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	)	Docket No. FIFRA-HQ-2022-0002

REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS BY AMVAC CHEMICAL CORPORATION

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TABLE OF ACRONYMS

CTA	Chronic Thyroid Assay
DCI/GDCI	Data Call In/Generic Data Call In
DCPA	Dimethyl Tetrachloroterephthalate
DER	Data Evaluation Record
EFED	Environmental Fate and Effects Division
EPA	Environmental Protection Agency
EUP	End Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HED	Health Effects Division
MRID	Master Record Identification
NOITS	Notice of Intent to Suspend
OCSPP	Office of Chemical Safety and Pollution Prevention
PBI	Plant Back Interval
PDMS	Pesticide Document Management System
PRD	Pesticide Reevaluation Division
RD	Registration Division
TPA	Tetrachloroterephthalic Acid

INTRODUCTION AND REQUEST FOR HEARING

1. AMVAC Chemical Corporation ("AMVAC") hereby requests a hearing pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, "FIFRA") to contest the proposed suspension of its registration of technical grade Dimethyl Tetrachloroterephthalate ("DCPA") (EPA Reg. No. 5481-495).

2. A Notice of Intent to Suspend DCPA was issued by the U.S. Environmental Protection Agency ("EPA" or "the Agency") and received by AMVAC on April 27, 2022. Exhibit ("Ex.") 1 (the "NOITS").

3. The NOITS was subsequently published in the Federal Register on April 28, 2022. EPA, *Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration* (87 Fed. Reg. 25,262) (Apr. 28, 2022) (the "NOITS Notice"), Ex. 2.

4. EPA is proposing to suspend the registration of technical DCPA (EPA Reg. No. 5481-495). Copies of the currently approved label for this product are attached as Ex. 3.

5. EPA alleges that AMVAC failed to take appropriate steps to comply with a 2013 FIFRA Section 3(c)(2)(B) DCI notice for twenty (20) data requirements out of the approximately eighty-nine (89) requirements that were originally imposed.

6. AMVAC objects to the suspension of DCPA (end use formulations of which are known commercially as "Dacthal") and provides this notice of its objections and related allegations of fact for purposes of requesting a hearing under 40 C.F.R. Part 164.

7. AMVAC has been taking appropriate steps to comply with EPA's 2013 FIFRA Section 3(c)(2)(B) DCI since immediately after the time it was issued.

8. AMVAC will submit evidence at a hearing substantiating all facts stated herein to which EPA is not prepared to stipulate.

Summary of the Data Requirements at Issue and the History of the DCI

9. With respect to the twenty (20) data requirements at issue in this proceeding, AMVAC has been involved in an extensive, iterative, and ongoing process with EPA since 2013 to provide the necessary data, pinpoint exactly what data EPA requires, respond to additional requests for information, and follow a tiered testing approach (not originally set forth in the DCI) to meet certain requirements.

10. EPA's "Explanatory Appendix" to the NOITS, Ex. 1, which purports to summarize the communications between EPA and AMVAC concerning the twenty data requirements at issue is factually incomplete. It is also misleading because it glosses over and fails to acknowledge EPA's own actions which

contributed substantially in delaying AMVAC's responses to a significant number of data requirements which EPA now characterizes as "outstanding" in the NOITS.

11. As the full factual record will show, EPA took substantial amounts of time to complete reviews of documents supplied by AMVAC (where such reviews were necessary in order for AMVAC to proceed with the next step in generating required data). EPA failed to timely transmit data reviews and responses it had already generated (in one case, not providing a response for five years after it was completed). EPA also failed to timely respond to AMVAC's request for conditional waivers, thereby leading AMVAC to believe that studies would likely not be required based on the results of other studies. It further encouraged AMVAC to suggest alternate approaches to sequencing studies and meeting data requirements that it would later reject.

12. For three (3) requirements, final studies are on-going and EPA has been aware of AMVAC's plan concerning these studies for some time. All of the studies are very near completion with final reports due to be submitted in the next 30 to 45 days (DCPA SS-thyroid; DCPA 850.1400 bluegill; DCPA 850.1400 sheepshead minnow).

13. For four (4) requirements, AMVAC has submitted studies to meet the requirement, but EPA took years to review them and only recently (on April 27, 2022, concurrently with the issuance of the NOITS), informed AMVAC that some

information must be submitted to supplement them. None of the studies were deemed "unacceptable" or "rejected" (DCPA 850.2100; DCPA 850.4100; DCPA SS-1069; DCPA 850.1350).

14. For four (4) requirements, the requirements are not outstanding at all because EPA is already in possession of proposed label amendments that would eliminate the need for these studies. EPA agreed to this labeling approach and has been working with AMVAC on it since 2017. EPA has been reviewing final versions of the labeling amendments since 2019 (all Guideline "860" series studies referenced in the NOITS).

15. For the remaining nine (9) requirements, AMVAC and EPA have been in a dialogue for quite some time regarding exactly what data is required. All of these requirements are for Ecological Effects/Environmental Fate data. During the course of those discussions, AMVAC has submitted data and other information to EPA in support of data waivers. EPA issued its final decision rejecting all but one of these waiver requests on April 27, 2022, concurrently with the issuance of the NOITS. It is unreasonable that EPA made its final position regarding these requirements clear to AMVAC only in documentation that was first provided to AMVAC simultaneously with the NOITS. Additional detail on these studies is provided in the sections that follow. None of the data associated with these 9 data

requirements are needed to conduct the ecological risk assessment for DCPA for Registration Review.

16. In short, the facts show that AMVAC acted in good faith in responding to the DCI, and its conduct with respect to the 20 data requirements at issue (and the DCI overall) has not been dilatory, unreasonable, or otherwise inappropriate.

17. The iterative process reflected in the factual record here is typical of the process EPA and registrants go through when EPA issues a DCI involving an extensive number of data requirements. The practical realities of that process, and certainly the DCI at issue here, require a dialogue between the registrant and the Agency. What constitutes "reasonable steps" on the part of the registrant must be viewed in the light of the Agency's conduct as well as that of the registrant. If this were not the case, only the Agency's prosecutorial discretion would stand between all registrants subject to a DCI and suspension, given the outsized role the Agency plays in how a DCI progresses.

18. For these and the reasons more fully set forth below, AMVAC has not failed to take appropriate steps in response to the DCI and EPA's proposed suspension is otherwise not consistent with the factual record and FIFRA.

Background of DCPA

19. DCPA is a chlorinated benzoic acid herbicide whose pesticidal mode of action involves the inhibition of cell division of root tips in target plants. DCPA is used to control many annual grasses and broadleaf weeds for a variety of agricultural crops including collards and onions, among other crops.

20. Tolerances for DCPA residues for certain food and feed crops have been established under 40 C.F.R. § 180.185.

21. DCPA was first registered in 1958 and was successfully reregistered under FIFRA Section 4, 7 U.S.C. § 136a-1 in 1998 and tolerances were reassessed in 2005.

22. DCPA has been the subject of several DCIs prior to the 2013 DCI at issue here, including in 1987, 1992, and 1995.

23. DCPA technical is listed as Category IV (practically non-toxic) for acute-oral toxicity and dermal irritation and Category III (slightly toxic) for dermal LD50, inhalation LC50, and eye irritation.

24. AMVAC is the only registrant of DCPA and DCPA EUPs formulated with the technical DCPA at issue in this proceeding is the only source of DCPA EUPs for domestic growers.

25. Onions and brassica (mustard family crops, including kale and bok choy) are among the largest domestic uses of DCPA.

26. Many crops that rely on DCPA are so-called "minor use crops" that are only grown on limited acreage, but that may have major importance to the communities in which they are grown and to consumers.

27. More information concerning the importance of DCPA for these crops is set forth in the section below concerning the Administrator's existing stocks determination.

Statutory and Regulatory Background

28. Congress has provided statutory procedures EPA must follow if it intends to suspend an existing pesticide registration. FIFRA § 6 "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (emphasis in original).

29. These provisions ensure that registrants receive due process and that suspension decisions consider the risks and benefits of suspension. Notices of Intent to Suspend can be challenged through this administrative hearing process. The procedures and requirements for cancellation of an existing FIFRA registration are set forth in FIFRA § 6, 7 U.S.C. § 136d, and EPA's implementing regulations at 40 C.F.R. Part 164.

30. The procedures also recognize that third parties including growers and other government agencies may have an interest in suspension proceedings. The

provisions thus explicitly allow "[any] person adversely affected" to participate in the hearing process. 7 U.S.C. § 136a(c)(2)(B)(iv).

31. Decisions of the ALJ may be appealed to the Environmental Appeals Board. 40 C.F.R. §§ 164.100-111.

32. Under FIFRA § 16(b), after completion of the hearing and any appeal, EPA may issue its final cancellation order, which in turn is subject to judicial review by the federal Court ofAppeals. FIFRA § 16(b), 7 U.S.C. § 136n(b).

CONCISE STATEMENT OF OBJECTIONS

Issues for Resolution Concerning the Propriety of AMVAC's Steps to Comply with the DCI

33. There is only one statutory determination by the Administrator that may serve as the basis for a NOITS, which is that a registrant must have "failed to take *appropriate steps* to secure the data required" by a DCI. 7 U.S.C. § 136a(c)(2)(B)(iv) (emphasis added).

34. There is no timeframe established by FIFRA or its implementing regulations in which a registrant must necessarily complete all studies (or finalize all waiver requests or take other actions) required by a DCI. Nor do the requirements of the registration review program supply such a timeline.

35. As a result, the inquiry in connection with a suspension hearing is not whether the registrant has completed all studies (or finalized all waiver requests or

taken other actions) by any specific date, but whether the actions taken by the registrant have been *appropriate* under the circumstances presented.

36. EPA's conduct in connection with a DCI, including its correspondence with the registrant, is relevant to whether a registrant's actions are *appropriate* under the circumstances presented.

37. AMVAC restates and incorporates into its objections its brief summary of the status of each of several categories of studies referred to in the NOITS appearing at Paragraphs 9-18, above.

38. Detailed factual allegations concerning AMVAC's and EPA's conduct relevant to establishing the propriety of AMVAC's response to the DCI are set forth in Paragraphs 53-374, below.

39. For these reasons, AMVAC respectfully requests that the ALJ find that AMVAC has taken (and is taking) appropriate steps within the meaning of 7 U.S.C. § 136a(c)(2)(B)(iv) and that suspension is not warranted.

Issues for Resolution Concerning Existing Stocks

40. EPA defines "existing stocks" as "stocks of a registered pesticide product that are currently in the United States and that have been packaged, labeled, and released for shipment before the effective date" of an amendment, cancellation, or suspension affecting the registration under which the stocks were

produced. EPA, *Existing Stocks of Pesticide Products, Statement of Policy*, 56 Fed. Reg. 29,362 (June 26, 1991) (the "Existing Stocks Policy").

41. 7 U.S.C. § 136a(c)(2)(B)(iv) provides that the Administrator "may include … provisions" concerning the distribution of existing stocks while a product is suspended in a NOITS.

42. The NOITS Notice states, in Section V "Status of Products That Become Suspended," at 25,265, that "[a]fter the suspension becomes final and effective, [AMVAC] may not legally distribute, sell, use (including use to formulate another pesticide product), offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, [DCPA], except for the purpose of disposal ….". Ex. 2.

43. The foregoing quotation constitutes the Administrator's determination with respect to the disposition of existing stocks during a potential period of suspension as contemplated by 7 U.S.C. § 136a(c)(2)(B)(iv), even though it is not denominated as such in the NOITS Notice.

44. If the restrictions in the NOITS quoted in Paragraph 42 do not apply to existing stocks, if the suspension of DCPA were to become effective, EPA would likely apply the Existing Stocks Policy, 56 Fed. Reg. 29,362 for suspended pesticide products.

45. The Existing Stocks Policy states, at 29,367, that "the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of [a] suspension."

46. The "general" rule set forth in the Existing Stocks Policy applicable to registrants (quoted in Paragraph 45) is broadly consistent with the restrictions in the NOITS Notice quoted in Paragraph 42.

47. AMVAC asserts that a hearing is required both to clarify the specific restrictions contemplated by the Administrator, and to determine whether the Administrator's determination (once clarified) is consistent with FIFRA, as expressly provided for in 7 U.S.C. § 136a(c)(2)(B)(iv).

48. EPA's statement in the NOITS that "the risks and benefits associated with the continued registration of the affected product," NOITS Notice at 25,264, Ex. 2, may not be considered in a hearing does not apply to hearings regarding proposed suspensions under 7 U.S.C. § 136a(c)(2)(B)(iv), given that one of the express purposes of such a hearing is to determine whether the Administrator's determination regarding existing stocks is "consistent with [FIFRA]." 7 U.S.C. § 136a(c)(2)(B)(iv).

