

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;)	Docket No. FIFRA-HQ-2022-0002
1 /	,	DUCKET NO. 1111 NA-11Q-2022-0002
Grower-Shipper Association of Central)	
California; Sunheaven Farms, LLC; J&D)	
Produce; Ratto Bros., Inc.; and Huntington)	
Farms,)	
Petitioners.)	

ORDER ON MOTIONS FOR ADDITIONAL DISCOVERY

On September 28, 2022, the Environmental Appeals Board ("EAB") issued a Decision and Remand Order requiring that a hearing be conducted in this matter to resolve certain factual and legal disputes. *See* AMVAC Chem. Corp., 18 E.A.D. 769 (EAB, 2022) ("Remand Order"). Thereafter, I issued orders providing time for the parties to engage in mutually agreed upon discovery and setting deadlines to seek other discovery. *See* Hearing and Scheduling Order Following Remand (Oct. 3, 2022); Order on Respondent's Motion to Amend Hearing and Scheduling Order (Oct. 18, 2022).

On October 25, 2022, Petitioner AMVAC Chemical Corporation and Respondent both timely submitted motions for additional discovery ("AMVAC Motion" and "EPA Motion"). Each party also filed response briefs in opposition to the discovery motions on October 31, 2022. ("AMVAC Response" and "EPA Response").

I. Standard for Additional Discovery

EPA and AMVAC previously engaged in the primary discovery contemplated by the rules governing this proceeding when they completed their prehearing exchanges of witness lists and documents. *See* 40 C.F.R. § 164.50.

But the rules also allow for further discovery "upon determination by the Administrative Law Judge

- (1) that such discovery shall not in any way unreasonably delay the proceeding,
- (2) that the information to be obtained is not otherwise obtainable and

(3) that such information has significant probative value. The Administrative Law Judge shall be guided by the procedures set forth in the Federal Rules of Civil Procedure, where practicable, and the precedents thereunder, except that no discovery shall be undertaken except upon order of the Administrative Law Judge or upon agreement of the parties.

40 C.F.R. § 164.51(a).

With respect to depositions, the rules additionally provide that they may be ordered "upon a showing of good cause and upon a finding that (1) the information sought cannot be obtained by alternative methods, or (2) there is a substantial reason to believe that relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing." 40 C.F.R. § 164.51(b).

II. AMVAC's Motion for Additional Discovery

AMVAC seeks further discovery in the form of 49 Requests for Admission, 18 Interrogatories, 31 Requests for Production of Documents, and seven depositions. AMVAC Mot., attachs. A & B. In its Motion, AMVAC groups its written discovery requests by topic. This Order addresses those topics as ordered and categorized by AMVAC.

a. Typicality

According to AMVAC, in its remand order "[t]he EAB held that whether AMVAC's actions were 'typical of how registrants address data call-ins' is material to whether AMVAC took appropriate steps in connection with the DCPA data call-in." AMVAC Mot. at 9. "More information about how other registrants have approached similar data call-ins and whether it is actually atypical for some requests to remain outstanding for comparable lengths of time is therefore required," AMVAC argues. AMVAC Mot. at 9.

I disagree with the breadth of AMVAC's assertion. This case was remanded for a "hearing to determine whether AMVAC failed to take appropriate steps to secure the data listed in Table 2 of the DCPA NOITS." Remand Order at 796. The extent to which information has significant probative value depends in part on what constitutes "appropriate steps." The EAB did not attempt to define "appropriate steps" beyond its ordinary, contemporary meaning: "Appropriate' is defined as 'specially suitable: fit, proper.' 'Step' is defined as 'an action, proceeding, or measure often occurring as one in a series." Remand Order at 790 (citing Webster's Third New International Dictionary 106, 2236 (1993)). Thus, the EAB concluded, "[w]hether an action was appropriate is a factual inquiry." Remand Order at 790. This means an inquiry "that naturally and traditionally includes consideration of all the relevant factors" and in which the "parties' course of performance [is] 'highly significant'." Remand Order at 790 (quoting Michigan v. EPA, 576 U.S. 743, 752 (2015); Alabama v. North Carolina, 560 U.S. 330, 346 (2010)) (emphasis added).

Within that framework, the EAB cited *examples* of three genuine factual disputes relevant to an "appropriate steps" inquiry in this proceeding. First, the Board referred to dueling verified statements from two of the parties' expert witnesses, in which EPA witness Jill Bloom testified that AMVAC's response to the DCI was "abnormally dilatory and repetitive," and AMVAC witness Ephraim Gur stated that AMVAC's response was "typical of how registrants address data call-ins." Remand Order at 790. The EAB determined that "[t]hese conflicting statements appear to be 'material' in that they relate to whether the actions AMVAC took in response to the [DCI] were appropriate." Remand Order at 790. Second, the EAB cited Ms. Bloom's "verified written statement that '[i]t is common for registrants to request extensions of time for responding to individual data requirements," contrasting it to Mr. Gur's statement that "so long as communication between the registrant and EPA is on-going regarding the progress and status of completion of a study, and the EPA staff has not requested a formal extension request be filed' registrants understand that there is no need to ask for one," and "that some EPA staff do not want registrants to file extension requests" Remand Order at 790. Thus, the EAB held, "[t]he parties' 'course of performance' with respect to how they handled extension requests would appear to be material to whether AMVAC's submission of only one extension request was inappropriate." Remand Order at 790 (emphasis added). Third, the EAB ruled, there is a dispute as to whether AMVAC's waiver requests may have satisfied, "at least in part, the appropriate steps requirement," given that the regulations and the DCI contemplate waiver requests and that the Agency granted some of AMVAC's waiver requests. Remand Order at 791. To that extent, "AMVAC's waiver requests and the responses thereto may be relevant as to whether it took appropriate steps to secure the data required." Remand Order at 791.

