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;)	Docket No. FIFRA-HQ-2022-0002
Grower-Shipper Association of Central)	
California; Sunheaven Farms, LLC; J&D)	
Produce; Ratto Bros., Inc.; and Huntington)	
Farms,)	
Petitioners.)	

<u>VERIFIED WRITTEN STATEMENT OF AMVAC FACT WITNESS</u>
<u>JON C. WOOD</u>

- I, Jon C. Wood, 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 degree in Zoology in 1980 from California State University, Long Beach and a Master of Business Administration in 1994 from California State Polytechnic University-Pomona.
- 3. Prior to joining AMVAC Chemical Corp ("AMVAC,"), from 1980 to 1995, I worked for the Union Oil Company of California ("UNOCAL") in the Agricultural Research Group. During my employment with UNOCAL, I was promoted from a Chemical Research Technician, to a Quality Assurance Manager, to a Senior Research Scientist while serving as the company's Registration Manager from 1987 to 1995. Following my employment with UNOCAL, from May 1995 to May 1996, I worked as a Registration Manager for the agricultural chemical company ENTEK International. From May 1996 to February 1998, I worked as an Independent Contract Consultant specializing in federal and state pesticide registrations.
- 4. I worked at AMVAC from 1998 to 2022. From 1998 to 2012, I worked as a Regulatory Manager for the company. From 2012 to 2016, I served as AMVAC's Director of Registrations. Most recently, from 2016 to 2022, I worked as AMVAC's Senior Regulatory Product Manager.
- 5. In these roles, I worked in the research, development, and registration management of agricultural chemicals (mostly crop protection products) for over forty years. This work included the successful navigation of the U.S. Environmental Protection Agency's ("EPA") Reregistration and Registration Review programs for several chemicals including

Dimethyl Tetrachloroterephthalate ("DCPA").

- 6. In my roles as AMVAC's Director of Registrations and Senior Regulatory Manager, I was 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 DCPA Technical Registration received by AMVAC on April 27, 2022 that is the subject of the proceeding.
- 7. Specifically, in September 2016, I replaced Julie Porter of AMVAC as the primary AMVAC employee interfacing with EPA on the DCPA DCI response. In that role, I was directly involved in work and communications relating to the AMVAC Residue and Field Accumulations Studies, Fish Early Life Stage Studies, and Leptocheirus Chronic Sediment Toxicity Study, as discussed below, as well as the rest of the response to the DCI.
 - 8. I retired from AMVAC in April 2022.

The Residue and Field Accumulations Studies

- 9. AMVAC worked closely with EPA to develop label amendments for DCPA that would obviate the need for certain studies discussed in this section (Guidelines 860.1300, 860.1340, 860.1480, and 860.1900).
- 10. Interactions with EPA related to these studies prior to those described below are set forth in the witness statement of my former colleague Julie Porter.
- 11. AMVAC submitted these proposed label amendments beginning in 2017, and all amendments were submitted by May of 2019, as set forth in more detail below. I understand that EPA has been reviewing these proposed label amendments since they were submitted.
- 12. On February 17, 2015, EPA's Office of Pesticide Programs, Health Effects

 Division ("HED") drafted a written response to AMVAC's position concerning the 860.1900

 data requirement. Joint Exhibit ("JX") 32.

- 13. AMVAC, however, did not receive the February 17, 2015, HED response document, JX 32, until March 27, 2017 when HED transmitted the document to AMVAC via email. JX 36.
- 14. In the February 17, 2015, HED response document, HED concluded that specific crop rotational restrictions are appropriate and that rotation to a crop with an established tolerance for residues of DCPA could be permitted with a minimum plant-back interval ("PBI") of 8 months. According to HED, rotation to any other crop could not be permitted. HED concluded that all labels for DCPA use on agricultural crops should be modified to reflect the specific identified rotational crop restrictions. Further, HED stated that if the described label modifications were made, additional field rotational crop data would not be needed, and the 860.1900 data requirement would be considered fulfilled. JX 32.
- 15. On March 17, 2017, AMVAC and EPA met on a teleconference to discuss the status of the DCPA DCI.
- 16. On March 17, 2017 and March 27, 2017, EPA emailed AMVAC two summaries and sets of action items resulting from the March 17, 2017, call. JX 33 (attachment to JX 34); JX 35 (attachment to JX 36).
- 17. The March 27, 2017, email (JX 36) also provided three EPA response documents (dated March 21, 2014; February 17, 2015; and June 27, 2016) (JX 37-39) that had not previously been sent to AMVAC.
- 18. The March 17, 2017, and March 27, 2017, email and accompanying documents (JX 33-39) indicate that EPA had outstanding action items at this time related to the AMVAC Residue and Field Accumulations Studies.
 - 19. On April 7, 2017, Jordan Page, Chemical Review Manager with the Pesticide Re-

