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 NIAMH MCMAHON

January 9, 2023

I, Niamh McMahon, 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 a Product Regulatory Manager at AMVAC Chemical Corp ("AMVAC"). I have worked for AMVAC in this role since June 2017.

3. I received a Bachelor of Science in Chemistry in 1992 from University College Cork and a Doctor of Philosophy in Inorganic Chemistry in 1995 from the University of Sussex.

4. Prior to working for AMVAC, from June 2003 to July 2009, I served as a Regulatory Compliance Specialist and then as the Head Regulatory Compliance for Product Safety and Regulatory Affairs for Plastic Additives Division CIBA Specialty Chemicals.

5. From January 2009 to May 2017, I worked as the U.S. Regulatory Technical Team Leader, Federal Regulatory Manager, and then as the Global Product Stewardship Leader for Dow AgroSciences LLC.

6. Throughout my career in the U.S., I have navigated the U.S. Environmental Protection Agency's ("EPA") Reregistration and Registration Review programs numerous times and have experience in managing responses to EPA Data-Call Ins ("DCIs").

7. In my role as AMVAC's Product Regulatory Manager, I have been involved in AMVAC's response to the 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 this proceeding as set forth in more detail below. Responsibility for AMVAC's DCPA registration transitioned to me upon the retirement of the previous Regulatory Manager for DCPA, Jon Wood, on April 30, 2022.

8. Just prior to the formal transfer of responsibility for DCPA within AMVAC, on April 30, 2022, I received a phone call and email (Joint Exhibit ("JX") 92) from James Douglass, EPA's Chemical Review Manager, on April 27, 2022, indicating that the NOITS was being issued. This was my first personal interaction with EPA on AMVAC's response to the DCPA DCI. Any of my testimony below concerning events prior to this is based on my review of AMVAC's records related to the DCPA DCI.

Background Facts Regarding DCPA

9. DCPA is a chlorinated benzoic acid herbicide whose pesticidal mode of action involves the inhibition of cell division of root tips in target plants. DCPA is used to control many annual grasses and broadleaf weeds for a variety of agricultural crops including collards and onions, among other crops. Joint Exhibit ("JX") 3.

10. Contrary to the assertion made in EPA's Motion for an Accelerated Decision in this matter, DCPA is not registered for use on corn or soybeans. JX 3.

11. Tolerances for DCPA residues for certain food and feed crops have been established under 40 C.F.R. § 180.185.

12. DCPA was first registered in 1958 and was successfully reregistered under FIFRA Section 4, 7 U.S.C. § 136a-1 in 1998 and tolerances were reassessed in 2005.

13. DCPA has been the subject of several DCIs prior to the 2013 DCI at issue here, including in 1987, 1992, and 1995.

14. AMVAC is the only registrant of DCPA and DCPA end use products ("EUPs") formulated with the technical DCPA at issue in this proceeding and is the only source of DCPA EUPs for domestic growers.

Summary of Data Requirements at Issue and the DCI

15. Based on my review of documentation related to AMVAC's response to the DCI, AMVAC has been involved in an extensive, iterative, and ongoing process with EPA since 2013 to provide the necessary data, pinpoint exactly what data EPA requires, respond to additional requests for information, and follow a tiered and/or bridging testing approach (not originally set forth in the DCI) to meet certain requirements.

16. EPA's "Explanatory Appendix" to the NOITS, JX 1, omits many communications between AMVAC and EPA which demonstrate this iterative process and demonstrate that AMVAC was frequently waiting, often long periods of time, for necessary information from EPA. Details about these communications are provided primarily in the fact witness statements of other AMVAC employees and in the Joint Exhibits and Petitioner AMVAC's Exhibits ("PAX") filed in this matter.

17. EPA took substantial amounts of time to complete reviews of documents supplied by AMVAC. Specific time intervals are set forth in the verified statements of other AMVAC witnesses.

18. EPA on several occasions failed to timely transmit data reviews and responses it had already generated (in one case, not providing a response until five years after it was completed).

19. EPA also often took long periods of time to respond to AMVAC's requests for waivers, thereby leading AMVAC to believe that studies would likely not be required based on the results of other studies and, in any event, making compliance with the nominal timeframes set out in the DCI for completing certain data requirements impossible.

20. The DCI originally requested performance of studies to satisfy more than 60 data

requirements, considering a single Guideline required to be performed on both the parent compound (DCPA) and the degradate (TPA), and/or on more than one species, to be independent requirements. Counting preliminary studies needed to support performance of the definitive Chronic Thyroid ("CTA") study, this number would be over 70.