Although the EAB highlighted the opposing opinions of Ms. Bloom and Mr. Gur with respect to whether AMVAC's response to the DCI was "abnormally dilatory and repetitive" or instead "typical" of other registrants' responses, the Board did not instruct that a hearing be held to broadly consider the conduct of other registrants or EPA's conduct during other registration reviews. Rather, the EAB cited these witnesses' opinions as an example of disputed evidence that "relate[s] to whether the actions AMVAC took in response to the [DCI] were appropriate." The "typicality" of AMVAC's conduct relative to other registrants may be a factor in this factual inquiry, but it is not necessarily a significant one. Registrants widely differ from one another. Pesticides widely differ from one another. The state of the established science surrounding each pesticide may vary widely. It only follows that EPA DCIs and registrant responses to DCIs will play out differently depending on the pesticide and registrant involved. In that regard, whether AMVAC's actions were typical of how registrants address data call-ins is less material to whether AMVAC took "appropriate steps" than is the *parties*' course of performance during the specific registration review of DCPA. Conceivably, many or all registrants could engage in the same inappropriate act. That AMVAC engaged in the same inappropriate conduct might make it typical, but it would not make it "appropriate." On the other hand, AMVAC may have established a "typical" procedure with EPA for responding to DCIs that no other registrant had and, as a result, its steps were appropriate, albeit in its own unique way. Thus, although the typicality of AMVAC's conduct in relation to other registrants may not be totally meaningless, it carries less weight than the steps AMVAC actually did or did not take to respond to the DCI in this specific registration review of DCPA. Therefore, despite AMVAC's assertion, information does not have "significant probative value" simply because it tends to show the "typicality" of AMVAC's conduct relative to other registrants.

i. Requests for Admissions

Requests for Admission Nos. 4-9 seek information about registration review processes involving other registrants and pesticides. They ask EPA to admit that: "it is common for registrants to not meet some deadlines set forth in registration review DCIs" (4); "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 nonsubmissions in view of the total number of data requirements in the DCPA DCI" (5); "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" (6); "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" (7); "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" (8); and 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 time of issuance of such documents, there were outstanding data requirements from a DCI in connection with such active ingredient" (9).

EPA objects that these requests seek information beyond the scope of the hearing because they seek to compare the conduct of other registrants in complying with DCIs, and AMVAC can easily develop this information at hearing through cross examination of Ms. Bloom. EPA Response at 17-18.

I agree that, beyond what Ms. Bloom may testify to at hearing, this Requests for Admission have limited probative value to the extent that they seek additional information about other registrants and registration reviews. <u>Accordingly, this discovery request is DENIED, and EPA is not required to respond to Requests for Admission Nos. 4-9.</u>

ii. Interrogatories

Interrogatories 1-3 and 8 seek information regarding registration reviews other than DCPA's. They ask for: all currently outstanding data requirements for each DCI issued by EPA between 2009 and 2015 in cases other than DCPA's (1); all registration review cases in which a Draft Risk Assessment or Proposed Interim Decision, Final Interim Decision, or Final Decision was published in 2015 or later even if at least one DCI data requirement remained outstanding (2-3); and for EPA to identify the grounds supporting Ms. Bloom's testimony that the outstanding data requirements for DCPA represent an abnormally high ratio of non-submissions and waiver requests (8).

The Agency opposes these interrogatories because they seek to compare the conduct of other registrants in complying with DCIs, seek to demonstrate a "selective enforcement" claim that is not at issue in this proceeding, and would impose an unreasonable burden likely to result in an unreasonable delay. EPA Response at 17. Further, argues the Agency, Interrogatories 2-3 seek publicly available information and Interrogatory 8 addresses information protected by the "deliberative process privilege." EPA Response at 17.

I accept EPA's argument. These interrogatories do not seek information that has significant probative value because they relate to the conduct of other registrants during other registration reviews. But the issue in this proceeding is the appropriateness of AMVAC's conduct during the registration review of DCPA. Further, much of the information may be otherwise obtained from the public dockets for registration reviews of other pesticides or through cross examination at hearing. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Interrogatories 1-3 and 8.

iii. Requests for Production of Documents

Document Requests Nos. 5-6 and 12-13 ask for certain communications made and records utilized by potential EPA witnesses. This includes: communications between Mary Elissa Reaves, Jill Bloom, Michael Goodis, Cathryn Britton, and any personnel within EPA discussing the need to issue or basis for issuing the NOITS (5); documents that summarize the status of any registrant's submissions in response to any DCI issued since 2009 (6); calculations, memoranda, or other documents Ms. Bloom prepared to substantiate assertions made in her verified statement, as well as any other documents she used or referred to in preparing her statement (12-13).

As with other discovery of this nature, EPA opposes these document requests on grounds that they seek to compare the conduct of other registrants in complying with DCIs, demonstrate a selective enforcement claim that is not at issue here, seek information protected by the deliberative process privilege, and would cause an unreasonable delay. EPA Response at 17.

