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.	)	

JOINT SET OF STIPULATED FACTS

Petitioner AMVAC Chemical Corporation ("AMVAC"), the Grower-Shipper Association of Central California; J&D Produce; Ratto Bros., Inc.; and Huntington Farms (the "Grower Petitioners," and, together with AMVAC, "Petitioners"), and Respondent Office of Pesticide Programs ("OPP") (collectively, the "Parties") hereby submit the following factual stipulations, in addition to the stipulations concerning authenticity and admissibility of documents and official notice submitted with Respondent's Status Report on December 23, 2022. The stipulations below do not provide a complete chronology of all events potentially relevant to each data requirement at issue.

I. GENERAL

1. Generic Data Call-In Notice ID# GDCI-078701-1140, issued by OPP's Pesticide Re-evaluation Division ("PRD") on January 31, 2013 (the "DCI"), included over 60 individual studies for DCPA and/or its degradate TPA.

2. On October 21, 2022, OPP deemed the SS-thyroid (chronic thyroid study) data requirement to be satisfied.

3. On December 9, 2022, OPP's Health Effects Division ("HED") issued "DCPA. Label Amendments for Plant Back Intervals (PBIs)," DP Barcode D466682. This document set forth label amendments which, if implemented, would enable waiver of four additional data requirements identified in the Notice of Intent to Suspend, JX 1 (the "NOITS") (Guidelines 860.1300, 860.1340, 860.1480, and 860.1900). This document, and an associated transmittal memorandum from PRD to AMVAC, are filed with these stipulations as JX 89 and JX 90, respectively. The parties stipulate as to the authenticity and admissibility of JX 89 and JX 90, consistent with the stipulations in the Status Report filed on December 23, 2022.

4. On December 28, 2022, AMVAC submitted proposed labels intended to implement the amendments identified in Stipulation 3. OPP is currently reviewing the proposed labels and will notify the Presiding Officer if the status of the four data requirements identified in Stipulation 3 are waived or if OPP is otherwise no longer pursuing suspension under the NOITS.

5. On December 23, 2022, OPP indicated that it no longer alleged that AMVAC had failed to take appropriate steps with respect to, and hence was no longer pursuing suspension under the NOITS based on, the following data requirements: OCSPP Guideline 850.2100, DCPA Acute Avian (passerine); OCSPP Guideline 850.4100, DCPA Seedling Emergence (lettuce); Guideline 850.1350, DCPA Aquatic Invertebrate Life-Cycle, Estuarine/Marine Mysid; Special Study 1069, DCPA chironomus; Guideline 850.1400, DCPA Fish Early Life-Stage (Bluegill Sunfish); Guideline 850.1400, DCPA Fish Early Life-Stage (Sheepshead Minnow).

II. STIPULATIONS BASED ON ADMISSIONS, INTERROGATORY RESPONSES, AND DOCUMENT REQUEST RESPONSES

6. OPP did not provide DERs to AMVAC for studies with MRIDs 49500701; 49307505; 49307511; 51398105; 49307510; 49307514; 51398104; 49307512; 49477601; 49307513; 49307506; 49307509; 49307504; 51499402; 49307508; 49307507; 49865801; 49865802; 49307519; 49307518; 51235101; 51235102; 51499401; or Joint Exhibits ("JX") 57, 59, 69, 79, or documents with Regulations.gov Doc. IDs EPA-HQ-OPP-2011-0374-0053 and EPA-HQ-OPP-2011-0374-0054 until contemporaneously with the NOITS. OPP RFA 1 Response.

7. OPP provided AMVAC the documents identified in Stipulation 6 contemporaneously with the NOITS based on OPP's desire to avoid another round of receiving and reviewing data waiver requests. OPP RFA 1 Response.

8. JX 37, JX 38, and JX 39 were not provided to AMVAC until on or about March 27, 2017. OPP RFA 38 Response.

9. AMVAC provided an adequate 90-day response for each data requirement identified in the NOITS. OPP RFA 14 Response.

10. OPP did not request that AMVAC request extensions in connection with any data requirement identified as not being satisfied in the NOITS. OPP RFA 17 Response.

11. On the one occasion in the course of AMVAC and OPP's correspondence related to the DCI when AMVAC made an express request for an extension, OPP did not respond to the request. OPP RFA 18 Response.

12. OPP is unable to locate 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, that are or were current at any point since 2009. OPP RFP Response 7.

13. Two versions of OPP's "SOP Registration Review Guidance DCI Issuance to Decision" document have been utilized by OPP since 2009. These include a version dated March 12, 2014 and the current version that superseded it, dated September 7, 2016. These documents have been identified as Respondent's Exhibit ("RX") 14 and RX 13, respectively.

14. The filepath link (http://intranet.epa.gov/pesticides/divisionswork/srrd/regulatory/suspension_sop.pdf) found in RX 13 and RX 14 is no longer active in OPP's system.