The Restrictions that Would be in Effect During a Suspension are Inconsistent with FIFRA

49. DCPA is a critical herbicide for crops in the allium family (onion family) and brassica family (broccoli and mustard family). For these crops, there are few, if any alternative herbicides with similar selectivity and efficacy as DCPA. DPCA does not have a direct substitute, and thus one or multiple possible replacement herbicides would have to be used but would only provide a partial spectrum of weed control.

50. Brassica crops are an important component of many growers' crop rotation plans. AMVAC believes that many growers would suffer substantial increases in production costs per acre if they did not have access to DCPA.

51. AMVAC understands that a group of growers intends to submit information in advance of the hearing concerning the effects that a suspension would have on their operations. AMVAC reserves the right to rely on additional facts that may be supplied by these growers.

52. The information presented above, and such other information as may be presented at a hearing, demonstrates that the restrictions on the distribution of existing stocks proposed by the Administrator is not consistent with FIFRA.

SPECIFIC FACTUAL ALLEGATIONS CONCERNING DATA REQUIRED BY THE DCI AND BASIS FOR OBJECTIONS TO SUSPENSION

The Data-Call In

53. EPA issued a "Generic Data Call-In Notice" on January 31, 2013 (the "DCI") (Ex. 4). The DCI set forth various data that EPA asserted were necessary to maintain AMVAC's DCPA technical registration. The DCI required AMVAC to respond within 90 days (*i.e.*, by Wednesday, May 1, 2013), advising EPA how it planned to satisfy each of the data requirements identified in the DCI.

54. The DCI provided AMVAC with options for responding in connection with each data requirement in the DCI. These included, as relevant here, Option 1 (Developing Data); Option 4 (Submitting Existing Data); Option 5 (Upgrading a Study); Option 6 (Citing a Study); Option 7 (Deleting Uses); and Option 9 (Requesting a Waiver).

55. EPA has accepted AMVAC's responses with regard to a majority of the data requirements set forth in the DCI as discussed in Paragraph 5, above; the NOITS refers to only a subset of the data requirements in the DCI.

56. AMVAC provided its initial response to the DCI on April 29, 2013 (the "Initial Response"), within the statutorily required 90-day time frame. Ex. 5.

57. AMVAC's Initial Response advised EPA how AMVAC intended to satisfy each of the data requirements in the DCI, based on the options provided by

EPA. The option chosen with respect to each data requirement referred to in the NOITS, as well as the steps AMVAC has taken to fulfill its obligations in connection with each such requirements, is set forth in the following sections.

The Human Health Studies

The Comparative Thyroid Study

58. In the DCI, EPA requested data identified as the "comparative thyroid toxicity study." Ex. 4. at Attachment 3, page 5 of 5. The NOITS refers to this data requirement as being outstanding. But, as noted above and more fully explained in the paragraphs below, the final study for completing this data requirement is expected to be submitted to EPA within the next 30 days, likely before any hearing that will be held in this matter, and EPA is well aware of (and acquiesced to) the schedule that it has been progressing on.

59. The 2013 DCI included a reference to the "Guideline Requirement Number," for each data requirement which corresponded to the OCSPP Testing Guidelines that provide information on how to design and conduct specific studies required for registration under 40 C.F.R. Part 158.

60. The "Guideline Requirement Number" for the "comparative thyroid toxicity study" in the DCI was listed as "SS-thyroid tox."

61. The designation "SS" means a "special study." A special study is one for which there are no established EPA data requirements under 40 C.F.R. Part

158, no OCSPP Testing Guidelines, and no standardized protocols to use in conducting the study.

62. At the time the DCI was issued, the "comparative thyroid toxicity study" requirement was so rare that only 2 other registrants had been required to conduct such a study in the history of EPA's pesticide registration program.

63. The DCI did not provide any information on what testing should be done to satisfy the comparative thyroid ("CTA") data requirement.

64. The only instruction provided in the DCI was a footnote indicating that a protocol must be submitted to EPA for review and approval prior to study inception.

65. EPA and AMVAC have worked together diligently since the DCI was issued to develop a testing program to satisfy this requirement. The program involves a tiered approach to data development where a significant amount of preliminary data and information was required to be generated, submitted and reviewed by EPA before AMVAC could move to the next step in the program and initiate a final comprehensive study to complete this requirement.

66. The DCI provided a time-period of only 24 months for the completion of the CTA data requirement including the time for development, submission, review and approval of the protocols.

67. AMVAC advised EPA in the April 29, 2013, Initial Response that it would develop new data to satisfy the CTA data requirement. Ex. 5 at Attachment 2, page 5 of 5.

68. The lack of testing guidance for meeting the CTA data requirement created significant challenges in determining how to (i) design the testing program, (ii) develop appropriate protocols, and (iii) determine the specific analyses to be done to ensure that the data would be scientifically acceptable and would address all the toxicological questions EPA sought to answer.

69. The CTA data requirement was a moving target. EPA and AMVAC engaged in a lengthy iterative process over 8 years to determine precisely what testing program should be followed to generate the data needed to address the requirement.

70. Under the testing program that EPA approved, a significant amount of preliminary data and information was required to be generated, submitted and reviewed by EPA before AMVAC could move to the next step in the program and initiate a final comprehensive study to complete this requirement. The CTA data requirement in the DCI ultimately evolved into a testing program with a tiered approach that included multiple studies conducted consecutively over several years.

71. EPA has been deeply involved in this iterative process and is fully aware that it could not practically have been completed more rapidly than the schedule it has been progressing on.

72. AMVAC has fully cooperated with EPA and acted in good faith to produce all the data under the testing program for the CTA requirement.

73. To date, AMVAC has generated and submitted eleven (11) individual studies (including two dose range finding studies) in response to the DCI's CTA requirement, all of which were determined to be necessary as EPA's view of the data requirement evolved over time. Dose range finding studies necessarily must be conducted before the final study.

74. None of the 11 individual studies referenced in the paragraph immediately above were identified in the DCI.

75. Each study provided data which often led to requests for additional assays and information, which in turn informed the design and conduct of the final study for the CTA requirement scheduled to be completed in June 2022.

76. During the course of developing the data under the testing program for the CTA data requirement, AMVAC provided EPA with consistent and regular updates including projected milestones and study completion dates.

77. At no time did EPA establish any specific end dates or deadlines for completing the testing program, although EPA was well-aware that the testing

program would take longer than the initial default 24 months referenced in the DCI.

78. EPA's Attachment III – Explanatory Appendix to the NOITS, summarizing communications between EPA and AMVAC, Ex. 1, shows the extensive and continuous dialogue between EPA and AMVAC regarding the CTA data requirement. However, it omits several important facts.

79. The iterative process between EPA and AMVAC regarding the CTA data requirement began on April 29, 2013, when AMVAC submitted initial protocols for conducting four studies to meet the CTA data requirement to EPA as part of its 90-day response to the DCI.

80. The protocols were based on AMVAC's experience with comparative cholinesterase assays that had been conducted for DCPA, which had looked at toxicologic endpoints over different rat life stages.

81. AMVAC's proposed testing program for the CTA data requirement consisted of four studies: (1) DCPA: Single and Repeat Dose Range Finding Study in Male and Female Juvenile Rats by Oral Gavage Administration; (2) DCPA: Single Dose Comparative Thyroid and Thyroid Hormone Study in Young Adult and 11 Day Old Juvenile CD Rats by Oral Gavage Administration; (3) DCPA: Repeat Dose Comparative Thyroid and Thyroid Hormone Study in young Adult and 11 Day Old Juvenile CD Rats by Oral Gavage Administration and (4)

Gestational Exposure Comparative Thyroid and Thyroid Hormone Study in the CD Rat by Oral Administration.

82. On November 19, 2013, approximately 7 months after AMVAC submitted the initial protocols for the studies identified in the paragraph immediately above, EPA completed a memorandum summarizing its review of the protocols indicating that all were inadequate, and that a new protocol for a range-finding study for 11-day old juvenile rats should be drafted and submitted to EPA before any further testing to meet the data requirement was performed. Ex. 6

83. EPA's November 19, 2013, review was not provided to AMVAC until October 21, 2014, almost 12 months after it had been completed and approximately 18 months after the protocols were submitted by AMVAC. Ex. 7 (email from M. Manupella, EPA to J. Porter, AMVAC) (Oc. 21, 2014).

84. The review also referenced an internal EPA guidance document dated 2005 entitled "Thyroid Assays in Pregnant Animals, Fetuses and Postnatal Animals, and Adult Animals."

85. EPA did not provide AMVAC a copy of the internal EPA guidance document, which contained critical and important information regarding EPA's positions regarding such studies.

86. On October 22, 2014, AMVAC wrote to EPA requesting a copy of the 2005 guidance document referenced in the November 19, 2013, review.

87. EPA provided the 2005 guidance document referenced in Paragraph 86 on October 23, 2014.

88. Prior to its receipt of the 2005 guidance document on October 23, 2014, AMVAC was not aware of it, and had no reason to know of or suspect that the document existed.

89. On October 21, 2014, when AMVAC received EPA's review rejecting the initial protocols for the CTA data requirement and referencing the 2005 internal guidance document, approximately 22 months of the 24-month time-period provided in the DCI for completing the CTA data requirement had elapsed.

90. On November 26, 2014 – only 30 days after receiving EPA's review and the 2005 guidance document – AMVAC submitted a revised protocol for the range finding study in juvenile rats requested by EPA.

91. Three months later, on February 10, 2015, EPA requested additional data on the protocol and methods described therein.

92. The following day, on February 11, 2015, AMVAC provided the data and methods requested in the paragraph immediately above to EPA.

93. On March 19, 2015, EPA and AMVAC held a conference call to review the protocols and discuss a path forward for the testing program to meet the CTA data requirement.

94. During the March 19, 2015 conference call, EPA provided comments on the protocol and instructed AMVAC to provide an updated protocol for the range finding study and another protocol to integrate three other phases of the testing program into one.

95. On April 1, 2015, thirteen days after the March 19, 2015, meeting, AMVAC submitted a testing plan for five (5) studies and revised protocols incorporating the comments and direction received from EPA at the meeting.

96. The protocols were submitted by AMVAC EPA on April 1, 2015, and consisted of: (1) a protocol for a range-finding study to identify appropriate dose ranges for the definitive study – "DCPA Range Finding Pre and Post Natal Developmental Thyroid Study in Sprague Dawley Rats by Oral Administration (Envigo Study: BDG0204)"; (2) a protocol for a definitive comparative toxicity study – "Definitive Main Pre and Post Natal Developmental Thyroid Study in CD Rats by Oral Administration (Envigo Study BDG0202)" and (3) a study plan for a PTU Positive Control Study (HLS1095).

97. AMVAC is now aware that, in a memorandum dated April 16, 2015, EPA approved the revised protocols referenced in the paragraph immediately above and recommended that AMVAC submit positive control data and the results from the range-finding study before beginning the definitive study. Ex. 8.

98. AMVAC has no record of receiving the April 16, 2015, memorandum from EPA, or of seeing it, before it was posted to the docket for the NOITS proceeding on April 28, 2022.

99. On June 17, 2015, EPA contacted AMVAC via email to check on the status of the conduct of the testing outlined in the updated CTA protocols. In the email message from EPA to AMVAC's registration manager, EPA indicated that "HED has no additional comments on the revisions." Ex. 9.

100. AMVAC replied to EPA's June 17, 2015, email inquiry the same day stating that "we were waiting for EPA's acceptance of our protocols and testing strategy, before we committed to go ahead. As we have that now, by receipt of your email, we will now go ahead and get these studies scheduled at the performing laboratory." Ex. 9.

101. On June 18, 2015, EPA replied to AMVAC's registration manager's June 17, 2015, email stating "Sorry for the delay in response . . .please do begin conducting the studies and keep me posted on progress." Ex. 9.

102. Thus, when EPA made AMVAC aware on June 17, 2015, that the revised protocols and testing plan were approved for the CTA studies to be initiated, the 24-month deadline for completing the requirement in the DCI had already elapsed by more than six months.

103. EPA's Attachment III – Explanatory Appendix, Ex. 1, summarizing communications between EPA and AMVAC states that on June 29, 2015, EPA recommended that AMVAC conduct a special thyroid assay in pregnant animals, fetuses, postnatal animals and adult animals.

104. The recommendation noted in the paragraph above was documented in an EPA data evaluation record for Tier I assays under EPA's Endocrine Disruptor Screening Program which is not associated with the DCI.