I agree that these requests target information that is either not significantly probative because it addresses other non-DCPA registration reviews, would create unreasonable delay, or is protected by the deliberative process privilege. This privilege, as the Agency notes, "protects from discovery documents 'reflecting advisory opinions, recommendations and deliberations comprising part of the process by which governmental decisions and policies are formulated." Safety-Kleen Corp., EPA Docket No. V-W-003-93, 1994 WL 16787160, at *3 (ALJ July 1, 1994) (Order Denying Respondent's Request for Production of Documents) (quoting Chautaugua Hardware Corp., EPCRA Appeal No. 91-1, 3 E.A.D. 616, 1991 WL 310028, at *5 (June 24, 1991) (Order on Interlocutory Review)). Such documents must be both "predecisional" and "deliberative." Id. "To be 'predecisional,' a document must involve 'only those communications that occur before the adoption of the final rule or policy." Id. "To be 'deliberative,' a document must 'somehow reflect or reveal the deliberative process by which a final policy was formulated." Id. Internal EPA communications or memoranda discussing the registration review of DCPA and issuance of the NOITS are "predecisional" to the extent they were generated before the NOITS was issued, and they are "deliberative" to the extent they reflect the process by which the NOITS was formulated. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Document Requests Nos. 5-6 and 12-13.

b. Course of Performance/Extensions/Waivers

i. Requests for Admissions

Requests for Admissions Nos. 17-18 ask EPA to admit that it "never requested that AMVAC request extensions in connection with any data requirement identified as outstanding in the NOITS" (17) and 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" (18).

The Agency states that it will voluntarily comply with these requests. EPA Response at 18. <u>Accordingly, this discovery request is GRANTED, and EPA shall respond to Requests for Admissions Nos. 17-18.</u>

ii. Requests for Production of Documents

Document Request No. 24 asks the Agency to 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."

The Agency states that it will voluntarily comply with these requests. EPA Response at 18. Accordingly, this discovery request is GRANTED, and EPA shall respond to Document Request No. 24.

c. OPP Contentions Regarding Specific AMVAC Actions

AMVAC argues that, based on the EAB's decision that "appropriate steps" requires more than showing that data has not been submitted, EPA "must identify which actions taken by AMVAC were not appropriate." AMVAC Mot. at 10.

i. Requests for Admissions

Requests for Admissions Nos. 11-14 ask whether certain conduct was dilatory, repetitive, or responsive to EPA requests.

The Agency states that it will voluntarily comply with these requests. EPA Response at 19. <u>Accordingly, this discovery request is GRANTED, and EPA shall respond to Requests for Admissions No. 11-14.</u>

ii. Interrogatories

Interrogatories 9-11 and 14-18 also ask the Agency to state its position on the appropriateness of certain conduct. Interrogatory 9 asks EPA to "[s]tate 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 10 asks EPA to "[i]dentify each communication from AMVAC that

Ms. Bloom asserts 'did not offer any additional, substantive rationale' as compared to a prior request." Interrogatory 11 asks EPA to state the specific inadequacy that EPA alleges exists regarding AMVAC's 90-day response to each data requirement cited in the NOITS. Interrogatories 14-17 ask whether EPA contends that AMVAC is responsible for certain delays between the dates a study was submitted, reviewed by EPA, and transmitted back to AMVAC, as well as the bases for any such contention. Interrogatory 18 asks, 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," that EPA "identify such communication and state the basis of OPP's contention that it did not provide an additional substantive rationale for granting a waiver."

EPA objects to Interrogatories 9-10, arguing that AMVAC seeks information that can easily be developed at hearing through cross examination of Ms. Bloom. EPA Response at 19. I agree. Respondent may pose these questions about Ms. Bloom's assertions directly to Ms. Bloom at the hearing. It is not necessary to inquire in advance. <u>Accordingly, this discovery</u> request is DENIED, and EPA is not required to respond to Interrogatories 9-10.

EPA states that it will voluntarily comply with Interrogatory 11. EPA Response at 19. Accordingly, this discovery request is GRANTED, and EPA shall respond to Interrogatory 11.

EPA objects that Interrogatories 14-17 seek information beyond the scope of the hearing because the timeliness of the Agency's responses is not relevant to the factual basis of the NOITS. EPA Response at 18. I disagree. This information may be probative of the appropriateness of AMVAC's conduct during the registration review before the NOITS was issued. Accordingly, this discovery request is GRANTED, and EPA shall respond to Interrogatories 14-17.

EPA objects that Interrogatory 18 "seeks discovery on non-factual matter" that I have required the parties to address in prehearing briefs. EPA Response at 19. I agree that this Interrogatory appears to seek potentially non-factual information or the Agency's legal conclusions. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Interrogatory 18.

iii. Requests for Production of Documents

AMVAC's Document Requests Nos. 12 and 13 have been rejected for the reasons stated above.

d. Time Frames in the DCI

In response to my directive to the parties to file prehearing briefs to address the meaning of the phrases "within the time required by the Administrator" and "failed to take appropriate steps to secure the data required," as used in 7 U.S.C. § 136a(c)(2)(B)(iv), AMVAC seeks discovery it contends "will elicit information concerning whether OPP itself understands the timelines set out in the DCI to include time for necessary review of protocols and OPP's own

review of the data submitted." AMVAC Mot. at 11; see also Order on Respondent's Motion to Amend Hearing and Scheduling Order (Oct. 18, 2022).

i. Interrogatories

Interrogatories 6-7 ask EPA to state whether any of the timeframes set forth in the DCI have built-in time to permit EPA to review either the data or protocols submitted by registrants and the amount of time built in for such review.

