UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In re FIFRA Section 3(c)(2)(B) Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration	)	
AMVAC Chemical Corporation; Grower-Shipper Association of Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms, **Petitioners.**	)	**Docket No. FIFRA-HQ-2022-0002**

VERIFIED WRITTEN STATEMENT OF AMVAC FACT WITNESS ANN JONYNAS

I, Ann Jonynas, declare and state as follows:

1. The following statements are true and correct to the best of my knowledge and belief and are based on my personal knowledge.

Background and Curriculum Vitae

2. I am the Director of Toxicology at AMVAC and have been in this position since 1991.

3. Prior to working at AMVAC, I held the position of Toxicology Project Manager at ICI Americas from 1989 to 1991, and the positions of Pharmacologist and Toxicology Project Manager at ICI Pharmaceuticals UK and the ICI Central Toxicity Laboratory UK, respectively from 1973 to 1989.

4. I have a Master's degree in Biology/Pharmacology from the University of Manchester, UK, and a Master's degree in Toxicology from the University of Birmingham, UK.

5. I am a diplomate of the Royal College of Pathologists with board certification in Toxicology.

6. As the Director of Toxicology at AMVAC I am responsible for all toxicological data development necessary to obtain and maintain the registration of AMVAC's global portfolio of pesticides. I work primarily on data development to support registration for pesticides with EPA, and analogous pesticide regulatory bodies in the EU, UK, Canada and Australia. I work continually with contract research laboratories to initiate, monitor and review studies in support of AMVAC's products. This work includes laboratory selection, development and review of study protocols, and review of draft and final reports. In my career, I estimate that I have been responsible for developing and reviewing approximately 5,000 protocols, study reports, and testing results. I am the main contact with the contract research laboratories involved in

conducting toxicology studies in support of AMVAC's pesticide products. My work also involves the use of animal toxicology data in human health assessments.

7. I have been directly involved in AMVAC's response to the Data-Call In ("DCI") that is the subject of the Notice of Intent to Suspend ("NOITS") AMVAC's Dimethyl Tetrachloroterephthalate ("DCPA") Technical Registration received by AMVAC on April 27, 2022 that is the subject of the proceeding.

8. Specifically, I was the study monitor and primary contact with the contract research laboratory conducting the testing to meet EPA's request for comparative thyroid assay ("CTA") data in the DCI.

The Comparative Thyroid Study

9. In the DCI, EPA requested data identified as the "comparative thyroid toxicity study." Joint Exhibit ("JX") 4. at Attachment 3, page 5 of 5. The NOITS refers to this data requirement as being outstanding. As noted above and more fully explained below, a number of study reports and data have been submitted to meet EPA's request, and the final study for completing this data requirement is being prepared for submission to EPA on June 20, 2022.

10. EPA has been kept informed, via regular quarterly updates and other correspondence as discussed in more detail below, concerning the schedule that the testing program and final study have been progressing on.

11. 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.

12. The "Guideline Requirement Number" for the "comparative thyroid toxicity

study" in the DCI was listed as "SS-thyroid tox." JX 4.

13. 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.

14. At the time the DCI was issued, the "comparative thyroid toxicity study" requirement was new and extremely rare.

15. The DCI did not provide any information on what testing should be done to satisfy the CTA data requirement. JX 4.

16. 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. JX 4.

17. Prior to initiating any study, analytical and other methods had to be developed and validated for use.

18. This initially included methods for the analysis of all thyroid hormones, but also analysis of DCPA both in plasma and milk in the test animals (rats), which was a subsequent request by EPA.

19. Other aspects of the testing program agreed upon by EPA included identifying and testing a positive control group and conducting dose range finding studies. These range finding studies were a prerequisite for conducting other phases of the testing program.

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

21. 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.

22. 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. Each time a phase of the testing program was finalized with EPA, the testing then had to be scheduled with the contract research laboratory. Many significant delays were experienced at the contract research laboratory which were beyond AMVAC's control.

