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**

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

Respondent, the United States Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs ("OPP"), pursuant to 40 C.F.R. § 164.51 and the Presiding Officer's November 4, 2022 Order on Additional Discovery ("Discovery Order"), hereby provides responses to certain of Petitioner AMVAC Chemical Corporation's ("AMVAC") discovery requests, as described in AMVAC's Motion for Additional Discovery ("AMVAC Motion"), including the attachments AMVAC's First Requests for Admission to Respondent ("RFA") and AMVAC's First Set of Interrogatories ("INT") and Document Requests ("RFP"), as limited by the Discovery Order.

I. AMVAC Requests for Admission

RFA 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; 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.

OPP Response 1: Admit. OPP provided those documents contemporaneously with the NOITS in order to avoid another round of receiving and reviewing data waiver requests similar to those previously denied.

RFA 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.

OPP Response 3: Admit. There is no requirement for OPP to inform a registrant concerning the Agency's ability to conduct risk assessments.

RFA 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.

OPP Response 11: Respondent is without knowledge as to the intent or purpose of AMVAC's actions. To the extent that many of AMVAC's actions resulted in delays to OPP's receipt of data required by the DCPA DCI, Respondent denies this request. For example, in February 2018, AMVAC noted that it would prefer to wait for EPA to review "a limited set of toxicity tests initially for TPA (for example an acute and chronic toxicity study in daphnids)" before conducting a full suite of TPA studies, including an 835.4400 anaerobic aquatic metabolism study. JX 67. However, AMVAC neither submitted nor offered a plan for conducting the limited set of TPA studies, and did not offer additional explanation as to why the 835.4400 anaerobic aquatic metabolism study (among other DCPA DCI data requirements for TPA) should be waived. That strategy is arguably dilatory.

RFA 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.

OPP Response 12: Deny. For example, the proposed label language submitted by AMVAC in 2017 and 2019 (JX 44, JX 45) was substantively identical to label language previously submitted in 2014 (*see* JX 38) in that both of the later-submitted proposed labels contained identical plant-back interval language that EPA had determined was inadequate to consider waiving the DCPA DCI data requirements.

RFA 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.

OPP Response 13: Deny. *See* OPP Response 12.

RFA 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.

OPP Response 14: Admit. AMVAC's 90-day response was not a factual basis for the NOITS, and to Respondent's knowledge, the adequacy of AMVAC's 90-day response has never been at issue in this proceeding or briefed by any of the parties. Reference to the 90-day response was a formatting discrepancy resulting from the NOITS form submitted to the Federal Register.

Compare JX 1 (copy of NOITS sent directly to AMVAC) with JX 2 (copy of NOITS published in Federal Register). Although JX 2 referenced "Inadequate 90-day response received" for multiple data requirements, Respondent has not, and does not now, assert that Petitioner submitted an inadequate 90-day response to the DCPA DCI. The basis for suspension—Petitioner's failure to take appropriate steps to secure the data required by the DCPA DCI—is clearly explained in the context of both JX 1, JX 2, and Respondent's filings in this matter.

RFA 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).

OPP Response 15: Respondent admits that AMVAC submitted a study pursuant to the DCPA DCI requirement for this data on June 8, 2022, during the pendency of this suspension proceeding. Respondent reserves the right to determine whether this study is ultimately "responsive" to the DCPA DCI, as OPP has not yet completed its review of the study.

RFA 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).

OPP Response 16: Respondent admits that AMVAC submitted a study pursuant to the DCPA DCI requirement for this data on June 30, 2022, during the pendency of this suspension proceeding. Respondent reserves the right to determine whether this study is ultimately "responsive" to the DCPA DCI, as OPP has not yet completed its review of the study.

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

OPP Response 17: Admit. There is no requirement for OPP to solicit extension requests where a registrant may need additional time to respond to a DCI.

RFA 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.

OPP Response 18: Admit. On March 6, 2014, AMVAC agreed to use the approved HLS passerine acute protocol and requested a submission deadline extension to October 30, 2014, for the Guideline 850.2100 study required by the DCPA DCI. On September 30, 2014, AMVAC submitted data (MRID 49477601) in response to the data requirement.

RFA 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.