105. After receiving the indication that EPA approved the revised protocols for the studies to meet the CTA testing program under the DCI from the June 17, 2015, e-mail exchange described above in Paragraphs 99 to 101, AMVAC took steps to initiate the preliminary work necessary to conduct the range-finding study in accordance with the testing plan and approved protocol.

106. Because the CTA studies were unique and rare, the number of laboratories capable of conducting the CTA testing program was extremely limited.

107. AMVAC selected the laboratory that it was confident had sufficient experience with DCPA, Envigo in the UK.

108. Considerable challenges had to be met before the range-finding study could be initiated with laboratory, including the need for the laboratory to get

approval from the UK Home Office before any testing could be commenced as this is a non-guideline EPA study.

109. Testing and analytical methods had to be developed to measure three thyroid hormones. An entire positive control study had to be conducted across a range of dose levels and shown to be successful.

110. During 2016, the lab continued to conduct analyses and other preliminary work for Phase I of the range finding study. Initial analysis of the thyroid hormone was started with specifically manufactured kits for plasma, but difficulties developed with kit supply, consistency between batches and measurement with the kits. The laboratory then switched over to analysis in serum, but new methods for serum had to be developed and fully validated.

111. On May 3, 2016, AMVAC submitted the Validation Report for the Immunoassay Method which was part of Phase 1 of the range finding study.

112. By January or 2017, the lab determined that Phase I of the range finding study had to be rerun because the immunoassay used at the time the validation was performed for the study noted in the paragraph above, the assay was not able to detect quantifiable levels of T4 and T3 in plasma from rat fetuses, which were critical endpoints for the range finding study.

113. To address the problem identified in the paragraph immediately above, the lab developed a new assay with lower detection limits and validated the method for accuracy and precision.

114. Initiation of Phases II and III of the range finding study were delayed pending the rerun of Phase IA.

115. On January 25, 2017, AMVAC informed EPA of the problems encountered in Phase I of the range finding study, the need to rerun it and the new schedule for completing Phases I, II and III of the study.

116. The updated study plan as communicated on January 25, 2017, indicated that Phase I would be completed by late April 2017, and that Phases II and III could be completed during Q4 2017. The new completion date for the last CTA study (the definitive study) under the CTA testing program was estimated to be Q4 2018.

117. Beginning in March, 2017, EPA requested quarterly updates on the CTA testing program. AMVAC submitted these updates consistently from April, 2017, through January, 2022. Each update included a "Study Update" prepared by the lab. Updates were filed quarterly between March, 2017, and January, 2022.

118. On May 30, 2017, AMVAC submitted an "Update on DCPA Developmental Thyroid Studies" concerning the dose range finding study then in progress. Ex. 10 (attachment omitted).[1]

119. The May 30, 2017, update indicated that Phase I had been reconducted to correct for the issues regarding detection of values for T4 and T3 hormones in fetuses reported to EPA on January 25, 2017, and discussed in the quarterly status report submitted on April 11, 2017. *Id.*

120. The May 30, 2017, update also summarized the results of the reconducted Phase I study and outlined key points for conducting Phases II and III. In the email providing the May 30, 2017, update, AMVAC requested confirmation of proposed dose levels and times for hormone measurements to proceed with Phase II and III testing. *Id.*

121. On August 14, 2017, AMVAC reiterated its request to EPA to confirm the proposed dose levels and timing so that the lab could proceed to Phases II and III. Ex. 11 (attachments not included).

122. On August 17, 2017, the PTU – positive control study report – was submitted to EPA. Ex. 12.

[1] AMVAC has not provided all attachments to all emails and attachments to certain other documents referenced in this filing. If EPA believes that any omitted attachment is relevant to whether AMVAC has taken appropriate steps, AMVAC is prepared to provide copies of any such excluded attachments at the hearing.

123. In the October 2017 quarterly report, the lab noted that the dose levels and timing from the reconducted Phase I study were still being reviewed by EPA. The update also indicated that testing for Phases II and III were on hold pending the results of EPA's review of the Phase I results and the PTU positive control data. Ex. 13.

124. On December 12, 2017, EPA provided AMVAC with its November 16, 2017, review of the Phase I study. EPA recommended that a new range finding study be conducted to determine dose levels, time points, and the potential for DCPA to be transferred to milk to avoid the necessity of the direct dosing of pups in the definitive study. Ex. 14 (review), Ex. 15 (email transmitting).

125. EPA's review of the Phase I study described in the paragraph above necessitated a new design for an entirely new range finding study.

126. Between January, 2018, and August, 2018, AMVAC worked with the lab to develop a new study outline and design for the range finding study.

127. There were considerable delays in finalizing the new study outline due to a ransomware attack on the lab which halted progress due to the impact on the lab's computer systems.

128. AMVAC noted the IT disruptions at the lab in its January status update (submitted on February 12, 2018) and its May status update (submitted on May 17, 2018).

129. The May, 2018, status update included Study Plan JW36WK (Appendix 1) for the new range finding study – Phases I, II and II and a summary table of validated thyroid hormone analysis methods and measured level using methods of analysis at different developmental stages (Appendix 2). Regarding timing for initiating the new range finding study, the report states that "the new range-finding pre- and post-natal development thyroid study (Envigo Study No. JV36WK) will proceed as soon as possible following authorization to proceed is received from EPA."

130. The EPA Chemical Review Manager acknowledged receipt of the May, 2018, status update by email on May 18, 2018.

131. On August 24, 2018, AMVAC submitted three study reports, one protocol, a data table, and an update for the CTA testing program: (1) Validation of an Immunoassay Method for the Measurement of Thyroid Stimulating Hormone (TSH) in Rat Serum. June 2018 (Envigo Study No. SL13SG); (2) Validation of Bioanalytical Method for the Determination of 3,3,5'-Triiodo-L-Thyronine (T3) and Thyroxine (T4) in Rat Serum using Liquid Chromatography with Tandem Mass Spectrometric Detection (LC-MS/MS). June 2018 (Envigo Study No. FF58YR); (3) DCPA: Dose Range Finding Pre-Natal Developmental Thyroid Study in Sprague-Dawley Rats by Oral Administration. June 2018 (Envigo Study No. BDG0204) (MRID No. 50663603); (4) Summary Table of Thyroid Hormone

Methods and Control Ranges – Sprague Dawley Rats (Envigo); and (5) Study Outline and Design (Envigo Study Plan No. JW36WK) for the new range finding study.

132. The August 24, 2018, letter transmitting the above-referenced reports noted that a Study Protocol for the new dose range finding study (Envigo Study Plan JW36WK) would be submitted as soon as possible for EPA's review and approval, before commencing the study. Ex. 16.

133. On November 15, 2018, AMVAC submitted the November, 2018, quarterly status update on the CTA testing program and the proposed protocol for the new range finding study: DCPA Dose Range Finding Pre and Post Natal Developmental Thyroid Study (Including Positive Control Group) in Sprague-Dawley Rats by Oral Administration: Study Plan 4 (November 9, 2018). AMVAC again indicated that it would await EPA's review and acceptance of the range finding protocol before finalization and commencing the study. Ex. 17 (email transmitting).

134. EPA's Attachment III to the NOITS, Ex. 1, is incomplete and misleading because none of the 2018 submissions or actions taken by AMVAC identified in the preceding paragraphs are included.

135. On February 21, 2019, AMVAC submitted the first quarterly status update for calendar year 2019. AMVAC specifically asked EPA to provide an

update on the status of EPA's review of the draft protocol for the new dose range finding study submitted in November, 2018. Ex. 18.

136. The February, 2019, status update provided a summary of all the preliminary work and study reports provided to EPA after the Agency's November 16, 2017, rejection of the Phase I data from first dose range finding study and its request for a new range finding study. The update also notified EPA that the validation data for rat plasma and rat milk requested by EPA was projected to be ready for submission in March, 2019. *Id.*

137. On February 26, 2019, the EPA Chemical Review Manager responded that she would provide an update on the review of the protocol for the range finding study as soon as it was available.

138. On April 4, 2019, AMVAC submitted the validation data referenced in Paragraph 136. Two reports were submitted: (1) DCPA: Validation of a Bioanalytical Method for the Determination of DCPA in Rat Plasma (K2EDTA) using Liquid Chromatography with Tandem Mass Spectrometric Detection (Envigo Study No. DC87NT); and (2) DCPA: Validation of Bioanalytical Method for the Determination of DCPA in Rat Milk using Liquid Chromatography with Tandem Mass Spectrometric Detection (Envigo Study No. CH09GN).

139. In the April 4, 2019 letter, AMVAC also asked EPA to provide its review of the protocol for the new range finding study submitted in November,

2018, and indicated that the lab was now waiting to receive EPA's acceptance before scheduling and starting the study. Ex. 19.

140. AMVAC has no record of receiving any response from EPA regarding its April 4, 2019, request for an update on the Agency's review of the protocol for the new range finding study.

141. On June 17, 2019, AMVAC submitted its quarterly status update on the CTA testing program, again asking EPA to provide a status update on EPA's review of the protocol for the new range finding study submitted in November 2018. The update summarized all the reports and data provided to EPA since its November, 2017, request for additional data and its instruction to provide a protocol to conduct a new range finding study. Ex. 80 (attachments excluded).

142. The June, 2019, update referenced above showed that 8 study reports had been submitted by AMVAC between November 16, 2017, and April, 2019, addressing all of EPA's prior requests (including the protocol for the new range finding study submitted on November 15, 2018).

143. AMVAC again indicated that the dose range finding study could not be initiated without EPA's approval of the protocol and that the comprehensive (definitive) CTA study could not be initiated until the new range finding study was completed and the results (doses) were reviewed and approved by EPA. *Id.*

144. None of AMVACs submissions or communications to EPA noted in the preceding eight paragraphs are included in EPA's Attachment III- Explanatory Appendix to the NOITS, Ex. 1.

145. On September 17, 2019, EPA completed its review of the protocol for the new range finding study eleven months after it was submitted on November 15, 2018.[2]

146. On September 24, 2019, AMVAC received the EPA review identified in Paragraph 145. In that review, EPA concluded that the proposed study plan was acceptable if certain recommendations detailed in the review were followed. EPA also requested that AMVAC submit a detailed study protocol with EPA's recommendations before commencing any work.

147. On December 13, 2019, AMVAC submitted its quarterly status report for the CTA testing program and its response and questions regarding EPA's September 17, 2019, review.

148. On March 5, 2020, AMVAC submitted a proposed protocol for Phase I of the new dose range finding study to EPA.

[2] AMVAC is not providing copies of Special Study protocols and EPA's reviews thereof with these objections. These documents may contain confidential business information ("CBI"). If EPA believes that the contents of any protocol or related DER is relevant to whether AMVAC has taken appropriate steps, AMVAC is prepared to introduce such documents into evidence at the hearing subject to appropriate CBI protocols.

149. EPA completed a review of the proposed protocol for Phase I on March 19, 2020. The review was provided to AMVAC on April 14, 2020.

150. At the time the review was provided to AMVAC, EPA also asked for an updated schedule for the conduct of the dose range finding study.

151. On April 16, 2020, AMVAC informed EPA that the lab was reviewing EPA's comments on the protocol and that an update on the schedule would be forthcoming in the quarterly update. AMVAC also asked EPA for an estimate of time EPA will need to review the comprehensive CTA study once it was submitted.

152. On June 22, 2020, EPA indicated that the review time for the comprehensive study will be 3 months depending on the workload of the health effects team. Ex. 20.

153. On June 23, 2020, AMVAC submitted its quarterly status update on the CTA testing program and informed EPA that the estimated study dates for the new range finding study including various intermediate dates, with an estimated date for the final report of December, 2020. AMVAC noted that this schedule was not yet confirmed and that it would update EPA on confirmed scheduling as soon as possible. *Id.*

154. On August 6, 2020, AMVAC submitted its quarterly status update for the CTA testing program including updated scheduling from the lab for the new

range finding study. The updated schedule provided that a draft report would be available in January 2021.

155. On October 26, 2020, AMVAC received a letter from EPA outlining what EPA believed to be the status of all studies requested in the DCI. The letter requested a response within 30 days of receipt. The letter did not include any information on the numerous reports and other updates that had been submitted to EPA as part of the CTA testing program to meet the data requirement for "ss-thyroid tox" – Comparative thyroid study. Ex. 21.

156. On December 9, 2020, AMVAC submitted its quarterly status update on the CTA testing program. The update indicated that the end-of-life phase for the new dose range finding study had been completed on November 7, 2020 (as forecasted in the August, 2020, quarterly update). The update further projected that the draft study report would be completed by January 27, 2021 (also as forecasted in the August, 2020, quarterly update).

157. On December 9, 2020, EPA acknowledged receipt of the December 9, 2020, update and asked for an estimate of when the final report for the range finding study would be submitted to EPA.

