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; 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

January 9, 2023

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 as a Senior Residue Chemistry Group Leader for ICI America. From 1987 to 1998, I worked as a Manager of Regulatory Chemistry for Pennwalt/Elf Atochem. From 1998 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 TPA Ecotox Studies

8. With regard to TPA, AMVAC initially proposed to defer performance of the Fish Early Life Stage Studies (Guideline 850.1400), the Chronic Mysid (Guideline 850.1350) and the Algal Tox (Guideline 850.4500) (collectively, the "TPA Ecotox Studies") until EPA's review of the suite of DCPA studies was complete, after which EPA could determine if endpoints experimentally determined for DCPA may be utilized to waive the required TPA studies. Joint Exhibit ("JX") 5.

9. AMVAC's proposal to sequence the testing in this manner was made after a specific invitation from the U.S. Environmental Protection Agency ("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.

10. 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.

11. 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.

12. 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.

13. In view of EPA's statements in the DCPA Preliminary Problem Formulation, AMVAC's request to defer the TPA Ecotox Studies pending completion of the DCPA analysis was reasonable and an appropriate step, as were its subsequent efforts in connection with the acute and chronic daphnia studies suggested by the EPA Environmental Fate and Effects Division ("EFED"), discussed in more detail below.

14. EFED addresses AMVAC's request to defer the TPA Ecotox Studies pending completion of the DCPA analysis in a memorandum dated March 21, 2014. JX 66.

15. EFED's March 21, 2014, memorandum was not provided to AMVAC by EPA until March 27, 2017, three years after it was dated.[1] JX 36 (email); JX 66 (attachment).

16. 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 delay 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.

17. JX 66 stated that EFED was recommending that PRD deny AMVAC's request to completely defer the TPA Ecotox Studies until the DCPA studies were completed. JX 66.

18. However, instead of simply insisting that AMVAC proceed with the TPA Ecotox Studies, EFED raised an alternative ("one possible solution is conducting a limited set of toxicity

[1] 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.

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.

19. The specific proposed condition of conducting an acute and chronic daphnid study on TPA first, after which EFED would re-evaluate that data as set forth in JX 66, had not previously been proposed by EPA to AMVAC before AMVAC received a copy of JX 66 in 2017, though it was consistent with the concept stated in the Preliminary Problem Formulation that a "more limited testing strategy" for TPA might suffice.

20. On February 22, 2018, AMVAC responded to JX 66. 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." EPA never acknowledged this statement and did not refer to it in the Data Delay Letter, JX 21, which instead referenced EFED reviews predating JX 67.

21. 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.

22. Specifically, AMVAC compiled the results of a 2003 acute (MRID 49307519) and a 2019 chronic (MRID 51235101) TPA study in daphnids.

23. The 2003 acute study had already been conducted to satisfy data requirements in Europe and had already been submitted in connection with the DCPA DCI in January 2014.

24. The 2019 chronic study (MRID 51235101) was commissioned after receiving EFED's memorandum in March of 2017 (JX 66). AMVAC obtained a quote from the laboratory that performed the study on August 15, 2017. AMVAC signed the quote on September 8, 2017.

Subsequently, the laboratory experienced delays obtaining the test substance (TPA) from a third party. The third-party related delays were resolved in February 2018 and the material was provided to the contracting laboratory, which proceeded to begin the study, officially initiating it on May 23, 2018. The study was completed on January 23, 2019.

25. AMVAC understood itself to be proceeding down the *alternate* path suggested for it by EFED in JX 66.

26. 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, PAX 45, 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 that EPA should not require the TPA Ecotox Studies.

27. The acute and chronic daphnia studies referenced in PAX 45 were deemed scientifically sound and acceptable in DERs with DP Barcodes 420874 and 460199, respectively.

28. This was precisely the approach that EFED had laid out in the DCPA Preliminary Problem Formulation in 2011, JX 65, and again in JX 66. That is, that a limited set of data might be acceptable (JX 65) and that limited set should specifically include acute and chronic daphnia studies (JX 66).

29. AMVAC did not receive any response from EPA concerning PAX 45 until it received the "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.