OPP Response 19: Deny. OPP clearly stated that these data were "still needed for risk assessment." In contrast, where OPP determined that a DCPA DCI data requirement should be waived, it clearly stated so. *Cf.* JX 37 at 5 ("Therefore, EFED recommends that PRD *grant the waiver request for the avian reproduction study with the Northern Bobwhite Quail and Mallard Duck for DCPA.*"). Respondent further notes that EFED and HED only make recommendations that a waiver request be granted; the decision to waive or not waive data rests with PRD.

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

OPP Response 20: Deny. JX 78 (MRID# 51398102), in reference to anaerobic soil and aquatic metabolism studies, cited existing data and literature (from 1976-2016) on DCPA and chemicals broadly related to TPA by structure. The cited literature did not provide any additional TPA-specific data useful in quantifying the persistence (half-life) of TPA in these media, or in demonstrating the applicability of DCPA anaerobic soil/aquatic metabolism data to TPA, as AMVAC suggested in its earlier waiver requests. JX 78 did not provide information that would substantiate AMVAC's rationale for requesting the waiver of TPA anaerobic metabolism data requirements. JX 78 also asserted that TPA is less toxic than DCPA, and is non-lipophilic, non-volatile, and prone to leaching, but did not provide support for these statements. Thus, JX 78 added nothing new or directly responsive to JX 21, the Agency's denial of AMVAC's initial waiver request.

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

OPP Response 21: Deny. Although JX 79 did note that OPP would assume stability of TPA in the environment, the document also noted that making such assumptions could "reduce confidence in the risk assessment conclusions." Without data under this DCPA DCI requirement, OPP cannot reliably estimate TPA's environmental persistence, which will result in reduced confidence in OPP's ecological risk assessments and conclusions.

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

OPP Response 22: Deny. In JX 37, OPP clearly stated that "[t]oxicity data is needed for TPA," and that "depending on the results of [studies conducted on daphnia], a full suite of studies may or may not be subsequently required." In JX 67, AMVAC merely noted that it would prefer to wait for EPA to review those other studies but, in 2018, had neither submitted the daphnia studies nor offered additional explanation as to why other TPA toxicity data should not be required. JX 67 was repetitive of and did not substantiate AMVAC's earlier waiver request, and its submission arguably constituted a dilatory strategy. *See* OPP Response 11.

RFA 23: Admit that EPA did not review JX 67 prior to issuing the Data Delay Letter (JX 21) to AMVAC in October 2020.

OPP Response 23: Respondent is without knowledge as to whether JX 67 was reviewed, fully or partially, prior to OPP sending the Data Delay Letter. The lack of a document setting out OPP's position on JX 67 does not show that the waiver requests were "not review[ed]." As explained in OPP Response 22, JX 67 is simply a statement that AMVAC disagreed with OPP's prior conclusions in JX 37, and warranted no response.

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

OPP Response 24: Deny. *See* OPP Response 20.

RFA 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).

OPP Response 25: Admit.

RFA 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.

OPP Response 26: Deny. In a data evaluation record ("DER") dated January 19, 2017, EPA record number 420875, OPP provided analysis of MRID 49307515. In the footnotes of JX 79, OPP references DER 420875 and other environmental fate study waiver request response DERs, which were included in a transmittal memo dated February 7, 2017. JX 79 at 9. DER 420875 is provided as RX 12, attached here.

RFA 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).

OPP Response 27: Admit.

RFA 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.

OPP Response 28: Admit. However, Respondent notes that the language from JX 37 reads in full: "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." *See* OPP Response 11.

RFA 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.

OPP Response 29: Deny, to the extent that AMVAC characterizes MRID 51398103 as including "substantive" additions to its earlier waiver requests. AMVAC's initial requests to waive fish early life stage studies in TPA was based on the assertion that OPP should use DCPA endpoints to estimate TPA toxicity. MRID 51398103 is repetitive of this assertion, despite OPP's prior statements that TPA toxicity data were needed.

RFA 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.

OPP Response 30: Deny. Respondent admits that AMVAC presented the data described in RFA 30, but denies that the submission was responsive to the TPA fish ELS requirements of the

DCPA DCI. OPP did not, in JX 37, waive the requirement for AMVAC to submit other data. *See* OPP Response 28.

RFA 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).

OPP Response 31: Admit.

RFA 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.

OPP Response 32: Admit. *See* OPP Response 28.

RFA 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.

OPP Response 33: Deny. *See* OPP Response 29.

RFA 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.

OPP Response 34: Deny. *See* OPP Response 30.

RFA 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).