21. The NOITS alleged that AMVAC had 20 outstanding data requirements. OPP has now deemed one (1) of those to be satisfied and indicated that it is no longer alleging AMVAC failed to take appropriate steps as to six (6) more. AMVAC has submitted label amendments as discussed in Paragraph 35 below that should enable waiver of four (4) more. Beyond that, there are nine (9) date requirements that remain at issue: five (5) TPA ecotoxicology data requirements; one (1) DCPA ecotoxicology data requirement; and three (3) environmental fate data requirements.

22. Exhibit A to this Verified Statement depicts the quantity of studies from the DCI that have been submitted, waived, or that EPA no longer alleges AMVAC failed to take appropriate steps in connection with, compared to the quantity still at issue in this matter as discussed in Paragraphs 20 and 21, above.

23. AMVAC has expended considerable resources in response to the DCI. The cost of data generation alone has been more than three million dollars ($3,000,000). This figure does not account for any internal AMVAC costs such as overhead and other indirect expenses including interfacing with EPA, defending against the NOITS, and it also does not include the cost of studies that EPA accepted to satisfy data requirements that were performed prior to 2013.

Specific Data Requirement Information

24. The definitive DCPA SS-thyroid study (often referred to as the CTA study) has now been submitted to EPA. An initial version was submitted on June 20, 2022, and assigned MRID 51931701. An amended final study report was submitted on August 5, 2022 and assigned MRID 51957801.

25. Based on my search and review of a third-party database listing all EPA MRID study bibliographies, I understand that at the time the DCI was issued, the "comparative thyroid toxicity study" requirement was so rare that only 2 other registrants had been required to conduct such a study in the history of EPA's pesticide registration program.

26. More information relevant to the development of the CTA protocol may be found in the verified statement of AMVAC employee Ann Jonynas.

27. Pursuant to OPP's December 23, 2022 Status Report, OPP now considers the CTA data requirement to be satisfied.

28. The DCPA 850.1400 bluegill study, conducted on the acceptable alternative guideline species fathead minnow, has already been submitted (on June 7, 2022) and assigned MRID 51926601. Pursuant to OPP's December 23, 2022 Status Report, while OPP has not yet determined that this data requirement is satisfied in its view, OPP is no longer alleging that AMVAC failed to take appropriate steps in connection with this data requirement.

29. The DCPA 850.1400 sheepshead minnow study has already been submitted (on June 30, 2022) and assigned MRID 51918501. Pursuant to OPP's December 23, 2022 Status Report, while OPP has not yet determined that this data requirement is satisfied in its view, OPP is no longer alleging that AMVAC failed to take appropriate steps in connection with this data requirement.

30. For the DCPA Guideline 850.2100, 850.4100, 850.1350, and SS-1069 (Chronic Sediment toxicity – Chironomus) studies, AMVAC submitted studies to meet these requirements, but EPA took years to review them and only on April 27, 2022, concurrently with the issuance of the NOITS, informed AMVAC that it alleged that the submitted studies had not satisfied the data requirements.

31. For the Guideline 850.2100 DCPA data requirement, AMVAC submitted a guideline compliant study pursuant to a protocol agreed with EPA in 2014 (MRID 49477601). Pursuant to OPP's December 23, 2022 Status Report, while OPP does not consider this data requirement to be satisfied, OPP is no longer alleging that AMVAC failed to take appropriate steps in connection with this data requirement.

32. For the Guideline 850.1350 DCPA data requirement, AMVAC submitted additional information from the laboratory responsible for the study on October 14th, 2022. This additional information was assigned MRID 52026901. Pursuant to OPP's December 23, 2022 Status Report, while OPP does not consider this data requirement to be satisfied, OPP is no longer alleging that AMVAC failed to take appropriate steps in connection with this data requirement.

33. For the Special Study ("SS")-1069 (Chronic Sediment toxicity – Chironomus) data requirement, AMVAC submitted additional information from the laboratory responsible for the study on June 30, 2022. This additional information was assigned MRID 51918502. Pursuant to OPP's December 23, 2022 Status Report, while OPP does not consider this data requirement to be satisfied, OPP is no longer alleging that AMVAC failed to take appropriate steps in connection with this data requirement.

34. On December 9, 2022, OPP's Health Effects Division ("HED") issued "DCPA

Label Amendments for Plant Back Intervals (PBIs)," DP Barcode D466682. This document set forth label amendments which, if implemented, would enable waiver of four additional data requirements identified in the NOITS (Guidelines 860.1300, 860.1340, 860.1480, and 860.1900).