30. Because JX 69, was not received by AMVAC until the same day AMVAC received the NOITS, AMVAC therefore did not have any opportunity to discuss EFED's conclusions in JX 69 with any EPA personnel prior to the issuance of the NOITS.

31. In JX 69, EFED recommended granting AMVAC's requests for waivers in connection with six Guideline requirements. This demonstrated that EPA was still actively reviewing and approving waiver requests, including based, at least in part, on a review of the daphnia acute and chronic data discussed herein.

32. In JX 69, EFED recommended denying AMVAC's request for a waiver based on the TPA/DCPA endpoint comparison approach EPA had previously suggested.

33. With respect to the 850.1400 series Fish Early Life Stage studies, EFED stated that it had "reconfirmed the need for chronic freshwater and estuarine/marine fish toxicity studies for TPA" based on a review of the three DCPA studies MRIDs (49307520, 48670304, and 48670303). JX 69.[2]

34. These three MRIDs were submitted in January of 2014 (for 49307520) and in 2011 for the other two. As such, they were all available to EFED at the time EFED suggested the daphnia approach in JX 66.

35. With respect to the 850.4500 series TPA Algal Tox, EFED stated in April of 2022

[2] 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.

(in JX 69) that it was recommending waiving all species for this Guideline with the exception of the marine diatom. EFED stated that this was because "the marine diatom was the most sensitive algal species tested for DCPA," which was a reference to the results of MRID 49307504. As with the fish studies, above, EPA had been in possession of the study report with MRID 49307504 since January of 2014, which was prior to the time EFED suggested the daphnia approach in JX 66 (dated March 2014, provided to AMVAC March 2017).

36. With respect to the 850.1300 series Chronic Mysid TPA data requirement, EFED stated (in April of 2022, in JX 69) that it was recommending against waiving further TPA testing with mysid. EFED observed that, based on mysid DCPA data (MRID 49307512) it was concerned with mysid exposure to TPA because mysids were more sensitive to DCPA than daphnia on a chronic exposure basis. EFED further cited concerns with the lack of a definitive NOAEC in MRID 49307512.[3] As with the fish studies and diatom study, above, EPA had been in possession of the study report with MRID 49307512 since January of 2014, which was prior to the time EFED suggested the daphnia approach in JX 66 (document dated March 2014, provided to AMVAC March 2017).

37. 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, Guideline 850.1350, and Guideline 850.4500 TPA data would not satisfy EPA because of EPA's newly presented interpretation of DCPA studies that EPA had been in possession of since 2011 and

[3] EPA's concerns with the DCPA mysid study were not that DCPA was displaying significant toxicity but rather that there were solvent control issues that affected the interpretation of the results. AMVAC supplied additional information to EPA to address its concerns on October 14, 2022, as soon as it was able to obtain this information from the contracting laboratory. This additional information was assigned MRID 52026901. After receiving this additional information, OPP indicated that it was no longer alleging that AMVAC failed to take appropriate steps with respect to the DCPA Guideline 850.1350 study, though it did not state whether or to what extent the receipt of the additional information changed its view.

2014.

38. It was implicit in EFED's suggestion in JX 66 that "depending on the results of [and acute and chronic daphnia study for TPA], a full suite [of TPA ecotox studies] … may or may not be subsequently required" that AMVAC would have the opportunity to conduct any such studies if EPA determined that they were "subsequently required." AMVAC did exactly what EFED suggested – and EFED even determined after reviewing the acute and chronic daphnia data that some TPA ecotox studies were not "subsequently required." *See* JX 69 p. 2.

39. JX 69 states that EPA is able to conduct a risk assessment in the absence of the Guideline 850.1400 Fish ELS TPA data, using either "available supplemental data" cited in JX 69 or the Guideline 850.1400 DCPA data. All of the Guideline 850.1400 studies for DCPA have been submitted at this time.

40. With regard to the Tier I/II Algal Toxicity and Mysid Chronic Toxicity data requirement, EFED stated in 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[.]"

41. With regard to the Mysid Chronic Toxicity data requirement, EFED stated in 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."