Evaluation Division ("PRD"), followed up with AMVAC regarding the March 17, 2017, call. Page requested clarification concerning the timetable for AMVAC's submission of certain label amendments and usage data. Page also set out the conditions that EPA asserted would have to be met to support waiver requests for the Guideline 860.1300, 860.1340, and 860.1480 data requirements. JX 40.

- 20. On May 10, 2017, AMVAC submitted revised DCPA label language to address HED's required use terminations. JX 41.
- 21. On May 19, 2017, AMVAC and EPA held a phone conference to further discuss EPA's requested changes to the label amendments and exchanged related correspondence. JX 42.
- 22. Immediately following the phone conference held between AMVAC and EPA on May 19, 2017, AMVAC emailed EPA a revised proposed label for DCPA Technical. JX 43 (email); JX 44 (attachment).
- 23. On June 8, 2017, AMVAC submitted amended DCPA end use product ("EUP") labels to address EPA comments. JX 45.
- 24. On May 23, 2019, AMVAC resubmitted the amended DCPA Technical label to address EPA comments. JX 46.
- 25. On October 16, 2020, PRD Director Elissa Reaves corresponded with AMVAC concerning the status of the DCI data requirements. JX 21.
- 26. The October 16, 2020, correspondence from Reaves stated that in regard to the Guideline 860.1300, 860.1340, 860.1480, and 860.1900 data requirements, the "Study Status" was "In review" and that "label amendments [have been] submitted to satisfy [the requirements]." JX 21.
 - 27. AMVAC responded to the October 16, 2020, correspondence as discussed in

more detail in paragraphs 43-46, below.

- 28. On February 1, 2021, PRD wrote AMVAC and stated that EPA had questions regarding specific use parameters for DCPA. JX 47.
- 29. On February 9, 2021, AMVAC provided information to EPA addressing EPA's February 1, 2021, questions regarding DCPA use patterns. JX 47 (email); JX 48 (attachment).
- 30. On March 8, 2021, the EPA Environmental Fate and Effects Division ("EFED") posed several follow-up questions regarding AMVAC's DCPA use pattern information. EPA asked whether AMVAC would be willing (1) to commit to putting maximum annual use rates on the DCPA label and (2) for use on ornamentals, to clarify the number of applications per year and the total amount of active ingredient applied per acre per year. JX 47.
- 31. On March 23, 2021, AMVAC responded to EPA's March 8, 2021 questions by stating that the revised label amendments that AMVAC submitted to the EPA Registration Division ("RD") in 2017 and 2019 should be sufficient to address the maximum use restrictions proposed by EPA in its March 8, 2021, email. JX 47.
- 32. On March 24, 2021, EPA acknowledged receipt of AMVAC's March 23, 2021 response. JX 47.
- 33. On March 23, 2022, Jill Bloom from PRD contacted AMVAC by phone to request copies of submission documents for AMVAC's applications to amend DCPA EUP labels.
- 34. On March 25, 2022, in response to the March 23, 2022, call, AMVAC provided PRD with a compilation of prior correspondence concerning AMVAC's EUP DCPA label amendment requests that demonstrate that AMVAC had requested amendments to the relevant EUP labels to address all concerns previously identified by EPA. JX 50 (email); Petitioner

AMVAC Exhibit ("PAX") 37 (attachments).

- 35. With respect to guideline study data requirements 860.1300, 860.1340, 860.1480, and 860.1900, AMVAC made numerous revisions and submissions of DCPA labels to address all questions, concerns, and requirements outlined by EPA. These submissions have been under review by EPA since 2017, and AMVAC had timely responded to EPA comments and requests with additional information when requested, as outlined above.
- 36. EPA's statement in the NOITS that "AMVAC has neither submitted data to satisfy [these data requirements] nor amended its product labels," JX 1 at 18-22, misses the point with regard to the discussions between AMVAC and EPA concerning the need for these studies. AMVAC has been waiting on EPA for several years to confirm that *proposed* label amendments are acceptable and will obviate the need for the studies. The proposed label amendments were prepared by AMVAC following direction from EPA with intent to address the need for the studies and have been under review by EPA for 3-5 years.

