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 NIAMH MCMAHON

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 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 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.

Background Facts Regarding DCPA

8. 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.

9. 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.

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

11. 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.

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

13. AMVAC is the only registrant of DCPA and DCPA EUPs formulated with the technical DCPA at issue in this proceeding is the only source of DCPA EUPs for domestic growers.

Summary of Data Requirements at Issue

14. Based on my review of documentation related to AMVAC's response to the DCI, with respect to the twenty (20) data requirements at issue in this proceeding, 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.

15. 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 current and former AMVAC employees.

16. 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 who were individually involved in these exchanges.

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

18. EPA also often took long periods of time to respond 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.

19. The definitive DCPA SS-thyroid study (often referred to as the CTA study) will be submitted to EPA on June 20, 2022. 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.

20. More information relevant to the development of the CTA protocol may be found in the verified statement of AMVAC employee Ann Jonynas. Additional information concerning CTA studies generally may be found in the verified statement of AMVAC expert

witness Elaine Freeman.

21. 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.

22. The DCPA 850.1400 sheepshead minnow study is nearly complete, with an estimated submittal of the final study on July 15, 2022.

23. 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 (as detailed in the verified statements of other AMVAC employees) but EPA took years to review them and only recently (on April 27, 2022, concurrently with the issuance of the NOITS), informed AMVAC that some information must be submitted to supplement them. None of the studies were deemed "unacceptable" or "rejected." Additional information concerning these data requirements is contained in the verified statements of AMVAC employees Ms. Jonynas (850.2100) and Mr. Freedlander (850.4100, 850.1350, and SS-1069).

24. For all of the Guideline 860 series studies at issue in the NOITS, the requirements are not outstanding because EPA is already in possession of proposed label amendments intended to eliminate the need for these studies. AMVAC prepared those label amendments for submission in 2017 (subject to later amendment through May of 2019) in cooperation with Pesticide Reevaluation Division (PRD) staff at EPA as discussed in more detail in the verified statement of Jon Wood.

25. For the nine (9) studies referenced in the NOITS and not listed in any of the prior five paragraphs, AMVAC and EPA have been in a dialogue for quite some time regarding exactly what data is required. All of these requirements are for Ecological

Effects/Environmental Fate data. 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 statements of other AMVAC employees.

AMVAC's Actions in Response to Communications from EPA Contemporaneous with the NOITS

26. 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.

27. The one data requirement for which a waiver was not finally rejected concurrent with the NOITS (an aerobic metabolism study under Guideline 835.4300) is discussed in more detail in the verified statement of AMVAC employee Mr. Freedlander.

28. AMVAC intends to proceed 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 and, as requested, will provide a protocol for EPA review. AMVAC understands the EPA will "reconsider [its] waiver request for SS-1072" in view of these results, as stated in EPA's October 16, 2020, correspondence (JX 21), given that EPA did not specifically state that it would not so reconsider in the 2022 EPA Ecological Effects Waiver Response (JX 69).

29. AMVAC also intends to proceed with the 835.4200 and 835.4400 soil and aquatic metabolism studies for TPA after review of the 2022 EPA E-Fate Waiver Response, JX 79 (dated April 19, 2022). AMVAC had understood its waiver requests to be under consideration by the Agency prior to this time (*i.e.*, following its prior correspondence to the Agency in December of 2020). JX 78. AMVAC also intends to proceed with 850.1350, chronic toxicity mysid (most sensitive species), 850.1400 fish early life stage for sheepshead minnow (most sensitive species), and marine diatom (algal toxicity test-most sensitive species) per the outcome of 2022 EPA Ecological Effects Waiver Response, (JX 69), made available to AMVAC on April 27, 2022.

Authenticity of Exhibits

30. I have reviewed JX 1-3; 57-59; 63; and 69. 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 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, 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 17th day of June 2022.

/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, June 17, 2022, as indicated below.

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

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