ATTACHMENT B

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; J&D Produce; Ratto Bros., Inc.; and Huntington Farms,	)	**Docket No. FIFRA-HQ-2022-0002**
Petitioners.	)	

PETITIONER AMVAC CHEMICAL CORPORATION'S
FIRST SET OF INTERROGATORIES
AND DOCUMENT REQUESTS TO RESPONDENT

Petitioner AMVAC Chemical Corporation ("AMVAC"), hereby submits these Interrogatories and Document Requests to Respondent Office of Pesticide Programs ("OPP"), and requests that OPP respond within 30 days (or within such time as the Presiding Officer may order), pursuant to the Fed. R. Civ. P. as incorporated into the Order on Respondent's Motion to Amend Hearing and Scheduling Order, Dkt. 33, issued on October 18, 2022 (the "Discovery Order") and the Hearing and Scheduling Order Following Remand, Dkt. 30, issued on October 3, 2022 (the "Scheduling Order").

INSTRUCTIONS

1. These requests for production cover all information in your possession, custody, or control, including information in the possession of employees, agents, servants, contractors, representatives, attorneys, or other persons directly or indirectly employed or retained by you or anyone else acting on your behalf or otherwise subject to your control.

2. If any requested document is no longer in your possession, custody, or control, state when the document was last in your possession, custody, or control, what was done with the document, and the identity and address of the current custodian of the document (if any).

3. If you are unable to locate or produce documents in response to a request, state the steps that were taken to locate such documents and the reasons why you cannot produce the documents requested.

4. If an objection is made to any interrogatory or to producing any document, or any portion thereof, or to disclosing any information contained therein, based on any claim of privilege or protection from discovery, identify the claimed privilege or protection and the specific information to which it pertains.

5. If you assert that a part of an interrogatory or a document request is objectionable, respond to those remaining parts of the interrogatory or document request to which you do not object and state whether or not you are withholding potentially responsive documents based on the objection.

6. Unless otherwise indicated, these requests cover all documents whenever created, up to the present.

7. If any of the documents requested do not exist, indicate this in writing in response to these requests.

DEFINITIONS

1. The terms "any" and "all" shall be understood to include and encompass "any and all." "Including" means "including but not limited to." The words "and" as well as "or" shall be construed disjunctively or conjunctively as necessary to bring within the scope of the interrogatories all information, documents, or things which might otherwise be construed to be

outside their scope. The singular shall always include the plural, and the present tense shall also include the past tense. Words in the masculine, feminine, or neutral form shall include each of the other genders.

2. The terms "communication" and "communications" mean any transmittal of information, ideas, opinions, or thoughts made by any means, at any time or place, under any circumstances. Communication is not limited to direct transfers between persons but includes other transfers and memorialization, such as records, memoranda to file, or transfers of computer files. Communication may be embodied in any means or media, including writing, electronic or magnetic storage of computer files, electronic mail, voice mail, digital recording, or sound recording.

3. The terms "relate," "concern," and their derivatives shall be construed in their most inclusive sense, including to refer to, discuss, describe, summarize, reflect, constitute, contain, embody, evidence, pertain to, mention, consist of, comprise, show, comment on, or in any other manner be connected with the referenced subject matter.

4. "Document" means the original and each non-identical copy of any and all written, typed, printed, recorded, or graphic matter or electronically stored information, however produced, reproduced, or stored, in your actual or constructive possession, custody, or control, whether prepared, published, or released by you or by any other person or entity—including but not limited to letters, reports, agreements, correspondence, intra-office and inter-office correspondence, electronic mail or messages, minutes or records of meetings, expressions or statements of policy, memoranda, calendars, images, videotapes, photographs, presentations, press releases, summaries of conversations, or data compilations stored in any medium from which information can be obtained.