The Leptocheirus Chronic Sediment Toxicity Study

- 37. Interactions with EPA related to the Leptocheirus Chronic Sediment Toxicity
 Study are primarily set forth in the witness statements of my former colleagues Julie Porter and
 Richard ("Dick") Freedlander. This section discusses a specific interaction I had with EPA
 related to the Leptocheirus (and several other) studies.
- 38. On March 17, 2017, Dr. Marquea King from EPA emailed me, and others, a document containing "Action Items" based on a phone conversation held between AMVAC and EPA that morning. JX 34 (email); JX 33 (attachment). The Action Items recorded from the phone conversation indicated that AMVAC did not have any "Action Items" related to the Leptocheirus data requirement. By contrast, an Action Item was listed for EPA, which noted that

the Agency needed to "confirm with EFED whether a clean/negative 10-day study negates the need for the 21-day study." JX 33.

- 39. On March 27, 2017, Dr. Marquea King from EPA emailed to me, and others, various follow up information from the March 17, 2017, phone conference. JX 36 (email); JX 35 (attachment). The only additional information provided in this email concerning the Leptocheirus data requirement was that EPA's "Response to Amvac [was still] pending." JX 35.
- 40. As noted above, additional details regarding the Leptocheirus data requirement can be found in the statements of Mr. Freedlander and Ms. Porter.

Technical Issue Suggesting Internal Delays with EPA's Review of Fish Early Life Stage Studies

- 41. In August of 2020, when attempting to upload two studies (including a Daphnia Magna chronic toxicity study under Guideline 850.1300 (Goudie, 2019, MRID 51235101)) to EPA's Central Data Exchange ("CDX"), AMVAC encountered a technical issue with the upload. CDX support advised AMVAC that previously submitted correspondence from AMVAC to EPA concerning waivers dated February 22, 2018, that had been uploaded to CDX on February 23, 2018, had not been "properly pulled down into EPA's system." JX 68.
- 42. Although AMVAC is not privy to the specific workings of CDX, this suggested to me that EPA staff may not have reviewed AMVAC's February 22, 2018 correspondence, JX 67, until substantially after it was submitted.

Receipt of and Response to EPA's October 2020 Notification

43. As noted above in connection with the Residue and Field Accumulations Studies, on October 16, 2020, PRD Director Elissa Reaves corresponded with AMVAC concerning the status of the DCI data requirements. JX 21. I received this correspondence via email from the EPA Chemical Review Manager the same day. PAX 38.

- 44. This communication addressed the status of all data requirements that EPA stated were outstanding at that time. JX 21.
- 45. EPA stated that "You are requested to respond within seven days to acknowledge receipt of this letter and to provide a response in 30 days indicating how you intend to satisfy the remaining data requirements, including a timeline for the generation and submission of outstanding data. EPA would like to remind AMVAC that completion and submission of required studies will not necessarily lead to changes in the risk estimates or safety factors used in the Draft Risk Assessment. These data are required by the DCI and, *if submitted in a timely manner*, EPA expects to use them in Registration Review to assess the risks of the chemical.
- 46. I provided an acknowledgement and a response as requested, after requesting (and receiving) a minor extension of the 30-day time limit for a response. JX 22 (response); PAX 38 (email concerning extension).
- 47. Based on JX 21 as quoted above, and EPA's conduct throughout the DCI process, I concluded that there was still time for AMVAC to address the data requirements discussed in JX 21 in a "timely manner" provided that AMVAC continued to engage with EPA concerning its intentions for each study.
- 48. Substantive written responses from EPA concerning AMVAC's response to JX 21 (that is, responses to JX 22, submitted in December 2020) were not received by AMVAC until concurrent with the issuance of the NOITS in April of 2022, at which point EPA made a large number of DERs and other review documents available for the first time, as discussed in more detail in the written statement of Niamh McMahon, paragraph 26.

Authenticity of Exhibits

49. I have reviewed JX 8, 10-22, 24-25, 32-52, 55-56, 64, 66-68, 76-77, 79-80; and

PAX 8, 11, 14, 17, 20, 23, 26-27, 38, 40. 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, Jon C. Wood, 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/ Jon C. Wood

Jon C. Wood

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Verified Written Statement of AMVAC Fact Witness Jon C. Wood, 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
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