UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

VERIFIED WRITTEN STATEMENT OF AMVAC EXPERT WITNESS EPHRAIM GUR, MS

January 9, 2023

I, Ephraim Gur, declare and state as follows:

1. The following statement sets forth my expert opinions based on my training, experience, and my review of certain materials as described in more detail below.

Background and Curriculum Vitae

2. Currently, I am the President and founder of Ephi Gur Regulatory Consulting, Inc. ("EGRCI").

3. I have a Bachelors of Science in Biology and an Masters of Science in Zoology from the University of Tel Aviv, Israel.

4. In my position at EGRCI, I provide regulatory consulting services to companies in the agrochemical industry that manufacture, distribute, and sell pesticides regulated by the U.S. Environmental Protection Agency ("EPA") under the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA").

5. More specifically, my work involves providing regulatory and scientific advice to companies with respect to (i) obtaining and maintaining pesticide registrations under FIFRA; (ii) placing and monitoring studies required for initial registration or to maintain existing registrations; and (iii) responding to data call-ins for reregistration and registration review, including interfacing with EPA throughout all aspects of the data call-in process. I routinely represent registrants before EPA on registration issues, data development, study design, protocol review, tiered testing requirements, waiver requests and the full range of scientific issues related to conducting studies to address EPA's data requirements under 40 C.F.R. Part 158.

6. I am also the Chief Scientist at Gowan Company LLC ("Gowan"). Gowan holds more than one-hundred fifty (150) registrations with EPA. In my position as Chief Scientist, I am responsible for managing all of Gowan's regulatory and science teams on a global basis.

During the time I have been in my position with Gowan, I was also responsible for managing Gowan's product formulation departments and Gowan's research and development center in Italy.

7. More specifically, I have overall responsibility for supervising Gowan's regulatory teams in obtaining and maintaining registrations for Gowan's products with EPA and other registration authorities worldwide, including actions involving Gowan's response to data call-ins for registration review.

8. In my consulting work, I have advised a number of companies on their regulatory and registration strategies including new active ingredient and product registrations, preparing and managing pre-submission meetings, overseeing submission of waivers, placing and monitoring studies to be submitted to EPA and interacting with EPA on various issues including Data Call Ins ("DCI"). My consulting work also included training for regulatory personnel on responding to DCIs, data compensation rules, EDSP and related regulatory requirements involving pesticide registration.

9. Prior to my work at EGRCI, Inc. and Gowan, I held various regulatory and scientific positions at Makhteshim Agan of North America ("MANA") (and its parent company Makhteshim Chemical Works, Ltd.) ("MCW") from 1993 through 2011. During my time at MANA/MCW, the company was the largest generic registrant of pesticide active ingredients and products in the world, holding approximately 180 registrations for approximately 60 active ingredients under FIFRA.

10. I held various positions at MANA/MCW, starting as Director of Regulatory Affairs, and then Vice President of Regulatory & Scientific Affairs. My career at MANA/MCW spanned 18 years, all of which were focused on i) obtaining registrations for pesticide products at

EPA and other regulatory agencies worldwide; ii) managing data development for pesticide product registration (including interfacing with EPA and other regulatory agencies regarding data requirements, study design, protocol development, data generation and interpretation of study results); and (iii) defending/maintaining registrations for pesticide products undergoing reregistration or review at EPA and before other registration authorities. My experience and work defending/maintaining registrations for pesticide products includes the full scope of review under FIFRA, including Special Review, reregistration, registration review, FQPA tolerance reassessment and responding to DCIs.

11. For the last thirty (30) years, I have been managing and interfacing with EPA on pesticide regulatory and scientific matters and have been directly involved in and/or managed the response to approximately 40 generic DCIs involving approximately 20 active ingredients.

12. My full C.V. is attached as Exhibit A to this Statement.

13. Based on my training and experience as set forth in the preceding paragraphs, AMVAC is offering my testimony as an expert witness in the areas of pesticide registration, reregistration and registration review under FIFRA, including but not limited to the following: (1) responding to data call-ins; (2) data development, including but not limited to involvement in analysis of data requirements, study design, protocol development, data generation, and interpretation of study results; and (3) interfacing with EPA and other regulatory agencies regarding all of the above.