42. JX 69 does not indicate that EFED's 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. It indicates only that absent those studies, EPA's evaluation will have to use a conservative endpoint that might overestimate toxicity (that is, yield a conservative risk analysis).

43. Based on my review, using the endpoints for DCPA for TPA (as AMVAC has suggested since its initial response could be done) only has the potential to overestimate risks for these three species categories. EFED never has, and does not now, point to any concern that TPA is in fact more toxic to any of these categories of species than DCPA. In any event, AMVAC followed EFED's suggestion to provide acute and chronic daphnia data for TPA. The fact that EFED articulated, contemporaneously with the NOITS, new concerns about the need for other TPA studies, based on data that had been available to it for years (and critically, prior to its statements laying out the daphnia strategy in JX 66), does not negate the fact that AMVAC's conduct was appropriate as to the TPA Ecotox studies remaining in this matter.

44. Exhibit A to my Verified Written Statement is a timeline that shows the dates of relevant communications, when they were transmitted, and other events relevant to the TPA ecotoxicology data requirements still at issue in this matter as set forth in my testimony above. It was prepared by counsel for AMVAC in this matter. I reviewed it and confirmed that it accurately shows the timing of the events it displays.

The TPA Environmental Fate Data Requirements

45. 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 and remain subjects of the pending hearing.

46. EFED has only recently conceded that metabolism studies longer than that called for in the guideline may be required, JX 79, as AMVAC has maintained for some time. *See* JX 5

(the relevant portion of which, "Residue, Environmental Fate, and Ecotoxicology Response for Non-Terrestrial Animals" was assigned MRID 49115401) (see p. 8 of 12 "TPA is quite stable over the duration of the guideline studies").

47. Based on this alone, EFED has conceded that the Guideline requirements initially imposed in the DCI do not apply and that AMVAC's waiver requests were meritorious.[4]

48. 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 EFED asserts in its April 19, 2022, memorandum. JX 79.

49. If a risk assessment indicates a concern based on this assumption, the appropriate course is for EPA to require a higher tier study, discuss appropriate mitigation measures with the registrant, or take other appropriate action under FIFRA, not to attempt to re-write the previously referenced Guideline requirements into a higher tier study.

The TPA Aerobic Aquatic Metabolism Study

50. 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.

51. EFED first responded to AMVAC's request to defer the Guideline 835.4300 data

[4] Also, in JX 69, EFED recommended granting requested waivers for DCPA and TPA Guideline 835.6100 Terrestrial Field Dissipation data requirements. AMVAC had sought to rely on previously submitted studies for these data requirements in its initial response, JX 5. EFED had construed this request as a request for a waiver (and recommended denying the request) in JX 66, the same document that addressed the other data requirements discussed in this section. AMVAC then submitted further information in support of the 835.6100 waivers in December of 2020 with its response to the Data Delay Letter. This shows that EFED was still open to reviewing (and recommending granting) waiver requests up until the time of the NOITS.

requirement in the March 2017 Waiver Response, JX 66, which AMVAC received on March 27, 2017. JX 36.

52. 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 not recommended by EFED to be accepted until after the nominal 24-month timeframe EPA had provided for in the DCI had elapsed.

53. EFED observed in JX 66 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. This study assesses the aerobic aquatic metabolism of DCPA and 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.

60. 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 TPA. 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.

61. AMVAC now fully understands that its response did 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. AMVAC had generally asserted that the 835-series Guideline studies for DCPA could be used to derive relevant information for TPA as to each Guideline (i.e., that TPA would be stable over the ordinary duration of the 835.4200, 835.4300, and 835.4400 guideline studies). In view of this,

EPA apparently was able to correctly reach the conclusion AMVAC was urging it to, that MRID 49307515 provided a basis for deriving stability of TPA, as discussed in more detail in the next paragraph.

62. In JX 79, which AMVAC received concurrently with the NOITS, EFED does refer to MRID 49307515 to derive a stable half-life for TPA (see note 2 on p. 5), which is consistent with AMVAC's assertion that MRID 49307515 (and DCPA metabolism studies generally) can be used for purposes of concluding that TPA is stable and would not degrade over the course of a Guideline study.