EPA objects to this discovery, arguing it seeks information on non-factual matters that the parties will address in their briefs and information that is easily developed at hearing. EPA Response at 20. I agree that this topic can be easily addressed at the hearing. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Interrogatories 6-7.

ii. Requests for Production of Documents

Document Requests Nos. 9-10 seek "manuals, handbooks, guidelines, memoranda, PowerPoints or other presentations, standard operating procedures (SOPs), instructional materials, or other documents" that state the amount of time the Agency's review of data and protocol submissions must be limited to, should be limited to, or typically takes based on Agency experience.

EPA objects to this discovery, arguing it seeks information beyond the scope of the hearing to the extent it would be used to "show that EPA sometimes took long periods of time to reply to AMVAC's submissions, which is not relevant to the factual basis of the NOITS." EPA Response at 19. However, EPA later states that it will voluntarily provide responses to Document Requests Nos. 9-10 "to the extent that any such responsive production does not invoke [its] deliberative process privilege." EPA Response at 22. Accordingly, this discovery request is GRANTED, and EPA shall respond accordingly to Document Requests Nos. 9-10

e. Ability to Proceed with Risk Assessment

AMVAC argues that EPA commonly proceeds with risk assessments in the absence of data and thereafter reevaluates the need for certain data requirements. AMVAC also contends the evidence shows that EPA suggested it would follow that course in this case as well. AMVAC Mot. at 12. According to AMVAC, it "is relevant the extent to which OPP did 'typically' proceed with risk assessments in comparable circumstances in the past, and whether EPA's claims that uncertainty in the case of DCPA was so 'excessive,' are scientifically supported." AMVAC Mot. at 12.

i. Requests for Admissions

Requests for Admissions Nos. 2 and 10 ask EPA to 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" (2) and that Ms. Bloom's statement 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" (10).

EPA objects that these requests seek information concerning the Agency's need for certain data to complete risk evaluation and that it seeks to compare its ability to conduct risk assessments in other registration review cases with this one – topics that are beyond the scope of the hearing. EPA Response at 20.

I agree with EPA. The requests relate to information directed toward the Agency's conduct in other registration reviews, not to whether AMVAC took "appropriate steps" during the review of DCPA. This is not significantly probative information, and to the extent it has relevance, it can be developed through cross examination at hearing. <u>Accordingly, this discovery request is DENIED</u>, and EPA is not required to respond to Requests for Admission Nos. 2 and <u>10</u>.

ii. Interrogatories

AMVAC's Interrogatory 2 has been rejected for the reasons stated above.

iii. Requests for Production of Documents

Document Requests Nos. 11 and 14 ask for copies of all communications provided to AMVAC in which the Agency indicates it could not proceed with a risk assessment of DCPA, along with copies of any documents reflecting Agency guidance on when uncertainty is excessive or otherwise unacceptable for EPA to proceed with a risk assessment in the context of environmental fate or ecological effects data.

EPA objects that information concerning EPA's need for certain data to complete a risk evaluation is beyond the scope of the hearing; that comparisons of this case to others with respect to EPA's ability to conduct risk assessments is part of AMVAC's effort of demonstrate a "selective enforcement" claim; and that information regarding EPA's decision whether it could complete a risk assessment of DCPA without certain data required by the DCI is protected by the deliberative process privilege. EPA Response at 20. The Agency further adds that it is not required to reassert why it requires additional data, such as to complete a risk assessment, or that such notice is needed before issuing a NOITS. EPA Response at 21.

I agree with EPA. Whether the Agency has proceeded with risk assessments in the absence of requested data in other pesticide registration reviews does not affect whether AMVAC's took "appropriate steps" in the specific registration review of DCPA. Whether EPA decided to proceed that way or not during DCPA's review, AMVAC was still bound to secure the data required by the DCI. This is not significantly probative information. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Document Requests Nos. 11 and 14.

f. Communications Between PRD Team Leader and CRMs; PRD Files

Document Requests Nos. 1-2 ask for communications between Ms. Bloom, the Pesticide Reevaluation Division team leader, and the assigned Chemical Review Manager for DCPA, and communications between any two individuals who served as the Chemical Review Manager for DCPA, that refer to or discuss the DCPA DCI, any data requirement in the DCI, the performance of a risk assessment for DCPA, or the registration review of DCPA. Document Requests Nos. 3-4 ask for any paper or electronic files concerning the DCI or DCPA registration review. Document Request No. 30 asks for any documented meeting summaries that have not been provided to AMVAC previously.

EPA objects that these requests seek information concerning internal deliberations as to the issuance of the NOITS, which is beyond the scope of the proceeding; to probe the Agency's decision to issue the NOITS to demonstrate a "selective enforcement" claim; information protected by the deliberative process privilege; and that Document Requests Nos. 2 and 4 would constitute an unreasonable burden because they seek "voluminous and unbounded discovery of all Agency files concerning DCPA." EPA Response at 21-22.