15. The document once referenced by the filepath link in Stipulation 14 has been designated as Petitioner AMVAC's Exhibit ("PAX") 46 in this matter. This document was issued in April 2009 by OPP's Special Review and Reregistration Division ("SRRD") which was subsequently renamed as the Pesticide Re-evaluation Division ("PRD") on September 27, 2009.

16. OPP is unable to locate 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, that are or were current at any point since 2009. OPP RFP Response 9.

17. OPP does not have a standard for review timelines due to the highly variable nature of individual data submissions and variations in available OPP resources at a given time. OPP RFP Response 9.

III. GUIDELINE 850.1400 TPA FISH ELS; GUIDELINE 850.1350 TPA CHRONIC MYSID; GUIDELINE 850.4500 ALGAL TOXICITY

18. AMVAC's 90-day response to the DCI, JX 5, was timely submitted on April 29, 2013 and contained a proposed rationale for deferring completion of the Guideline 850.1400 TPA Fish ELS data requirement, the Guideline 850.1350 TPA Chronic Mysid data requirement, and the Guideline 850.4500 Algal Toxicity data requirements pending completion of a risk assessment that would use toxicological endpoints associated with DCPA. JX 5 at pp. 9-12 of 12.

19. AMVAC's proposed rationale referred to in Stipulation 18 referred to statements in the 2011 Preliminary Problem Formulation ("PPF"), JX 65, that OPP's Environmental Fate and Effects Division ("EFED") would "make highly conservative assumptions when evaluating the toxicity of TPA" in a "future assessment[]" in the absence of toxicity data for TPA. The PPF also indicated that "[t]he available data indicate that the adverse effects associated with TPA are much milder than those for the parent and tend to occur at doses that are lower by approximately an order of magnitude (U.S. EPA, 2008a)." The PPF noted that "a more limited testing strategy [for TPA would] be considered in lieu of a comprehensive data submission if one is proposed." JX 65.

20. The transmittal of JX 37 was OPP's first communication to AMVAC concerning AMVAC's request for a waiver of the Guideline 850.1400, 850.1350, and 850.4500 data requirements for TPA. OPP RFA 31 Response.

21. JX 37 provided that, "EFED indicated in the problem formulation if a limited testing strategy was proposed it would be considered in lieu of a comprehensive data submission. EPA would still consider a more limited testing strategy if proposed by the registrant. However, deferring all toxicity testing of the degradate TPA until DCPA studies are completed, is not an

acceptable alternative strategy; therefore, EFED recommends that PRD ***denies request to defer the data collection of TPA until DCPA studies are completed with the intention of using DCPA toxicity data in lieu of TPA toxicity data. Toxicity data is needed for TPA, therefore one possible solution is conducting a limited set of toxicity tests initially for TPA (for example, an acute and chronic toxicity study in daphnids); and depending on the results of these initial studies, a full suite of studies may or may not be subsequently required***." (Emphasis in original).

22. On February 22, 2018, AMVAC stated that it agreed with "[OPP]'s proposal for conducting acute and chronic TPA studies in daphnids and reviewing those results with [OPP] in order to determine whether additional aquatic organism testing is warranted." JX 67.

23. The Data Delay Letter, JX 21, did not refer to JX 67, and cited only to JX 37 in connection with the data requirements identified in Stipulation 20.

24. OPP is without knowledge as to whether JX 67 was reviewed, fully or partially, prior to OPP sending the Data Delay Letter. OPP RFA Resp. 23.

25. On December 17, 2020, AMVAC submitted Tetrachlorophthalic Acid (TPA): Selected Ecological Study Waiver Request, AMVAC Report No. 100-REV-049, MRID No. 51398103, which has been designated as PAX 45.

26. PAX 45 discussed a 2003 acute (MRID 49307519) and a 2019 chronic (MRID 51235101) TPA study in daphnids. These two studies were deemed scientifically sound and acceptable in DERs with DP Barcodes 420874 and 460199, respectively. These two DERs were not transmitted to AMVAC until contemporaneously with the NOITS. They are filed with these stipulations as JX 87 and JX 88, respectively. The parties stipulate as to the authenticity and

admissibility of JX 87 and JX 88, consistent with the stipulations in the Status Report filed on December 23, 2022.

27. JX 69 was the first communication to AMVAC concerning the Guideline 850.1400, 850.1350, and 850.4500 data requirements for TPA subsequent to the Data Delay Letter, JX 21.

IV. SPECIAL STUDY (SS-1072) LEPTOCHEIRUS CHRONIC SEDIMENT STUDY

28. The DCI requested data from a Special Study for chronic sediment toxicity of DCPA. The DCI referred to this Special Study as SS-1072.

