

Act (“FIFRA”). Such re-evaluation is performed during 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. Series 860 Residue Chemistry Studies

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 (Series 860 Residue Chemistry Studies: 860.1300, 860.1340, 890.1480, 860.1900) required by EPA’s January 31, 2013 Generic Data Call-In Notice (“DCI”) (GDCI-078701-1140), by the deadline set 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, including several studies on residue chemistry. 40 CFR § 158.1410 requires various data requirements that must be satisfied to support pesticide product registrations and provides OCSPP Guidelines as methods for satisfying those requirements. The residue chemistry data that can be satisfied with OCSPP Guidelines 860.1300, 860.1480, and 860.1900

are necessary for EPA to determine if the residues of DCPA and its degradates in food crops, animal feed crops, and livestock commodities (such as meat, milk, poultry, eggs) would require the establishment of tolerances on any of those crops or commodities. Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes EPA to set tolerances, or maximum residue limits, for pesticide residues on foods when EPA determines those residues are safe, i.e., that there is a reasonable certainty that no harm will result from aggregate exposure to residues of that pesticide chemical. In the absence of a tolerance (or an exemption from the requirement of a tolerance) for a pesticide residue, a food containing such a residue is adulterated and may be subject to seizure by the government. These required residue data are necessary to provide information on the potential residues of DCPA in foods for use in completing a dietary risk assessment and for EPA to determine if such tolerances are necessary. Acceptable data for OCSPP Guideline 860.1340 would ensure that analytical methodology is available for the enforcement of any tolerances for residues of DCPA and its degradates in livestock commodities.

Guideline No. 860.1300, Nature of the residue: poultry

The required poultry nature of the residue (metabolism) study (satisfied by OCSPP Guideline 860.1300) will delineate the residues of concern in poultry commodities for dietary risk assessment and tolerance enforcement. Poultry commodities may contain residues of DCPA and/or other metabolites due to poultry being fed crops that contain DCPA residues, in particular corn and soybean, which may contain DCPA residues due to soil drift or due to being planted successive to DCPA treatment in a prior growing season (i.e., rotated crops).

On April 19, 2013, AMVAC submitted a data waiver request based on this data requirement no longer being necessary if AMVAC removed uses of DCPA on alfalfa, a poultry feed item, from product labels. MRID 49115401. On October 23, 2013, EPA responded to

AMVAC's data waiver request, noting that, at the time of the request, no DCPA end-use products were labeled for use on alfalfa and there were no tolerances established for DCPA on alfalfa. EPA-HQ-OPP-2011-0374-0042. EPA also indicated that it may consider waiving the poultry residue data requirement depending on the outcome of the required rotational crop residue studies (satisfied by OSCPP Guideline 860.1900) in the major poultry feedstuffs corn and soybean, which may contain DCPA residues as a result of crop rotations and from soil drift. *Id.* There are no DCPA end-use products registered for use on corn or soybean but, there are "indirect or inadvertent residue" tolerances for DCPA on corn and soybeans, allowing for some residues as a result of soil drift. 40 C.F.R. § 180.185(d). Due to insufficient data, EPA is not able to determine the expected levels of residues in rotated crops. EPA indicated that, depending on the outcome of required residue studies on the major poultry feedstuffs corn and soybeans, the dietary burden for poultry eating corn, soybeans, and other feedstuffs that may have DCPA residues may be low enough to result in negligible residues of DCPA in poultry commodities, and possibly negating the need for the outstanding poultry data. EPA-HQ-OPP-2011-0374-0042. To date, AMVAC has not submitted data to satisfy the data requirement (which could be satisfied by OCSPP Guideline 860.1300 or, potentially OCSPP Guideline 860.1900, in the alternative). This data requirement remains outstanding.

Guideline No. 860.1340, Residue analytical method: livestock commodities

The required residue analytical method data (satisfied by OCSPP Guideline 860.1340) would ensure that analytical methodology is available for the enforcement of any necessary tolerances for residues of DCPA and its degradates in livestock commodities. Without an acceptable method, there is no approved means for quantifying residues in livestock

commodities, which means that tolerances, if needed, could not be established. 21 U.S.C. § 346a(b)(3).