Summary of Materials Reviewed

14. My opinions set forth below relate to AMVAC Chemical Corporations' s ("AMVAC's") actions in response to a DCI issued for Dimethyl Tetrachloroterephthalate ("DCPA") Technical (EPA Reg. No. 5481-495) by EPA on January 31, 2013.

15. I base the opinions set forth below on, in addition to my training and experience set forth above, my review of

a. the DCI;

b. the documents referred to in the following paragraphs;

c. AMVAC's Request for Hearing and Objections filed in this matter and all of the Exhibits referenced in it;

d. the Verified Written Statements of AMVAC employees, Ann Jonynas, Richard Freelander, and Niamh McMahon and the Exhibits to those statements;

e. EPA's Motion for Accelerated Decision; and

f. the parties' Joint Stipulated Facts as filed in this matter on January 6, 2023.

Statement of Expert Opinions

The DCPA DCI

16. The DCPA DCI is typical of most DCIs I have responded to and been involved in over the course of my career that were issued around the same time, in terms of its scope and the types of studies and data requirements included in it. The types of studies required in the DCPA DCI are mostly similar to studies that were required for many pesticide technical products/active ingredients for registration review during the time it was issued in 2013. It includes a significant number of data requirements that had been updated or newly identified in the years preceding it. During registration review, EPA issues DCIs to ensure that active ingredients contained in existing products (often registered for many years) are "caught up" on new/updated data requirements.

17. The details of the requirements for studies typically required by EPA in DCIs are compiled by EPA in published testing guidelines and standardized protocols. This was true for most of the studies included in the DCPA DCI. However, the requirements in the DCPA DCI included several data requirements that were so new they did not have an established testing guideline or standardized protocol. These are identified in the DCPA DCI as special studies "SS" and include SS- thyroid tox. (CTA), SS-1066, SS-1069, and SS-1072 (the sediment organism studies).

18. Developing a testing guideline for a study is a long process that includes reaching a scientific consensus on how to perform the study, what data needs to be collected and how to analyze the data. To ensure that the testing will produce a study with meaningful results, the testing procedures outlined in the guideline must be validated by performing several studies in various labs using the same methodology in the same chemicals and ensuring that similar results are obtained. This process called ring testing may take several years. It is a complex process that includes up to 15 labs that share their experiences on the technical matters of running such a study using the procedure and methods for the testing guideline.

19. EPA often requests data in DCIs before the process for establishing a testing guideline for conducting that data/study is completed. In that case, the registrant responding to the DCI must engage in extensive interactions with EPA on study design, protocols, study objectives and methodology before the study is initiated (and throughout the course of conducting it) to ensure that the data generated from it will meet the scientific purpose that EPA intends to use it for. In this case, AMVAC engaged in extensive interactions on these same issues with respect to the SS-thyroid (CTA) and SS-1072 (leptocheirus) data requirements.

20. Even for studies with testing guidelines, it may be necessary to engage with EPA

on methodology, study design and protocols, particularly where the active ingredient has certain properties, or the data requirement calls for testing on degradates or metabolites of the active ingredient. The DCPA DCI includes several ecotoxicity and environmental fate data requirements for testing both DCPA and its degradate TPA.

DCI "Time Frames"

21. All generic DCIs include a table called the "Requirements Status and Registrant's Response." This table lists each data requirement requested under the DCI along with footnotes providing additional instructions for conducting the study, the guideline testing number and a column with the heading "time frame" in months (among other information). The time frames in the table for the DCPA DCI range from 9 to 12, 24 and 36 months. This column is filled in by EPA before the DCI is sent to a registrant.

22. Based on my experience in managing the conduct of studies, the "months" indicated are usually grossly underestimated except for very routine, short-term studies, none of which are in the DCPA DCI. This is particularly true with special studies ("SS") or when the table includes instructions for a study indicating that a protocol must be submitted to EPA for review and approval prior to study inception. Another example of where deadlines are grossly underestimated is where the notations for the data requirement indicate that the data requirement must follow a tiered testing approach. In all these cases, it is common for the time frame to become a moving target because the timing for the study becomes dependent on when EPA approves the protocol or completes its review of data from certain preliminary work, or when results from a first testing tier must be generated before testing under the second tier can be initiated.

