 and Guideline 835.4200 studies, AMVAC submitted timely waiver requests in April 2013 to the January 2013 DCI. AMVAC then waited almost four years for a response (February and March, 2017). AMVAC then provided clarifying technical details in February of 2018 in the form of supplemental waiver requests. Having received no response for more than two years, AMVAC provided additional information on its own initiative in December of 2020. No response was provided until April of 2022, concurrent with EPA's NOITS. AMVAC has thus been waiting for a response from EPA for approximately 96 of the 108 months (8 out of 9 years, April 2013 – April 2022, excepting February 2017-2018) since AMVAC's timely 90-day response.

The Leptocheirus Chronic Sediment Toxicity Study

127. Information concerning AMVAC's interactions with EPA related to the data requirement discussed in this section prior to the events discussed below is provided in the written statement of my colleague Julie Porter.

128. On March 7, 2016, AMVAC supplied a supplementary waiver request that discussed the relative sensitivity of amphipods and midges for the purpose of considering the value of the Leptocheirus study. The information also indicates the insensitivity of DCPA to survival effects in sediment dwelling organisms, providing additional evidence that the study proposed by the Agency would provide no useful information.

129. In November 2016, AMVAC supplied a supplementary waiver request to EPA that provided additional literature information concerning the expectation for DCPA in estuarine sediments and an assessment of the likely effect of toxicity to sediment organisms such as Leptocheirus. JX 76.

130. The supplementary waiver request, which was assigned MRID 50116601, provided 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 (inter alia, because available results for water-column species are expected to be protective of sediment dwelling amphipods) and also explained why EPA's proposed 10-day OCSPP 850.1740 study would not be useful for risk assessment.

131. EPA has never responded to the November 2016 supplementary waiver request which was assigned MRID 50116601. Only the AMVAC March 2016 waiver request is discussed (MRID49865803) in EPA's 2022 EPA Ecological Effects Waiver Response (JX 69).

132. AMVAC's February 2018 Waiver Correspondence, JX 67 (February 22, 2018), indicated that AMVAC had still not received a response in connection with EPA's "Action Item" from the March 17, 2017, phone meeting to confirm with EFED whether "a clean/negative 10-day study negates the need for the 21-day study" as stated in the Action Items related to the March 17, 2017 call. JX 33.

133. On October 16, 2020, EPA transmitted correspondence to AMVAC concerning the data requirements from the DCI. JX 21. EPA advised that, with regard to the Leptocheirus data requirement, the "[w]aiver request [was] 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."

134. This recognized that some requirements of the chronic study Guideline are still not validated and EPA had therefore requested that AMVAC conduct an acute study in the interim.

135. On December 17, 2020, AMVAC responded to EPA's October 16, 2020 correspondence. AMVAC stated it would "await a specific DCI requirement for [the Leptocheirus] acute study [i.e., the Guideline 850.1740 spiked whole sediment 10-day toxicity test] or will wait for confirmation that the chronic study guideline has been validated." AMVAC further stated, "[c]onsidering the very low toxicity associated with DCPA to aquatic organisms, AMVAC believes that this delay will not impact the Agency's conclusions concerning sediment dwelling organisms that can be made based on the available studies." JX 22.

136. AMVAC did not receive further written communication from EPA in response to its December 17, 2020 correspondence until EPA's 2022 EPA Ecological Effects Waiver Response obtained concurrently with the NOITS. JX 69.

137. EPA's 2022 EPA Ecological Effects Waiver Response, JX 69, was received by AMVAC the same day as the NOITS, and AMVAC therefore did not have any opportunity to discuss EPA's conclusions in the 2022 EPA Waiver Response with EPA personnel prior to the issuance of the NOITS.

138. EPA's requested 10-day acute study is not listed on the 2013 DCI and represents a new requirement. As there is currently no validated protocol for the chronic special study envisioned by EPA in the DCI.[7] The Agency should issue a new DCI for the acute study if it

[7] Laboratories in general have had difficulty maintaining this organism through its lifecycle as needed for chronic testing. EPA looked to the efforts of the Society of Environmental Toxicology and Chemistry ("SETAC") for developing an acceptable protocol, but that effort was unsuccessful, as I understand from a conversation with Smithers Laboratory. It is my understanding that EPA has generally moved to change this requirement on all of its DCIs where the chronic study was requested and that future DCIs also adopted this change to request the acute study.

wants to substitute it for the chronic study.

Authenticity of Exhibits

139. I have reviewed JX 73 and 78. These exhibits are true and correct copies of documents generated, transmitted, or received by me in the course of my employment with AMVAC. To the extent I cite JX or PAX exhibits in my testimony that are not listed above, I have conferred with other AMVAC fact witnesses who have confirmed that those exhibits are true and correct copies of documents generated, transmitted, or received by them in the course of their employment with AMVAC.

I, Richard S. Freedlander, declare under penalty of perjury under the laws of the United States that the statements contained in the written statement above are true and correct to the best of my knowledge. Executed this 17th day of June 2022.

/s/ *Richard S. Freedlander*
Richard S. Freedlander

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Verified Written Statement of AMVAC Fact Witness Richard S. Freedlander**, was served on the following parties today, June 17, 2022, as indicated below.

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

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

Copies by Electronic Mail to:

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

Counsel for Respondent

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

Counsel for Grower Petitioners