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 JULIE PORTER

I, Julie Porter, 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 am currently the Director of Regulatory Compliance at AMVAC Chemical Corp ("AMVAC").

3. I received a Bachelor of Science degree in Business in 1999 from California Polytechnic State University, San Luis Obispo.

4. I have worked at AMVAC since 2002. From 2002 to 2004, and again from 2008 to 2010, I served as a Regulatory Assistant for the company. From 2011 to 2012, I held the role of Regulatory Specialist. From 2012 to 2015, I served as Regulatory Product Manager. From 2015 to 2016, I served as Product Manager. From 2016 to 2017, I served as Director of Registrations, US and Canada. Most recently, from 2017 to the present, I have served as AMVAC's Director of Regulatory Compliance.

5. During my tenure at AMVAC, I have been involved in the U.S. Environmental Protection Agency's Reregistration and Registration Review process for approximately a dozen chemicals, including metaldehyde and naphthalene acetic acid (NAA).

6. I have also 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 January, 2013, to September, 2016, I served as the AMVAC employee primarily responsible for corresponding with EPA concerning DCPA DCI response.

In that role, I was directly involved in relaying to EPA information developed by AMVAC's technical staff regarding the data relating to the AMVAC Data-Call In, Residue and Field Accumulations Studies, and the Leptocheirus Chronic Sediment Toxicity Study, as discussed below, as well as the rest of the response to the DCI.

8. The NOITS refers to only a subset of the data requirements in the DCI. Joint Exhibit ("JX") 1, 4.

The Data-Call In

9. EPA issued a Generic Data Call-In Notice to AMVAC on January 31, 2013. JX 4. The DCI set forth various data that EPA asserted were necessary to maintain AMVAC's DCPA technical registration. The DCI stated that AMVAC should respond within 90 days advising EPA how it planned to satisfy each of the data requirements identified in the DCI.

10. The DCI provided AMVAC with options for responding in connection with each data requirement in the DCI. These included Option 1 (Developing Data); Option 4 (Submitting Existing Data); Option 5 (Upgrading a Study); Option 6 (Citing a Study); Option 7 (Deleting Uses); and Option 9 (Requesting a Waiver). JX 4.

11. AMVAC timely provided its initial response to the DCI on April 29, 2013, (the "Initial Response"). JX 5.

12. AMVAC's Initial Response to the DCI advised EPA of how AMVAC intended to satisfy each of the data requirements in the DCI, based on the options provided by EPA. JX 5.

The Residue and Field Accumulations Studies

13. The DCI requested data for OCSPP Guidelines 860.1300, 860.1340, 860.1480, and 860.1900. JX 4.

14. In its Initial Response, JX 5, AMVAC stated that it intended to satisfy the

860.1300, 860.1340, 860.1480, and 860.1900 data gaps as follows.

15. For Guideline 860.1300 (Nature of the residue – plants, livestock (poultry)), AMVAC stated that it would remove from the DCPA labels uses for alfalfa, which would eliminate treated feedstocks for poultry. JX 5.

16. For Guideline 860.1340 (Residue analytical method: Livestock Commodities), AMVAC stated that it would remove from the DCPA labels uses for ruminant commodities. JX 5.

17. For Guideline 860.1480 (Meat/milk/poultry/eggs (ruminant)), AMVAC stated that it would remove from the DCPA labels uses for alfalfa, white potatoes, and peas, which would eliminate treated feedstocks for ruminants. JX 5.

18. For Guideline 860.1900 (Field accumulation in rotational crops), AMVAC proposed that this data requirement should be considered fulfilled once the integrity of samples in two studies could be established (*i.e.*, that the studies would be "upgraded"). JX 5.

19. In its April 29, 2013, Initial Response, AMVAC also provided justification for the existing DCPA field accumulation data in rotational crops residue data. JX 5.

20. On October 23, 2013, EPA issued a response to AMVAC's positions concerning the residue and field accumulation studies for the DCI. JX 26 (the "October 2013 Residue Chemistry Response"). However, no copy of EPA's October 2013 Residue Chemistry Response was made available to AMVAC until July 31, 2014. JX 29.

21. In EPA's October 2013 Residue Chemistry Response, with respect to whether removing alfalfa use from the DCPA Technical label would eliminate the need for the poultry metabolism study requirement 860.1300, EPA's Office of Pesticide Programs, Health Effects Division ("HED") stated that specific data (DCPA residues in corn and soybean as rotated crops)

was required so that a dietary burden could be estimated for poultry. HED's response further stated that if the dietary burden estimates resulted in sufficiently low anticipated secondary residues in poultry tissue and eggs, then "it may not be necessary to perform a poultry metabolism study." JX 26.

22. With respect to the guideline study requirement 860.1340, the October 2013 Residue Chemistry Response stated that once the tolerances for DCPA residues in corn and soybean as rotated crops were reassessed, a dietary burden could be estimated for ruminants. The October 2013 Residue Chemistry Response further stated that if the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, then "a livestock residue analytical method would not be necessary." JX 26.

23. With respect to the guideline study requirement 860.1480, the October 2013 Residue Chemistry Response stated that, once the tolerances for DCPA residues in corn and soybean as rotated crops have been reassessed, a dietary burden can be estimated for ruminants. If the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, "then a ruminant feeding study would not be necessary." JX 26.

