

ATTACHMENT A

PROPOSED REQUESTS FOR ADMISSION

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,)

Petitioners.)

Docket No. FIFRA-HQ-2022-0002

**PETITIONER AMVAC CHEMICAL CORPORATION'S
FIRST REQUESTS FOR ADMISSION TO RESPONDENT**

Petitioner AMVAC Chemical Corporation (“AMVAC”), hereby submits these Requests for Admission to Respondent Office of Pesticide Programs (“OPP”), and requests that OPP respond to these Requests for Admission 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

As set forth in Fed. R. Civ. P. 36, as referenced in the Scheduling Order, you are required to admit the truth of the facts, and application of the law to the facts, as set forth below. If a matter is not admitted, the answer must specifically deny it or state in detail why the answering party cannot truthfully admit or deny it. A denial must fairly respond to the substance of the matter; and when good faith requires that a party qualify an answer or deny only a part of a matter, the answer

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must specify the part admitted and qualify or deny the rest. The answering party may assert lack of knowledge or information as a reason for failing to admit or deny only if the party states that it has made reasonable inquiry and that the information it knows or can readily obtain is insufficient to enable it to admit or deny.

DEFINITIONS

As used in these Requests, the following terms are to be interpreted in accordance with these definitions:

1. The terms “any” and “all” shall be understood to include and encompass “any and all.” “Including” means “including but not limited to.”
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, electronic or transfer 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. 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.

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5. “JX” and a number shall mean the correspondingly numbered Joint Exhibit previously filed in this proceeding.

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

7. 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.

8. “DCPA” shall mean Dimethyl Tetrachloroterephthalate or AMVAC’s registration of technical grade DCPA (EPA Reg. No. 5481-495) as appropriate based on the context.

9. “TPA” shall mean tetrachlorophthalic acid, a degradate of DCPA.

10. 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 Mary 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).

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

12. “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.

13. “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

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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.

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

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

16. “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.

17. “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.

18. “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.

19. “CRM” shall mean the position of Chemical Review Manager within OPP.

REQUESTS FOR ADMISSION

1. Admit that EPA did not provide any of the following documents to AMVAC until April 27, 2022, or later: DERs for studies with MRIDs 49500701; 49307505; 49307511; 51398105; 49307510; 49307514; 51398104; 49307512; 49477601; 49307513; 49307506; 49307509; 49307504; 51499402; 49307508; 49307507; 49865801; 49865802; 49307519;

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49307518; 51235101; 51235102; 51499401; JX 57, 59, 69, 79, and documents with Regulations.gov Doc. IDs EPA-HQ-OPP-2011-0374-0053 and EPA-HQ-OPP-2011-0374-0054.

2. Admit that JX 21 does not indicate that EPA cannot proceed with a risk assessment of DCPA as of the time JX 21 was issued.
3. Admit that at no time after the date of JX 21 (October 16, 2020) did EPA indicate to AMVAC that it could not proceed with a risk assessment of DCPA prior to April 27, 2022.
4. Admit that it is common for registrants to not meet some deadlines set forth in registration review DCIs.
5. Admit that the data requirements identified in the DCPA NOITS as being unfulfilled at the time the NOITS was issued did not represent an abnormally high ratio of non-submissions in view of the total number of data requirements in the DCPA DCI (i.e., including those that had been fulfilled).
6. Admit that the number of waiver requests made by AMVAC over the course of its response to the DCPA DCI did not represent an abnormally high number of waiver requests in view of the total number of data requirements in the DCPA DCI, when viewed in comparison with other DCIs of similar scope.
7. Admit that it is common for data to remain outstanding for the length of time that certain DCPA DCI data was outstanding at the time of the NOITS.
8. Admit that AMVAC's correspondence and communications with EPA in responding to the DCPA DCI were typical of correspondence and communications from other registrants in the course of DCIs with similar scope.
9. Admit that EPA has issued Draft Risk Assessments, Proposed Interim Decisions, and/or Interim Decisions in registration review cases for active ingredients even though, at the

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time of issuance of such documents, there were outstanding data requirements from a DCI in connection with such active ingredient.

