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,	)	**Docket No. FIFRA-HQ-2022-0002**
Petitioners.	)	

VERIFIED WRITTEN STATEMENT OF AMVAC EXPERT WITNESS EPHRAIM GUR, MS

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 B.S. in Biology and an M.S 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; (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 (i) all of Gowan's regulatory and science teams on a global basis;

(ii) Gowan's product formulation departments; and (iii) 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. 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.

9. 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 data call-ins.

10. 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 data call-ins involving approximately 20 active ingredients.

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

12. 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

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

14. I base the opinions set forth below on, in addition to my training and experience set forth above, my review of 1) the DCI; 2) the documents referred to in the following paragraphs; 3) AMVAC's Request for Hearing and Objections filed in this matter and all of the Exhibits referenced in it; and 4) EPA's Motion for Accelerated Decision.

Statement of Expert Opinions

The DCPA DCI

15. The DCPA DCI is typical of most data call-ins I have responded to and been involved in over the course of my career, 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 data call-ins to ensure that active ingredients contained in existing products (often registered for many years) are "caught up" on new/updated data requirements.

16. 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 "SS" (special studies) and include SS- thyroid tox. (CTA), SS-1066, SS-1069, and SS-1072 (the sediment organism studies).

17. 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 guideline 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 and 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.

18. EPA often requests data in data call-ins before the process for establishing a testing guideline for conducting that data/study is completed. In that case, the registrant responding to the data call-in 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.

19. 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 data requirements for testing both DCPA and its degradate TPA.

DCI "Time Frames"

20. All generic data call-ins include a table called the "Requirements Status and Registrant's Response." This table lists each data requirement requested under the data call-in along with footnotes for 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 data call-in is sent to the registrant.

21. 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 is where the notations for the data

requirement indicate that the data requirement must follow a tiered testing approach. 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.

22. An example of this problem is the SS (Special study requirement). As I indicated above, the SS data requirements have no guidelines established. Contract research laboratories have little to no experience in running such studies. There 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.).

23. It becomes even more complex if the study requires testing of new species of animals under new conditions such as the case with the studies in the DCPA DCI for testing sediment dwelling organisms.

24. 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.

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

26. There is extensive communication back and forth between EPA and the registrant because often the comments provided by EPA are not feasible or even technically possible. 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.

27. It is my experience that several discussions are required between EPA, the labs and the registrant in order to complete the protocol.

28. 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 or have difficulties in sampling the testing medium adequately. If this happens the results may be unacceptable or too variable to provide meaningful data.

29. 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 are not firmly documented through a formal written extension or other communication from EPA.

30. In view of preceding discussion, it is my experience that the "time frame" indicated in the table in the data call-in is more of an aspirational goal for non-standard, non-guideline or complex studies, 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.

31. 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

32. 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 data call-in 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.

33. 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.

34. My experience is that when you file a formal extension, EPA also is very inconsistent in responding to them and that the extension requests will 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.

35. In some cases, the extension request is never acted upon or you receive approval of the extension after the data already have been submitted. 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 discussed in the written

statement of AMVAC employee Julie Porter. This is typical of the dynamic I discuss in this section.

36. 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. 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 and keeping the Agency updated on the status of your efforts to meet the data requirements and conduct the necessary studies. 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.

Waivers

37. 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 data call-in. AMVAC's experience with nine (9) data requirements at issue in the NOIS involve waivers that were under consideration for many years. This is typical of what registrants usually experience.

38. One of the first steps a registrant must take in responding to a data call-in is to identify whether (i) they have existing data that could address a data requirement and if not, whether a new study is needed; or (ii) there are scientific grounds for why a new study is not required and thus, the data requirement should be waived. Registrants are required to make these choices and indicate their selections as to how they will address each data requirement when they provide their 90-day response to the data call-in.

39. In some cases, a data requirement is driven by the results of a risk assessment. When a risk assessment fails, refining or reducing certain application parameters in the product

labels may mitigate the calculated risk and provide the basis for a waiver 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. An example of such discussions occurred in the context of DCPA, where AMVAC proposed label changes to support a waiver for certain Residue Chemistry studies. JX 47. Unfortunately, the process of approving labels at EPA is long, complex and involves several departments including the Registration Division and the Pesticide Reevaluation Division.

40. 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.

41. EPA's response to a waiver request can take months or even years. The length of time often 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 waver and this can take months or even years. The registrant 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 not atypical for a DCI deadline to pass while EPA is considering a waiver, without comment from EPA.

42. Often, when a waiver is denied by EPA, the reviewer denying the waiver will indicate the basis for the denial, which might be 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 could be approved. 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.

Overall Conclusions

43. Based on my experience and my review of the facts at issue, AMVAC's response to the DCI is typical of how registrants address data call-ins to fulfill the data requirements subject to the NOITS. The correspondence and communications between EPA and AMVAC are typical for data call-ins of this scope. EPA's actions and delays in responding to AMVAC are also typical of what registrants routinely experience with large generic data call-ins.

44. What is unusual in my experience is that EPA's last formal written communication to AMVAC prior to the NOITS was its October 26, 2020 letter regarding outstanding data requirements in the DCI. JX 21. This letter is not unusual as the Agency prepares to deal with the registration review workload. No sense of urgency is conveyed by this letter except to request that AMVAC provide an update on the outstanding data requirements within 30 days. In fact, the letter advises AMVAC that data it has not yet submitted at that time may still be considered "timely." JX 21. AMVAC provided a timely response (after requesting and receiving an extension to the 30 day timeframe via email), PAX 38, and continued to provide updates thereafter. EPA did not correspond with AMVAC until April 27, 2022 when it provided AMVAC with copies of the final waiver denials that had been pending for a sometime, and the NOITS.

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 17th day of June 2022.

/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, June 17, 2022, as indicated below.

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

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