I agree with EPA regarding Document Requests Nos. 1-4 and 30. Internal EPA communications among Agency personnel discussing DCPA's registration review, the DCI, or the issuance of the NOITS go beyond the question of whether AMVAC took "appropriate steps" to secure the requested data. They are also likely to be protected by the deliberative process privilege. Likewise, Agency documents memorializing meetings between EPA and AMVAC personnel are likely to contain internal Agency impressions and would not otherwise address AMVAC's conduct. As for Document Requests Nos. 3-4, they are so broad and open ended as to exceed the scope of this proceeding. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Document Requests Nos. 1-4 and 30.

g. Agency Operating Procedures/Policy Statements

AMVAC argues that because the EAB has imposed a "typicality" requirement on this proceeding, "it is correspondingly relevant what [the Agency] required of other registrants." AMVAC Mot. at 14. Accordingly, it seeks discovery that targets various "standard operating procedures" of the Agency with respect to DCIs.

i. Interrogatories

Interrogatories 4 and 5 ask EPA to identify and describe all instances after August 2020 in which senior Agency personnel have met with individuals outside of EPA and made statements concerning registrants' obligations when responding to DCIs, including with respect to extension and waiver requests.

EPA objects that these requests are beyond the scope of this proceeding because they concern EPA's DCI-related discussions with other non-party registrants; that they seek information to support an unalleged "selective enforcement" claim; and that it seeks "voluminous and unbounded discovery" concerning any DCI-related meetings with non-party

registrants.

I agree with EPA. The information sought is beyond the scope of this proceeding. What Agency personnel may have said to other registrants is not significantly probative information in the same respect as what Agency personnel may have said to AMVAC about the DCPA registration review. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Interrogatories 4 and 5.

ii. Requests for Production of Documents

Document Requests Nos. 7-8 seek documents reflecting Agency procedure advising how personnel should address or respond to extension requests, waiver requests, or registrant rebuttals of EPA waiver denials in connection with DCIs. Document Requests Nos. 9-10 seek documents that state the amount of time the Agency's review of data and protocol submissions must be limited to, should be limited to, or typically takes based on Agency experience.

EPA states that it will voluntarily provide responses to these requests to the extent the responses are not subject to the deliberative process privilege. EPA Response at 22. Accordingly, this discovery request is GRANTED, and EPA shall respond accordingly to Document Requests Nos. 7-10.

Document Request No. 14 has been rejected for the reasons stated above.

h. Non-Issuance/Receipt of Documents

AMVAC states that it hopes to narrow the issues for hearing by asking the Agency to confirm receipt of certain documents or that it never issued or reviewed certain documents. AMVAC Mot. at 15.

i. Requests for Admissions

Requests for Admissions numbers 1, 3, 15, 16, 23, 25, 27, 31, 38, 40, 41, 43, 45, and 46 ask EPA "to confirm that it either never issued nor reviewed a certain document (either at all, or within a specified time frame) or that it did receive a certain document." AMVAC Mot. at 15. The Agency states that it will voluntarily comply with numbers 1, 15, 16, 23, 25, 27, 31, 38, 40, 41, 45, and 46. EPA Response at 16. Accordingly, these discovery requests are GRANTED, and EPA shall respond to Requests for Admissions Nos. 1, 15, 16, 23, 25, 27, 31, 38, 40, 41, 45, and 46.

The Agency opposes request numbers 3 and 43 because they seek "information concerning a variety of topics intended to distract from the factual bases of the NOITS." EPA Response at 23. Request for Admission number 3 asks EPA to "[a]dmit 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." Number 43 asks EPA to 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."

I reject EPA's argument. I find that these requests for admission will, as AMVAC contends, confirm whether and when the Agency provided it certain documents or information and eliminate the need to establish these basic facts at hearing. <u>Accordingly, these discovery requests are GRANTED</u>, and EPA shall respond to Requests for Admission Nos. 3 and 43.

ii. Interrogatories

Interrogatory 12 asks EPA to state whether it "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" and to state the basis for any such allegation.

EPA states that it will voluntarily provide a response to this interrogatory. <u>Accordingly, this discovery request is GRANTED</u>, and EPA shall respond to Interrogatory 12.

iii. Requests for Production of Documents

Document Request No. 12 has been denied as set forth above.

Document Request No. 16 asks EPA, if it denies Request for Admission No. 23, to "provide all documents or communications constituting, referring to, or providing evidence of EPA's review of JX 67[.]" The Agency objects to this request because it seeks information concerning topics intended to distract from the factual bases of the NOITS, going beyond the scope of the hearing; and because it is protected by the deliberative process privilege.

I agree with EPA that this request seeks information concerning EPA's internal review process. But whatever this process might have been is not significantly probative with respect to whether AMVAC took "appropriate steps" to secure data required by the DCI. <u>Accordingly, this discovery request is DENIED, and EPA is not required to respond to Document Request No. 16.</u>

Document Requests Nos. 21-22 ask the Agency to provide copies of various Data Evaluation Record transmittal memoranda. The Agency states it will voluntarily provide responses to these requests. <u>Accordingly, this discovery request is GRANTED, and EPA shall respond to Document Requests Nos. 21-22.</u>

Document Request No. 24 has been granted as set forth above.

Document Request No. 29 asks EPA to provide a copy of any documents that it does not admit the non-existence of in response to Requests for Admission Nos. 1, 3, 17, 18, 23, 25, 27, 31, 38, 40, 41, 43, 45, and 46. EPA objects that this constitutes an unreasonable burden likely to result in unreasonable delay, because "AMVAC is apparently asking EPA to newly generate potentially voluminous data supporting any decision not to admit any of AMVAC's specified RFAs," and the purpose of the request is unclear. EPA Response at 23.