23. An example of this problem are SS requirements. As I stated above, SS data

requirements have no guidelines established. Neither EPA nor contract research laboratories have experience in running such studies. There therefore is uncertainty and complexity in writing the protocol and determining the study design (i.e., the number of test subjects to be treated, the number of samples to be taken, the measurements to be taken, etc.).

24. It becomes even more complex to respond to a DCI requesting a SS if the study requires testing of new species of animals under new conditions. This was the case with the studies in the DCPA DCI for testing sediment dwelling organisms.

25. In these cases, once a protocol is available it is sent to EPA for approval. EPA then needs to review the protocol and provide comments before all the parameters in the protocol are agreed on.

26. Based on my experience with handling many DCIs, the protocol approval process (where there are multiple rounds of discussion with EPA on various study parameters) takes years to complete. This is because it takes EPA a long time to review the protocols, discuss them internally, consult with others, and provide comments.

27. There is extensive communication back and forth between EPA and the registrant because often the requests, suggestions, or other issues addressed in the Agency's comments are proposed actions that are not technically possible or likely to provide useful data. An example of this is requesting the registrant to collect more blood samples in a rat study when the collection would exceed the amount of blood available from the rat.

28. It is my experience that several discussions are required between EPA, the labs and the registrant in order to complete a protocol. The discussion shown in JX 60, Attachment IV, and JX 71 and 72 in this matter is typical of these discussions.

29. In many cases, even when a protocol is finally agreed upon between EPA and the

registrant, the execution of the study is not straightforward. An example of this is when a new species is being tested under new conditions. The lab may have problems in maintaining the health of the species, have difficulties in sampling the testing medium adequately, or come across other difficulties. If this happens the results may be unacceptable or too variable to provide meaningful data.

30. When this occurs, additional discussions with EPA may take place to refine the protocol and determine new dates for when the study will be submitted. These discussions are often very fluid. EPA simply accepts the fact that more time is needed to initiate and complete the study, and a new time frame for submitting the study is not firmly documented through a formal written extension or other communication from EPA.

31. In view of the preceding discussion, it is my experience that for non-standard, non-guideline or complex studies the "time frame" indicated in the table in the DCI is more of an aspirational goal, and it is routine for the deadlines arising from these time frames to come and go without being enforced (or even commented upon) by EPA. This is not to imply that DCI time frames for studies with established Guidelines are accurate; they often are not. The default Guideline durations referenced in DCIs were first adopted by EPA many years ago, and also often understate the realistic amount of time needed to place and execute a study, compile the results, write the report, and submit it to EPA.

32. As a result, registrants do not understand the time frames set forth in DCIs to represent EPA's actual requirement regarding when the studies must be submitted, and, in my experience, neither do the EPA staff who interact with the registrants. They too understand that the durations in the DCI are aspirational "default" values that may not be practical or even possible to achieve.

Requests for Extension of DCI Requirements

33. It is also my experience that there is no consistent policy at EPA regarding whether a formal extension request is required. In some cases, the EPA staff who are managing the DCI will ask the registrant to submit a formal request for an extension. In other cases, the EPA staff will indicate that the submission of a formal request for an extension is not necessary and they don't want the registrant to file one because it adds to their workload of actions that require processing.

34. Based on my experience, so long as communication between the registrant and EPA is on-going regarding the progress and status of completion of a study, and the EPA staff has not requested a formal extension request be filed, both the registrants and EPA staff do not understand that there is a need to ask for, or grant, a formal extension to the time frame set out in a DCI.

35. My experience is that when you file a formal extension, EPA also is very inconsistent in responding and that the extension requests almost always sit with EPA for extended periods of time – months to years – before you get a response. It is my understanding that responding to/acting on extension requests are a low priority for EPA because of constraints and prioritization of resources.