5. "Identify" and "Identity" mean:

   a. With respect to an act, transaction, or event of some kind, to state all relevant names, dates, places, amounts, values, and significance;

   b. With respect to documents, to state the type of document, date, identification of the person or persons who prepared the document, identification of the person or persons for whom the document was prepared, the name(s) of each signatory thereof, and the person to whom it was delivered, and the identity of the present custodian and current location of the document.

6. "State the basis" means:

   a. to identify each and every document (and, where pertinent, the section, article, or subparagraph thereof), which forms any part of the source of your information regarding the alleged facts or legal conclusions referred to by the interrogatory or document request;

   b. to identify every communication which forms any part of the source of your information regarding the alleged facts or legal conclusions referred to by the interrogatory or document request, and any person who made or received such communication; and

   c. to state separately any fact which forms the basis of your information regarding the alleged facts or legal conclusions referred to in the interrogatory or document request.

7. The "matter" or the "proceeding" shall mean the above-captioned action pending before the EPA Office of Administrative Law Judges under Docket Number FIFRA-HQ-2022-0002 and any related appeals.

8. "JX" and a number shall mean the correspondingly numbered Joint Exhibit previously filed in this proceeding.

9. "Guideline" and a number or numbers shall mean the correspondingly numbered Office of Chemical Safety and Pollution Prevention Harmonized Test Guideline(s).

10. The terms "EPA," or "the Agency," shall mean the United States Environmental Protection Agency and any branch or division thereof, all persons employed thereby, and any contractors or consultants who perform work on behalf thereof.

11. "DCPA" shall mean Dimethyl Tetrachloroterephthalate or AMVAC's registration of technical grade DCPA (EPA Reg. No. 5481-495) as appropriate based on the context.

12. "TPA" shall mean tetrachlorophthalic acid, a degradate of DCPA.

13. The "NOITS" or the "DCPA NOITS" shall mean the Notice of Intent to Suspend AMVAC's DCPA registration as set forth in both the letter from Elissa Reaves, Director, Pesticide Re-evaluation Division, Office of Pesticide Programs, EPA to Jon C. Wood, AMVAC Chemical Corporation dated April 21, 2022 (JX 1) and the Federal Register Notice concerning that letter at 87 Fed. Reg. 25,262 (Apr. 28, 2022) (JX 2).

14. The "DCPA DCI," or "the DCPA Data Call-In" shall mean GDCI-078701-1140, issued January 31, 2013 (JX 4).

15. "DCIs," "a DCI," "Data Call-In," or similar shall mean Data-Call In notices issued to registrants under the authority of 7 U.S.C. § 136a(c)(2)(B) generally, including the DCPA DCI.

16. "Data Requirement" shall mean a request from EPA in a DCI for a response from a registrant in connection with a particular Guideline or "Special Study." As used herein, a request from EPA for data in connection with a particular Guideline or "Special Study" for a

technical grade active ingredient and a degradate thereof constitutes two data requirements. As used herein, a request from EPA for data in connection with a particular Guideline or "Special Study" that requires testing multiple species is a separate "data requirement" as to each required test species.

17. "MRID," shall mean Master Record Identification Number, the numeric codes assigned by the Agency to track studies submitted by pesticide registrants

18. "DER" shall mean a Data Evaluation Record of the type routinely prepared by the Agency concerning studies submitted by pesticide registrants.

19. "OPP" shall mean the Office of Pesticide Programs within the Agency, and any precursor division or branch that performed any tasks now performed by OPP, and any contractors working on behalf thereof.

20. "PRD" shall mean the Agency's Pesticide Re-evaluation Division within OPP, and any precursor division or branch that performed any tasks now performed by PRD, and any contractors working on behalf thereof.

21. "RD" shall mean the Agency's Registration Division within OPP, and any precursor division or branch that performed any tasks now performed by PRD, and any contractors working on behalf thereof.

22. "HED" shall mean the Agency's Health Effects Division, and any precursor division or branch that performed any tasks now performed by HED, and any contractors working on behalf thereof.