OPP Response 35: Admit. Respondent highlights that in JX 69, OPP specifically denied AMVAC's request to waive Guideline 850.4500 ecological toxicity studies using the marine diatom, which is one of the data requirements at issue in the NOITS.

RFA 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.

OPP Response 36: Admit.

RFA 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.

OPP Response 37: Admit.

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

OPP Response 38: Admit.

RFA 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).

OPP Response 39: Respondent admits that Jordan Page took over as the CRM for OPP's registration review of DCPA in approximately April 2017. Respondent denies that Page "began" discussions concerning necessary label changes. In Page's April 7, 2017 email to AMVAC representative Jon Wood, Page listed several steps that would be necessary for OPP to consider waiving the four Guideline Series 860 residue data requirements of the DCPA DCI, including prohibition of rotation to any livestock feedstuffs on DCPA product labels, as there were no set residue tolerances for livestock commodities. JX 40. That prohibition was one aspect of the necessary label changes that OPP had previously provided to AMVAC in JX 38 prior to Page's assumption of CRM duties for DCPA registration review.

RFA 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.

OPP Response 40: Admit. There was no requirement for OPP to provide additional direction or notice that its denial of AMVAC's waiver requests in JX 38 was still the operative document. At no point did OPP indicate that it was waiving the residue data requirements of the DCPA DCI based on further conversation with AMVAC.

RFA 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.

OPP Response 41: Deny. OPP's James Douglass responded on August 7, 2020. That response is provided as RX 11.

RFA 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.

OPP Response 42: Deny. The record does not indicate that OPP had reconsidered its position (*i.e.*, JX 38) against waiving the residue chemistry data requirements of the DCPA DCI without the specified label changes. The fact that OPP may not have reviewed AMVAC's subsequent label language at the time of the Data Delay Letter is not an indication that the—unchanged—plant-back language was now acceptable. It was reasonable for AMVAC to interpret JX 21 as reflecting that OPP was still reviewing AMVAC's most recent proposed label submissions. However, it was not reasonable for AMVAC to assume that language identical to that already rejected by OPP would potentially satisfy the DCI.

RFA 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.

OPP Response 43: Deny. Respondent objects to the characterization of the conversation between the parties. The post-2017 label amendments contained identical plant-back language to that proposed in 2014 and rejected by OPP as not resolving the need for the Guideline 860 data

requirements. There is no requirement for OPP to re-affirm that such language was insufficient to consider waiver of the residue studies.

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

OPP Response 44: Admit.

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

OPP Response 45: Admit.

RFA 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.

OPP Response 46: Admit.

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

OPP Response 47: Admit.

RFA 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).

OPP Response 48: Admit.

RFA 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.

OPP Response 49: Deny. As explained in JX 74, the 28-day special study would "remain an outstanding DCI requirement," and explicitly stated that JX 74 "does not constitute a waiver" of that data requirement. OPP indicated that, "pending the results of the 10-d study and any other supporting data," it would consider whether to waive the 28-day study at a later point.

II. AMVAC Interrogatories

INT 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.

OPP Response 11: AMVAC's 90-day response was not a factual basis for the NOITS, and to Respondent's knowledge, the adequacy of AMVAC's 90-day response has never been at issue in this proceeding or briefed by any of the parties. Reference to the 90-day response was a formating discrepancy resulting from the NOITS form submitted to the Federal Register. Compare JX 1 (copy of NOITS sent directly to AMVAC) with JX 2 (copy of NOITS published in Federal Register). Although JX 2 referenced "Inadequate 90-day response received" for multiple data requirements, Respondent has not, and does not now, assert that Petitioner submitted an inadequate 90-day response to the DCPA DCI. The basis for suspension—Petitioner's failure to take appropriate steps to secure the data required by the DCPA DCI—is

clearly explained in the context of both JX 1, JX 2, and Respondent's subsequent filings in this matter.

INT 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.