36. In some cases, the extension request is never acted upon or you receive approval of the extension after the data already have been submitted. The former was the case here. AMVAC asked for one extension early on in the process of this DCI, in connection with an acute oral passerine study. AMVAC submitted the study by the date indicated in its extension request (six months after making the extension request), but never received any response from EPA

granting or denying the extended date (or even acknowledging that the request had been made). This is typical of the dynamic I discuss in this section.

37. It is widely understood in the pesticide industry that a registrant likely will not receive a formal response from EPA to a request for an extension, but this doesn't mean the requestor is expected to be proceeding with the study. To the contrary, it is also understood that although study submission dates come and go, a formal extension is not needed if you are engaging with EPA on a consistent basis, awaiting a response on a waiver or science review, and keeping the Agency updated on the status of your efforts to meet the data requirements and conduct the necessary studies. An example of this is JX 62, which includes a 12-month status update that AMVAC submitted to EPA along with other data for the DCI. In the status update, AMVAC noted the "current status" on a number of data requirements as "waiting for response from EPA." It is also common to receive no response from EPA to an update regarding a data requirement, including the testing schedule for a study underway or the expected submission dates for a study.

38. In the past companies would meet with the Pesticide Reevaluation Division ("PRD") (which was renamed PRD in 2009 after previously having been known as the Special Review and Reregistration Division or "SRRD") periodically (in my experience twice a year) to review all on going issues, including pending waiver requests. Somewhere around 2016, the Office of Pesticide Programs ("OPP") was experiencing heavy workloads and a loss of employees. As a result, they slowly discontinued this practice, cut the number of meetings they were willing to hold, and thus the efficiency of discussing the outstanding issues decreased.

Waivers

39. In my experience, waivers can take a very long time for EPA to review and

address. This adds significant delays in the time frame for meeting the requirements in the DCI. AMVAC's experience with nine (9) data requirements at issue in the NOITS involve waivers that were under consideration for many years. This is typical of what registrants usually experience.

40. One of the first steps a registrant must take in responding to a DCI is to identify whether (i) it has existing data that could address a data requirement; or (ii) there are scientific grounds for why a new study is not required and, thus, the data requirement should be waived. Registrants must decide whether they will assert that one of these conditions exists and indicate their selections as to how they will address each data requirement when they provide their 90-day response to the DCI.

41. In some cases, a data requirement is driven by the results of a risk assessment. It is not uncommon for the Agency to complete a risk assessment even if there is outstanding data from a DCI or otherwise, where the Agency can make conservative assumptions in place of the outstanding data.

42. When a risk assessment identifies risks of concern based on the data available and any assumptions used, refining or reducing certain application parameters in the product labels may mitigate the calculated risk and provide the basis for a waiver of one or more studies to be accepted. In these situations, there is an interactive discussion between EPA and the registrant to identify the use patterns that will allow EPA to make a safety determination without conducting certain additional studies.

43. If the registrant identifies existing data that could address a data requirement, it must undertake a scientific assessment as to whether that data may satisfy the requirement. If not, then a new study would be needed unless there is a scientific basis for obtaining a waiver.

In many cases external experts may need to be engaged or consulted in the assessment process to help make the determinations on existing data and waivers. Some waivers are based on the rationale that EPA's objective in requiring the data can be adequately addressed without additional data.

44. EPA's response to a waiver request can take months or even years. The length of time depends on several factors. In some cases, the decision to grant or deny a waiver is a "simple" scientific judgement call made by a scientist or two at EPA. In other situations, a committee (e.g., HAZPOC) may need to meet to discuss the waiver, and this can take months or even years. The registrant generally is not kept in the loop by EPA and is not informed about the internal process taken by EPA to review the waiver. It is common for a DCI deadline to pass while EPA is considering a waiver, without comment from EPA.

45. While a registrant is waiting for a response from EPA on a waiver, it doesn't normally start conducting a new study because it needs to be sure that the generation of a new study is required. It is important to wait for the EPA science branch review because that review may provide a new insight into why EPA wants the study or what precise question it is trying to answer. The information in the review can affect the study design because the registrant may become aware of a new concern EPA is trying to address that was not previously clear. Due to this possibility, starting a study before receiving the Agency's response is inefficient. In addition, when the registrant places a study with a contract laboratory, it is making a financial and contractual commitment to conduct the study. If the registrant starts the study and then the waiver is granted, it may not be able to back out or terminate the study without substantial expense.