158. AMVAC's in-house toxicologist responded to EPA's question the same day, December 9, 2020 – indicating that the final report for the range finding study was anticipated to be available for submission at the end of March, 2021.

159. AMVAC responded to EPA's October 26, letter on December 17, 2020. Ex. 22. EPA reminded the Agency that AMVAC "continue[s] to provide the Agency with quarterly updates" concerning the thyroid study.

160. On February 16, 2021, EPA requested an update on the status of the dose range finding study and whether a final report was still on track for submission in March, 2021.

161. AMVAC's in-house toxicologist responded on February 19, 2021, indicating that the draft report had been delayed. The lab had experienced severe flooding over the Christmas holiday which led to various complications and was expected to delay the submission of the final report by 1 month.

162. On February 19, 2021, AMVAC provided an update on progress in preparing the report for the range finding study, confirming that the lab was anticipating having the draft report ready in early March, with a final report expected to be ready for submission in April.

163. On March 24, 2021, EPA contacted AMVAC for an update on the reports referenced in the paragraph immediately above. AMVAC responded the same day, indicating that the draft report had been received and the final report was still expected in April for submission to EPA. AMVAC offered to submit the draft report to EPA ahead of finalization of the final report to expedite the schedule as much as possible. Ex. 23.

164. On March 24, 2021, EPA responded to the communication described in the paragraph immediately above and confirmed that it would review the draft report in advance of the final report. *Id.*

165. On March 25, 2021, AMVAC submitted the draft dose range finding report – Dose Range Finding QA'd Draft Report (Covance: PM86YP/8441728) (Covance was formerly known as "Envigo") to facilitate EPA's review. *Id*. (attachment not included).

166. On March 25, 2021, AMVAC also submitted the proposed protocol for the comprehensive/definitive CTA study to EPA for review – Protocol DCPA Main Pre and Post Natal Developmental Comparative Thyroid Study in CD Rats by Oral Administration (Covance: 8432592). AMVAC noted that this definitive study had a proposed schedule with the lab and that animal arrival could be done by June, 2021, if EPA was able to review the protocol and provide authorization to proceed. *Id*. (attachment not included).

167. EPA acknowledged receipt of the draft report identified in Paragraph 165 and the proposed protocol identified in Paragraph 166 on the same day they were submitted (March 25, 2021). In its acknowledgement, EPA noted that it would pass both submissions onto the internal team and get back to AMVAC with any questions.

168. On April 6, 2021, AMVAC submitted its quarterly status report for the CTA testing program. The report noted the anticipated completion of the final report for the range finding study and the submission of the proposed protocol for the definitive CTA study provided to EPA on March 25, 2021.

169. On May 27, 2021, AMVAC submitted the final report for the range finding study identified in Paragraph 168. AMVAC noted that it was moving forward with planning and scheduling for the definitive CTA study and would like to receive EPA's comments on the protocol submitted on March 25, 2021.

170. On June 22, 2021, AMVAC contacted EPA to check on the status of the review of the protocol for the definitive CTA study. AMVAC noted that the lab was set to receive the animals for the study on July 22, 2021, and needed the EPA's comments on the protocol to stay on schedule.

171. EPA respond to AMVAC's June 22, 2021 communication on June 23, 2021, indicating that the EPA internal team was scheduled to produce a finalized memorandum of the proposed protocol on July 15, 2021.

172. AMVAC responded on June 28, 2021, and asked if any of EPA's comments on the proposed protocol could be shared in advance of the formalized review in order to minimize any time period for initiating the definitive study. AMVAC indicated that there was a very tight timeline before the animal delivery at the lab to meet the proposed study schedule. AMVAC further explained that

because the definitive study was such a large and complex study, the lab would not be able to delay the start of the study by even a few weeks, and if such a delay occurred (even of short duration), the study would have to be completely rescheduled, causing significant delays in completing the last part of the CTA testing program.

173. AMVAC initiated steps to commence the definitive CTA study on July 5, 2021.

174. On July 8, 2021, AMVAC contacted EPA again to see if any information on EPA's review of the protocol for the definitive CTA study could be provided.

175. EPA responded the same day that some preliminary comments would be provided on July 9, 2021.

176. EPA provided the preliminary comments to AMVAC on July 9, 2021.

177. On July 9, 2021, AMVAC responded to EPA to ask if any additional substantive comments beyond those contained in the preliminary comments were anticipated in the final memorandum for the protocol review. Ex. 24.

178. EPA did not respond to AMVAC's July 9, 2021, communication referenced in the paragraph immediately above until July 21, 2021. In the July 21, 2021 response, EPA provided the final protocol review memorandum.

179. EPA requested an update on the status of the definitive CTA study on August 17, 2021 (specifically asking for an "aspirational date for submission of the final study[.]") *Id.* AMVAC responded to EPA's inquiry on the same day, stating that the study started on July 5, 2021; the completion of the in-life phase was projected for September, 2021; the completion of an audited draft report was projected for January, 2022; and the final report for EPA submission was scheduled for June, 2022. AMVAC also informed EPA that it was planning to submit an amended study protocol with the now scheduled study dates. *Id.*

180. EPA acknowledged receipt of AMVAC's August 17, 2021, update described in the paragraph immediately above on August 18, 2021.

181. At no time since the communication of the projected dates for definitive CTA study on August 17, 2021, had EPA questioned, rejected or expressed to AMVAC any concerns or problems regarding the projected completion date until the NOIS issued on April 27, 2022.

182. On January 26, 2022, AMVAC submitted the quarterly status update on the CTA testing program to EPA. It stated that the in-life phases of the definitive CTA study were successfully completed in August and September, 2021. AMVAC further indicated that the draft study report was projected to be completed on February 18, 2022, and that the final report was still projected for submission to EPA in June, 2022. Ex. 25.

183. On February 7, 2022, EPA requested test substance stability studies from the dose range finding study.

184. AMVAC submitted the test substance stability studies to EPA on February 9, 2022.

185. On February 9, 2022, EPA requested additional data regarding historical control thyroid hormone data.

186. On February 15, 2022, AMVAC submitted to EPA the historical control data referenced in the paragraph immediately above.

187. No further requests regarding the definitive CTA study have been received from EPA by AMVAC since February 9, 2022.

188. As indicated in AMVAC's prior communications regarding study status dating back to August, 2021, the projected schedule for submission of the final report for the definitive CTA study remains on track for June, 2022, well before a hearing would occur in this proceeding.

189. EPA has been deeply involved in the iterative process for conducting the CTA testing program required under the DCI and acquiesced to the schedule for completing it.

The Residue and Field Accumulations Studies

190. The NOITS refers to four data requirements under the "860" prefix testing guidelines for Residue Chemistry data as being outstanding. As more fully

explained in Paragraphs 192-232 below, these data requirements are not outstanding because EPA is already in possession of proposed label amendments that would eliminate the need for these studies. AMVAC initially submitted the relevant proposed label amendments in May and June, 2017.

191. EPA and AMVAC went through multiple iterations of review and comments on the proposed label amendments, and AMVAC submitted the final versions of the proposed label amendments July and August, 2019. EPA has been reviewing these proposed label amendments since they were submitted.

192. The January 31, 2013, DCI, Ex. 4, requested data for OCSPP Guidelines 860.1300, 860.1340, 860.1480, and 860.1900.

193. In its April 29, 2013, Initial Response, Ex. 5, AMVAC stated that it intended to satisfy the 860.1300, 860.1340, 860.1480, and 860.1900 data gaps as follows.

194. For Guideline 860.1300 (Nature of the residue – plants, livestock (poultry)), AMVAC stated that it would remove from the DCPA labels uses for alfalfa, which would eliminate treated feedstocks for poultry. *Id.*

195. For Guideline 860.1340 (Residue analytical method: Livestock Commodities), AMVAC stated that it would remove from the DCPA labels uses for ruminant commodities. *Id.*

196. For Guideline 860.1480 (Meat/milk/poultry/eggs (ruminant)), AMVAC stated that it would remove from the DCPA labels uses for alfalfa, white potatoes, and peas, which would eliminate treated feedstocks for ruminants. *Id.*

197. For Guideline 860.1900 (Field accumulation in rotational crops), AMVAC proposed that this data requirement should be considered fulfilled once the integrity of samples in two studies[3] could be established (*i.e.*, that the studies would be "upgraded"). Initial Response, Ex. 5, at 2.

198. In addition, AMVAC provided justification for the existing DCPA field accumulation data in rotational crops residue data.

199. On October 23, 2013, EPA responded to AMVAC's positions concerning the residue and field accumulation studies for the DCI. Ex. 26 [DCPA (Dacthal): HED Response to Comments on the Residue Chemistry Requirements of the Generic Data Call In (GDCI-0798701-1140), (the "October 2013 Residue Chemistry Response")].

200. With respect to whether removing the alfalfa use from the DCPA Technical label would eliminate the need for the poultry metabolism study

[3] "Determination of Residues of [DCPA], SDS-893, Its Degradation Products and HCB on Crops and Soil from a Crop Rotation Study Near Donalsonville, GA – 1989, 1990" by Fowanik, J. B. (MRID 42155504) and "Determination of Residues of [DCPA], SDS-893, Its Degradation Products and HCB on Crops and Soil from a Crop Rotation Study Near Rosa, LA – 1989, 1990" by Fowanik, J. B. (MRID 42298303).

requirement 860.1300, HED's October 2013 Residue Chemistry Response stated that specific data was required (DCPA residues in corn and soybean as rotated crops). Once residue data in rotated crops are determined, a dietary burden could be estimated for poultry. HED's Response further stated that if the dietary burden estimates result in sufficiently low anticipated secondary residues in poultry tissue and eggs, then "it may not be necessary to perform a poultry metabolism study." Ex. 26 at 2.

201. With respect to the guideline study requirement 860.1340, the October 2013 Residue Chemistry Response stated that once the tolerances for DCPA residues in corn and soybean as rotated crops have been reassessed, a dietary burden can be estimated for ruminants. If the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, then a livestock residue analytical method would not be necessary. If the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, "then a ruminant feeding study would not be necessary." *Id.*

202. With respect to the guideline study requirement 860.1480, the October 2013 Residue Chemistry Response stated that, once the tolerances for DCPA residues in corn and soybean as rotated crops have been reassessed, a dietary burden can be estimated for ruminants. If the dietary burden results in sufficiently

low anticipated secondary residues in ruminant tissue and milk, "then a ruminant feeding study would not be necessary." *Id.*

203. With respect to the guideline study requirement 860.1900, the October 2013 Residue Chemistry Response stated that EPA believed that rotational crop field trials were required to determine the appropriate tolerance levels for rotated crop commodities. The scope of the required tests would be dependent on AMVAC's intent with respect to (1) the crops to be allowed in rotation and (2) the desired PBIs for these crops. EPA asked AMVAC to specify its intent regarding these two points. *Id.* at 5.

204. On January 29, 2014, AMVAC submitted a "12-Month Response," Ex. 27.

205. Regarding the 860.1900 guideline study, AMVAC stated in the January 29, 2014, response that (1) data concerning the storage interval of crops associated with the crop rotational study MRID 41255504 is provided in Appendix VI of the final report; (2) sampling intervals were determined based on the number of days between sampling and sample extraction; (3) the maximum interval for all commodities was 407 days; (4) data concerning the storage interval of crops associated with the crop rotational study MRID 42298303 is provided in Appendix VII of the final report; (5) sampling intervals were determined based on the

number of days between sampling and sample extraction; (6) the maximum interval for all commodities was 423 days. *Id.* at 4-5.

206. AMVAC further stated that data supporting the conclusion that the samples were viable upon analysis are found in MRID 43938901. That study was performed on frozen samples associated with six diverse crop matrices, and demonstrated that the parent compound DCPA and SDS-954 (TPA) residues are stable for a 4-year period. *Id.* at 5.

207. In a July 7, 2014, science review ("DCPA: HED Response to (12 Month) Comments on the Residue Chemistry Requirements of the Generic Data Call-In (GDCL- 0798701-1140)"), Ex. 28, HED addressed AMVAC's statements in the 12-Month Response, Ex. 27, concerning the Guideline 860.1380 and 860.1900 studies. HED stated (1) that AMVAC's submitted information regarding the storage durations of samples in the 860.1900 rotational crop studies (MRIDs 41255504 and 42298303) was not relevant because this information was never identified as a data gap and is not part of the GDCI; and (2) that the 860.1900 GDCI requirement specifically pertains to the need for additional field trials on rotated crops to determine the appropriate tolerance for residues of DCPA on those rotated crops, and that those data remained outstanding.