On April 19, 2013, AMVAC submitted a data waiver request based on this data requirement no longer being necessary if AMVAC removed uses of DCPA on certain livestock feedstuffs (alfalfa, white potatoes, peas) from product labels. MRID 49115401. On October 23, 2013, EPA responded to AMVAC's data waiver request, noting that no DCPA end-use products were labeled for use on alfalfa, white potatoes, or peas and there were no tolerances established for DCPA on alfalfa. However, there are tolerances for indirect residues of DCPA (from soil drift) on potato and on blackeyed peas. JX 26. EPA also indicated that it may consider waiving the livestock analytical method data requirement depending on the outcome of the required rotational crop residue studies (satisfied by OSCPP Guideline 860.1900) in the major livestock feedstuffs corn and soybean, which may contain DCPA residues as a result of crop rotations and from soil drift. *Id.* There are no DCPA end-use products registered for use on corn or soybean but, there are "indirect or inadvertent residue" tolerances for DCPA on corn and soybeans, allowing for some residues as a result of soil drift. 40 C.F.R. § 180.185(d). Due to insufficient data, EPA is not able to determine the expected levels of residues in rotated crops. EPA noted that, depending on the outcome of those major crop residue studies, the dietary burden for ruminants (*e.g.*, cattle, goats, sheep) eating corn, soybeans, and other feedstuffs that may have DCPA residues may be low enough to result in negligible residues of DCPA in livestock commodities, and possibly negating the need for the outstanding residue analytical method data. EPA-HQ-OPP-2011-0374-0042. To date, AMVAC has not submitted these required data (which could be satisfied by OCSPP Guideline 860.1340 or, potentially OCSPP Guideline 860.1900, in the alternative). This data requirement remains outstanding.

Guideline No. 860.1480, Meat/milk/poultry/eggs (livestock feeding study)

The required livestock feeding study (satisfied by OCSPP Guideline 860.1480) will be used to determine the secondary transfer of residues from animal feed items to livestock commodities and whether tolerances are needed for DCPA and its degradates (and if so, the appropriate tolerance levels) on livestock commodities. Without these data, EPA cannot account for residues of DCPA and its degradates in livestock commodities present as the result of consuming animal feed items that contain such residues and cannot determine if tolerances are needed for livestock commodities.

On April 29, 2013, AMVAC submitted a data waiver request, based on this data requirement no longer being necessary if AMVAC removed uses of DCPA on alfalfa, white potatoes, and peas. MRID 49115401. On October 23, 2013, EPA responded to AMVAC's data waiver request, noting that no DCPA end-use products were labeled for use on alfalfa, white potatoes, or peas and there were no tolerances established for DCPA on alfalfa. However, there were tolerances for indirect residues of DCPA (from soil drift) on potato and on blackeyed peas. JX 26. EPA also indicated that it may consider waiving the livestock feeding study data requirement depending on the outcome of the required rotational crop residue studies (satisfied by OSCPP Guideline 860.1900) in the major livestock feedstuffs corn and soybean, which may contain DCPA residues as a result of crop rotations and from soil drift. *Id.* EPA also noted that, depending on the outcome of those major crop residue studies, the dietary burden for animals eating corn, soybeans, and other feedstuffs that may have DCPA residues may be low enough to result in negligible residues of DCPA, and possibly negating the need for the outstanding

livestock feeding study data. *Id.*. To date, AMVAC has not submitted these required data (which could be satisfied by OCSPP Guideline 860.1480 or, potentially OCSPP Guideline 860.1900, in the alternative). This data requirement remains outstanding.

Guideline No. 860.1900, Field accumulation in rotational crops

The required rotational crop studies (satisfied by OCSPP Guideline 860.1900) demonstrating the degree of residue uptake by crops rotated into fields that were previously treated with DCPA will be used to determine the appropriate tolerances (if needed) for DCPA and its degradates in rotated, *i.e.*, subsequently planted, crops. The data may also be used to determine if appropriate crop rotation restrictions (time from application to planting of rotational crop) should be established. The appropriate tolerance levels for rotated crops cannot be assessed until data are submitted showing the residues levels at the specific plantback intervals (PBIs) that the registrant desires. Current labels for products containing DCPA do not broadly prohibit the planting of crops in fields that have previously been treated with DCPA products. Labels for these products merely warn that the replanting of crops other than those included on the label in previously treated soils within eight months of product application may result in crop injury. Without restrictions on planting other crops, it remains possible for crops to be planted in formerly treated fields, and for the uptake of DCPA and its degradates by these crops to occur and result in the potential for subsequent crops to be adulterated due to the lack of a tolerance and subject to seizure.

On April 29, 2013, AMVAC submitted a request for EPA to consider two previously submitted studies to satisfy the requirement. MRID 49115401. On October 23, 2013, EPA determined that these studies were not sufficient to fulfill the rotational crop data requirement and that AMVAC would need to submit additional rotational crop data showing the residues

levels in rotated crops at the specific PBIs that the registrant desires on the labels. EPA-HQ-OPP-2011-0374-0042.