23. "CRM" shall mean the position of Chemical Review Manager within OPP.

INTERROGATORIES

Interrogatory No. 1: For each Data Call-In issued by EPA in calendar years 2009 through 2015, except the DCPA DCI, provide a list of all data requirements that EPA considers not to be satisfied as of the response to this Interrogatory, and the identity of the DCI associated with each unsatisfied requirement.

Interrogatory No. 2: Identify all PRD registration review cases in which a *Draft Risk Assessment* was published in or after 2015 notwithstanding the fact that at least one data requirement from a DCI for the subject active ingredient was considered outstanding at the time the DRA was published.

Interrogatory No. 3: Identify all PRD registration review cases in which a *Proposed Interim Decision, Final Interim Decision, or Final Decision* was published in or after 2015 notwithstanding the fact that at least one data requirement from a DCI for the subject active ingredient was considered outstanding at the time the PID or ID was published.

Interrogatory No. 4: Identify all instances in or after August of 2020 in which a PRD Team Leader, or more senior Agency personnel, including without limitation Mary Elissa Reaves, Ed Messina, and Michael Goodis, has participated in a meeting that included individuals outside of EPA and made statements concerning registrants' obligations when responding to DCIs, including without limitation the need to make formal extension requests and how EPA would analyze initial or subsequent waiver requests, or registrant "rebuttals" of EPA waiver denials.

Interrogatory No. 5: For each instance identified in response to Interrogatory No. 4, describe the substance of the statements made at each meeting concerning registrants' obligations when responding to DCIs as set forth in Interrogatory No. 4.

Interrogatory No. 6: State whether any of the "Time Frame[s]" set forth in Column 8 of the DCPA DCI tables (JX 4) for any of the OSCPP/OPPTS "Guidelines" (or Special Studies) pertaining to any of the data requirements identified in the NOITS have any time built in to permit EPA to review the data submitted and state the amount of time built in for such review.

Interrogatory No. 7: State whether any of the "Time Frame[s]" set forth in Column 8 of the DCPA DCI tables (JX 4) for any of the OSCPP/OPPTS "Guidelines" (or Special Studies) pertaining to any of the data requirements identified in the NOITS have any time built in to permit EPA to review protocols submitted by registrants and state the amount of time built in for such review.

Interrogatory No. 8: Identify what other DCIs Jill Bloom was comparing the DCPA DCI to in connection with each of the comparative statements in the following quote from pp. 4-5 of her prior Verified Written Statement:

> *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.*

Interrogatory No. 9: At p. 6 of her prior Verified Written Statement, Jill Bloom asserts that "*AMVAC's actions as to the DCI are abnormally dilatory and repetitive*." State the criteria used by Ms. Bloom to identify actions as "dilatory" or "repetitive" and identify all actions Ms. Bloom

asserts AMVAC took that were "dilatory" and all actions Ms. Bloom asserts AMVAC took that were "repetitive."

Interrogatory No. 10: At p. 6 of her prior Verified Written Statement Jill Bloom asserts that, "*In some cases, AMVAC simply opposed the Agency's denials and did not offer any additional, substantive rationale*." Identify each communication from AMVAC that Ms. Bloom asserts "did not offer any additional, substantive rationale" as compared to a prior request.

Interrogatory No. 11: For all data requirements for which EPA alleges in the NOITS that AMVAC's 90-day response was inadequate (per Table 2, "Inadequate 90-day response"), state with specificity the inadequacy EPA alleges regarding each such response.

Interrogatory No. 12: State whether EPA alleges that the initially submitted special study protocol for SS-1069 contained any deficiencies such that EPA alleges that the submittal of the study was not, at the time it was submitted, an "appropriate step" as the term is used in the NOITS. To the extent that EPA alleges that the submittal of the initial SS-1069 protocol did not constitute an "appropriate step," state the basis for that contention.