208. AMVAC finally received the October 23, 2013, HED science review, Ex. 26, on July 31, 2014. Ex. 29 (email transmitting); Ex. 30 (science review).

209. On September 24, 2014, AMVAC responded to EPA's July 30, 2014, correspondence, Ex. 29, and the HED July 7, 2014, science review, Ex. 28, which had accepted the Guideline No. 860.1380 information but rejected the Guideline No. 860.1900 justification, Ex. 31. In this response, AMVAC noted that the HED science review also referenced an October 23, 2013 HED science review, titled "DCPA: HED Response to Comments on the Residue Chemistry Requirements of the Generic Data Call-In (GDCI-0798701-1140)," which EPA had not provided to AMVAC.

210. In its September 24, 2014, response to the October 2013 and July 2014, HED science reviews, Ex. 31, AMVAC provided justifications to (1) fulfill the Guideline No. 860.1900 requirement, and (2) justify data requirements waivers for Guidelines No. 860.1300, 860.1340, and 860.1480.

211. On February 17, 2015, HED addressed AMVAC's residue chemistry justifications for the 860.1900 data requirement. EPA, DCPA (Dacthal): HED Response to Comments on the Residue Chemistry Requirement 860. 1900 (Field Accumulation in Rotational Crops) of the Generic Data Call In (GDCl-0798701-1140). Ex. 32.

212. AMVAC did not receive the February 17, 2015, HED document, Ex. 32, until March 27, 2017, see Ex. 36, as discussed in Paragraph 216.

213. HED concluded that specific crop rotational crop restrictions are appropriate and that rotation to a crop with an established tolerance for residues of DCPA could be permitted with a minimum PBI of 8 months; rotation to any other crop could not be permitted, according to HED. HED concluded that all labels for DCPA use on agricultural crops should be modified to reflect the specific identified rotational crop restrictions. Further, HED stated if the described label modifications were made, additional field rotational crop data would not be needed, and the 860.1900 data requirement would be considered fulfilled. Ex. 32.

214. On March 17, 2017, AMVAC and EPA met on a teleconference to discuss the DCI status.

215. After the March 17, 2017, call, EPA provided two summaries and sets of actions items for this meeting: (1) (DCPA (078701) Registration Review Registrant Check-In Meeting). *See* Ex. 33, provided as an attachment to Ex. 34 (March 17, 2017); and Follow-up from DCPA Registration Review Registrant Meeting; March 17, 2017, Ex. 34, provided as an attachment to Ex. 36 (March 27, 2017).

216. The March 27, 2017, email, Ex. 36, also provided three EPA response documents (dated March 21, 2014, Ex. 37, February 17, 2015, Ex. 38 and June 27, 2016, Ex. 39) that had not previously been sent to AMVAC.

217. The emails and accompanying documents referenced in Paragraph 216 indicate that EPA had outstanding action items at this time related to the Residue and Field Accumulations Studies discussed in this section.

218. On April 7, 2017, Jordan Page, Chemical Review Manager with PRD, followed up with AMVAC regarding the March 17 call. Page requested clarification concerning the timetable for submission of certain label amendments and usage data. Page also set out the conditions that EPA asserted would have to be met to support waiver requests for the Guideline 860.1300, 860.1340, and 860.1480 data requirements. Ex. 40.

219. On May 10, 2017, AMVAC submitted revised DCPA label language to address the required use terminations. AMVAC, Technical Chlorthal Dimethyl (EPA Reg. No. 5481-495); Label Amendment to Terminate Uses per FR notice (FRL-7726-5, 27 Jul 05), Ex. 41.

220. On May 19, 2017, AMVAC and EPA held a phone conference to discuss requested changes to the label amendments and exchanged related correspondence, Ex. 42.

221. On May 19, 2017, in response to the phone conference referenced in the prior paragraph, AMVAC provided a revised proposed label for DCPA Technical. Ex. 43 (email); Ex. 44 (updated label and redline).

222. On June 8, 2017, AMVAC submitted amended DCPA end use ("EUP") labels to address EPA comments. Ex. 45.

223. On May 23, 2019, AMVAC resubmitted the amended DCPA Technical label to address EPA comments. Ex. 46.

224. On October 16, 2020, PRD Director Elissa Reaves corresponded with AMVAC (the October 2020 Notification, Ex. 21) concerning the status of the DCI data requirements.

225. The October 16, 2020, Notification stated that the Guideline 860.1300, 860.1340, 860.1480, and 860.1900 data requirements, the "Study Status" was "In review" and that "label amendments [have been] submitted to satisfy [the requirements]." *Id.* at 5.

226. On February 1, 2021, EPA PRD wrote AMVAC and stated that EPA had questions regarding specific use parameters. Ex. 47.

227. On February 9, 2021, AMVAC provided information addressing EPA's questions regarding DCPA use patterns. *Id.*; Ex. 48, 49 (attachments to Feb. 9, 2021 email).

228. On March 8, 2021, EFED posed several follow-up questions regarding the DCPA use pattern information. EPA asked whether AMVAC would be willing (1) to commit to putting maximum annual use rates on the DCPA label

and (2) for use on ornamentals, to clarify the number of applications per year and the total amount of active ingredient applied per acre per year. Ex. 47.

229. On March 23, 2021, AMVAC responded that draft revised label amendments that had been submitted to RD in 2017 and 2019 should be sufficient to address the requested maximum use restrictions.

230. EPA acknowledged receipt of this information on March 24, 2021. *Id.*

231. On March 25, 2022, to confirm that all outstanding questions regarding the end use labels had been addressed, AMVAC provided PRD with a compilation of prior correspondence concerning AMVAC's EUP DCPA label amendments that demonstrate that AMVAC had amended the relevant end use labels to address all concerns previously identified by EPA. Ex. 50 (attachments omitted).

232. AMVAC has made revisions outlined by EPA during March and May, 2017, meetings to the DCPA labels to address questions and concerns raised by EPA. Therefore, with respect to guideline study data requirements 860.1300, 860.1340, 860.1480, and 860.1900, AMVAC has made submissions addressing these requirements. These submissions are still under review by EPA as recognized by the October 2020 Notification.

The Ecological Effects Studies

233. The NOITS refers to twelve data requirements under the "850" prefix testing guidelines for Ecological Effects data as being outstanding. Five of these relate to a metabolite of DCPA referred to as TPA. In the sections following this introduction, the DCPA data requirements are discussed first, followed by the TPA data requirements.

234. EPA has accepted AMVAC's contention that certain data for DCPA can be applied to TPA, and that risk assessment can proceed in the absence of TPA-specific data, even if this leads to conservative results for purposes of risk assessment, as discussed in more detail in the sections concerning each data requirement, below. EPA has nonetheless refused to grant waivers for the TPA ecological effects studies referenced in the NOITS.

235. AMVAC will run the TPA ecological effects studies for which EPA finally denied its waiver requests in April 2022, concurrently with the issuance of the NOITS, but AMVAC's original waiver requests and subsequent interactions with the Agency were appropriate.

236. The other seven ecological effects data requirements referenced in the NOITS relate to DCPA. AMVAC has submitted full studies to guideline requirements for four of these seven requirements. For one study EPA rejected AMVAC's request for waiver on the same day that it issued the NOITS.

237. Each of the relevant DERs in this category show initial reviews and signatures in 2016, but final signoffs only in December of 2021. AMVAC was not made aware of the DERs and the conclusions therein and EPA did not attempt to send the DERs until April 27, 2022, the same day AMVAC received the NOITS.

The DCPA Ecological Effects Studies

The Fish Early Life Stage Studies

238. In the DCI, EPA requested data for Guideline No. 850.1400 "Fish Early Life-Cycle Toxicity Test" for DCPA. The footnotes associated with this requirement indicated that the preferred test species are Rainbow Trout, bluegill, and sheepshead minnow. Ex. 4.

239. AMVAC indicated in the Initial Response that it would submit existing data for the Fish Life-Cycle Toxicity Tests for DCPA and request a waiver for the requirement to do the Fish Life-Cycle Toxicity Tests with TPA. Initial Response, Ex. 5. The Fish Life-Cycle Toxicity Tests with TPA are discussed separately in Paragraphs 282 to 304 below.

240. On January 30, 2014, AMVAC submitted existing study Chlorthal-dimethyl (DCPA): Prolonged Toxicity Test to Juveniles [Rainbow Trout] Under Semi-Static Conditions: Final Report. Project Number: 1708/034, 1708/034/D2149, identified by MRID No. 49307520.

241. On October 16, 2020, EPA sent a letter to AMVAC summarizing the outstanding data requirements from the DCI. Ex. 21. The letter included a chart entitled "Status of DCPA GDCI-078701-1140 with Current Due Dates (as of October 16, 2020)." For Guideline 850.1400, three separate data requirements are listed for DCPA – Fish Early Life-Cycle (Rainbow Trout), Fish Early Life-Cycle (bluegill sunfish), and Fish Early Life-Cycle (sheepshead minnow). EPA indicates that the status as "supplemental; additional data not required" for rainbow trout, and "outstanding" for the bluegill and sheepshead minnow. The chart references two EPA data evaluation records dated February 17, 2019, Ex. 51, and February 26, 2019, Ex. 52. The data evaluation records were provided with EPA's October 16, 2020, letter.

242. The first DER referenced shows that EPA did not complete its review of the Rainbow Trout study (MRID No. 49307520) submitted by AMVAC on January 30, 2014, until February 17, 2019 (5 years after it was submitted). Ex. 51.

243. The second document referenced in the chart is a memo dated February 26, 2019, from EPA's Environmental Fate and Effect Division to the Pesticide Re-Evaluation Division transmitting the February 17, 2019 data review. Ex. 52.

244. AMVAC has no record of ever receiving the memo or the DER reviewing the 2014 Rainbow Trout study prior to receiving EPA's October 16,

2020 letter. The Rainbow Trout DCPA 850.1400 Guideline study was not listed as being outstanding in the NOITS.

245. Shortly after receiving EPA's data review in October, 2020, AMVAC took steps to conduct the Fish Life-Cycle Toxicity data for bluegill and sheepshead minnow with DCPA.

246. AMVAC informed EPA of its plan to initiate the studies in a December 17, 2020, letter to EPA. Ex. 22.

247. Both of these studies began on March 21, 2021. The in-life phase of both studies has been completed and final reports are projected to be available on June 15, 2022 (bluegill study) and July 15, 2022 (sheepshead minnow).

248. It took EPA 5 years to review the existing data initially submitted in response to the DCI and another 20 months to provide a copy of the review to AMVAC.

249. AMVAC has taken appropriate steps regarding these data requirements under the circumstances; EPA's failure to timely review data and transmit data reviews it had already generated does not provide a basis for suspension.

The Acute Avian Oral Toxicity (Passerine) Study

250. AMVAC indicated in the Initial Response that it would submit new data to satisfy the Guideline No. 850.2100 Acute Avian Oral Toxicity (Passerine) data requirement. Initial Response, Ex. 5.

251. EPA, in a February 19, 2014, email from J. Bloom, PRD, to J. Porter, informed AMVAC that EFED had accepted from other registrants a particular protocol for a study that addresses this data requirement and asked if AMVAC would be willing to conduct the 850.2100 study using that protocol. Ex. 53.

252. AMVAC, in a March 6, 2014, email from J. Porter to J. Bloom, PRD, agreed to conduct the Guideline No. 850.2100 study using the protocol identified by EPA. Ex. 53.

253. On September 30, 2014, AMVAC submitted a study conducted using the protocol identified by EPA. *See* Letter, J. Porter, AMVAC, to S. Bartow, EPA, re Data Submission to Fulfill Guideline No. 850.2100, Acute Avian Oral Toxicity (Passerine) (September 30, 2014). Ex. 54.

254. On October 1, 2014, EPA acknowledged receipt of the Guideline No. 850.2100 Acute Avian Toxicity (Passerine) study, confirmed that it met submission requirements, and assigned the study MRID Number 49477601. Letter from OCSPP to AMVAC re September 30, 2014, submission complies with PR 2011-03 submission requirements. *Id.*

255. An EFED DER, with the last date of signature December 2, 2021, "Data Evaluation Record Acute Oral Toxicity of DCPA (Chlorthal Dimethyl) to Zebra Finch (Passerine), MRID Number 49477601," states that DCPA would be classified as practically non-toxic to zebra finch on an acute oral basis. EFED assessed MRID 49477601 as "scientifically sound" and classified it as "supplemental, may be used to calculate risk quotients." The review noted, "if application rates result in higher estimated exposure concentrations on dietary items than the concentration tested in this study, additional data may be required." Ex. 55.

256. EPA proposed an alternative feeding-based study, however, the Agency's own guideline prohibits testing at levels above those that already have been tested in the oral study.