On January 29, 2014, AMVAC provided some storage stability data in response to this data requirement. MRID 49307500. On July 7, 2014, EPA determined that the storage stability data were not responsive to the rotational crop data requirement and reiterated that additional field trial data were required to determine appropriate DCPA tolerances for rotated crops. JX 28.

On August 11, 2014, AMVAC responded to EPA's determinations, again citing as justification for its position existing data and also proposing label restrictions that did not appropriately address the crop rotation restrictions that would be needed to obviate the need to satisfy this data requirement. Rather than prohibiting rotation to any other crop for which DCPA is not registered, the proposed labeling only cautions the user that rotation to non-registered crops within eight months after application of DCPA could result in crop injury. While this labeling would provide potentially important information to the grower, it does not address the Agency's potential dietary risk concerns or the potential for subsequent crops to be adulterated due to the lack of a tolerance. On February 17, 2015, EPA responded, reiterating its prior position and noting that the Agency could consider amending the data if AMVAC made certain specific modifications, outlined in a table, to DCPA end-use product labels. JX 32. To date, AMVAC has not submitted the required data nor amended its product labels in a manner that would obviate the need to conduct crop rotational studies on DCPA (*e.g.*, only allowing rotation to crops with established tolerances for DCPA, with a minimum PBI of 8 months, and prohibiting rotation to all other crops).¹ AMVAC has not requested label amendments consistent

¹ Note: This specific conclusion regarding label amendments/restrictions applied only to the Guideline No. 860.1900, Field accumulation in rotational crops data requirement discussion. EPA had not offered a conclusion on whether label amendments would obviate the need for the other residue chemistry data requirements. However, in

with the modifications suggested in EPA's February 17, 2015 response; the only amendments requested by AMVAC would not accomplish the same purpose. This data requirement remains outstanding.

III. Conclusion

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

Danette Drew
Chemist
Risk Assessment Branch 5
Health Effects Division
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency

Respondent's Motion for Accelerated Decision (June 13, 2022) the quoted text erroneously implies that EPA had made a conclusion with regard to label amendments. That language appears in the following sections: section III.B.16, Guideline No. 860.1300, Nature of the residue: poultry, "...and has not amended its product label to restrict or prohibit certain crop rotations in a manner that would obviate the need to conduct studies of DCPA residues on poultry (*e.g.*, only allowing rotation to crops with established tolerances for DCPA, with a minimum PBI of 8 months)"; section III.B.17, Guideline No. 860.1340, Residue analytical method: livestock commodities, "...and has not amended its product label to restrict or prohibit certain crop rotations in a manner that would obviate the need to conduct studies of DCPA residues on livestock commodities (*e.g.*, only allowing rotation to crops with established tolerances for DCPA, with a minimum plantback interval (PBI) of 8 months)"; section III.B.18, Guideline No. 860.1340, Residue analytical method: livestock commodities, "...and has not amended its product label to restrict or prohibit certain crop rotations in a manner that would obviate the need to conduct studies of DCPA residues on livestock (*e.g.*, only allowing rotation to crops with established tolerances for DCPA, with a minimum PBI of 8 months)."

***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

CERTIFICATE OF SERVICE

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

Forrest Pittman
Attorney Advisor
Counsel for Respondent

Copy by OALJ E-Filing System to:
Mary Angeles, Headquarters Hearing Clerk
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(Grower-Shipper Association of
Central California, et al.)*

Dated June 17, 2022

Danette Lynn Stormont Drew

CONTACT

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WORK EXPERIENCE

- 1) Chemist (GS-1320-14)**
From 8/98 to Present (2022)

Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention (OCSPP)
Office of Pesticide Programs (OPP)
Health Effects Division (HED; Mail code 7509T)
1301 Constitution Ave. NW
Washington, DC 20004

Supervisor: Michael S. Metzger, Branch Chief (HED, Risk Assessment Branch V/VII), 202-566-1981

DUTIES AND ACCOMPLISHMENTS

As a senior chemist and lead risk assessor in EPA's Health Effects Division (HED), I am experienced in preparing comprehensive, aggregate risk assessments that characterize the potential human health risks from pesticide exposure through multiple pathways such as food, drinking water, and occupational and residential exposures. Working with teams of multi-disciplinary scientists, I analyze and evaluate scientific and technical information pertinent to human health assessments including toxicology, hazard characterization, residue chemistry, dietary assessment, and occupational/residential exposure data.