23. For example, hormone assay kits were not always readily available from the manufacturer and there were problems with the reliability of the kits. Analytical methods had to be developed in different matrices over time and through different phases of testing, starting with plasma and then moving to serum. All of these efforts regarding analytical methods and method verifications were necessary to obtain consistent and reliable results as the testing program required extensive analyses across all the different rat life stages.

24. 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 the final study protocol 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.

25. 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 at which it has been progressing due to the availability of resources, the workload at the contract research laboratory,

and other complications and need for EPA approval of intermediate steps as discussed in this section.

26. AMVAC has fully cooperated with EPA and acted in good faith to produce all the data under the testing program for the CTA requirement as rapidly as practically possible.

27. 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, including all the needed parameters, necessarily must be conducted before the final study.

28. None of the 11 individual studies referenced above were identified as prerequisites in the DCI.

29. 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 submitted to EPA on June 20, 2022. JX 24, JX 25.

30. 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.

31. At no time did EPA establish any revised 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 both before (and of course after) that deadline passed. EPA did not request that AMVAC formally request an extension, and AMVAC saw no need to do so at any point because EPA continually received updates concerning the status of completion of the study (and prerequisite studies) and did not object to

the timeframes discussed therein at any point.

32. As late as February of 2022, EPA's Chemical Review Manager was thanking AMVAC for *AMVAC's patience with EPA* in responding to additional data requests from the EPA team concerning data that had been previously submitted on prerequisite studies. Petitioner AMVAC Exhibit ("PAX") 35. AMVAC reasonably did not see the need to request a formal extension based on the fact that AMVAC and EPA had been working together on the protocol and the correspondence related to that collaboration.

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

34. 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. JX 5.

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

36. 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. JX 5.

37. 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. JX 6

38. 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. JX 7 (email from M. Manupella, EPA to J. Porter, AMVAC) (Oc. 21, 2014).

39. The review also referenced an internal EPA guidance document dated 2005 entitled "Thyroid Assays in Pregnant Animals, Fetuses and Postnatal Animals, and Adult Animals." JX 6.

40. 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.

41. On October 22, 2014, AMVAC wrote to EPA requesting a copy of the 2005 guidance document referenced in the November 19, 2013, review. PAX 1.

42. EPA provided the 2005 guidance document on October 23, 2014. PAX 1 (email); JX 81 (attachment).

43. 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.

44. 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 nominal 24-month time-period provided in the DCI for completing the CTA data requirement had already elapsed.

45. 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. PAX 2.

46. Three months later, on February 11, 2015, EPA requested additional data on the protocol and methods described therein. PAX 3.

47. That same day, on February 11, 2015, AMVAC provided the data and methods requested by EPA. PAX 3 (email); PAX 4 (attachment).

48. 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.

49. 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.

50. On April 1, 2015, thirteen days after the March 19, 2015, meeting, AMVAC submitted a testing plan for the studies and revised protocols incorporating the comments and direction received from EPA at the meeting. PAX 5 (email); PAX 6 (attachment).

51. The protocols were submitted by AMVAC to 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). PAX 5 (email); PAX 6 (attachment).

52. 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. JX 8.

53. 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.

54. 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." JX 9.

55. 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." JX 9.

56. 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." JX 9.

57. 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. JX 9, as quoted in the paragraph above, is another prime example of a communication occurring after the nominal 24-month deadline for submittal of the CTA study that contributed to AMVAC's understanding that EPA understood the schedule on which the study was progressing, and that there was no need for the formality of requesting an extension of the already-passed deadline.

58. EPA's Attachment III – Explanatory Appendix to the NOITS, JX 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.

59. This was not part of EPA's communications to AMVAC on the DCI. The information was contained in the June 29, 2015 EDSP WOE Conclusions of the Tier I Screening Assays for List 1 Chemicals under EPA's Endocrine Disruptor Screening Program which is not associated with the DCI.