257. Thus, unless and until notified that EECs are exceeding the concentrations already tested, AMVAC has satisfied the Guideline No. 850.2100 Acute Avian Toxicity (Passerine) data requirement with a scientifically sound study that met the guidance limit.

The Mysid Life-Cycle Chronic Toxicity Test

258. AMVAC has worked diligently to address the Guideline 850.1350 Chronic Toxicity Mysid – DCPA data requirement, for which it indicated in the Initial Response that it would develop new data. Ex. 5.

259. To address the Guideline No. 850.1350 Mysid Life-Cycle Chronic Toxicity Test, on January 30, 2014, AMVAC submitted "Dacthal: A flow-through life-cycle toxicity test with the saltwater mysid (*Americamysis bahia*)," MRID Number 49307512. Ex. 56 (DER for that study).

260. The DER, Ex. 56, (which, based on reviewer signatures, was "approved" on December 1, 2021, but which had been initially "reviewed" by a staff scientist on October 10, 2016) assessed the Mysid Life-Cycle study as "scientifically sound" and classified the study as "supplemental, may be used for risk characterization." *Id*.

261. EPA did not inform AMVAC that EPA had determined that the Mysid Life-Cycle Test, OCSPP 850.1350, MRID No. 49307512, did not satisfy the corresponding GDCI requirements and that EPA would require additional data until (by providing a copy of the December 2021 DER) *after* the NOITS was issued. Ex. 57. (April 27 email from J. Douglass to N. McMahon).

262. AMVAC is timely responding to EPA's communication regarding the DCPA Guideline OCSPP 850.1350 study.

263. AMVAC has contacted the responsible contract laboratory and awaits its input concerning EPA's DER evaluation.

The Terrestrial Vascular Plant Seedling Emergence Study

264. AMVAC has worked diligently to address the Guideline 850.4100 Terrestrial Vascular Plant Seedling Emergence – DCPA ecological effects data requirement, for which it indicated in the Initial Response that it would develop new data. Ex. 5.

265. To address the Guideline No. 850.4100 Terrestrial Vascular Plant Seedling Emergence data requirement, on January 30, 2014 (date noted as being uploaded in PDMS), AMVAC submitted the study "Dacthal: A Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Ten Species of Plants," MRID 49307513. Ex. 58 (DER for MRID 49307513).

266. The DER, Ex. 58, having a last signature December 10, 2021, concluded that, of the ten crops tested, the study was acceptable for all except lettuce. The lettuce portion of the study is classified as "supplemental and may be used for risk characterization only". Further, EFED concluded that if application rates result in higher estimated exposure concentrations than the concentration tested in this study, additional data may be required for lettuce (only). *Id.*

267. In a January 6, 2022 Memorandum from EFED to PRD, EFED concluded that the Terrestrial Vascular Plant Seedling Emergence study, MRID 49307513, is acceptable for all tested crops, except lettuce and ryegrass. The study was graded as supplemental for lettuce and ryegrass and may be used to (1)

calculate risk quotients for ryegrass and (2) for risk characterization for lettuce. The memorandum stated that only lettuce requires additional testing. Ex. 59 (an attachment to Ex. 57).

268. AMVAC has taken appropriate steps to determine if it should begin testing for lettuce since receiving the January 6, 2022 Memorandum, which was not received by AMVAC until April 27, 2022, after receipt of the NOITS. Ex. 57.

269. After receiving and reviewing the January 6, 2022, memorandum, AMVAC immediately contacted the responsible laboratory and requested that it review the Agency's assessment.

270. AMVAC believes there may be a discrepancy relevant to lettuce between the dose range finding study and the definitive study. AMVAC will confirm this with the laboratory. AMVAC will provide a response with supplemental information within 90 days of April 27, 2022.

The Chronic Sediment Toxicity Chironomus Special Study

271. AMVAC has worked diligently to address the SS-1069 (non-guideline) Chronic Sediment Toxicity – *Chironomus dilutus* ecological effects data requirement, for which it indicated in the Initial Response that it would develop new data. Ex. 5.

272. The designation "SS" means a "special study" for which there are no established EPA data requirements under 40 C.F.R. Part 158, no OSCPP Testing Guidelines, and no standardized protocols for use in conducting the study.

273. AMVAC's April 29, 2013, Initial Response included three proposed protocols to address chronic sediment toxicity testing of *Chironomus dilutus* (ss-1069), *Hyalella azteca* (ss-1066), and *Leptocheirus plumulosus* (ss-1072). Ex. 5.

274. On October 20, 2014, EPA provided AMVAC with the Agency's response to these protocols, "DCPA (Chlorthal-dimethyl): Review of Study Protocols for Determining Chronic Toxicity to Sediment-Dwelling Estuarine/Marine and Freshwater Organisms." Ex. 60 at 1.

275. EPA's protocols review was dated March 20, 2014, but was not provided to AMVAC until October 20, 2014. Ex. 60 at 1, Attachment I.

276. On December 15, 2014, AMVAC submitted detailed responses to EPA's protocols review and submitted updated full protocols for Agency review that addressed the Agency's comments. *Id.*[4]

277. On March 19, 2015, EPA confirmed approval of the revised protocols, including for the SS-1069 data requirement. Ex. 61.

[4] This is incorrectly characterized in the NOITS as a notification by AMVAC that the final protocol report for SS-1069 would be submitted by June 15, 2016. AMVAC submitted the protocol on December 15, 2014, and in that protocol proposed the final study date would be June 15, 2016, provided the EPA approved the protocol in a timely manner.

278. AMVAC submitted "Sediment Chronic Toxicity Testing – ss-1069, Life Cycle Chronic Toxicity Test, *Chironomus dilutus*, MRID No. 49865802" on March 15, 2016, ahead of the initially expected final study date of June 15, 2016. Ex. 62.

279. An EFED DER, last signed December 1, 2021, "Data Evaluation Record, Life-Cycle Sediment *Chironomus dilutus* Toxicity Test, MRID No. 49865802," assessed MRID 49865802 as "scientifically sound" and classified it as "supplemental" because of potential solvent control issues. Ex. 63.

280. In a letter dated April 27, 2022, EPA transmitted the EFED DER referenced above to AMVAC (after issuing the NOITS). Ex. 57. (April 27 email from J. Douglass to N. McMahon); Ex. 64 (attachment to Ex. 57).

281. AMVAC is reviewing the DER and is working with the performing lab to investigate the solvent control issue and compile additional information/data regarding the conduct of the study.

The TPA Ecological Effects Studies

The Fish Early Life Stage Studies

282. As discussed above, AMVAC advised EPA in the Initial Response that it would submit existing data to satisfy the Fish Early Life Stage studies for the TGAI, DCPA.

283. With regard to the metabolite, TPA, AMVAC proposed to the DCI to defer performance of the Fish Early Life Stage Studies until EPA's review of the DCPA study was complete, after which EPA could determine if endpoints experimentally determined for DCPA may be utilized to waive the required TPA studies. Initial Response, Ex. 5, at 10.

284. AMVAC's proposal to sequence the testing in this manner was made after a specific invitation from EPA (made in EPA's May 31, 2011, document titled, "Registration Review – Preliminary Problem Formulation for the Ecological risk Assessment of Dimethyl 2,3,5,6-Tetrachlorophthalate (DCPA)") (the "DCPA Preliminary Problem Formulation") (Ex. 65) to consider such a strategy.

285. The DCPA Preliminary Problem Formulation specifically stated that "a more limited testing strategy [for the metabolite TPA] will be considered *in lieu* of a comprehensive data submission if one is proposed." DCPA Preliminary Problem Formulation. *Id.* at 2.

286. EPA also stated in the DCPA Preliminary Problem Formulation that it could complete a risk assessment for DCPA even without the TPA-specific data, though it would have to "make highly conservative assumptions when evaluating the toxicity of TPA." *Id.* at 25.

287. In view of EPA's statements in the DCPA Preliminary Problem Formulation, AMVAC's request to defer the TPA fish early life-stage toxicity tests pending completion of the DCPA analysis was reasonable and an appropriate step.

288. EPA first responded to AMVAC's request to defer the TPA fish early life-stage toxicity tests pending completion of the DCPA analysis in a memorandum dated March 21, 2014 (EPA, Response to registrant's data waiver requests for environmental fate and ecological effects related date for the parent DCPA and degradate TPA) (the "March 2014 Waiver Response") (Ex. 66).

289. The March 2014 Waiver Response was not provided to AMVAC by EPA until March 27, 2017, three years after it was dated.[5] Ex. 36 (to which Ex. 66 was attached). So as to provide the proper context for AMVAC's subsequent actions in response, the March 2014 Waiver Response, Ex. 66, will be referred to as the March 2017 Waiver Response.

290. The March 2017 Waiver Response denied AMVAC's request to completely defer the TPA fish early life-stage toxicity tests until the DCPA studies were completed, contrary to direction given in the preliminary work plan. Instead of simply insisting that AMVAC proceed with the Guideline 850.1400 studies for the three species that EPA now lists in the NOITS (rainbow trout, bluegill sunfish,

[5] AMVAC does not have an explanation for EPA's delay in providing these materials, although the provision of the 2014 documents in 2017 coincided with a change in Chemical Review Managers at EPA.

and sheepshead minnow), EFED raised an alternative ("one possible solution is conducting a limited set of toxicity tests … for TPA (for example, an acute and chronic toxicity study in daphnids); and depending on the results of these initial studies, a full suite … may or may not be subsequently required.") *Id.* at 7.

291. The proposed condition on using DCPA study data for TPA referenced in Paragraph 290 had not previously been proposed by EPA.

292. On February 22, 2018, AMVAC provided a response to the March 2017 Waiver Response (the "February 2018 Waiver Correspondence") (Ex. 67). AMVAC stated that it "agrees with the Agency's proposal for conducting acute and chronic TPA studies in daphnids and reviewing those results with the Agency in order to determine whether additional aquatic organism testing is warranted."

293. AMVAC proceeded to collect and or conduct acute and chronic *Daphnia Magna* TPA toxicity test data that would permit a comparison with DCPA data as it understood the Agency to have proposed.

294. In August of 2020, when attempting to upload two studies (including a *Daphnia Magna* chronic toxicity study under Guideline 850.1300 (Goudie, 2019, MRID 51235101)) to CDX, AMVAC personnel encountered a technical issue with the upload. CDX support advised AMVAC that the Correspondence dated February 22, 2018, that it had uploaded to CDX on February 23, 2018, had not been "properly pulled down into EPA's system." *See* email from Jon Wood to

James Douglass and Carol Baumgartner (Aug. 11, 2020) (Ex. 68). Although AMVAC is not privy to the specific workings of CDX, this implies that EPA staff did not review AMVAC's February 2018 correspondence until some point after August of 2020.

295. Shortly after uploading the Goudie 2019 Study (MRID 51235101), AMVAC submitted, on December 13, 2020, a document entitled Tetrachlorophthalic Acid (TPA): Selected Ecological Study Waiver Request ("The December 2020 Waiver Analysis") (Ex. 22).

296. The December 2020 Waiver Analysis provided a table showing DCPA and TPA endpoints derived from various studies and explained, in detail, why AMVAC concluded that TPA demonstrated a lower toxicity than DCPA and therefore the data generated as of that time should be sufficient for EPA's risk assessment purposes and EPA should not require any further Guideline 850.1400 studies of TPA. This was precisely the approach that EPA had laid out in the DCPA Preliminary Problem Formulation (in 2011) and again in the March 2017 Waiver Response.

297. AMVAC did not receive any response from EPA concerning AMVAC's December 2020 Waiver Analysis until it received EPA's "Response to Data Waiver Requests for Ecological Effects Related Data for Dimethyl 2,3,5,6-Tetrachloroterephthalate (DCPA) and Its Degradate Tetrachlorophthalic Acid

(TPA)," (Ex. 69, dated April 19, 2022) which was not sent to AMVAC by EPA until April 27, 2022. Ex. 57.

298. Because the 2022 EPA Ecological Effects Waiver Response, Ex. 69, was not received by AMVAC until the same day AMVAC received the NOITS, AMVAC therefore did not have any opportunity to discuss EPA's conclusions in the 2022 EPA Ecological Effects Waiver Response with EPA personnel prior to the issuance of the NOITS.

299. The 2022 EPA Ecological Effects Waiver Response, Ex. 69, granted AMVAC's requests for waivers in connection with six Guideline requirements, demonstrating that EPA was still actively reviewing and approving waiver requests.