63. EFED's reference to MRID 49307515 in JX 79 also shows that, whether EFED's attention was called to MRID 49307515 by AMVAC, or whether EFED independently concluded that MRID 49307515 could be used to derive a stable half-life for TPA, EFED's review was not meaningfully impacted by the events discussed in Paragraphs 54-60.

The TPA Anaerobic Metabolism Studies

64. 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.

65. 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.

66. EFED 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 27, 2017.

67. 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 not recommended by EFED to be accepted until after the nominal 24-month timeframe EPA had provided for in the DCI had elapsed.

68. EFED stated in JX 66 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.

69. EFED 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.

70. JX 77 was not sent by EPA to AMVAC until concurrently with the Data Delay Letter, JX 21, in October of 2020.

71. Thus, as with the Guideline 835.4400 waiver request, EPA did not provide evidence to 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 not recommended by EFED to be accepted until after the nominal timeframe EPA had provided for in the DCI had elapsed.

72. In JX 77, EFED stated that it "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."

73. In 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.

74. In December 2020, having received no formal response from EPA to the JX 67 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 (JX 78).

75. AMVAC did not receive any response from EPA concerning the JX 78 until it received JX 79 (dated April 19, 2022).

76. 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]

77. JX 79 recommended granting 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.

78. JX 79 recommended denying AMVAC's request for a waiver of the Guideline 835.4200 and 835.4400 anaerobic soil and aquatic metabolism data requirements.

79. With regard to the Guideline 835.4200 anaerobic soil metabolism data requirement, EFED 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

[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.

actual persistence[.]" JX 79. Thus, EPA can proceed with its risk assessment, but the results will be conservative, as EFED had stated in JX 77.

80. For the Guideline 835.4400 anaerobic aquatic metabolism data requirement, EFED 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]

81. EPA's refusal to waive the data requirements given that it is able to proceed with 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. EFED acknowledged that "longer-than-standard" studies might be needed only concurrently with the NOITS.

82. 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 four or more years for a response (March 2017 for JX 66 and October 2020 for JX 77). AMVAC provided clarifying technical details in February of 2018 in the form of supplemental waiver requests. Having received no response for more than two years (apart from the October 2020 Data Delay Letter, and the EFED memorandum concerning 835.4200 only provided therewith), AMVAC provided additional information in December of

[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.

2020.

83. JX 79 presents a partial risk assessment performed by EFED. It shows, for the first time, EFED's concern that if full stability of TPA is assumed, average concentrations will continually increase in the water column. EFED's simplified modelling analysis omits other potential dissipation pathways including, as it notes, transport to the benthic region or the potential for processes not measured in (or measurable by) the laboratory metabolism studies requested in the DCI.

84. EFED's concern also does not negate that AMVAC's request for a waiver of the fate studies was appropriate. Even if a substantially longer-than-guideline study is conducted and is successful in reliably establishing a half-life for TPA despite issues with extending such studies to be "longer than standard" as discussed in footnote 6, the half-life would still exceed any value that would meaningfully change the results of EFED's modelling approach as presented in JX 79. Resolving EFED's concern expressed in the modelling implicates consideration of other lines of evidence and other types of studies, it cannot be addressed (as AMVAC has contended from the outset) by performing additional standard guideline metabolism studies for TPA.

85. Exhibit B to my Verified Written Statement is a timeline that shows the dates of relevant communications, when they were transmitted, and other events relevant to the DCPA chronic Leptocheirus (SS-1072) data requirement still at issue in this matter as set forth in my testimony above. It was prepared by counsel for AMVAC in this matter. I reviewed it and confirmed that it accurately shows the timing of the events it displays.

The Leptocheirus Chronic Sediment Toxicity Study

86. In its April 29, 2013, Initial Response, AMVAC advised EPA that it would develop new data to satisfy the Leptocheirus Chronic Sediment Toxicity Study data requirements, referred to also as SS-1072. JX 5 (full text of protocol omitted).

87. In the April 29, 2013, Initial Response, AMVAC also submitted a proposed study protocol for the Leptocheirus Chronic Sediment Toxicity Study. JX 5.