60. 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, JX 9, AMVAC took steps to initiate the preliminary work necessary to conduct the range-finding study in accordance with the testing plan and approved protocol. All this work had to then be scheduled into the existing work schedule at the contract laboratory. The lead-in time for most studies is in the order of many months at the laboratory.

61. Because the CTA studies were unique and rare, the number of laboratories capable of conducting the CTA testing program was extremely limited. Only 2 contract research laboratories had the capability for conducting CTA assays.

62. AMVAC selected the laboratory that it was confident had sufficient experience with DCPA, having conducted other mammalian toxicology DCI required studies: Envigo in the UK.

63. Considerable challenges had to be met before the range-finding study could be initiated with selected 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. The study protocol then needed UK Home Office approval to be performed in the UK contract laboratory.

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

65. 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 from the manufacturer, consistency between batches, and then measurement with the kits. The laboratory then switched over to LC-MS/MS analysis in serum, but new methods for serum had to be developed and then fully validated.

66. By January of 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.

67. 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.

68. Initiation of Phases II and III of the range finding study had to be rescheduled pending the rerun of Phase IA.

69. 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 at the contract laboratory for completing Phases I, II and III of the study. PAX 8.

70. 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. PAX 8.

71. 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. See JX 10-12; 15; 17-18; 20; 24; 80; PAX 11; 14; 21; 27; 35; 40 (emails); JX 13, 14; PAX 9-10, 12-13, 15-16, 18, 22, 28-29, 32, 39, 41 (attachments).

72. On May 30, 2017, AMVAC submitted an "Update on DCPA Developmental Thyroid Studies" concerning the dose range finding study then in progress. JX 10 (email); PAX 9 (attachment).

73. 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. PAX 9.

74. 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. PAX 9.

75. 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. JX 11 (email); PAX 10 (attachments).

76. On August 17, 2017, the PTU – positive control study report – was submitted to EPA. JX 12 (email); PAX 39 (attachment).

77. 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. PAX 40 (email); JX 13 (attachment).

78. 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. JX 14 (review); JX 15 (email transmitting).

79. EPA's request described in the paragraph immediately above necessitated a new design for an entirely new range finding study.

80. Between January, 2018, and August, 2018, AMVAC worked with the lab to develop a new study outline and design for the range finding study while it was also developing and validating analytical methods for detecting DCPA in both rat milk and plasma.

81. There were considerable delays at the contract laboratory of approximately 6

months 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.

82. AMVAC noted the IT disruptions at the lab in its January status update (submitted on February 12, 2018), PAX 11 (email), PAX 12 (attachment), and its May status update (submitted on May 17, 2018), PAX 14 (email), PAX 13 (attachment). AMVAC received no substantive response from EPA or any indication (at this or any other time) that it should consider requesting an extension on the basis of these delays beyond its control.

83. 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. 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." PAX 13.

84. The EPA Chemical Review Manager acknowledged receipt of the May, 2018, status update by email on May 18, 2018. PAX 14.

85. On August 24, 2018, AMVAC submitted three study reports, one protocol, a data table, and an update for the CTA testing program.[1] PAX 42.

86. The August 24, 2018, letter transmitting the above-referenced reports noted that a

[1] These were: (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.

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. JX 16.

87. 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. JX 17 (email transmitting); PAX 15 (attachment).

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

89. 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. JX 18 (email); PAX 16 (attachment).

90. 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, response to 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. PAX 16.

91. On February 26, 2019, the EPA Chemical Review Manager responded that he

would provide an update on the review of the protocol for the range finding study as soon as it was available. PAX 17.

92. On April 4, 2019, AMVAC submitted the validation data for rat plasma and rat milk requested by EPA. Two reports were submitted.[2] JX 19 (pages omitted).

93. 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. JX 19.

94. 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.

95. 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. JX 80 (email); PAX 18 (attachment).

96. The June, 2019, update referenced above showed that 7 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). PAX 18.

97. AMVAC again indicated that the dose range finding study could not be initiated

[2] These were: (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).

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. PAX 18.

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

99. 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. PAX 19.

