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 WITNESS, JILL BLOOM,
IN SUPPORT OF RESPONDENT'S NOTICE OF INTENT TO SUSPEND

I. Background

I, Jill Bloom, declare under penalty of perjury that the following statements are true and correct to the best of my knowledge and belief and that they are based upon my personal knowledge, information contained in the records of Respondent, the United States Environmental Protection Agency ("EPA"), and/or information supplied to me by EPA employees under my supervision and in other EPA offices. *See* 28 U.S.C. § 1746.

I am a lead environmental protection specialist in the Risk Management and Implementation Branch Five ("RMIBV"), Pesticide Reevaluation Division ("PRD"), Office of Pesticide Programs ("OPP"), Office of Chemical Safety and Pollution Prevention ("OCSPP"), EPA. I have served in several positions within OPP since February 1989. I started with EPA as a review manager for pesticides. About nine years ago, I began work in a leadership position in RMIBV, and have been primarily involved in the registration review program within OPP,

working on approximately 50 registration review cases. My curriculum vitae is attached to this declaration.

PRD is the division within OPP assigned with the responsibility to develop EPA's regulatory position regarding the re-evaluation of conventional pesticides that are currently registered under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Part of PRD's responsibility includes overseeing the periodic "registration review" of conventional pesticides as required by section 3(g) of FIFRA, 7 U.S.C. § 136a(g). EPA's essential responsibility under registration review is to review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration, which is clearly laid out in 40 C.F.R. § 155.40(a).

This verified statement is filed in support of EPA's April 28, 2022 Notice of Intent to Suspend ("NOITS") Petitioner AMVAC Chemical Corporation's ("AMVAC") registered pesticide product, Technical Chlorthal Dimethyl (EPA Registration Number 5481-495), containing the active ingredient dimethyl tetrachloroterephthalate ("DCPA"). This verified statement constitutes my direct statement as a fact witness in the hearing prompted by AMVAC's May 27, 2022 Request for Hearing, pursuant to the Presiding Official's June 3, 2022 Order Scheduling Hearing and Prehearing Procedures.

II. EPA's Registration Review of DCPA and AMVAC's Failure to Submit Data

As laid out in Respondent's June 13, 2022 Motion for Accelerated Decision, and the supporting Memorandum, AMVAC failed to take appropriate steps to secure the data required by EPA's January 31, 2013 Generic Data Call-In Notice ("DCI") (GDCI-078701-1140), by the deadlines set out in the DCI. The DCI required AMVAC to submit data necessary for EPA to complete registration review and for AMVAC to maintain the continued registration of its DCPA

product under FIFRA. In the preliminary work plan for registration review, EPA described the additional data it believed were necessary to make a decision concerning continued registration of DCPA pesticide products.

EPA provided a 60-day public comment period on the DCPA registration review preliminary work plan and invited comment on all aspects of the plan, including proposed data submission needs. Neither AMVAC nor any other entity submitted comments on the preliminary workplan for DCPA. In EPA's registration review of other pesticide active ingredients, it is common for registrants and other stakeholders to submit comments concerning the anticipated data requirements. The consideration of public comments may result in revisions to the prospective data requirements. The registration review process then continues with a final work plan in which the list of prospective data requirements may have been revised. Following release of the final work plan, EPA submits a draft DCI to the Office of Management and Budget ("OMB") for review. Upon OMB approval, EPA then issues a DCI. Most registration review cases involve issuance of such a DCI.

The DCI for DCPA, issued on January 31, 2013, set deadlines for AMVAC to submit data responsive to the requirements, in most cases one to two years after receipt of the DCI, and in one case, three years. EPA sets deadlines for studies in DCIs based on a number of months it is expected to take to conduct the studies, counting from the registrant's receipt of the DCI, rather than for specific dates. EPA set no deadlines for submitting required data that were later than approximately January 31, 2016. The registrant must respond to the DCI within 90 days of its receipt of the DCI to indicate how it intends to satisfy each data requirement, for example by generating new data, citing existing data, or requesting data waivers, and explaining its rationales for the option chosen.