35. On December 28, 2022, AMVAC submitted proposed labels intended to implement the amendments identified in Paragraph 34 by email to OPP CRM James Douglass as requested by him. I understand that OPP is currently reviewing the proposed labels.

36. For the nine (9) Ecotoxicology and Ecological Fate studies referenced in the NOITS that remain at issue in this matter, AMVAC and EPA had been in a dialogue for quite some time regarding exactly what data is required. During the course of those discussions, AMVAC has submitted data and other information to EPA in support of data waivers. These discussions are set forth in more detail in the verified statement of Dick Freedlander.

Currently Ongoing Studies

37. AMVAC is currently proceeding with the Guideline 850.1400 TPA study assessing the Sheepshead minnow (anticipated to be the most sensitive species based on the results for the three Guideline 850.1400 studies for DCPA). AMVAC anticipates being able to provide a final report for this study no later than November of 2023.

38. AMVAC is currently proceeding with the Guideline 850.1350 TPA study assessing the mysid. AMVAC anticipates being able to provide a final report for this study no later than November of 2023.

39. AMVAC is currently proceeding with the Guideline 850.4500 TPA Algal Toxicity study assessing the marine diatom only, consistent with EFED's statement in JX 69 that it recommends waiving this data requirement as to the other species originally called for in the DCI. AMVAC anticipates being able to provide a final report for this study no later than April

of 2023.

40. AMVAC is currently proceeding with the Guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates) for DCPA based on EPA's position as set forth in documents made available concurrent with the NOITS. AMVAC anticipates being able to provide a final report for this study no later than October of 2023.

41. AMVAC is currently proceeding with the 835.4200, 835.4300, and 835.4400 metabolism studies. AMVAC expects to be able to provide interim final reports no later than November of 2023 based on the guideline study timeframe of 120 days (soil) and 100 days (aquatic). The studies will continue data generation beyond 120/100 days up to 365 days (soil) and 200 days (aquatic) such that data will be available for an updated final report, which AMVAC will produce if EPA advises that additional data beyond 120/100 is needed after reviewing the 120/100 day data.

42. AMVAC is currently proceeding to re-run the portion of the Guideline 850.4100 DCPA Seedling Emergence study (lettuce) that AMVAC submitted in 2014, and with which EPA first expressed concerns in documents issued concurrent with the NOITS even though OPP no longer alleges that AMVAC failed to take appropriate steps in connection with this data requirement, as set forth in the December 23, 2022 status report. AMVAC expects to be able to provide a final report for lettuce under this data requirement by May of 2023.

Transmittal of Certain Documents from EPA to AMVAC

43. EPA made several documents available to AMVAC at the same time as the NOITS. These documents contained, in many instances, substantive responses from EPA concerning waivers that AMVAC is now responding to as described in the following paragraphs. These documents include twenty-three (23) DERs, for studies with MRIDs 49500701;

49307505; 49307511; 51398105; 49307510; 49307514; 51398104; 49307512; 49477601; 49307513; 49307506; 49307509; 49307504; 51499402; 49307508; 49307507; 49865801; 49865802; 49307519; 49307518; 51235101; 51235102; 51499401; and five (5) other EPA documents relevant to the ongoing discussions between AMVAC and EPA concerning the DCI: JX 57, 59, 69, 79, EPA-HQ-OPP-2011-0374-0053.

44. Certain EFED reviews were first transmitted to AMVAC as stated in the following paragraphs.

45. JX 66 (dated March 21, 2014): as an attachment to an email dated March 27, 2017 from Jill Bloom, which has been designated as JX 36.

46. JX 69 and 79 (both dated April 29, 2022): as an attachment to an email dated April 27, 2022 from James Douglas, which has been designated as JX 57.

47. JX 74 (dated June 27, 2016): as an attachment to an email dated July 18, 2016, from Chris Davis (forwarded from Marquea King), which has been designated as JX 75.

48. JX 77 (dated February 7, 2017): in a .zip file attached to an email dated October 16, 2020 (also attaching the Data Delay Letter, JX 21), which has been designated as JX 91. The documents identified in footnotes 3 and 4 of JX 21 were also not sent to AMVAC prior to being transmitted with JX 21.

I, Niamh McMahon, 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/ *Niamh McMahon*
Niamh McMahon

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Verified Written Statement of AMVAC Fact Witness Niamh McMahon**, was served on the following parties today, January 9, 2023, as indicated below.

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

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