100. On September 24, 2019, AMVAC received the EPA review of the protocol for the new range finding study. 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. PAX 20 (email); PAX 19 (attachment).

101. In December, 2019, AMVAC submitted the T3, T4 and TSH -- Validation Report for the Immunoassay Method which was part of Phase 1 of the range finding study. PAX 7.

102. On December 13, 2019, AMVAC submitted its quarterly status report for the CTA testing program and its response to questions regarding EPA's September 17, 2019, review. PAX 21 (email); PAX 22 (attachment).

103. On March 5, 2020, AMVAC submitted a proposed protocol for Phase I of the new dose range finding study to EPA. PAX 23 (email); PAX 24 (attachment).

104. EPA completed a review of the proposed protocol for Phase I on March 19, 2020. PAX 25. The review was provided to AMVAC on April 14, 2020. PAX 26 (email).

105. At the time the review was provided to AMVAC, EPA's Chemical Review

Manager also asked for an updated schedule for the conduct of the dose range finding study. When transmitting the protocol review, EPA's Chemical Review Manager stated, "I understand the lab has been awaiting this review to proceed, so please provide an updated schedule as soon as you can." PAX 26. This is another exemplar of the correspondence that led AMVAC to conclude that EPA understood the "schedule" for completion and that there was no need to seek a formal extension.

106. On April 16, 2020, AMVAC informed EPA that the lab was reviewing EPA's comments on the dose range finding 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. JX 20.

107. 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. JX 20.

108. 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 dose range finding study including various intermediate dates, with an estimated date for the final report for the range finding study 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. JX 20 (email); PAX 41 (attachment).

109. 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 stated that a draft report would be available in January 2021. PAX 27 (email); PAX 28 (attachment).

110. On October 16, 2020, AMVAC received a letter from EPA outlining what EPA

believed to be the status of all studies requested in the DCI. 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 the CTA study. JX 21 (letter); PAX 38 (email).

111. 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 forecast in the August, 2020, quarterly update). The update further projected that the draft study report would be completed by January 27, 2021 (also as forecast in the August, 2020, quarterly update). JX 24 (email); PAX 29 (attachment).

112. 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. JX 24.

113. I 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. JX 24.

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

115. 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. JX 23.

116. I 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. JX 23.

117. 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. JX 23.

118. 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. JX 23.

119. 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. JX 23.

120. 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. JX 23 (email); PAX 30 (first attachment).

121. 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, subject to EPA's review and approval of the protocol. JX 23 (email); PAX 31 (second attachment).

122. EPA acknowledged receipt of the draft dose range finding report – Dose Range

Finding QA'd Draft Report (Covance: PM86YP/8441728) (Covance was formerly known as "Envigo") and the proposed protocol identified in the paragraphs immediately above 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. JX 24.

123. 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. JX 24 (email); PAX 32.

124. On May 27, 2021, AMVAC submitted the final report for the range finding study. 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. JX 24.

125. 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. JX 24.

126. EPA responded 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. JX 24.

127. 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 delays in 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. JX 24.

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

129. 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. JX 24.

130. EPA responded the same day that some preliminary comments would be provided on July 9, 2021. JX 24.

131. EPA provided the preliminary comments to AMVAC on July 9, 2021. JX 24 (email); PAX 33 (attachment).

132. 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. JX 24.

133. EPA did not respond to AMVAC's July 9, 2021, communication referenced in the paragraph immediately above until July 21, 2021. JX 24. In the July 21, 2021 response, EPA provided the final protocol review memorandum. PAX 34 (attachment).

134. 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[.]"), JX 24.[3]

[3] The message from EPA's Chemical Review Manager on August 17, 2021 read in full, "Hi Ann and Jon, I just wanted to check in on the CTA study. Has the study commenced? *For our planning purposes*, could you provide us with *an updated, best-case scenario timeline for the study, including an aspirational date for submission* of the final study? Thank you, [EPA's Chemical Review Manager]" JX 24 (emphasis added). As a result of this communication and the others referenced herein, AMVAC understood EPA to be well apprised of the schedule for completion and saw no need to seek a formal extension.