The Agency typically sets a deadline specific to the nature of the data requirement and the deadlines in the DCPA DCI were standard deadlines for EPA's registration review of pesticide active ingredients. It is common for registrants to request extensions of time for responding to individual data requirements when they believe they will be unable to meet the original deadlines imposed by the DCI. Registrants may request that certain data requirements be waived or request that EPA rely on previously submitted data, typically making these requests within the 90-day period after issuance of the DCI, but occasionally after that period. EPA is generally accommodating of unexpected delays in conducting required studies, or new waivers or substitute studies submitted even after the 90 days, if accompanied by a rationale the Agency deems valid. In the case of the DCPA DCI, AMVAC submitted only one explicit extension request subsequent to issuance of the DCI, and has submitted many data waiver requests since receiving the DCI.

As discussed in the Memorandum, and also in AMVAC's Request for Hearing, EPA has engaged in substantial discussion with AMVAC concerning the submission of data responsive to the DCI over the past eight years. AMVAC had not satisfied approximately 41 DCI data requirements as of October 16, 2020, at which point EPA created a list of outstanding data requirements and notified AMVAC that it intended to move forward with the registration review of DCPA without the required data and would make conservative assumptions in place of such data in order to complete the necessary risk assessments. Such assumptions may take the form of extrapolating from related studies or databases or adding safety factors to account for uncertainties resulting from the lack of data.

At the time the NOITS was issued, AMVAC had still failed to satisfy 20 of the DCI data requirements. While it is not unusual for registrants to fail to meet some deadlines for

registration review DCIs, these as-yet unfulfilled DCPA data requirements represent an abnormally high ratio of non-submissions and waiver requests and an abnormally long time for data to remain outstanding after they are required.

In the case of DCPA, review of data from a preliminary component of the CTA suggested that the toxicity of DCPA was much greater than previously thought and that DCPA may affect fetal thyroids at much lower doses than adult thyroids. Based on review of the preliminary data, EPA scientists determined that they could not assign appropriate safety factors to adequately account for the uncertainties posed by the lack of definitive thyroid data and could not produce a human health risk assessment that was reasonably protective. Accordingly, the Agency is unable to proceed with the DCPA registration review.

A number of the environmental fate and ecological effects data requirements listed in the DCPA DCI are outstanding. The absence of data from these required studies would impart excessive uncertainty into the ecological risk assessment and/or the drinking water exposure assessment, particularly related to testing with the primary degradate of DCPA, tetrachloroterephthalic acid (TPA). Without these data, the Agency would need to rely on assumptions about the persistence of TPA in the environment and/or the toxicity of TPA to certain species. The available data suggest that TPA is persistent in the aquatic environment, but without the required data, EPA is unable to definitively characterize the half-life of TPA in water and would need to assume that it is stable (having a long and indeterminate half-life). EPA could potentially develop an ecological risk assessment built on the assumption that TPA is stable and use DCPA endpoints as surrogates for the missing TPA endpoints. However, in such a situation, risk estimates would be very high, and EPA would not be able to refine the estimates with any certainty. The missing environmental fate and ecological effects data are particularly critical

because of the magnitude of expected TPA concentrations in the water column and limitations in the ecological toxicity database for DCPA chronic data. Chronic testing with DCPA has shown effects in estuarine/marine invertebrates at all test doses, so that the Agency knows only that the lowest dose tested resulted in adverse effects, and it is possible that adverse effects could have occurred at an even lower dose. Without a precise endpoint, the registration review decision would be based on considerable uncertainty in the science, and the proposed risk mitigation developed to address the risks to man and the environment may be overly restrictive. For example, an assumption that TPA does not degrade in water or degrades more slowly than can be estimated by existing data, coupled with the Agency's policy of making conservative (protective) assumptions when data are lacking, could result in onerous restrictions affecting the users of DCPA and the production of some agricultural commodities.

