

ASSISTANT ADMINISTRATOR FOR CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

September 24, 2024

Dr. Steven Lasee
Environmental Toxicologist
Lasee Research & Consulting
Via Email: Hello@LaseeConsulting.com

Mr. Timothy Whitehouse
Executive Director
Public Employees for Environmental
Responsibility (PEER)
962 Wayne Ave., Suite 610
Silver Spring, MD 20910
Via Email: twhitehouse@peer.org

Re: Response to Request for Correction of Information under the Information Quality Act:
Retraction of Research Memo Entitled "Verification Analysis for PFAS in Pesticide Products
(ACB Project B23-05b)" dated May 18, 2023, and Accompanying Press Release dated May 23,
2023 (RFC 24001)

Dear Dr. Lasee and Mr. Whitehouse,

This letter is the response to the Request for Correction (RFC), (referred to as a "Demand for Correction" by the requestor), dated May 28, 2024 and assigned RFC # 24001 for tracking purposes, that was submitted to the U.S. Environmental Protection Agency pursuant to EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA (EPA IQG). In the RFC, PEER (on its own behalf and on behalf of PEER's client, Dr. Steven Lasee) seeks the correction of information by retracting the following EPA documents disseminated by the Office of Pesticide Programs in May 2023:

"Verification Analysis for PFAS in Pesticide Products (ACB Project B23-05b)" dated May 18, 2023, and Accompanying Press Release dated May 23, 2023 (EPA Document # EPA-740-R1-8007)." ³

In the RFC, PEER provides the following reasons the challenged material should be retracted, and claims a violation of EPA Guidelines for Information Quality:

- 1. Challenged Material Is Subject to Information Quality Act;
- 2. Challenged Material Is Categorized as "Influential" and Thus Subject to Most Rigorous Scientific Standards;

¹ A copy of the RFC is posted on the EPA IQG site at: https://www.epa.gov/quality/requests-correction-and-reconsideration#24001.

² https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.

³ https://www.epa.gov/pesticides/epa-completes-scientific-testing-pesticide-products-pfas.

- 3. Egregious EPA Misconduct Demonstrates Significant Departures from accepted scientific practices;
- 4. Challenged Materials Violated Procedures for Maximizing Information Quality;
- 5. EPA's Results Are Not Being Reproduced by Independent Researchers; and
- 6. Demand for Prompt Correction to Minimize Public Health Threat.

The EPA IQG outlines administrative mechanisms for the EPA's pre-dissemination review of information products and describes mechanisms to enable affected persons to seek and obtain corrections from the EPA regarding disseminated information that they believe does not comply with the EPA IQG or Office of Management and Budget guidelines (i.e., OMB Information Quality Guidelines and Memorandum M-19-15).⁴ The EPA is committed to applying the OMB guidelines, including each of the updates outlined in M-19-15, to the EPA IQG. The RFC process under the EPA IQG is intended to provide a mechanism to correct errors where the disseminated product does not meet information quality standards. As stated in Section 8.5, the EPA IQG are not intended to duplicate or interfere with the orderly conduct of a process involving public comment opportunities that allow for the correction of any information that does not comply with the Guidelines.

In May 2023, the Agency released on our website a summary of laboratory results related to the analysis of ten pesticide products reported to contain PFAS residues (*Per- and Polyfluoroalkyl Substances (PFAS) in Pesticide and Other Packaging | US EPA*). EPA did not find any PFAS in the tested pesticide products, differing from the results of a published study in the Journal of Hazardous Materials. EPA also released newly developed analytical methodology used in the testing process alongside the summary of its findings. The EPA's publicly available study report can be found on the EPA website. EPA is confident in the results of this newly released method which is specifically targeted to analyze for PFAS in pesticide products formulated with surfactants. PEER raised questions and concerns related to the previously mentioned EPA study results and its conclusions in a letter submitted to the EPA Administrator in March 2024. After much review and consideration, the Agency provided detailed information and responses to all of PEER's questions in a written response in April 2024. PEER subsequently submitted RFC #24001, and after reconsideration EPA concludes that the issues raised are largely the same as comments and questions previously submitted by PEER, and were appropriately addressed.

While the EPA adequately addressed PEER's questions and concerns, the Agency is providing further response on two issues: (1) the spike of the products by Dr. Lasee prior to sending the samples to the ACB lab; and (2) identification of possible PFAS peaks near the background level (these issues were previously raised in the letter of 3/4/2024).

(1) It is common analytical practice to document and verify the recovery of the spiking levels and compounds to ensure that both are valid and acceptable for the intended purpose. To date, Dr. Lasee

⁴ https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.

⁵ https://www.epa.gov/pesticides/pfas-packaging.

⁶ https://www.epa.gov/system/files/documents/2023-05/BEAD%20PFAS%20Study%20Results%20203.pdf.

⁷ https://www.epa.gov/system/files/documents/2024-08/demand-for-retraction-and-apology.pdf.