88. On October 20, 2014, AMVAC received for the first time (see JX 60) a document dated March 20, 2014, in which EFED recommended "additional detail [be] added to the protocols to help ensure study acceptability," but noted that it anticipated that the protocols would be adequate once updated. JX 70.

89. On December 15, 2014, AMVAC provided EPA with an update concerning the chronic sediment studies including the Leptocheirus study. JX 60. AMVAC informed EPA that the lab that was to conduct the Leptocheirus studies required additional time to address EPA's comments on the protocol and otherwise ensure that the protocol was sufficiently robust. Notably, the lab stated that it had been working since late 2013 to "develop formulated sediment that is suitable for use in this testing" because the "locally collected natural sediment used historically" had not been producing useable test results. EPA was made aware of this issue as early as 2013. JX 60, Attachment V.

90. The lab conducting AMVAC's sediment studies further explained that sediment suitability testing issues had resulted in a backlog of Leptocheirus studies. The lab noted, however, that it anticipated being able to begin clearing the backlog in early 2015. JX 60. AMVAC indicated that it would update the Agency by March 31, 2015, concerning the progress at the lab. JX 60.

91. On March 30, 2015, AMVAC provided EPA with an initial update from the lab. JX 61 (email), 71 (attached update). The lab had explained that its work to finalize the protocols had recently been presented at the North Atlantic Regional Chapter of the National Society for Environmental Toxicology and Chemistry ("NACSETAC") in Vancouver and that an "ad hoc advisory group include[ing] both industry and government scientists" had held a meeting regarding the Leptocheirus test method. The lab advised that pilot testing was ongoing, but that it anticipated being able to begin clearing the backlog in Q3 of 2015. JX 71. AMVAC requested permission to provide another status update in 6 months. JX 61.

92. AMVAC received no response to the March 30, 2015, update provided to EPA or to its request to provide another status update in 6 months. JX 61, 71.

93. Nonetheless, on September 22, 2015, AMVAC provided EPA with a 6 month update on the progress of the lab in conducting sediment suitability and Leptocheirus testing. JX 61, 72. In this update, the lab explained that it believed it had addressed the issues with the protocol and that it had independently communicated this information to EPA. According to the lab's update, "EPA ha[d] reviewed the revised protocol and approved of the changes made to the test method." JX 72. The lab advised that it anticipated being able to begin clearing the backlog in Q4 2015 using the updated protocol. JX 72. AMVAC requested permission from EPA to provide another status update in 6 months. JX 61.

94. On March 15, 2016, AMVAC submitted correspondence to the EPA that included a request to waive the Leptocheirus chronic sediment study. JX 62. In support of the request, AMVAC provided a Waiver Request dated March 7, 2016, (JX 73), that was noted as received in EPA's Pesticide Document Management System ("PDMS") on March 18, 2016. In the waiver request, AMVAC explained that, in light of testing then 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.

95. On July 18, 2016, EPA provided a response from EFED concerning the waiver request. JX 75, attaching JX 74.

96. In JX 74, EFED acknowledged several of the points raised by AMVAC concerning the relative toxicity of DCPA to sediment dwelling amphipods but disputed that environmental concentrations of DCPA would not be expected to reach levels that might affect Leptocheirus. JX 74. Recognizing the issues with the protocol that had been previously raised by the lab, and the resulting delays at testing labs, EFED stated that AMVAC could conduct an OCSPP 850.1740 study, (10-day Whole Sediment Acute Toxicity Invertebrates) prior to the 28-day Leptocheirus study (SS-1072). JX 74.

97. In JX 74, EFED stated that "[a] waiver may be considered at a later date pending the results of the 10-d study and any other supporting data." JX 74.

98. As a result of EPA's statements in JX 74 in July of 2016, AMVAC understood EPA to be suggesting that AMVAC conduct a different study than the one called for by the DCI, after which point EPA would reconsider whether the SS-1072 special study was needed.

99. 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. JX 76 specifically responded to JX 74 and, even though JX 76 necessarily re-stated some information concerning historical chronic toxicity studies of sediment dwelling

organisms that had been presented in JX 73, JX 76 provided additional case studies and analysis to support its conclusions based on what EPA had communicated in JX 74.

