# 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; Ratto Bros., Inc.; and Huntington	)
Farms, Petitioners.	) )
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# <u>VERIFIED WRITTEN STATEMENT OF AMVAC FACT WITNESS</u> <u>JULIE PORTER</u>

January 9, 2023

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").
- 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 the U.S. Environmental Protection

Agency ("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, including the Residue and Field Accumulations Studies as discussed below, as well as the rest of the response to the DCI.

## The Residue and Field Accumulations Studies

- 8. The DCI requested data for OCSPP Guidelines 860.1300, 860.1340, 860.1480, and 860.1900. Joint Exhibit ("JX") 4.
- 9. 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.
- 10. 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.
- 11. 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.
- 12. 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.
- 13. 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.
- 14. 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.

- 15. 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.
- 16. 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.
- 17. 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.
- 18. 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.

- 19. 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.
- 20. On January 29, 2014, AMVAC submitted a "12-Month Response" to the DCI. JX 27.
- 21. 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.
- 22. 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.
- 23. AMVAC further stated that the 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.

- 24. 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.
- 25. 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.
- 26. 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.
- 27. 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.
- 28. 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.
- 29. 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).

30. 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.

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 9th day of January 2023.

/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, January 9, 2023, as indicated below.

/s/ Hume M. Ross
Hume M. Ross

## Copy by OALJ E-Filing System to:

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