300. The 2022 EPA Ecological Effects Waiver Response, Ex. 69, denied AMVAC's request for a waiver based on the TPA/DCPA endpoint comparison approach EPA had previously suggested. EPA stated that EFED had "reconfirmed the need for chronic freshwater and estuarine/marine fish toxicity studies for TPA" based on a review of three MRIDs (49307520, 48670304, and 48670303). *Id.*

301. MRID 49307520 was submitted to EPA by AMVAC on January 20, 2014. MRIDs 48670303 and 48670304 were submitted to the Agency on March 27, 2012.

302. EPA did not advise AMVAC until 2022, the same day as the NOITS was transmitted, that the path EPA had set AMVAC upon for the Guideline 850.1400 TPA data from the outset would not satisfy EPA in view of DCPA studies that EPA had been in possession of since 2012 and 2014.

303. The 2022 EPA Ecological Effects Waiver Response states that EPA will be able to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects in the absence of the Guideline 850.1400 TPA data so long as the Guideline 850.1400 DCPA data is available, *id.* at 11, which is expected to be complete soon.

304. Based on the 2022 EPA Ecological Effects Waiver Response, received the same day as the NOITS, and despite the fact that EPA has indicated that additional data is not needed to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects standard, AMVAC is proceeding to run the sheepshead minnow Guideline 850.1400 TPA study per EPA's instructions because the DCPA results have indicated that species to be the most sensitive. AMVAC expects these results will be available in 2023.

The Tier I/II Algal Toxicity Test and Mysid Chronic Toxicity Study

305. AMVAC advised EPA in the April 29, 2013, Initial Response that it would develop new data to satisfy the Algal Toxicity Test, Tier I/II data requirement under OSCPP Guideline 850.5400 and the Mysid Chronic Toxicity

data requirement under OSCPP Guideline 850.1350 for the TGAI, DCPA, but it requested a waiver for corresponding data requirements for DCPA's primary metabolite, TPA. Initial Response, Ex. 5.

306. AMVAC specifically proposed to defer these two TPA studies and perform the assessments for TPA using the endpoints determined in the corresponding DCPA studies. *Id.* at 11.

307. AMVAC's proposal to sequence the testing in this manner was made in view of a specific invitation from EPA (made in the DCPA Preliminary Problem Formulation, *supra* Paragraph 285, Ex. 65) to propose such a strategy.

308. The DCPA Preliminary Problem Formulation specifically stated that "a more limited testing strategy [for the metabolite TPA] will be considered *in lieu* of a comprehensive data submission if one is proposed." DCPA Preliminary Problem Formulation, Ex. 65, at 2.

309. EPA also stated in the DCPA Preliminary Problem Formulation that it could complete a risk assessment for DCPA even without the TPA-specific data, though it would have to "make highly conservative assumptions when evaluating the toxicity of TPA." *Id.* at 25.

310. In view of EPA's statements in the DCPA Preliminary Problem Formulation, AMVAC's request to defer the TPA Tier I/II Algal Toxicity test and

the Mysid Chronic Toxicity test pending completion of the DCPA analysis was reasonable and appropriate.

311. EPA first responded to AMVAC's request to defer the TPA Tier I/II Algal Toxicity test and the Mysid Chronic Toxicity test pending completion of the DCPA analysis in the March 2017 Waiver Response, Ex. 66, which AMVAC received on March 27, 2017, *supra* Paragraph 216.

312. The March 2017 Waiver Response denied AMVAC's request to completely defer the TPA Tier I/II Algal Toxicity test and the Mysid Chronic Toxicity until the DCPA study was completed. However, instead of simply insisting that AMVAC proceed with these studies, EFED raised an alternative ("one possible solution is conducting a limited set of toxicity tests … for TPA (for example, an acute and chronic toxicity study in daphnids); and depending on the results of these initial studies, a full suite … may or may not be subsequently required.") *Id.* at 7.

313. On February 22, 2018, AMVAC provided the February 2018 Waiver Correspondence, Ex. 67, in which AMVAC stated that it "agrees with the Agency's proposal for conducting acute and chronic TPA studies in daphnids and reviewing those results with the Agency in order to determine whether additional aquatic organism testing is warranted."

314. AMVAC proceeded to collect and or conduct acute and chronic *Daphnia Magna* TPA toxicity test data that would permit a comparison with DCPA data as it understood the Agency to have proposed.

315. In August of 2020, when attempting to upload two studies (including a *Daphnia Magna* chronic toxicity study under Guideline 850.1300 (Goudie, 2019, MRID 51235101)) to CDX, AMVAC personnel encountered a technical issue with the upload. CDX support advised AMVAC that the Correspondence dated February 22, 2018, that it had uploaded to CDX on February 23, 2018, had not been "properly pulled down into EPA's system." *See* email from Jon Wood to James Douglass and Carol Baumgartner (Aug. 11, 2020) (Ex. 68). Although AMVAC is not privy to the specific workings of CDX, this implies that EPA staff did not review AMVAC's February, 2018, correspondence until some point after August of 2020.

316. Shortly after uploading the Goudie 2019 Study (MRID 51235101), AMVAC submitted, on December 13, 2020, the December 2020 Waiver Analysis, Ex. 22.

317. The December 2020 Waiver Analysis provided a table showing DCPA and TPA endpoints derived from various studies and explained, in detail, why AMVAC concluded that TPA demonstrated a lower toxicity than DCPA and therefore the data generated as of that time should be sufficient for EPA's risk

assessment purposes and EPA should therefore not require a Guideline 850.5400 (now known as 850.4500) Tier I/II Algal Toxicity study, or a Mysid Chronic Toxicity study (Guideline 850.1350) for TPA. *Id.*

318. AMVAC did not receive any response from EPA concerning the December 2020 Waiver Analysis until it received the 2022 EPA Ecological Effects Waiver Response, Ex. 69.

319. The 2022 EPA Ecological Effects Waiver Response was received by AMVAC the same day as the NOITS, and AMVAC therefore did not have any opportunity to discuss EPA's conclusions in the 2022 EPA Waiver Response with EPA personnel prior to the issuance of the NOITS.

320. The 2022 EPA Waiver Response granted AMVAC's requests for waivers in connection with six Guideline requirements, demonstrating that EPA was still actively reviewing and approving waiver requests.

321. The 2022 EPA Waiver Response partially denied (with regard to tests on marine diatoms) and partially granted (with respect to all other species) AMVAC's request for a waiver of Tier I/II Algal Toxicity and Mysid Chronic Toxicity data requirements based on the TPA/DCPA endpoint comparison approach EPA had previously suggested.

322. With regard to the Tier I/II Algal Toxicity and Mysid Chronic Toxicity data requirement, EPA stated in the 2022 EPA Waiver Response that,

because "[t]he marine diatom was the most sensitive species tested for DCPA," using the "endpoint from MRID 49307504 for both DCPA and TPA … may overestimate the toxicity of TPA to aquatic plants and yield uncertain risk conclusions[.]" Ex. 69 at 13.

323. With regard to the Mysid Chronic Toxicity data requirement, EPA stated in the 2022 EPA Waiver Response that, "in the absence of TPA chronic mysid toxicity data, the Agency will rely on the submitted data for DCPA" which may "overestimate the toxicity of TPA and therefore, the potential risks." *Id.* at 8.

324. EPA thus does not state in the 2022 EPA Waiver Response that its ability to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects standard will be compromised as a result of lacking the Guideline 850.4500 TPA marine diatom data or the Guideline 850.1350 Mysid Chronic Toxicity, only that it will have to use a conservative endpoint that might overestimate toxicity (*i.e.*, yield a conservative risk analysis).

325. Based on the 2022 EPA Waiver Response, received at the same time as the NOITS, and despite the fact that EPA has indicated that additional data is not needed to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects standard, AMVAC is proceeding to run the 850.4500 marine diatom TPA study (as the DCPA results have indicated that species to be the most sensitive). AMVAC expects these results will be available in 2023.

326. Based on the 2022 EPA Waiver Response, received at the same time as the NOITS, and despite the fact that EPA has indicated that additional data is not needed to evaluate AMVAC's registration against the FIFRA-based unreasonable adverse effects standard, AMVAC is proceeding to run the Guideline 850.1350 Mysid Chronic Toxicity TPA study. AMVAC expects these results will be available in 2023.

The Leptocheirus Chronic Sediment Toxicity Study

327. AMVAC advised EPA in the April 29, 2013, Initial Response that it would develop new data to satisfy the *Leptocheirus* Chronic Sediment Toxicity Study data requirements, referred to also as SS-1072. Initial Response, Ex. 5, at 2.

328. AMVAC submitted a proposed study protocol for the *Leptocheirus* Chronic Sediment Toxicity Study with the Initial Response. Initial Response, Ex. 5.

329. In a document dated March 20, 2014 (EPA, DCPA (Chlorthal-dimethyl): Review of Study Protocols for Determining Chronic Toxicity to Sediment-Dwelling Estuarine/Marine and Freshwater Organisms; DP Barcode: 413319, 413320, and 413321) (the "March 2014 EPA Chronic Tox Protocol Response") (Ex. 70) EFED recommended "additional detail [be] added to the protocols to help ensure study acceptability," but noted that it anticipated that the protocols would be adequate once updated. *Id.* at 1-2.

330. On December 15, 2014, AMVAC provided EPA with an update concerning the three chronic sediment studies. Ex. 60. AMVAC informed EPA that the lab that was to conduct the *Leptocheirus* study required additional time to address EPA's comments on the protocol and otherwise ensure that the protocol was robust. Notably, the lab stated that it had been working since late 2013 to "develop formulated sediment that is suitable for use in this testing" because the "locally collected natural sediment used historically" had not been producing useable test results. EPA was made aware of this issue as early as 2013. *Id.*, Attachment V.

331. The lab further explained that the test sediment suitability issue had resulted in a backlog of *Leptocheirus* studies, but it anticipated being able to begin clearing the backlog in early 2015. *Id.* AMVAC indicated that it would update the Agency by March 31, 2015, concerning the progress at the lab. *Id.* at 1.

332. On March 30, 2015, AMVAC provided an initial update from the lab. Email from Julie Porter, AMVAC, to Dr. Marquea King, EPA (March 30, 2015) (Ex. 61) (email) (Ex. 71) (attached update). The lab had explained that its work to finalize the protocols had recently been presented at the North Atlantic Regional Chapter of the National Society for Environmental Toxicology and Chemistry (NACSETAC) in Vancouver and that an "ad hoc advisory group include[ing] both industry and government scientists" had held a meeting regarding the *Leptocheirus*

test method. The lab advised that pilot testing was ongoing, but that it anticipated being able to begin clearing the backlog in Q3 of 2015. Ex. 71. AMVAC requested permission to provide another status update in 6 months.

333. AMVAC received no response to the initial update described in the preceding paragraph.

334. AMVAC provided the next promised 6 month update on September 22, 2015. Ex. 61; Ex. 72 (attached update). The lab explained that it believed it had addressed the issues with the protocol and that it had independently communicated this information to EPA. According to the lab's update, "EPA ha[d] reviewed the revised protocol and approved of the changes made to the test method." Ex. 72. The lab advised that it anticipated being able to begin clearing the backlog in Q4 2015 using the updated protocol. *Id.* AMVAC requested permission to provide another status update in 6 months. Ex. 61 (email).

335. On March 15, 2016, AMVAC submitted correspondence that included a request to waive the *Leptocheirus* chronic sediment study. Ex. 62. In support of the request, AMVAC provided a Waiver Request dated March 7, 2016 (noted as received in PDMS March 18, 2016) (AMVAC, Proposed Waiver for Dacthal (DCPA) Chronic Study Testing on *Leptocheirus plumulosus*, MRID 49865803) (Ex. 73). In the waiver request, AMVAC explained that, in light of testing then completed on other aquatic invertebrates, further testing of *Leptocheirus* should not

be needed because, inter alia: DCPA concentrations were unlikely to reach levels demonstrated to affect aquatic invertebrates and sediment dwelling amphipods (like *Leptocheirus*) had demonstrated less sensitivity to DCPA than other aquatic invertebrates.

336. EPA responded to the waiver request in a document dated June 27, 2016 (EPA, DCPA: Response to Waiver Request for the Chronic Sediment Toxicity Study with *Leptocheirus plumulosus*, DP Barcode 432677) (Ex. 74). This document was not provided to AMVAC until the following month. Email from Chris Davis, [EPA], to Julie Porter, AMVAC (July 18, 2016) (Ex. 75, attaching Ex. 74).

337. In the response, EPA acknowledged several of the points raised by AMVAC concerning the relative toxicity of DCPA to sediment dwelling amphipods but disputed that environmental concentrations of DCPA would not be expected to reach levels that might affect *Leptocheirus*. *Id.* Recognizing the issues with the protocol that had been previously raised by the lab, and the resulting delays at testing labs, EPA offered that AMVAC could conduct an OCSPP 850.1740 study, (10-day Whole Sediment Acute Toxicity Invertebrates) prior to the 28-day *Leptocheirus* study (SS-1072).