100. 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.

101. 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 (MRID 49865803) in EFED's 2022 EPA Ecological Effects Waiver Response (JX 69).

102. In its discussion in JX 69, EFED cites ground water monitoring data for DCPA indicating a recorded concentration of .986 mg/L. Although EFED does not elaborate on this result, it is obviously an error because (as EFED states in the same passage) the solubility limit of DCPA is .5 mg/L. In other words, concentrations of DCPA in excess of about .5 mg/L will not occur in groundwater because if DCPA was added in greater concentrations, it would not enter solution (i.e., it would precipitate out) and the measured concentration would not exceed .5 mg/L. These reports do not have the same level of scientific integrity as studies conducted under EPA GLPs. For both these reasons, reported groundwater measurements in excess of the limit of solubility should not drive risk assessment. Further, EPA uses chemical concentration measurements in groundwater as an indication of human exposure associated with drinking water wells. The Agency does not use such information as an indication of ecological risk, which is confined to considerations relating to surface water.

103. In JX 67, AMVAC stated that it 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.

104. 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." EPA's citation for this statement was to JX 74, the 2016 EFED memorandum discussed above.

105. 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.

106. 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." JX 22. 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.

107. 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.

108. 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.

109. EPA's requested 10-day acute study is not listed on the 2013 DCI and represents a new requirement.

110. There is currently no validated protocol for the chronic special study envisioned by EPA in the DCI.

111. 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 I am not aware that an updated protocol resulted from those discussions.

112. EPA has never communicated with AMVAC until concurrent with the issuance of the NOITS (in JX 69) about other registrants' attempts to conduct chronic Leptocheirus studies similar to SS-1072. EPA referred to two such studies in JX 69 but did not identify the DERs.

113. I am aware of only one DER issued by EPA addressing a chronic Leptocheirus study similar to SS-1072, and I only located this as a result of my preparation for the hearing. That DER (discussing MRID 50451701 for Fipronil) suggests to me that laboratories continue to experience the same control population survival issues with the study that EPA has acknowledged. Although EPA deemed MRID 50451701 to be "scientifically sound," it classified the study as Supplemental, and useful only for "qualitative characterization" purposes, because of a "high degree of uncertainty in interpretation of the results due to (1) poor performance of control survival and (2) excessive variability of control reproduction which may

have masked treatment related effects. Significant differences were reported in survivability between the earlier 10-day acute study and this 28-day chronic study, which attests to questions concerning the validity of the chronic study for conducting regulatory assessments with this particular species.

114. It is my understanding that EPA has generally moved to change this requirement on all of its DCIs and that future DCIs required only an acute study of Leptocheirus.

115. The Agency never responded to AMVAC's request that it formally request the Guideline 850.1740 spiked whole sediment 10-day toxicity test in addition to, or as an alternative to, the chronic Leptocheirus study. EPA should issue a new DCI or other formal request for the acute study if it wants to substitute it for the chronic study.

116. Exhibit C to my Verified Written Statement is a timeline that shows the dates of relevant communications, when they were transmitted, and other events relevant to the TPA Guideline 835.4200, 835.4300, and 835.4400 data requirements still at issue in this matter as set forth in my testimony above. It was prepared by counsel for AMVAC in this matter. I reviewed it and confirmed that it accurately shows the timing of the events it displays.

General

117. In my experience, it is unprecedented for EPA to issue a NOITS at the same time that it provides EFED's conclusions regarding certain waivers as occurred here in JX 69 and JX 79. EPA's course of conduct with respect to this DCI led AMVAC to believe that it could and would proceed with risk assessment, making certain assumptions as stated, and that waiver requests would be re-evaluated after that risk assessment was complete. AMVAC had no notice that the agency did not intent to follow this approach until the NOITS was issued.

118. JX 21, the Data Delay Letter, reinforces this point. It states that, despite the

outstanding data, “EPA expects to complete the draft risk assessments in June 2021.” It further states that “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.”

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 9th day of January, 2023.

/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, January 9, 2023, as indicated below.

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

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