46. EPA's science branches (the Environmental Fate and Effects Division ("EFED")

and the Health Effects Division ("HED") initially review registrant waiver requests. EFED or HED then typically issues an internal memorandum to PRD in which EFED or HED recommends for or against granting the waiver.

47. Historically, PRD's conclusions about whether to waive a data requirement based on a recommendation from EFED or HED were usually memorialized in a transmittal document from an official at PRD to the registrant(s). More recently, it is increasingly common that the Chemical Review Manager in PRD will simply forward EFED or HED's technical review without providing a cover letter, or without even stating whether PRD agrees or disagrees with the recommendation contained in the EFED or HED memoranda. This often results in uncertainty about whether the Agency will review further waiver requests directed to the same data requirement(s).

48. The Agency almost always will entertain further attempts to justify a waiver request, even if EFED or HED initially recommended against granting the waiver, unless PRD has stated unequivocally that no further requests will be considered. On reviewing the Joint Exhibits and Petitioner AMVAC's Exhibits filed in this matter, I have not seen any instance in which PRD or any other branch or division stated (or even implied) that no further attempts to justify a waiver would be considered.

49. Often, when EFED or HED recommends denying a waiver, the reviewer will indicate the basis for the recommendation. This explanation may identify an issue that could be answered with additional information. The registrant may be able to provide the additional information so that the scientific issue is resolved, and the waiver then could be approved. Thus, it is common for a registrant to make a further submission after it receives EFED or HED's initial response, and for additional exchanges between a registrant and Agency personnel to

continue thereafter, both verbally and in writing. AMVACs waiver requests for DCPA are typical of this approach. The approach is scientifically valid and efficient as it saves EPA resources in reviewing complex studies that may be found redundant or unnecessary. In this case, there are instances where EFED recommended granting the waiver after it reviewed further submissions by AMVAC in response to a science review. JX 69 and JX 79.

Review of Waiver Requests in this Matter

50. AMVAC requested, at some point, a waiver for each of the nine (9) ecotoxicology and environmental fate data requirements that I understand remain at issue in this matter. Having reviewed these requests, I believe that AMVAC's conduct was reasonable, and appropriate in the circumstances presented. Its waiver requests had scientific merit and the Agency's responses did not indicate that further attempts to justify a waiver would not be entertained following an initial response from EPA. In fact, EPA always did entertain such attempts in the course of this DCI, in some cases granting waivers based on additional information supplied after EFED initially recommended denying a waiver request.

51. With respect to the **remaining five (5) TPA ecotoxicology data requirements that are among these nine studies**, AMVAC provided a proposed rationale in JX 5 that was consistent with the Agency's statements in the Preliminary Problem Formulation, JX 65; that "a more limited testing strategy will be considered *in lieu* of a comprehensive data submission if one is proposed." JX 5. The concept that a limited testing strategy would be appropriate made sense in view of the fact that existing data suggested that TPA was generally less toxic than its parent, DCPA. Thus, use of DCPA endpoints in the absence of some TPA data would still yield a conservative risk assessment. Using data from a parent (or degradate, as the case may be) that is known to be more toxic than its degradate (or parent, as the case may be) is a well-recognized

risk assessment tool and is a very typical basis on which waivers are granted.

52. EFED did not recommend granting all of the requested waivers for these five studies, however. Rather, EFED suggested that AMVAC conduct "a limited set of toxicity tests initially for TPA (for example, an acute and chronic toxicity study in daphnids) and depending on the results of these initial studies, a full suite of studies may or may not be subsequently required." JX 66.

53. Based on the testimony of Richard Freedlander, AMVAC proceeded to do exactly what EFED had suggested, an acute and chronic daphnia study. It signed the contract for the needed chronic daphnia study only a few months after receiving JX 66 and provided a comprehensive analysis of not only the acute and chronic daphnia results, but also endpoints then available for other species, to the Agency in JX 22/PAX 45.