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. JX 24.

135. EPA acknowledged receipt of AMVAC's August 17, 2021, update described in the paragraph immediately above on August 18, 2021. JX 24.

136. At no time since the communication of the projected dates for the 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 NOITS issued on April 27, 2022.

137. 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 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. JX 25.

138. On February 7, 2022, EPA requested test substance stability studies from the dose range finding study. JX 25.

139. AMVAC submitted the test substance stability studies to EPA on February 9, 2022. PAX 35 (email).

140. On February 9, 2022, EPA requested additional data regarding historical control thyroid hormone data. PAX 35.

141. On February 15, 2022, AMVAC submitted to EPA the historical control data referenced in the paragraph immediately above. PAX 35 (email); PAX 36 (attachment).

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

143. As indicated in AMVAC's prior communications regarding study status dating back to August, 2021, the projected date for submission of the final report for the CTA study is June 20, 2022. The final report is in the final stages of review and preparation for submission. JX 24.

144. EPA has been deeply involved in the iterative process for conducting the CTA testing program required under the DCI and has been kept continually up to date on progress via quarterly updates and other correspondence as set forth above.

The Acute Avian Oral Toxicity (Passerine) Study

145. AMVAC indicated in its Initial Response that it would submit new data to satisfy the Guideline No. 850.2100 Acute Avian Oral Toxicity (Passerine) data requirement. Initial Response, JX 5. AMVAC submitted a protocol for EPA's review in the Initial Response.

146. 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. JX 53.

147. AMVAC, on March 6, 2014, agreed to conduct the Guideline No. 850.2100 study using the protocol suggested by EPA. JX 53.

148. In connection with transitioning to the protocol suggested by EPA, Julie Porter with AMVAC said that AMVAC "would like to request a time extension until 10/30/2014" and she asked Jill Bloom with EPA if EPA "would like a formal request." JX 53.

149. No one from EPA ever responded to JX 53 indicating that a formal request was

necessary (or not necessary in this case) or acknowledging the request for an extension in any.

150. This lack of a response early in the response process to the DCI contributed to AMVAC's understanding that formal requests for extension (or even informal ones) were needed as a supplement to AMVAC's ongoing communications with the agency.

151. On September 30, 2014, AMVAC submitted a study conducted using the protocol identified by EPA. JX 54.

152. On October 1, 2014, EPA acknowledged receipt of the study, confirmed that it met submission requirements, and assigned the study MRID Number 49477601. JX 54.

153. 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." JX 55.

154. The DER, JX 55, states that "if application rates result in higher estimated exposure concentrations on dietary items than the concentration tested in this study, additional data may be required" (emphasis added).

155. EPA proposed an alternative feeding-based study, *see* JX 1, however, the Agency's own guideline at the time the study was conducted prohibits testing at levels above those that already have been tested in the oral study.

156. Thus, AMVAC has satisfied the Guideline No. 850.2100 Acute Avian Toxicity (Passerine) data requirement with a scientifically sound study that fully met the Guideline.

Authenticity of Exhibits

157. I have reviewed JX 23; and PAX 2, 4, 6-7, 9-10, 12-13, 15-16, 18-19, 21-22, 24-25, 28-37, 39, 41-44. These exhibits are true and correct copies of documents generated, transmitted, or received by me in the course of my employment with AMVAC. To the extent I cite JX or PAX exhibits in my testimony that are not listed above, I have conferred with other AMVAC fact witnesses who have confirmed that those exhibits are true and correct copies of documents generated, transmitted, or received by them in the course of their employment with AMVAC.

I, Ann Jonynas, declare under penalty of perjury under the laws of the United States that the statements contained in the written statement above are true and correct to the best of my knowledge. Executed this 17th day of June 2022.

/s/ *Ann Jonynas*
Ann Jonynas

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Verified Written Statement of AMVAC Fact Witness Ann Jonynas**, was served on the following parties today, June 17, 2022, as indicated below.

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

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