I agree that this request is unclear as written, and therefore may result in an unreasonable burden or delay. For that reason, this discovery request is DENIED, and EPA is not required to respond to Document Request No. 29.

i. Requests Concerning Specific Data Requirements

AMVAC also proposes a set of requests that relate to individual studies for which data requirements are unsatisfied. AMVAC Mot. at 16. AMVAC argues the requests are relevant because "they may pertain to typicality, course of performance, ability to proceed with risk assessment, and the agency's internal evaluation of the propriety of AMVAC's conduct in a prelitigation posture." AMVAC Mot. at 16-17.

i. Requests for Admissions

Requests for Admissions Nos. 19-22, 24, 26, 28-30, 32-37, 39, 42, 44, 47-49 relate to the specific data requirements that remain outstanding. AMVAC Mot. at 16. The Agency states that it will voluntarily comply with these requests. EPA Response at 25. <u>Accordingly, these discovery requests are GRANTED</u>, and EPA shall respond to Requests for Admissions Nos. 19-22, 24, 26, 28-30, 32-37, 39, 42, 44, 47-49.

ii. Interrogatories

Interrogatory 13 asks EPA to "[i]dentify all DCIs issued in or after 2009 that have required a study substantially equivalent to the SS-1072 study in the DCPA DCI."

EPA objects, observing that "AMVAC is equally situated . . . to search the public dockets of EPA registration review cases" to find the information requested. EPA Response at 24. The Agency further notes that responding to this request would constitute an unreasonable burden that "would require searching through hundreds of registration review cases and thousands of DCI data requirements for chronic sediment toxicity studies in *leptocheirus*." EPA Response at 24.

I agree with the Agency's objection. The information AMVAC seeks is otherwise obtainable in the public record, and to require EPA to respond would create an unreasonable burden. Accordingly, this discovery request is DENIED, and EPA is not required to respond to Interrogatory 13.

iii. Requests for Production of Documents

Document Request No. 16 has been denied as set forth above.

Document Requests Nos. 15, 17-20, 23, 25-28, and 31 concern specific data requirements cited as outstanding in the NOITS. This includes communications among EPA personnel regarding certain data requirements and submissions, AMVAC's initial requests for waivers connected to certain data, and the Agency's ability or inability to proceed with a risk assessment absent that additional data (Nos. 15, 17-20, 23); communications in which the assigned chemical

review manager refers to JX 38 as the definitive source for the required amendments to eliminate the need for any of the residue chemistry data requirements (No. 25); communications among Agency personnel regarding AMVAC's proposed label amendments (Nos. 26, 31); communications between Agency personnel regarding the need for SS-1072 and how the absence of such data affected a potential risk assessment (No. 27); and copies of DERs assessing studies substantially equivalent to the SS-1072 study (No. 28).

EPA objects to these requests on several grounds: that they seek "to probe [the Agency's] internal decision process concerning the need for additional data and the sufficiency of AMVAC's submissions," which is "beyond the scope of the hearing"; that they seek information to support AMVAC's theory of "selective enforcement," which is not at issue; that the information sough would invoke the deliberative process privilege; and that, as to Nos. 19 and 28, the requests create an unreasonable burden likely to cause delay. EPA Response at 24.

I agree with the Agency's objections. Most of these document requests relate to internal Agency deliberations, which are not significantly probative of whether AMVAC took "appropriate steps" to secure data requested in the DCI and are also likely to be covered by the deliberative process privilege. And Document Request No. 28 appears to request information that would be in the public record and create an unreasonable burden if the Agency were required to respond to it. Accordingly, these discovery requests are DENIED, and EPA is not required to respond to Document Requests Nos. 15, 17-20, 23, 25-28, and 31.

j. Depositions

AMVAC contends that it should be permitted to take the depositions of several Agency personnel connected to this matter. This would include a deponent representing the Agency under Fed. R. Civ. P. 30(b)(6); Michael Goodis, in his capacity as the OPP Deputy Director of Programs; Mary Elissa Reaves, in her capacity as Director of the Pesticide Reevaluation Division; Jill Bloom, a lead environmental protection specialist involved with the DCPA DCI; Danettte Drew, a scientist in the Health Effects Division; Christina Wendel, a scientist in the Environmental Fate and Effects Division; and Stephen Wente, also a scientist in the Environmental Fate and Effects Division. AMVAC Mot. at 19-25.

The Agency objects, and counters that AMVAC has not satisfied the requirements of 40 C.F.R. § 164.51(b), i.e., it has not demonstrated good cause for the proposed depositions, that the information it seeks cannot be obtained by alternative methods, or that there is reason to believe that evidence may not be preserved for presentation at hearing. EPA Response at 4.

The Agency is correct. As a general proposition, "depositions are not a routine part of these administrative adjudicatory proceedings and consequently the showing required to justify depositions is substantial." *Heser*, EPA Docket No. CWA-05-2006-0002, 2007 WL 1219959, at *2 (ALJ, Feb. 23, 2007) (Order on Respondents' Motions for Additional Discovery) (quoting *Nova Chemicals Inc.*, EPA Docket No. CERCLA-01-2005-0051 (ALJ, Aug. 2, 2006)). AMVAC has not made that substantial showing.