Interrogatory No. 13: Identify all DCIs issued in or after 2009 that have required a study substantially equivalent to the SS-1072 study in the DCPA DCI.

Interrogatory No. 14: For any DER concerning a study submitted by AMVAC to fulfil a data requirement at issue in this matter for which OPP indicated that there was "inadequate data received" in the NOITS (at 87 Fed. Reg. 25,262) indicate whether EPA believes that AMVAC is responsible for any portion of the delay between the date the study was submitted and the date of the earliest signature of any primary or secondary reviewer on such DER.

Interrogatory No. 15: For any DER concerning a study submitted by AMVAC to fulfil a data requirement at issue in this matter for which OPP indicated that there was "inadequate data received" in the NOITS (at 87 Fed. Reg. 25,262) indicate whether EPA believes that AMVAC is responsible for any portion of the delay between the date of the earliest signature of any primary or secondary reviewer and the date of the latest signature of any primary or secondary reviewer on such DER.

Interrogatory No. 16: For any DER concerning a study submitted by AMVAC to fulfil a data requirement at issue in this matter for which OPP indicated that there was "inadequate data received" in the NOITS (at 87 Fed. Reg. 25,262) indicate whether EPA believes that AMVAC is responsible for any portion of the delay between the date of the latest signature of any primary or secondary reviewer and the date the DER was transmitted to AMVAC.

Interrogatory No. 17: To the extent EPA asserts AVMAC was responsible for any delay identified in the previous three interrogatories, state the basis for that contention.

Interrogatory No. 18: For any AMVAC waiver request (or response to the Agency's denial of a waiver, or comments on a prior waiver request) that the Agency asserts did not provide an additional substantive rationale for granting a waiver, identify such communication and state the basis of OPP's contention that it did not provide an additional substantive rationale for granting a waiver.

[Document Requests Follow]

DOCUMENT REQUESTS

Document Request No. 1: Provide copies of all communications between Jill Bloom and any individual acting in the capacity of CRM for DCPA dated subsequent to issuance of the DCPA DCI that refer to or discuss the DCPA DCI, any data requirement in the DCPA DCI, the performance of a risk assessment for DCPA, or the registration review of DCPA.

Document Request No. 2: Provide copies of all communications between any two individuals who served as the CRM for DCPA dated subsequent to issuance of the DCPA DCI that refer to or discuss the DCPA DCI, any data requirement in the DCPA DCI, the performance of a risk assessment for DCPA, or the registration review of DCPA.

Document Request No. 3: Provide a copy of any paper files maintained by PRD concerning the DCPA DCI or the registration review of DCPA.

Document Request No. 4: Provide a copy of any electronic files (other than emails) maintained within a PRD electronic database concerning the DCPA DCI or the registration review of DCPA.

Document Request No. 5: Provide copies of all communications between Mary Elissa Reaves, Jill Bloom, Michael Goodis, Cathryn Britton, and any personnel within EPA discussing the need to issue the NOITS, or the basis for issuing the NOITS, dated on or before April 28, 2022.

Document Request No. 6: Provide copies of all documents in the custody or control of, or otherwise accessible to, James Douglass, Jill Bloom, Cathryn Britton, or Mary Elissa Reaves that summarize the status of any registrant's (or registrants') submissions in response to any DCI issued in or after 2009.

Document Request No. 7: Provide copies of any manuals, handbooks, guidelines, memoranda, PowerPoints or other presentations, standard operating procedures (SOPs), instructional materials, or other documents that advise how PRD personnel should, may, or must require, respond to, or otherwise address extension requests from registrants in connection with DCIs generally, or in connection with any specific DCI, at any point since 2009.

Document Request No. 8: Provide copies of any manuals, handbooks, guidelines, memoranda, PowerPoints or other presentations, standard operating procedures (SOPs), instructional materials, or other documents that advise how PRD personnel should, may, or must respond to initial or subsequent waiver requests, or registrant "rebuttals" of EPA waiver denials, in connection with DCIs generally, or in connection with any specific DCI, at any point since 2009.