As risk assessor, I arrange and participate in various briefings and meetings with team, division, and Agency personnel, including managers and high-level officials. These meeting may also include chemical companies, agricultural grower's groups, and other stakeholders to determine the key elements for inclusion in the assessment, discussion of assessment results and, in cases where there are unacceptable risks, to help formulate risk mitigation plans. I also routinely interact and coordinate with organizations such as the United States Department of Agriculture, the Food and Drug Administration, and California Department of Pesticide Regulation (DPR). On an international level, I coordinate with Canada's Pest Management Regulatory Agency (PMRA) and representatives of international chemical companies. I also stay abreast of Codex Alimentarius and NAFTA issues in an effort to maintain global harmonization with regards to pesticide safety and regulatory decisions. I have prepared and/or presented technical briefings to the aforementioned groups and to the public to help ensure understanding and transparency of the assessment process. Through these briefings, I effectively communicate technical and policy

issues, orally and in written format, to be intelligible to both technical and non-technical audiences.

As an integral part of preparing health risk assessments, I perform complex dietary (food and drinking water) exposure assessments using modeling programs including advanced probabilistic analysis. I also evaluate the residue chemistry aspects of registration and reregistration actions for pesticide active ingredients which include the following: reviewing residue chemistry data submissions for accuracy and acceptability in meeting the Series 860 Residue Chemistry Guidelines, preparing Data Evaluation Records (DERs) for submitted studies, assessing or reassessing tolerances for residues of pesticide on food and feed commodities, and working with scientists and other members of OPP to obtain concurrence on complex issue resolution.

Because of my extensive background in chemistry, my experience with performing risk assessments, and my knowledge of Agency policies, procedures and guidelines, I have served as a chairperson and member of HED's Chemistry Science Advisory Council (ChemSAC) and as a chairperson and member of HED's Risk Assessment Review Committee (RARC). In these committee roles, I have been directly involved in developing and interpreting OPP/HED science policies, procedures and guidelines as they pertain to residue chemistry and health risk assessment. I also interpret and apply specific exposure issues relating to the law under the Food Quality Protection Act (FQPA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the Federal Food, Drug, and Cosmetic Act (FFDCA).

As a senior level chemist and lead risk assessor in HED, I ensure that work assignments are effectively distributed, and milestones and critical deadlines are met. I provide scientific guidance and support to diverse team members. I provide quality control/quality assurance for branch and division interdisciplinary science products, ensuring that the assessment process is transparent and that the conclusions drawn are based on scientific policies and sound scientific judgment.

In addition to my duties as chemist and risk assessor, I have served as the HED Work Assignment Manager (WAM) for chemistry contracts. As such, I coordinated all interaction between the Agency and the contractor, including prioritizing workload, allocating resources, preparing and sending Task Orders to the contractor, and receiving and distributing completed packages to the secondary reviewers. I also answered all scientific and technical questions from the contractor and assure that they are aware of new Agency policies and directives. I assure that the contractor is in government compliance and evaluate contractor performance. As a certified government Contract Officer Representative (COR), I have training in basic federal government contracting.

AWARDS

On-The-Spot Award (HED; 2011): Chlorpyrifos risk assessment.
EPA Gold Medal for Exceptional Service (2010). Carbofuran risk assessment.
On-The-Spot Award (HED; 2005): Carbofuran risk assessment.
OPP Chuck Trichilo Award (2003): High quality and exemplary performance.
OPP Honor Award for Excellence in Teamwork (2003): Use reports development team.
EPA Bronze Medal for Commendable Service (2002): Diazinon risk assessment.
On-The-Spot Award (HED; 2002): Performance as the Work Assignment Manager.
On-The-Spot Award (Biological and Economical Analysis Division; 2002): Risk assessment use reports development.
OPP Honor Award for Excellence in Teamwork (2001): Diazinon assessment team.
On-The-Spot Award (Registration Division; 2001): Expeditious registration action support.

2) Chemist

From 5/91 to 8/98

Naval Surface Warfare Center (NSWC), Indian Head Division
Test and Evaluation Department
101 Strauss Avenue
Indian Head, MD

This position involved several facets of environmental, ordnance and ordnance-related chemical analyses including project management, method development, instrumental analysis, and data interpretation and presentation. Area of specialization was in the management of projects requiring a non-routine approach. These projects required frequent interaction with co-workers, clients and vendors, the ability to research and evaluate available technology and to develop new specialized methods of analysis. Also called upon to participate in programs requiring the provision of technical support and consultation to organizations DOD wide. As a chemist, I also utilized EPA and ASTM protocols for chemical analysis and waste management as well as my experience operating, troubleshooting and maintaining a variety of instruments. Techniques include gas chromatography /mass spectrometry (GC/MS), x-ray diffractometry (XRD), Fourier transform infrared spectroscopy (FTIR), and differential scanning calorimetry (DSC).