⁸ https://www.epa.gov/system/files/documents/2024-05/5-28-24-epa-response-to-peer_4-22-24.pdf.

has not provided EPA with the level(s) of PFOS he asserts to have spiked in his samples before sending them to EPA, nor any results pertaining to sample spiking recovery from his laboratory. Without proper documentation and verification of the spiking levels in the samples, it is not possible to determine if or how much PFOS was added to the samples and whether the spiking level was adequate. For example, if samples were spiked below 0.1 ppm, this would have been a level much less than 0.5 ppm, which is the lowest limit of quantitation of our validated dilution method. EPA performed a dilution method following the same approach as Lasee *et al.* 2022 published method.⁹ The re-analyses of these samples were done using the Agency developed method for PFAS, which has an estimated detection limit of 0.2 ppb (0.0002 ppm)) but did not detect any PFAS (including PFOS). It is also worth noting that, in our study, the Agency spiked samples with all target PFAS analytes around the limits of quantitation of the two tested methods (1 ppm and 2 ppb, respectively). The recoveries of all spiked analytes were greater than our SOP's stated acceptable level of 40%, with PFOS recovered at greater than 90%. Therefore, if samples had been spiked at 2 ppb or higher with PFOS, it would have been detected.¹⁰

(2) As described in EPA's April 2024 response, the method used by the Agency for the analysis of PFAS in pesticide formulations containing non-ionic surfactants and oil is based on a QuEChERS (Quick, Easy, Cheap, Effective, Rugged and Safe) extraction approach, followed by Solid Phase Extraction (SPE) cleanup to remove excess oily substances, and analysis using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS). This method is intended for use by analysts skilled in the performance of solid phase extractions, the operation of LC-MS/MS instrumentation, and the interpretation of the associated data - including distinguishing chromatographic noise and background signals from those of target PFAS compounds in samples of pesticide products as it is often difficult to distinguish PFAS signals from those of the matrix and background noise, at trace levels. Laboratory contamination and artifacts of PFAS introduced during sample preparation, particularly in complex sample matrices, are widespread and further complicate the identification and separation of PFAS in samples from the background. Furthermore, for complex matrices, such as pesticide products, presence of a signal at or around the retention times of a target analyte does not constitute presence of that analyte in the sample. Confirmation criteria such as ratios of monitored ions, and/or confirmation by different analytical techniques are often needed for positive identification at trace levels. Using their expertise in pesticide residue analysis, EPA scientists carefully examined those criteria (and did not merely rely on the instrument printouts) and the levels of background contamination to determine and confirm presence of PFAS in the samples (as described in the 5/18/23 study report). Again, EPA is confident with the validity of our test results and conclusions. The criteria and rationale for EPA's identification of PFAS near the background were fully documented in Agency SOPs, laboratory notebooks, and checklists, which were provided to PEER in response to its FOIA request.

The EPA's Analytical Chemistry Branch laboratory is an ISO-17025 accredited laboratory and conducts the studies and sample analyses, such as the analysis of Dr. Lasee's samples, following our established standard operating procedures (SOP) and quality assurance guidelines. These procedures and guidelines are approved by A2LA (American Association for Laboratory Accreditation), the accreditation body for ISO-17025. The quality control data and measurements generated during the

⁹ Steven Lasee, Kaylin McDermett, Naveen Kumar, Jennifer Guelfo, Paxton Payton, Zhao Yang, Todd A. Anderson, Targeted Analysis and Total Oxidizable Precursor assay of several insecticides for PFAS - ScienceDirect. Journal of Hazardous Materials Letters, Volume 3, November 2022,100067. https://www.sciencedirect.com/science/article/pii/s266691102200020X?ssrnid=4144035&dqcid=SSRN redirect SD.

¹⁰ https://foiapublicaccessportal.epa.gov/app/ReadingRoom.aspx.

analysis for PFAS in Dr. Lasee's samples, were fully documented and provided to PEER in response to PEER's FOIA requests.

The EPA has concluded that the issues raised in this RFC have been appropriately addressed as discussed above and in the previous responses which can be found on our website.¹¹ The EPA has also determined that this IQG request overlaps with previous FOIA public process and letter to the Administrator⁵ to which EPA fully responded.⁶ Responsive FOIA documents are accessible to the public by visiting the EPA FOIA Reading Room¹² and searching for FOIA case numbers: 2023-OCSPP-04811, 2023-OCSPP-06302, and 2024-EPA-03080.

The EPA has also determined that the data generated in the cited lab report was not part of rulemaking activity or support for a rulemaking activity and are not an "influential product" as asserted by the requestor for the purposes of external peer review. In addition, upon review of the quality assurance procedures for data generation and analysis "no egregious errors" were found for this accredited laboratory. The EPA has determined this RFC to be duplicative with PEER's previous letter and FOIA requests to which EPA has fully and appropriately responded.

In conclusion, for the reasons explained in this letter, the EPA is denying your RFC.

Thank you for your interest in the EPA's information quality efforts and involvement in considerations of environmental measurement methods for PFAS substances. Challenges remain in the ever-evolving field of PFAS analytical detection methods, and EPA encourages the continued scientific efforts of independent researchers and constructive scientific discussions. Should you have questions or need additional information about the EPA's IQG process, you may contact us via email to *quality@epa.gov* (our preferred method), or via regular mail to the EPA Enterprise Quality Management Division, Mail Code 2821T, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.



cc: Vaughn Noga, Chief Information Officer, and Deputy Assistant Administrator for Information
Technology/Information Management
Katherine Chalfant, Director of Enterprise Quality Management Division, Office of Mission Support

¹¹ https://www.epa.gov/pesticides/pfas-packaging.

¹² https://foiapublicaccessportal.epa.gov/app/ReadingRoom.aspx.