Document Request No. 9: Provide copies of any manuals, handbooks, guidelines, memoranda, PowerPoints or other presentations, standard operating procedures (SOPs), instructional materials, or other documents that state the amount of time that the Agency's review of data submitted under any OSCPP/OPPTS "Guideline" (or Special Studies): (1) must be limited to; (2) should be limited to; or (3) typically takes, based on Agency experience.

Document Request No. 10: Provide copies of any manuals, handbooks, guidelines, memoranda, PowerPoints or other presentations, standard operating procedures (SOPs), instructional materials, or other documents that state the amount of time that the Agency's review of protocols submitted for review by the agency in connection with DCIs: (1) must be limited to; (2) should be limited to; or (3) typically takes, based on Agency experience.

Document Request No. 11: Provide copies of all communications subsequent to the Data Delay Letter, JX 21, provided to AMVAC prior to April 21, 2022, in which EPA indicates that it could not proceed with a risk assessment of DCPA.

Document Request No. 12: Provide a copy of any calculations, memoranda, or other documents prepared by Jill Bloom to substantiate any of her statements referred to in Interrogatory Nos. 8-10.

Document Request No. 13: Provide a copy of any documents used or referred to by Jill Bloom in the preparation of her Verified Witness Statement filed in this matter other than those requested in Document Request No. 12.

Document Request No. 14: Provide copies of any Agency documents (as defined above, and specifically including any manuals, handbooks, guidelines, memoranda, PowerPoints or other presentations, standard operating procedures (SOPs), or instructional materials) that contain guidance on when uncertainty is "excessive" or otherwise unacceptable to the agency for proceeding with a risk assessment in the context of: (1) environmental fate data; or (2) ecological effects data.

Document Request No. 15: Provide copies of all communications between personnel at OPP's Environmental Fate and Effects Division (including Richard Shamblen, Stephen Wente, Karen Milians, Rochelle Bohaty, James Lin, Brian Anderson, Elyssa Arnold) and personnel at PRD (including Marquea King, Linda Arrington, James Douglass, Jill Bloom, Cathryn Britton) discussing: (1) AMVAC's initial request to rely on MRID 00114651 to satisfy Guideline 835.4200 for TPA; (2) AMVAC's subsequent request to waive Guideline 835.4200 for TPA; or

(3) EFED's ability (or inability) to proceed with risk assessment absent additional data under this Guideline between April 29, 2013 and April 19, 2022.

Document Request No. 16: If EPA does not admit Request for Admission No. 23, provide all documents or communications constituting, referring to, or providing evidence of EPA's review of JX 67 dated between Feb. 22, 2018 and October 16, 2020.

Document Request No. 17: Provide copies of all communications between personnel at EFED (including Christina Wendel, James Lin, Jean Holmes, R. David Jones, Donna Reed Junkins, Brian Anderson, Richard Shamblen, Stephen Wente, Karen Milians, Rochelle Bohaty, Michael Wagman) and personnel at PRD (including Jill Bloom, Kevin Costello, James Douglass, Cathryn Britton) discussing: AMVAC's initial request to waive Guideline 835.4300 or Guideline 835.4400 for TPA; (2) EFED's ability (or inability) to proceed with risk assessment absent additional data under either Guideline between April 29, 2013 and April 19, 2022; (3) EPA's review of JX 67 (at any time); or (3) EPA's review of MRID 49307515.

Document Request No. 18: Provide copies of all communications between personnel at EFED and personnel at PRD (including the individuals identified in Document Request No. 17) discussing: (1) AMVAC's initial request to waive Guideline 850.1400 for TPA; (2) EFED's ability (or inability) to proceed with risk assessment absent additional data under this Guideline between April 29, 2013 and April 19, 2022.