10. Admit that the claim made on page 6 of the Verified Written Statement of Witness, Jill Bloom (Dkt. 18.10 in this matter) that making conservative assumptions as the available data would require “could result in onerous restrictions affecting the users of DCPA and the production of some agricultural commodities” was made without reference to any specific restriction that might be necessary based on a risk assessment that had been performed by EPA or otherwise.

11. Admit that no action AMVAC took in connection with the DCPA DCI was dilatory, in the sense that it was intended to cause delay.

12. Admit that no action AMVAC took in connection with the DCPA DCI was repetitive, in the sense that it was the same as a prior action.

13. Admit that every AMVAC waiver request (or response to the Agency’s denial of a waiver, or comments on a prior waiver request) provided additional substantive rationale as compared to the prior communications that AMVAC was supplementing in connection with the same data requirement.

14. Admit that AMVAC provided an adequate 90-day response for each data requirement identified in the NOITS, in that AMVAC identified a permissible response code (*e.g.*, 1 = develop new data, 9 = request waiver) and provided all information required to accompany each response code elected for each data requirement.

15. Admit that, as of the response date to this RFA, EPA has received a study from AMVAC that is responsive to Guideline 850.1400 Fish early life-stage (bluegill sunfish) (DCPA).

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16. Admit that, as of the response date to this RFA, EPA has received a study from AMVAC that is responsive to Guideline 850.1400 Fish early life-stage (sheepshead minnow) (DCPA).

17. Admit that EPA never requested that AMVAC request extensions in connection with any data requirement identified as outstanding in the NOITS.

18. Admit that, on the one occasion in the course of AMVAC and EPA's correspondence related to the DCPA DCI when AMVAC made an express request for an extension, EPA never responded to the request.

Requests Regarding Guideline 835.4200 Anaerobic soil metabolism (TPA)

19. Admit that EPA's statement in JX 77 that "EFED believes that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment, but will assume stability in the absence of a study" could reasonably be construed as a grant of a waiver provided the registrant is willing to accept the assumption of stability.

20. Admit that AMVAC's response to JX 21 and JX 22, incorporated by reference a substantive further response concerning this data requirement (JX 78) which was neither dilatory, repetitive, or otherwise unsubstantiated.

21. Admit that JX 79 indicated that EFED would be able to proceed with risk assessment even without additional data under this guideline.

Requests Regarding Guideline 835.4400 Anaerobic aquatic metabolism (TPA)

22. Admit that AMVAC's response to JX 37 and JX 67 (dated Feb. 22, 2018), provided a substantive further response concerning this data requirement which was neither dilatory, repetitive, or otherwise unsubstantiated.

23. Admit that EPA did not review JX 67 prior to issuing the Data Delay Letter (JX

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21) to AMVAC in October 2020.

24. Admit that AMVAC's response to JX 21 and JX 22, incorporated by reference a substantive further response concerning this data requirement (JX 78) which was neither dilatory, repetitive, or otherwise unsubstantiated.

Requests Regarding Guideline 835.4300 Aerobic aquatic metabolism (TPA)

25. Admit that EPA did not communicate with AMVAC concerning this data requirement (after receipt of the initial response, JX 5) until on or after March 17, 2017 (JX 37).

26. Admit that EPA has never analyzed whether data available in MRID 49307515 is relevant to the Guideline 835.4300 Aerobic aquatic metabolism data requirement, including whether a waiver would be appropriate (or a risk assessment could proceed) based on data available in MRID 49307515.

Requests Regarding Guideline 850.1400 Fish ELS (all three test species) (TPA)

27. Admit that EPA did not communicate with AMVAC concerning this data requirement (after receipt of the initial response, JX 5) until on or after March 27, 2017 (JX 37).

28. Admit that JX 37 indicated that if an "acute and chronic toxicity study in daphnids" was performed, the Guideline 850.1400 TPA Fish ELS studies would potentially not be needed, depending on the results of the daphnid studies.

29. Admit that JX 22 provided a substantive further response concerning this data requirement (specifically, MRID 51398103) which was neither dilatory, repetitive, or otherwise unsubstantiated.

30. Admit that MRID 51398103 presented acute and chronic toxicity data in daphnids as potentially relevant to this data requirement, consistent with EPA's statement in JX 37 referenced above.