OPP Response 12: While AMVAC's April 29, 2013 submission of a protocol for this study constituted an appropriate *first* step towards satisfying the DCPA DCI data requirement, submission of a protocol alone does not constitute "appropriate steps to secure the data required" as that phrase is interpreted by the EAB. Although this data requirement does not have an OCSPP Guideline associated with it, the DCPA DCI cited the EPA Office of Research and Development's Test Method 100.5,[1] which provides "[t]he concentration of solvent used must not adversely affect test organisms." JX 4 at 32, 34. In its March 20, 2014 review of AMVAC's protocol, OPP "recommend[ed] that the concentration/volume of the [solvent] to be used is provided and any changes or additions to the protocol from the addition of a solvent be described (e.g., whether the range-finding test will include a solvent control)." JX 60, att. 1 at 2. The results of this study, MRID 49865802, conducted based on the protocol and submitted by AMVAC in response to this DCPA DCI data requirement, were likely affected by the solvent used. JX 59. The adequacy of AMVAC's protocol for this study is not the relevant issue; rather, the relevant question is whether AMVAC should have been aware, given the guidance provided by OPP, that

[1] EPA Test Method 100.5: Life Cycle Test for Measuring the Effects of Sediment-associated Contaminants on Chironomus tentans, at 49, available at https://www.nemi.gov/methods/method_summary/9323/.

the study ultimately conducted and provided to OPP did not constitute appropriate steps to secure the data required by the DCPA DCI.

INT 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.

OPP Response 14: Respondent objects to the relevance of AMVAC's involvement with or responsibility for the OPP-internal period between receipt of a study and signature by an OPP reviewer.

INT 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.

OPP Response 15: Respondent objects to the relevance of AMVAC's involvement with or responsibility for the OPP-internal period between any initial and final signature by OPP reviewers.

INT 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.

OPP Response 16: Respondent objects to the relevance of AMVAC's involvement with or responsibility for the OPP-internal period between signature by an OPP reviewer and transmission of a document to AMVAC.

INT 17: To the extent EPA asserts AVMAC was responsible for any delay identified in the previous three interrogatories, state the basis for that contention.

OPP Response 17: Respondent objects to the relevance of AMVAC's involvement with or responsibility for any OPP-internal time period or action.

III. AMVAC Document Requests

RFP 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.

OPP Response 7: Respondent is unable to locate or produce any document responsive to this request. Respondent consulted the list of SOPs, internal guidance, and other best-practice documents, last compiled by OPP in July 2022. That list is the result of a detailed search,

conducted independent of this matter, by OPP staff of EPA websites, internal network folders, and other sources to reference all such documents in a central location. To the extent that any document potentially responsive to this request exists but is not referenced in OPP's list, it is either outdated or not referenced by OPP as an organization.

RFP 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.

OPP Response 8: *See* RX 13, RX 14, RX 15, RX 16, attached to this response.[2] To the extent that any other document potentially responsive to this request exists but is not referenced in OPP's list, it is either outdated or not referenced by OPP as an organization. See OPP Response to RFP 7.

RFP 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.

OPP Response 9: Respondent is unable to locate or produce any document responsive to this request. *See* OPP Response to RFP 7. To the extent that any document potentially responsive to

[2] These four RX were not filed electronically with the Office of the Administrative Law Judges ("OALJ"). Each was submitted directly to counsel for Petitioners in this matter and to the OALJ Hearing Clerk.

this request exists but is not referenced in OPP's list, it is either outdated or not referenced by OPP as an organization. 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.

RFP 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.

OPP Response 10: *See* RX 13, RX 14, attached to this response. To the extent that any other document potentially responsive to this request exists but is not referenced in OPP's list, it is either outdated or not referenced by OPP as an organization. *See* OPP Response to RFP 7. OPP does not have a standard for protocol review timelines due to the highly variable nature of individual protocols and variations in available OPP resources at a given time.

RFP 21: Provide a copy of the "EFED DER transmittal memo (dated January 21, 2022)" referenced in Footnote a to Table 3 in JX 69.

OPP Response 21: The January 21, 2022 date referenced in the footnote is misleading. The transmittal memo is dated January 6, 2022, although the last signature is January 21, 2022. The transmittal memo is already in the record as JX 59.

RFP 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.

OPP Response 22: See RX 12, RX 17, RX 18, attached to this response.

RFP 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.

OPP Response 24: No such document exists. There is no requirement for OPP to solicit extension requests where a registrant may need additional time to respond to a DCI. It is the responsibility of registrants to request such extensions.

Respectfully submitted,

FORREST PITTMAN

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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 **Respondent's Responses to Petitioner AMVAC Chemical Corporation's First Requests for Admissions and First Set of Interrogatories and Document Requests to Respondent**, dated December 2, 2022, was sent this day to the following parties in the manner indicated below.

FORREST PITTMAN
Digitally signed by FORREST PITTMAN
Date: 2022.12.02 20:50:19 -05'00'

Forrest Pittman
Attorney Advisor

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Dated December 2, 2022