54. EFED ultimately did grant several waivers after reviewing this updated data from AMVAC as set forth in JX 69. It recommended against granting others based on an apparent concern that certain species would be comparatively more sensitive to TPA as compared to DCPA than others. It appears that the Agency's concern in that regard was motivated by documents that it had in its possession since at least 2014, prior to EFED's suggestion that AMVAC conduct specifically the acute and chronic daphnia studies as a first step.

55. Regardless of the scientific merit of EFED's concerns in JX 69, AMVAC acted reasonably by providing EFED with precisely the subset of studies that EFED had requested in JX 66.

56. The reasonableness of AMVAC's approach is supported by reference to Exhibit A to the Verified Witness Statement of Dick Freedlander, which is a timeline showing the events discussed above. It shows graphically the extent to which AMVAC was frequently waiting on

EPA to respond to a communication, and that AMVAC reasonably quickly responded to all communications from EPA.

57. With respect to the **DCPA Leptocheirus ("SS-1072") data requirement**, AMVAC originally indicated it would develop new data but then requested a waiver in 2016 after extensive discussion with EPA concerning a protocol and after no laboratory had proved capable of performing the chronic test on the species requested in the DCI. AMVAC did not rely solely on the impossibility of the study, however. It also provided a detailed technical document to support the proposition that sediment-dwelling aquatic organisms (like Leptocheirus) were generally less sensitive to DCPA than other types of organisms for which data was available. This is a very typical basis on which waivers are granted.

58. EFED did not recommend granting the waiver. It acknowledged the difficulties with the study requested in the DCI and suggested that AMVAC could perform an acute 10-day study (Guideline 850.1740) instead, and that EFED might reconsider its recommendation in view of the results of that study. JX 74.

59. AMVAC responded with an expanded technical justification for the waiver, JX 76. The response provided additional technical analyses and case studies as described in the testimony of Richard F. Freedlander at paragraph 99.

60. AMVAC indicated that it would not proceed with the acute 10-day study, Guideline 850.1740, in 2020. JX 22. In JX 22, AMVAC indicated that it would perform the acute study if EPA issued a new DCI for it. This was a reasonable request. Issuing a DCI for this study is an administrative task which was wholly within EPA's control. A reason a registrant may ask for a supplemental DCI is to protect its future FIFRA data compensation rights in the study once it is submitted to EPA. In my practice, I have requested that EPA issue a

supplemental DCI in a similar circumstance, and EPA agreed to do so.

61. AMVAC also reasonably requested that EPA notify it if, in EPA's view, the issues that were preventing laboratories from running chronic Leptocheirus studies consistent with the SS-1072 data requirement in the DCI had been resolved. EPA never so notified AMVAC until concurrently with the NOITS. At that time EPA stated only that "several studies" had at that time been submitted to EPA without identifying them.

62. The reasonableness of AMVAC's approach is supported by reference to the attached timeline, Exhibit B to the Verified Witness Statement of Dick Freedlander, which is a timeline showing the events discussed above. It shows graphically the extent to which AMVAC was frequently waiting on EPA to respond to a communication, and that AMVAC reasonably quickly responded to all communications from EPA.

63. With respect to the **remaining three (3) environmental fate data requirements for TPA**, based on Richard Freedlander's testimony, my understanding is that AMVAC generally sought waivers because: (1) TPA was not likely to degrade during a typical guideline-length laboratory study; and (2) EFED had stated that it would assume stability in the absence of data. This was a reasonable approach for two reasons. First, assuming stability is essentially a "worst case" assumption. Hence, even if a study was provided that would show faster degradation, assuming stability will still be conservative. Second, data from studies of the parent (which quickly degrades into the degradate) showed that the resulting degradate was unlikely to metabolize further during a typical guideline-length laboratory study. Thus, the requested study was not likely to provide a result that would be useful for risk assessment. Both of these reasons are typical grounds on which waivers are granted.