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Requests Regarding Guideline 850.1350 Chronic tox. Mysid & 850.5400 Algal tox. test, Tier I/II (TPA)

31. Admit that EPA did not communicate with AMVAC concerning these data requirements (after receipt of the initial response, JX 5) until on or after March 27, 2017 (JX 37).

32. Admit that JX 37 indicated that if an “acute and chronic toxicity study in daphnids” was performed, further studies would potentially not be needed for these data requirements, depending on the results of the daphnid studies.

33. Admit that JX 22 provided a substantive further response concerning these data requirements (specifically, MRID 51398103) which was neither dilatory, repetitive, or otherwise unsubstantiated.

34. Admit that MRID 51398103 presented acute and chronic toxicity data in daphnids as potentially relevant to these data requirements, consistent with EPA’s statement in JX 37 referenced above.

35. Admit that, with respect to Guideline 850.5400, JX 69 reflects EPA’s acceptance of outstanding waiver requests for three of the four species categories originally set out in the DCPA DCI (all except the marine diatom).

Requests Regarding Guideline 850.1350 Chronic tox. Mysid (DCPA)

36. Admit that AMVAC submitted MRID 49307512 to EPA on January 29, 2014, which was prior to the due date established in the DCPA DCI.

37. Admit that, with the exception of JX 21 (which noted that a study to satisfy Guideline 850.1350 for DCPA was “In review”), EPA did not communicate further with AMVAC concerning this data requirement until it provided a copy of JX 56 on April 27, 2022.

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Requests Regarding the Residue Studies (Guidelines 860.1300, 1340, 1480, 1900)

38. Admit that neither JX 37, JX 38, nor JX 39 were provided to AMVAC until on or after March 27, 2017.

39. Admit that shortly after JX 38 was provided to AMVAC, Jordan Page took over from Marquea King as the Chemical Review Manager and began discussions with AMVAC about necessary label changes (*see, e.g.*, JX 40-48, JX 50).

40. Admit that at no time after March of 2017 did Mr. Page (or any subsequent CRM) refer AMVAC back to JX 38 as the document setting out the required label amendments to eliminate the need for any of the residue chemistry data requirements.

41. Admit that James Douglass never responded to an email from AMVAC's Sr. Regulatory Manager in August of 2020 summarizing all label amendments submitted to address Guidelines 860.1300, 1340, 1480, 1900 and asking Mr. Douglass to "confirm that the status as we have described in the summary is current and that we have not missed a review or decision from the Agency." JX 50.

42. Admit that the most reasonable interpretation of the note in JX 21 (Oct. 16, 2020) concerning Guidelines 860.1300, 1340, 1480, and 1900 ("In review; label amendments submitted to satisfy guideline") was that EPA was in the process of reviewing label amendments submitted by AMVAC in 2017, 2018, 2019 (*see* JX 50) and that those amendments would potentially satisfy the need for data under Guidelines 860.1300, 1340, 1480 and 1900.

43. Admit that the NOITS was the first time that the Agency asserted that any of the label amendments provided by AMVAC subsequent to March of 2017 would not eliminate the need for data under Guidelines 860.1300, 1340, 1480, or 1900.

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Requests Regarding SS-1069 Chronic Sediment tox. - Chironomus (DCPA)

44. Admit that AMVAC submitted a protocol for EPA's review with its 90-day response (JX 5).

45. Admit that EPA did not communicate with AMVAC regarding AMVAC's revised protocol (submitted in December 2014) until March 19, 2015 (JX 61).

46. Admit that EPA did not communicate further with AMVAC concerning the data that it submitted in March of 2016 (MRID 49865802) until it provided a copy of JX 63 on April 27, 2022.

Requests Regarding SS-1072 Chronic Sediment tox. - Leptocheirus (DCPA)

47. Admit that AMVAC submitted a protocol for EPA's review with its 90-day response (JX 5).

48. Admit that AMVAC informed EPA of substantive issues with EPA's review provided in October of 2014 and advised that more time for protocol development was needed (JX 60).

49. Admit that, in March of 2017, EPA was aware of challenges performing studies similar to SS-1072 and, on that basis, was actively considering whether an acute 10-day study would negate the need for SS-1072 and had informed AMVAC that it was doing so.