338. EPA was clear that the DCI requirement for the 28-day *Leptocheirus* study was not being waived but did state that "[a] waiver may be considered at a

later date pending the results of the 10-d study and any other supporting data." Ex. 74 at 3.

339. In November, 2016, AMVAC supplied a supplementary waiver request (AMVAC, Revised Waiver Proposal for Chronic Sediment Guideline No: ss-1072 (November 22, 2016)) (Ex. 76). The supplementary waiver request, which was assigned MRID 50116601 (included with Ex. 76), provided additional details supporting AMVAC's contention that the 28-day *Leptocheirus* study would not produce useful endpoints for risk assessment based on the sensitivity of the subject species (inter alia, because available results for water-column species are expected to be protective of sediment dwelling amphipods) and also explained why EPA's proposed 10-day OCSPP 850.1740 study would not be useful for risk assessment.

340. On March 17, 2017, Dr. Marquea King with EPA emailed Jon Wood with AMVAC, and others, a document containing "Action Items" based on a phone conversation held between AMVAC and EPA that morning. Ex. 34 (email); Ex. 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; the only related action item was EPA's, which was to "confirm with EFED whether a clean/negative 10-day study negates the need for the 21-day study." Ex. 33 (attachment).

341. On March 27, 2017, Dr. Marquea King with EPA emailed Jon Wood with AMVAC, and others, concerning various follow up information to the March 17, 2017, phone conference. Ex. 36 (email); Ex. 35 (one of its attachments). The only additional information concerning the *Leptocheirus* data requirement was that EPA's "Response to Amvac [was still] pending." Ex. 35 (attachment).

342. AMVAC's February 2018 Waiver Correspondence, Ex. 67 (February 22, 2018), indicated that AMVAC had still not received a response in connection with EPA's "Action Item" from the March 17, 2017, phone meeting to confirm with EFED whether "a clean/negative 10-day study negates the need for the 21-day study" (in the words of the March, 2017, Action Item, Ex. 33).

343. On October 16, 2020, EPA transmitted correspondence to AMVAC concerning the data requirements from the DCI (Letter from Elissa Reaves, EPA, to Jon Wood, AMVAC, Subject: Notification of Outstanding Data Requirements, and Anticipated Registration Review) (Ex. 21) (the "October 2020 Notification"). Citing to EPA's June 27, 2016, document, Ex. 74, EPA advised that, with regard to the *Leptocheirus* data requirement, the "[w]aiver request [was] denied; outstanding; Guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates) may proceed in the interim and results may allow EPA to reconsider waiver request for SS-1072."

344. AMVAC believes that EPA did not, prior to this communication, fulfil its "Action Item" from the March 17, 2017 phone meeting, *supra* Paragraph 214, to determine if a negative result from the Guideline 850.1740 acute study would obviate the need for the *Leptocheirus* chronic study.

345. On December 17, 2020, AMVAC responded to EPA's October 16, 2020 correspondence. AMVAC advised that it would "await a specific DCI requirement for [the *Leptocheirus*] acute study or will wait for confirmation that the chronic study guideline has been validated." AMVAC futher stated its belief that, "[c]onsidering the very low toxicity associated with DCPA to aquatic organisms, AMVAC believes that this delay will not impact the Agency's conclusions concerning sediment dwelling organisms that can be made based on the available studies." AMVAC, Response to EPA Memorandum dated October 16, 2020 (December 17, 2020) (Ex. 22).

346. AMVAC did not receive any response from EPA until it received EPA's 2022 EPA Ecological Effects Waiver Response, Ex. 69 (dated April 19, 2022), which was not sent to AMVAC by EPA until April 27, 2022. Ex. 57.

347. The 2022 EPA Ecological Effects Waiver Response was received by AMVAC the same day as the NOITS, and AMVAC therefore did not have any opportunity to discuss EPA's conclusions in the 2022 EPA Waiver Response with EPA personnel prior to the issuance of the NOITS.

348. In the 2022 EPA Ecological Effects Waiver Response, EPA did not accept the waiver request for the *Leptocheirus* acute study and recommended that "the registrant submit a protocol for such a study to the Agency prior to study initiation." Ex. 69 at 18-19. EPA also advised AMVAC that "several studies conducted pursuant to EPA Test Method 600/R-01/020 were found to be acceptable and were used in other risk assessments."

349. AMVAC intends to proceed with the Guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates) and, as requested will provide a protocol for EPA review. AMVAC anticipates that results from this study will be available in 2023 subject to a timely protocol review by EPA and swift initiation of that study. AMVAC understands the EPA will "reconsider [its] waiver request for SS-1072" in view of these results, as stated in EPA's October 16, 2020, correspondence (Ex. 21), given that EPA did not specifically state that it would not so reconsider in the 2022 EPA Ecological Effects Waiver Response (Ex. 69).

The Environmental Fate Studies

350. The NOITS refers to three TPA data requirements under the "835" prefix testing guidelines for Environmental Fate as being outstanding.

351. For these data requirements, AMVAC requested waivers in its initial response to the DCI. EPA generally accepted the premise that the risk assessment

can proceed with conservative assumptions even absent these studies but has nonetheless denied the waiver requests.

352. It is unreasonable that EPA made its final position regarding many of the DCI data requirements clear to AMVAC only in documentation that was first provided to AMVAC simultaneously with the NOITS.

353. AMVAC is taking appropriate steps to satisfy these data requirements in view of the final waiver denial received concurrently with the NOITS.

The TPA Aerobic Aquatic Metabolism Study

354. For TPA, AMVAC proposed to defer performance of the Aerobic Aquatic Metabolism Study until EPA's review of the DCPA study was complete, after which AMVAC would be able to use the endpoint determined for DCPA Initial Response, Ex. 5, at 7.

355. EPA first responded to AMVAC's request to defer the Guideline 835.4300 data requirement in the March 2017 Waiver Response, Ex. 66, which AMVAC received on March 17, 2017.

356. EFED observed in the March 2017 Waiver Response that TPA was a residue of concern with a 100% conversion rate from DCPA and EFED recommended PRD deny the deferral request on that basis. *Id.* at 5.

357. In response, AMVAC informed EPA that it intended to submit a study providing appropriate fate data for DCPA and TPA. February 2018 Waiver Correspondence, Ex. 67 (Feb. 22, 2018).

358. It is unreasonable that EPA made its final position regarding many of the DCI data requirements clear to AMVAC only in documentation that was first provided to AMVAC simultaneously with the NOITS.

359. AMVAC is taking appropriate steps to satisfy these data requirements in view of the final waiver denial received concurrently with the NOITS.

The TPA Anaerobic Metabolism Studies

360. AMVAC advised EPA in the April 29, 2013, Initial Response that it would cite existing data, specifically, "Anaerobic Soil Metabolism of Dacthal," Duane, W. C. (MRID 114651), to satisfy the Guideline 835.4200 Anaerobic Soil Metabolism data requirement. Initial Response, Ex. 5, at 7.

361. Also in the Initial Response, AMVAC advised EPA that, just as EPA had concluded that the Guideline 835.4400 data requirement was satisfied for DCPA, AMVAC similarly concluded that the Guideline 835.4400 data requirement should be deemed satisfied for TPA. *Id.*

362. EPA first responded to AMVAC's contention that the Guideline 835.4400 data requirement should be deemed satisfied in the March 2017 Waiver Response, Ex. 66, which AMVAC received on March 17, 2017.

363. The March 2017 Waiver Response denied AMVAC's request to waive the Guideline 835.4400 data requirement, stating that "understanding the dissipation of TPA is a critical risk assessment question." *Id.* at 6.

364. EPA addressed AMVAC's request to waive the Guideline 835.4200 data requirement in a separate document dated February 7, 2017. This document (EPA, Transmittal of [DERs and] Response to Registrant's Data Waiver Requests for Environmental Fate Studies for TPA, DP Barcodes 413733, 413736, 420875, 420877, 420903) (the "February 2017 E-Fate Response") (Ex. 77) stated that EFED "believe[d] that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment," but stated that EFED "will [conservatively] assume stability [for risk assessment purposes] in the absence of a [TPA Guideline 835.4200] study." *Id.* at 3.

365. In the February 2018 Waiver Correspondence, Ex. 67, AMVAC requested that EPA "Agency review the combined data set for the aerobic soil metabolism study, the anaerobic soil metabolism study, and the pending submission on the aerobic aquatic metabolism study" to substantiate AMVAC's contention that TPA would not be degraded under anaerobic conditions in any way that would be observed in a Guideline 835.4400 study. AMVAC requested that EPA reconsider its requirement for a Guideline 835.4400 study after reviewing these materials in light of AMVAC's further comments.

366. In December, 2020, having received no formal response from EPA to the February 2018 Waiver Correspondence providing further information concerning why Guidelines 835.4200 and 835.4400 should be waived for TPA, AMVAC provided additional information in support of its waiver requests. *See* Tetrachlorophthalic Acid (TPA) Anaerobic Terrestrial and Aquatic Metabolism Waiver Request, MRID 51398102 (the "December 2020 E-Fate Waiver Analysis") (Ex. 78).

367. AMVAC did not receive any response from EPA concerning the December 2020 E-Fate Waiver Analysis until it received the 2022 EPA E-Fate Waiver Response, Ex. 79 (dated April 19, 2022).

368. The 2022 E-Fate EPA Waiver Response was received by AMVAC the same day as the NOITS, and AMVAC therefore did not have any opportunity to discuss EPA's conclusions in the 2022 EPA Waiver Response with EPA personnel prior to the issuance of the NOITS.

369. The 2022 EPA Waiver Response granted AMVAC's requests for waivers in connection with the Terrestrial Field Dissipation requirements for DCPA and TPA, demonstrating that EPA was still actively reviewing and responding to waiver requests.

370. The 2022 EPA Waiver Response denied AMVAC's request for a waiver of the Guideline 835.4200 and 835.4400 anaerobic soil and aquatic metabolism data requirements.

371. With regard to the Guideline 835.4200 anaerobic soil metabolism data requirement, EPA conceded that "a longer-than-standard study duration might be needed to quantify the potential anaerobic metabolism of TPA" in soil. 2022 EPA Waiver Response at 4. EPA further stated that "EFED will continue to assume stability of TPA in [soil]," even though doing so "may overestimate TPA's actual persistence[.]" 2022 EPA Waiver Response at 5. Thus, EPA can proceed with its risk assessment, but the results will be conservative, as EPA had stated in the February 2017 E-Fate Response, Ex. 77.

372. For the Guideline 835.4400 anaerobic aquatic metabolism data requirement, EPA conceded that "a longer-than-standard study duration may be needed to quantify the potential anaerobic metabolism of TPA" in water. 2022 EPA E-Fate Waiver Response, Ex. 79 at 6. EPA stated that even in the absence of Guideline 835.4400 anaerobic aquatic metabolism data, it could conservatively assume that TPA is stable for purposes of drinking water and ecological aquatic risk assessment purposes – a "conservative assumption may overestimate TPA's actual persistence[.]" *Id.*

373. EPA's refusal to waive the data requirements given that it is able to proceed with risk analysis (despite having to employ conservative assumptions) is arbitrary. EPA has essentially accepted the initial premise of AMVAC's initial waiver requests, which was that the required studies would not demonstrate degradation of TPA in the respective media over the time horizon of the studies. EPA acknowledged that "longer-than-standard" studies might be needed only immediately prior to the NOITS.

374. AMVAC took appropriate steps prior to the issuance of the NOITS to fulfill this data requirement.

CONCLUSION

375. For the reasons set forth above, AMVAC has taken appropriate steps to respond to EPA's DCI.

376. AMVAC continues to take appropriate steps in response to ongoing communications with EPA concerning several data requirements, including several for which substantive communications were not received by AMVAC until after EPA provided AMVAC with a copy of the NOITS.

377. For the reasons set forth above, the Administrator's determination with regard to existing stocks of DCPA is not consistent with FIFRA.

378. AMVAC requests that the Administrative Law Judge find that the Administrator did not have a basis for issuing the NOITS (*i.e.*, AMVAC has not

failed to take appropriate steps to secure the data required by the DCI), and that the existing stocks determination is not consistent with FIFRA.

Date: May 27, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 27, 2022, true and correct copies of the foregoing Request for Hearing and Statement of Objections, and all associated Exhibits, were filed electronically with the EPA Administrative Law Judges' E-Docket Database and additionally transmitted via email to the following parties:

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