As a member of a team of senior chemists specializing in forensic analysis, I proposed and executed investigative schemes pertaining to mishaps, misfires, and system failures. Investigations also include identification of unknown materials and characterization of raw materials, finished products, and new formulations using a wide array of analytical techniques.

I was contracted by the Defense Special Weapons Agency to provide technical assistance for the program to aid the environmental restoration of former Strategic Rocket Forces facilities in the Republic of Belarus. My technical expertise was focused on overseeing the establishment of a full-scale environmental testing laboratory in Belarus. I maintained frequent contact and

established a good working rapport with DSWA officials, contractors, officials of the Belarusian Ministry of Defense, and members of the Belarusian scientific community.

I was Project Manager for the laboratory support for the chemical/explosive decontamination effort at NSWC, White Oak Detachment as part of the base closure process. As manager, I interfaced daily with other members of the decontamination team and helped to devise effective decontamination, sampling, and disposal strategies. I proposed cost estimates for effort, procured necessary materials, maintained sample tracking records and assigned personnel to analyze samples in order to meet strict turnaround times.

3) Chemist

From 8/84 to 5/91

Versar, Incorporated
6850 Versar Center
Springfield, Virginia

Operated and maintained Finnigan GC/MS systems for Volatile Organic Compounds (VOC's) and semivolatile Base/ Neutral/ Acid compounds (BNA's) for ISAPI, various state programs and private companies using EPA methods 624, 625, 8240, and 8270. Interpreted and reported resulting data.

Performed analysis of trace metals in a variety of sample types and matrices by atomic absorption spectrophotometry (AAS) using Perkin Elmer spectrophotometers. EPA methods 785, 787, and 788 were routinely employed.

Reviewed data generated by chemists and technicians for adherence to QA/QC procedures. Prepared data packages for EPA validation using Ward Scientific software.

EDUCATION

BS Chemistry, 1983
University of Mary Washington
Fredericksburg, VA

PUBLICATIONS

1. Drew, D., "Characterization of LC-12-15 Ballistic Modifier by X-ray Diffraction and Thermal Analysis", 1993 Joint Army-Navy-NASA-Air Force (JANNAF) Propulsion Meeting, Lawrence Livermore Laboratory, CA, Chemical Propulsion Information Analysis Center (CPIAC) Publication.

2. Drew, D. and Smith, V., "Examination and Characterization of Lead Double Salt Ballistic Modifier Used in N-5 Propellant", 1993 Joint Army-Navy-NASA-Air Force (JANNAF) Propulsion Meeting, Lawrence Livermore Laboratory, CA, CPIA Publication.
3. Drew, D. and Smith, V., "Environmental Problems in Today's World of Energetics- Naval Surface Warfare Center's Current State of Environmental Activities", 2nd International Seminar on Environmental Problems of Demilitarization, Belarus, April 1995.
4. Contributing author to U.S. "Navy Environmental Compliance Sampling and Field Testing Procedure Manual", Publication NAVSEA T0300-AZ-PRO-010, originally published January 1997.

PROFESSIONAL DEVELOPMENT

TECHNICAL COURSES and SYMPOSIA ATTENDED

1. Mass Spectral Interpretation, Continuing Education Course, NIST.
2. Hewlett Packard GC/LC/MS/Particle Beam Operation and Maintenance Course, Hewlett Packard.
3. Fundamentals of FTIR, Spectros Associates.
4. Infrared Spectral Interpretation, Spectros Associates.
5. X- ray Diffraction Operation, Philips Electronics.
6. Air Pollution Control, Continuing Education Course, George Washington University.
7. Thermal Analysis Applications in High Energy Materials.
8. JANNAF Propulsion Development and Characterization Subcommittee (PDCS).
9. International Symposium on the Analysis and Detection of Explosives.
10. Erin Associates, Really Effective Presentations
11. HED Risk Assessment Training, 1998
12. Contract Officer Representative Training, 2001.
13. EPA Leadership Course: Getting Work Done with Others, 2001.
14. 39th Annual Florida Pesticide Residue Workshop, 2002.
15. OPM Management Development Seminar Training, 2004.

TECHNICAL SKILLS

Experienced in gas chromatography /mass spectrometry (GC/MS), x-ray diffractometry (XRD), Fourier transform infrared spectroscopy (FTIR), differential scanning calorimetry (DSC), and atomic absorption spectrophotometry (AAS). Competent in computer skills to perform required duties (Word, Excel, PowerPoint, Dietary Exposure Evaluation Model (DEEM), and other work-related databases for storage and retrieval of data).