64. EPA had initially indicated that it viewed TPA as stable or would make that

conservative assumption absent data. *See* JX 65, JX 21. In JX 69, EPA for the first time presented modeling indicating a concern that assuming stability would lead to a gradual increase in environmental concentrations. EPA had never articulated this concern in the past, even when it stated that it could and would assume stability.

65. The reasonableness of AMVAC's approach is supported by reference to Exhibit C to the Verified Witness Statement of Dick Freedlander, which is a timeline showing the events discussed above. It shows graphically the extent to which AMVAC was frequently waiting on EPA to respond to a communication, and that AMVAC responded reasonably quickly to all communications from EPA.

66. The conclusion that AMVAC behaved appropriately in connection with the three categories of waivers discussed above is bolstered by EPA's conduct throughout this DCI and against the backdrop of EPA's typical waiver practice. EPA consistently entertained further dialogue with AMVAC in this case and never indicated that no further waiver requests would be considered. This is consistent with the Agency's typical practice that it will consider multiple waiver requests as to the same data requirement.

67. PRD could have at any time, with the flick of a pen, or a quick email or phone call, informed AMVAC that no further waiver requests would be considered. I have seen no evidence that this occurred.

68. Not only did this never occur, PRD actively suggested to AMVAC that risk assessment would proceed prior to final decisions on the waiver requests, which is a sequence of events that often happens in connection with DCIs.

69. PRD most directly suggested that the risk assessment would proceed even before final decision on waiver requests in JX 21, when it stated in October of 2020 that "EPA expects

to complete draft risk assessments in June of 2021." EPA further stated that, "[t]he Agency will rely upon data available at the time when the risk assessments are being developed. Where the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments." I have seen no indication that EPA cannot proceed at this point. It is not stated explicitly or implicitly that any further data is needed for the Agency to complete, or prior to the Agency "complet[ing] the draft risk assessments in June 2021." EPA could easily have stated the opposite; that data was needed for risk assessment. EPA could also easily have informed AMVAC of a new date by which any responsive data would have to be provided, but EPA did not do so. A registrant receiving this letter would reasonably understand that waiver requests would be re-evaluated after the pending risk assessment, based on the results of that risk assessment.

Overall Conclusions

70. Based on my experience and my review of the facts at issue, AMVAC's overall approach and its response to the DCI was appropriate and typical of how registrants address data call-ins. The facts show that AMVAC took the DCPA DCI seriously and consistently worked on responding to it for over 8 years and invested considerable resources in time and money – approximately $3 million dollars in direct costs according to the testimony of Niamh McMahon.

71. As set forth elsewhere in this testimony, I believe that AMVAC's conduct, as to each of the data requirements still at issue, reflects a commitment by AMVAC to respond to the DCI in a serious, appropriate manner.

72. The frequency of the correspondence and communications between EPA and AMVAC is typical for DCIs of this scope. EPA's actions and delays in responding to AMVAC are also typical of what registrants routinely experience with large generic DCIs.

73. What is unusual in my experience is how EPA issued the NOITS to AMVAC without any advance warning or indication that it was even considering doing so. EPA's last formal written communication to AMVAC prior to the NOITS was its October 16, 2020 letter regarding outstanding data requirements in the DCI. JX 21. No sense of urgency was conveyed by this letter. It simply requested that AMVAC provide an update on the outstanding data requirements and conveyed that where EPA is lacking data, conservative assumptions could and would be used to complete risk assessments. EPA clearly stated that it expected to complete a draft risk assessment by June of 2021. EPA did not identify any data that it needed – either at all, or by any particular time – to enable it to do so. Based on EPA's statements that it could and would proceed with conservative assumptions where data was not yet available, AMVAC would reasonably have expected that EPA was going to perform the risk assessment as it stated, and then be in a better position to grant or deny any remaining waiver requests, which is a common practice as I have discussed above.

I, Ephraim Gur, declare under penalty of perjury under the laws of the United States that the statements above are true and correct to the best of my knowledge. Executed this 9th day of January 2023.

/s/ *Ephraim Gur*
Ephraim Gur

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Verified Written Statement of AMVAC Expert Witness Ephraim Gur**, was served on the following parties today, January 9, 2023, as indicated below.

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

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