29. A "special study" is one that does not have an established OPPTS "Guideline."

30. The DCI stated that AMVAC should submit a protocol to OPP within 90 days of its receipt of the DCI. JX 4. AMVAC submitted a proposed protocol and met this deadline. OPP RFA Response 47.

31. OPP responded to the protocol submitted by AMVAC in a document dated March 20, 2014, which has been designated as JX 70. This document was not provided to AMVAC by OPP until October 20, 2014, in an email from Matthew Manupella to Julie Porter.

32. On December 15, 2014, AMVAC informed OPP of substantive issues with the review provided in October of 2014 (JX 70) and advised that more time for protocol development was needed. JX 60; OPP RFA 48 Response.

33. AMVAC provided two six-month status updates to OPP on March 30, 2015, and September 22, 2015. These status updates were prepared by the laboratory that was working to conduct the study, Smithers Viscient, and have been designated as JX 71 and JX 72, respectively.

34. On March 15, 2016, AMVAC requested a waiver of SS-1072. JX 62. AMVAC's proposed rationale for the waiver was contained in a report identified as 100-AQU-028. JX 73.

35. AMVAC sent an additional communication which was received by OPP in November of 2016 which OPP assigned MRID 50116601. JX 76.

36. On March 17, 2017, Dr. Marquea King emailed Jon Wood of AMVAC, and others, a document containing "Action Items" based on a phone conversation held between AMVAC and OPP personnel within PRD that morning. JX 34 (email); JX 33 (attachment). The Action Items recorded from the phone conversation indicated that AMVAC did not have any "Action Items" related to the Leptocheirus data requirement.

37. JX 33 did list an Action Item for the "Agency," which noted that OPP would "confirm with EFED whether a clean/negative 10-day study negates the need for the 21-day study." JX 33.

38. On March 27, 2017, Dr. Marquea King emailed Jon Wood of AMVAC, and others, various follow up information from the March 17, 2017, phone conference. JX 36 (email); JX 35 (attachment). The only additional information provided in this email concerning the Leptocheirus data requirement was that a "Response to Amvac [was still] pending." JX 35.

V. GUIDELINE 835.4300 TPA AEROBIC AQUATIC METABOLISM

39. The DCI requested data under Guideline 835.4300 for DCPA degradate TPA. JX. 4.

40. AMVAC's 90-day response was timely submitted on April 29, 2013.

41. AMVAC's 90-day response stated that AMVAC had elected Code "9" – Data Waiver, for TPA for the Guideline 835.4300 data requirement. AMVAC provided a proposed rationale for the waiver at pp. 7-8 of 12 of JX 5.

42. OPP did not communicate with AMVAC concerning the Guideline 835.4300 TPA data requirement (after receipt of the initial response, JX 5) until on or about March 17, 2017 (JX 37). OPP RFA Response 25.

VI. GUIDELINE 835.4200 TPA ANAEROBIC SOIL METABOLISM; GUIDELINE 835.4400 TPA ANAEROBIC AQUATIC METABOLISM

43. The DCI requested data under Guidelines 835.4200 and 835.4400 for DCPA degradate TPA. JX. 4.

44. AMVAC's 90-day response was timely submitted on April 29, 2013. JX 5.

45. AMVAC's 90-day response stated that AMVAC had elected Code "9" – Data Waiver, for the Guideline 835.4400 TPA data requirement. AMVAC provided a rationale for the waiver at pp. 7-8 of 12 of JX 5.

46. AMVAC's 90-day response stated that AMVAC had elected Code "6" – Submit Existing Study, for the Guideline 835.4200 TPA data requirement. AMVAC proposed that OPP accept a previously submitted study, "Anaerobic Soil Metabolism of Dacthal", Duane, W. C. (MRID 114651), and provided additional justification at pp. 7-8 of 12 of JX 5.

47. OPP did not communicate with AMVAC concerning the Guideline 835.4400 TPA data requirement (after receipt of the initial response, JX 5) until on or about March 17, 2017 (JX 37).

48. OPP did not communicate with AMVAC concerning the Guideline 835.4200 TPA data requirement (after receipt of the initial response, JX 5) until on or about October 16, 2020 (JX 77).

49. AMVAC provided additional information in support of its request for a waiver of the Guideline 835.4400 TPA data requirement in February of 2018. JX 67.

50. In December of 2020, AMVAC submitted an additional document in further support of its waiver requests for both the Guideline 835.4200 and 835.4400 TPA data requirements. JX 78.

51. OPP did not provide any response to JX 78 until it provided JX 79 concurrently with the NOITS.

Dated: January 6, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Joint Set of Stipulated Facts** was sent on January 6, 2023, to the following parties in the manner indicated below.

/s/ *Hume M. Ross*
Hume M. Ross

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Copies by Electronic Mail to:

n/a

Dated January 6, 2023