Document Request No. 19: Provide copies of all communications between personnel at EFED and personnel at PRD (including the individuals identified in Document Request No. 17) discussing EPA's review of MRID 51398103 as it relates to any data requirement.

Document Request No. 20: Provide copies of all communications between personnel at EFED and personnel at PRD (including the individuals identified in Document Request No. 17) discussing: (1) AMVAC's initial request to waive either Guideline 850.1350 Chronic tox. Mysid or Guideline 850.5400 Algal tox. test, Tier I/II (TPA); (2) EFED's ability (or inability) to proceed with risk assessment absent additional data under either Guideline between April 29, 2013 and April 19, 2022.

Document Request No. 21: Provide a copy of the "EFED DER transmittal memo (dated January 21, 2022)" referenced in Footnote a to Table 3 in JX 69.

Document Request No. 22: Provide copies of all "transmittal memos" comparable to the "EFED DER transmittal memo (dated January 21, 2022)" referenced in Footnote a to Table 3 in JX 69 that address any science branch's review of any data relevant to the data requirements indicated as being outstanding in the NOITS, to the extent that such memoranda are not already available in the Regulations.gov Docket No. EPA-HQ-OPP-2011-0374.

Document Request No. 23: Provide copies of all communications between personnel at EFED and personnel at PRD (including the individuals identified in Document Request No. 17) discussing (1) the data submitted by AMVAC to satisfy the Guideline 850.1350 Chronic tox. Mysid (DCPA) data requirement; or (2) EFED's ability (or inability) to proceed with risk assessment absent additional data under this Guideline between April 29, 2013 and January 21, 2022.

Document Request No. 24: Provide all communications in which EPA informs AMVAC that an extension request is required or requested in connection with any data requirement identified as outstanding in the NOITS.

Document Request No. 25: If will not admit Request for Admission No. 40, provide copies of all communications in which Jordan Page or any subsequent CRM refers to JX 38 as being the definitive source for the required amendments to eliminate the need for any of the residue chemistry data requirements (Guidelines 860.1300, 1340, 1480, 1900).

Document Request No. 26: Provide copies of all communications and documents exchanged between or among PRD and Health Effects Divison personnel which discuss, refer to, or in any way analyze the sufficiency of proposed label amendments submitted by AMVAC in or after March of 2017, including without limitation James Douglass, Jill Bloom, Danette Drew, Michael Metzger, Marquea King, Jordan Page, Kathryn Montague, Elissa Reaves, and Cathryn Britton, including but not limited to any discussion between any of these personnel concerning how to describe the status of these data requirements in JX 21.

Document Request No. 27: Provide all documents and communications between Christina Wente and any other individual at EPA referring to or discussing the need for SS-1072 in the context of the DPCA DCI, or the degree to which "confidence" in a potential risk assessment would be decreased or the "uncertainty" in a potential risk assessment increased based on the absence of data from the SS-1072 study.

Document Request No. 28: Provide copies of all EPA DERs assessing studies substantially equivalent to the SS-1072 study in the DCPA DCI.

Document Request No. 29: For any Request for Admission that asks EPA to admit the non-existence of a document or communication (either in total, or that no such communication was issued during a certain time frame) which EPA does not admit (Requests for Admission Nos. 1, 3, 17, 18, 23, 25, 27, 31, 38, 40, 41, 43, 45, 46) provide a copy of the documents or

communications forming the basis for the refusal to admit, and indicate which Request for Admission each document produced for this reason pertains to.

Document Request No. 30: Provide copies of any documents prepared to memorialize or summarize meetings between AMVAC and any Agency personnel concerning the DCPA DCI (*e.g.*, meeting minutes, summaries), to the extent such records were not also provided to AMVAC.

Document Request No. 31: Provide copies of all communications between personnel in RD and personnel in PRD concerning amendments to DCPA labels between March 1, 2017 and April 27, 2022.