24. With respect to the guideline study requirement 860.1900, the October 2013 Residue Chemistry Response stated that EPA believed that rotational crop field trials were required to determine the appropriate tolerance levels for rotated crop commodities. The scope of the required tests would be dependent on AMVAC's intent with respect to (1) the crops to be allowed in rotation and (2) the desired plant-back intervals ("PBI") for these crops. EPA asked AMVAC to specify its intent regarding these two points. JX 26.

25. On January 29, 2014, AMVAC submitted a "12-Month Response" to the DCI. JX 27.

26. At the time that AMVAC developed and transmitted the "12-Month Response" to EPA, JX 27, AMVAC had still yet to receive EPA's October 2013 Residue Chemistry Response which, as noted above, would not be received by AMVAC until July 31, 2014. JX 29.

27. Regarding the 860.1900 guideline study, AMVAC stated in the January 29, 2014, 12-Month response that (1) data concerning the storage interval of crops associated with the crop rotational study Master Record Identification ("MRID") 41255504 is provided in Appendix VI of the final report; (2) sampling intervals were determined based on the number of days between sampling and sample extraction; (3) the maximum interval for all commodities was 407 days; (4) data concerning the storage interval of crops associated with the crop rotational study MRID 42298303 is provided in Appendix VII of the final report; (5) sampling intervals were determined based on the number of days between sampling and sample extraction; (6) the maximum interval for all commodities was 423 days. JX 27.

28. AMVAC further stated that data supporting the conclusion that the samples were viable upon analysis are found in MRID 43938901. That study was performed on frozen samples associated with six diverse crop matrices, and demonstrated that the parent compound DCPA and SDS-954 (TPA) residues are stable for a 4-year period. JX 27.

29. In a HED document entitled "Comments on the Residue Chemistry Requirements of the [DCI]" dated July 7, 2014, (JX 28), HED addressed AMVAC's statements in the 12-Month Response, (JX 27), concerning the Guideline 860.1380 and 860.1900 studies.

30. AMVAC did not receive this document until July 30, 2014. JX 29. In the document, HED stated (1) that AMVAC's submitted information regarding the storage durations of samples in the 860.1900 rotational crop studies (MRIDs 41255504 and 42298303) was not relevant because this information was never identified as a data gap and is not part of the GDCI;

and (2) that the 860.1900 GDCI requirement specifically pertains to the need for additional field trials on rotated crops to determine the appropriate tolerance for residues of DCPA on those rotated crops, and that those data remained outstanding. JX 28.

31. After receiving JX 28 on July 30, AMVAC reviewed it and observed that it referenced an October 23, 2013, HED science review, titled "DCPA: HED Response to Comments on the Residue Chemistry Requirements of the Generic Data Call-In (GDCI-0798701-1140)," (JX 26) which EPA had not provided to AMVAC as of that time.

32. AMVAC requested a copy of JX 26 the day after receiving JX 28, at which point EPA transmitted a copy of JX 26 to AMVAC for the first time on July 31. JX 29.

33. On September 24, 2014, AMVAC provided a further substantive response, including justifications to (1) fulfill the Guideline No. 860.1900 requirement, and (2) justify data requirements waivers for Guidelines No. 860.1300, 860.1340, and 860.1480. JX 31.

34. I did not understand, at the time that JX 31 was submitted or at any time prior, or in any other communications with EPA prior to that point, that EPA considered AMVAC to be untimely in its interactions with the Agency concerning the Guideline No. 860.1300 study (the only one of the four discussed in this section for which the nominal deadline in the DCI had passed at that time).

35. Further information concerning AMVAC's interactions with EPA related to the data requirements discussed in this section is provided in the written statement of my former colleague Jon Wood.

The Leptocheirus Chronic Sediment Toxicity Study

36. 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).

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

38. On October 20, 2014, AMVAC received for the first time (*see* JX 60) a document dated March 20, 2014, in which the EPA Environmental Fate and Effects Division ("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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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 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.

45. EPA responded to the waiver request in a document dated June 27, 2016, (JX 74), that was not provided to AMVAC until July 18, 2016. JX 75, attaching JX 74.

46. In the June 27, 2016, response, (JX 74), EPA 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, EPA 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.

47. In the June 27, 2016, response, JX 74, which was provided to AMVAC on July 18, 2016, JX 75, EPA was clear that the DCI requirement for the 28-day Leptocheirus study was not being waived but did state 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.

48. 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.

49. It seems the only possible interpretation of this communication, given that in June of 2016 the 36-month nominal time frame for the SS-1072 special study stated in the DCI had already expired, is that EPA had extended the deadline for completion of the 28-day Leptocheirus study to some unstated future point after EPA "considered at a later date … the results of the 10-d study and any other supporting data" and decided that the SS-1072 needed to be initiated. JX 74.

50. Further information concerning AMVAC's interactions with EPA related to the 28-day Leptocheirus study is provided in the written statement of my colleague Richard S. Freedlander.

Authenticity of Exhibits

51. I have reviewed JX 4-7, 9, 26-31, 53-54, 60-62, 65, 70-73, 74-75; and PAX 1, 3, 5. 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, Julie Porter, 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/ *Julie Porter*
Julie Porter

CERTIFICATE OF SERVICE

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

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

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