AMVAC's actions as to the DCI are abnormally dilatory and repetitive. Following EPA's denial of AMVAC's requests to waive certain data requirements, AMVAC followed up with additional waiver requests, which usually provided rationales similar to the originals, often with only minor or insignificant changes. In some cases, AMVAC simply opposed the Agency's denials and did not offer any additional, substantive rationale. During this cycle of waiver requests and denials, AMVAC did not initiate attempts to satisfy the subject data requirements. In my experience, this cycle of repeated waiver requests is not common for other registrants and registration review cases. Additionally, explicit statements like AMVAC's that it did not intend to submit certain data required by the DCI are not typical of registrants in general.

The provisions of the NOITS concerning existing stocks of the AMVAC product subject to suspension are typical for products suspended under FIFRA Section 3(c)(2)(B) and are consistent with the purpose of FIFRA. The existing stocks provisions of the DCPA NOITS are

similar to provisions from most prior FIFRA Section 3(c)(2)(B) suspensions where registrants have failed to submit data in response to EPA DCIs. The provisions are clearly laid out in the NOITS and are easily understandable by both AMVAC and users of DCPA products, but are restated in greater detail in the Memorandum. The existing stocks provisions in both this NOITS and prior cases are consistent with EPA's longstanding existing stocks policy, which generally does not allow registrants to sell or distribute existing stocks during the pendency of the suspension, as allowing such action would diminish the incentive for registrants to comply with the DCI in a timely manner.

With respect to the purposes of FIFRA, EPA is charged with determining if a pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). To do so, EPA typically starts by considering whether the pesticide presents risks of concern and, if it does, EPA considers the economic benefits of the pesticide in order to determine whether those risks are unreasonable. Meeting the standard of no unreasonable adverse effects is the burden of registrants, and almost always requires registrants to submit necessary data so that risks can be assessed. As explained above and in the Memorandum, EPA is unable to assess DCPA's risks to man and the environment, due to AMVAC's failure to submit necessary data years after the deadlines for submission imposed by the DCI. Accordingly, EPA would not be able to assess whether the risks are unreasonable and thus whether allowing the sale of the suspended product under an existing stocks provision would meet the standard under FIFRA.

FIFRA does not require EPA to allow for sale of existing stocks. Rather, provisions for sale and use of existing stocks is discretionary to the extent allowing the sale or use of existing stocks is consistent with FIFRA. Where the risk picture is so uncertain that EPA cannot even

make conservative estimates, not allowing existing stocks to continue to be sold or used by the registrant after issuance of a NOITS is fully consistent with FIFRA's goals to protect humans and the environment from unreasonable adverse effects. In the case of the NOITS for DCPA, consideration of this uncertainty was the reason behind the existing stocks provisions the Agency put forward.

III. Conclusion

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

JILL BLOOM

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Jill Bloom
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U.S. Environmental Protection Agency

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Docket No. FIFRA-HQ-2022-0002

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Verified Statement of Jill Bloom**, dated June 17, 2022, was sent this day to the following parties in the manner indicated below.

FORREST PITTMAN
Digitally signed by FORREST PITTMAN
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Dated June 17, 2022

Jill Bloom Curriculum Vitae

- 1980 Bachelor of Science in Agronomy, The Pennsylvania State University
- 1980-1984 Laboratory Technician, Kansas State University, Department of Plant Pathology
- 1984-1989 Laboratory Technician, United States Department of Agriculture, Biocontrol of Plant Diseases Laboratory
- 1989-2013 Environmental Protection Specialist at United States Environmental Protection Agency, Office of Pesticide Programs*
- 2013-present Lead Environmental Protection Specialist at United States Environmental Protection Agency, Office of Pesticide Programs

*During my time as an Environmental Protection Specialist, I served two temporary details as an acting Lead Environmental Protection Specialist before I received a permanent promotion.