With respect to a 30(b)(6) deposition, AMVAC seeks "historical facts about other registrants' responses to DCIs, and OPP's positions concerning the actions taken by AMVAC

during the course of the DCI[.]" For reasons discussed above, the actions of other registrants and EPA's internal deliberations do not constitute information of significant probative value. Likewise, with respect to Mr. Goodis, who is not a proposed witness, AMVAC seeks information beyond the scope of this proceeding that involve internal deliberations, the Agency's administration of other registration reviews, or areas that can be sufficiently explored through cross examination of other witnesses. From Dr. Reaves, who also is not expected to testify in this matter, AMVAC seeks similar information that is outside the scope of this proceeding, such as facts concerning other registrants and internal EPA policy formulation and application. More targeted subject matter, such as the factual basis for the NOITS in this case, is available in the existing record. Ms. Bloom, Ms. Drew, Ms. Wendel, and Mr. Wente are all expected to testify in this proceeding. Further, all four witnesses have provided verified statements that set forth the substance of their direct testimony. AMVAC will have ample opportunity at hearing to cross examine these witnesses on appropriate topics within the scope of their direct testimony. AMVAC has not shown any additional good cause for also deposing them in advance of the hearing.

Accordingly, AMVAC's request for depositions is DENIED.

III. EPA's Motion for Additional Discovery

EPA seeks further discovery in the form of 27 Requests for Admission and six Requests for Production of Documents. *See* Respondent's Requests for Admission and Document Requests to AMVAC.

In its Motion, the Agency contends its requests will not "unreasonably delay the proceeding" because they "are limited in scope to matters set forth in Respondent's filings before the Presiding Officer and the Environmental Appeals Board." EPA Mot. at 2. It also states that the information is possessed by or under the control of AMVAC and is most reasonably obtained from AMVAC. EPA Mot. at 2. EPA finally asserts that its requests have significant probative value: the Requests for Admission "would affirmatively show that AMVAC failed to take appropriate steps to secure several of the data requirements enumerated in the DCPA DCI," and its Requests for Production of Documents "are limited to addressing AMVAC's decision to take steps—with respect to securing the data required by the DCPA DCI—which were substantially similar to steps that EPA had previously rejected in waiver request denials or other communications." EPA Mot. at 2. Thus, the Agency asserts, "[s]uch documents would be expected to demonstrate that AMVAC's actions did not constitute reasonable steps to secure other data required by the DCPA DCI." EPA Mot. at 2.

Respondent generally opposes the Agency's motion. First, it contends the motion should be denied because the Agency failed to follow "orders requiring conferral prior to filing motions for additional discovery. OPP never indicated to AMVAC that it intended to seek *any* additional discovery, even as AMVAC conferred with OPP regarding the discovery that AMVAC is seeking." AMVAC Response at 2-4. Second, AMVAC asserts that EPA should be judicially estopped from obtaining further discovery because it previously argued that no additional discovery was warranted in this proceeding and now has adopted an opposing position by seeking discovery. AMVAC Response at 4-7. Third, AMVAC asserts that EPA's Requests for Production of Documents do not satisfy the standard for additional discovery because they do not seek probative information and are unreasonably vague and overbroad. AMVAC Response at 7-12.

a. Requests for Admissions

EPA's Requests for Admissions address different individual studies that comprise the outstanding data requested by the DCI, and they ask AMVAC to admit or deny certain conduct or communications connected to those studies. AMVAC states that it "has no substantive objections" to the Agency's Requests for Admissions. AMVAC Response at 2 n.2. But it argues that it still should not have to comply with the requests based on its lack of conferral and judicial estoppel arguments. AMVAC Response at 2 n.2. It adds that some of the Requests for Admissions "may be able to be adopted, in some form, as joint stipulations of fact in advance of the hearing." AMVAC Response at 2 n.2.

Regardless of the conduct AMVAC alleges that EPA engaged in while seeking additional discovery, it is ultimately in service of an efficient hearing and proceeding for AMVAC to respond now to requests to which it does not substantively object and would otherwise anticipate adopting later as joint stipulations. <u>Accordingly, these discovery requests are GRANTED, and AMVAC shall respond to the Agency's 27 Requests for Admission.</u>

b. Requests for Production of Documents

The Agency contends that its document requests seek information that has significant probative value because they "are limited to addressing AMVAC's decision to take steps—with respect to securing the data required by the DCPA DCI—which were substantially similar to steps that EPA had previously rejected in waiver request denials or other communications." EPA Mot. at 2. According to the Agency, "[s]uch documents would be expected to demonstrate that AMVAC's actions did not constitute reasonable steps to secure other data required by the DCPA DCI." EPA Mot. at 2.

Document Request No. 1 asks AMVAC to "[p]rovide all documents and communications in AMVAC's possession or control referring to or discussing the decision to submit label amendments without plant-back prohibitions or PBIs in the context of the DCPA DCI." AMVAC opposes this request, arguing that the Agency impermissibly "seeks documents concerning AMVAC's decision-making process." AMVAC Response at 8. This request does not have significant probative value, according to AMVAC, because the "appropriate steps" standard refers to "observable, objective phenomena" and does not include a subjective inquiry "whereby an otherwise appropriate course of action could be rendered inappropriate based on a registrant's subjective intent and/or its internal decision-making processes leading to that course of action, or vice versa." AMVAC Response at 9.

I reject AMVAC's assertion that a registrant's "subjective intent" is, as a general principle, inapplicable to an "appropriate steps" inquiry. But for purposes of this document request, I agree that at this time information concerning AMVAC's internal decision-making process does not appear to have "significant probative value" absent allegations or evidence that AMVAC intentionally sought to disrupt or delay the registration review of DCPA. Otherwise, the Agency may further explore this topic through cross examination at hearing. Accordingly, this discovery request is DENIED, and AMVAC is not required to respond to Document Request No. 1.

Document Request No. 2 asks AMVAC to "[p]rovide all documents and communications in AMVAC's possession or control referring to or discussing the decision not to conduct an alternate Guideline 850.1740 study in the context of the SS-1072 data requirement of the DCPA DCI." AMVAC opposes this request on the same grounds it opposed Document Request No. 1. AMVAC Response at 8-9.

Likewise, I find for the same reasons that Document Request No. 2 does not appear to have significant probative value. <u>Accordingly, this discovery request is DENIED, and AMVAC is not required to respond to Document Request No. 2.</u>

Document Request No. 3 asks AMVAC to "[p]rovide any documents in AMVAC's possession or control prepared or used to track the data requirements identified in the DCPA DCI and AMVACs response(s) and/or progress in responding to those data requirements." AMVAC opposes this request, pointing out that even if it can be construed to reach information beyond AMVAC's decision-making process, the Agency's Motion "contains only a conclusory assertion" without explaining the relevance of the request. AMVAC Response at 9. Further, AMVAC asserts, because the Agency did not first attempt to confer with AMVAC, EPA's request is overly broad and could be interpreted to encompass any email referring to the status of any data requirement from the NOITS at any point in time" AMVAC Response at 12.

I agree with AMVAC. EPA has not sufficiently explained why this request has significant probative value, and as written it appears to be overly broad. <u>Accordingly, this discovery request is DENIED</u>, and AMVAC is not required to respond to Document Request No. 3.

Document Request No. 4 asks AMVAC to "[p]rovide all documents and communications between AMVAC and any contract laboratory or consultant referring to or discussing the timing for initiation of any still-outstanding data requirement listed in the NOITS." AMVAC opposes this request on the same grounds it opposes Document Request No. 3. AMVAC Response at 9. It further argues that the request is overly broad and "should have been limited to only those data requirements (and related studies) for which OPP asserts timing of initiation is at issue," because there are many instances when "the precise timing of when AMVAC contacted a laboratory about initiating a study would not appear to have any relevance[.]" AMVAC Response at 11.

I agree with AMVAC. EPA has not sufficiently explained why this request has significant probative value, and as written it appears to be overly broad. Accordingly, this discovery request is DENIED, and AMVAC is not required to respond to Document Request No. 4.

Document Request No. 5 asks AMVAC to "[p]rovide all documents and communications in AMVAC's possession or control referring to or discussing the decision to not submit data responsive to any data requirement of the DCPA DCI for which OPP had previously denied AMVAC's initial waiver requests." AMVAC opposes this request on the same grounds it opposed Document Requests No. 1 and 2. AMVAC Response at 8-9.

Likewise, I find for the same reasons that Document Request No. 5 does not appear to have significant probative value. <u>Accordingly, this discovery request is DENIED, and AMVAC is not required to respond to Document Request No. 5.</u>

Document Request No. 6 asks AMVAC to "[p]rovide all documents and communications detailing what additional information AMVAC intended to provide to EPA with respect to any data requirement of the DCPA DCI for which OPP had previously denied AMVAC's initial waiver requests, or for which OPP had previously determined AMVAC's initial submission did not fully satisfy the DCPA DCI data requirement." AMVAC objects to this discovery on similar grounds as other document requests, in that it seeks information about what AMVAC "intended" to do." AMVAC Response at 8. The Agency must be seeking "to discover if AMVAC considered providing something but did not," AMVAC concludes, because it already knows what was actually provided. AMVAC also argues the request is overly broad in that it is not confined to particular individuals or date ranges. AMVAC Response at 11.

I agree with AMVAC. Documents and communications reflecting what AMVAC may have considered submitting but then chose not to submit do not appear to have significant probative value for discovery purposes. <u>Accordingly, this discovery request is DENIED, and AMVAC is not required to respond to Document Request No. 6.</u>

IV. CONCLUSION

AMVAC's Motion for Additional Discovery is **GRANTED** in part and **DENIED** in part as set forth above. The Agency shall respond to the applicable discovery requests included in Attachments A & B to AMVAC's Motion for Additional Discovery as soon as practicable, but no later than **December 2, 2022**.

EPA's Motion for Additional Discovery is **GRANTED** in part and **DENIED** in part as set forth above. AMVAC shall respond to the applicable discovery requests included in Respondent's Requests for Admission and Document Requests to AMVAC as soon as practicable, but no later than **December 2, 2022**.

SO ORDERED.

Susan L. Biro

Chief Administrative Law Judge

Dated: November 4, 2022 Washington, D.C.

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-HO-2022-0002

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Order on Motions for Additional Discovery**, dated November 4, 2022, and issued by Chief Administrative Law Judge Susan L. Biro, was sent this day to the following parties in the manner indicated below.

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Dated: November 4, 2022 Washington, D.C.