PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY
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December 30, 2024

Information Quality Guidelines Staff
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U.S. Environmental Protection Agency
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Washington, DC, 20460

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RE: Request for Reconsideration of Information Quality Act Decision

To Whom It May Concern:

On May 28, 2024, Public Employees for Environmental Responsibility (PEER) submitted a Demand for Correction under the Information Quality Act (IQA) of 2000 [Section 515 of the Fiscal Year 2001 Treasury and General Government Appropriations Act, Pub. L. No. 106-554],[1] the Office of Management and Budget (OMB) Guidelines for Ensuring and Maximizing the Quality, Utility, and Integrity of Information disseminated by Federal Agencies (hereinafter "OMB Guidelines")[2], and the Environmental Protection Agency's (EPA) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (hereinafter "EPA Guidelines").[3] PEER is submitting this Demand both on its own behalf but also on behalf of our client, Dr. Steven Lasee.

In a letter dated September 24, 2024, from EPA Assistant Administrator for Chemical Safety and Pollution Prevention Michal Freedhoff (hereinafter "AA Freedhoff") denied our Request for Correction on behalf of EPA (see attachment).

Through this letter we request that EPA reconsider its decision to deny our request for correction under the Information Quality Act and we hereby repeat our demand for correction. Specifically, this request contends that the EPA denial:

1. Failed to Address the Substance of the Complaint
2. Ignored the Identified Violations of Procedures for Maximizing Information Quality
3. Improperly Failed to Apply the Standard of Review for Influential Information

[1] Treasury and General Government Appropriations Act, Pub. L. No. 106-554, §515 (Fiscal Year 2001).
[2] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002).
[3] U.S. ENVIRONMENTAL PROTECTION AGENCY, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY, available at http://epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf [hereinafter *EPA Guidelines*].

4. Did Not Address Threat to Public Health Caused by EPA's Violations

Before turning to each of these contentions, we note that EPA did not dispute that: i) the material challenged was subject to the Information Quality Act guidelines, including the May 23, 2023 press release; ii) the challenged material was publicly distributed by EPA; and iii) we have standing to challenge the material and demand its correction.

Turning to our basis for this request for reconsideration, the EPA denial:

1. Failed to Address the Substance of the Complaint

Our demand for correction specified seven significant departures from accepted scientific practices scientific departures. AA Freedhoff's response addressed only two of the seven 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.

Her response on these two issues was inadequate because:

1) AA Freedhoff did not address that the EPA did, in fact, find PFOS in the exact samples Dr. Lasee spiked, but levels the EPA found were much lower than the concentration at which they were spiked. This indicates that EPA's extraction method performed poorly. Specifically, samples 1 and 2 were spiked at 1 part per billion (ppb), samples 3 and 4 at 5 ppb, and 5 and 6 at 10 ppb. Dr. Lasee told the EPA he spiked the samples at levels below 100 ppb on an email send to Dr. Qian dated February 24, 2023. Dr. Lasee never told the EPA the exact levels at which he spiked the products due to the fact that EPA was no longer communicating with him after he pointed out that their extraction method was performing poorly because it did not detect the spikes. Dr. Lasee intended to tell the EPA the exact spike levels after they showed him results that assured him the quality of their method; however, the EPA never did this.

2) AA Freedhoff dismissed the rampant PFAS contamination in their samples as chromatographic noise, background signal, and trace contamination. Given that this "contamination" (see original complain in Attachment 1 for an itemized list) was abundant in both the samples sent to the EPA and the samples they independently obtained, in concentrations above their lowest calibration curve points, and frequently in concentrations *orders of magnitude* higher than their procedure blanks, this contamination cannot simply be dismissed, and the EPA cannot assert that the samples were free of PFAS. Additionally, AA Freedhoff's assertion that the EPA followed their own Standard Operating Procedure (SOP) is indefensible. Referencing "SOP No. ACB-004 R 3.1 PROJECT B23-05c – PFAS in Pesticide Products-Method Validation and Sample Analysis" the EPA stated: "Pesticide sample analysis shows that all the detected peaks in some samples are near the background levels as in blanks and control blanks (generally < 2X of that in blanks). Therefore, all the peaks detected are all false positives and will not be reported." Given this statement, all PFAS concentrations found to be *above* 2 times the concentration found in blanks should ***not*** be dismissed, according to the EPA's own SOP. PFAS concentrations significantly higher than < 2X were found in both the pesticide sample Dr. Lasee sent to the EPA and the products they purchased for 4:2 FTS, 6:2 FTS, 8:2 FTS, N-EtFOSAA, PFUdA, PFDA, PFOS, PFOA, and FOSAA.

It is also of note that in "SOP No. ACB-004 R 3.1 PROJECT B23-05c – PFAS in Pesticide Products-Method Validation and Sample Analysis" the lack of peer review of the

results (Note N4 in the document) was mentioned and not addressed. At the end of the document, Dr. Yaorong Qian, who was primary scientist involved in the project, was listed as the peer reviewer. Taken from the "Memorandum on Peer Review and Peer Involvement at EPA" dated January 31, 2006, "Peer review, a process based on the principles of obtaining the best technical and scientific expertise with appropriate independence, is central to sound science and helps the Agency meet these important criteria. Peer review occurs when scientifically and technically based work products are evaluated by relevant ***experts who were not involved in creating the product***" (emphasis added). Given that Dr. Qian was intimately involved the product, he is not capable of serving as a peer reviewer.

In addition, AA Freedhoff's response did not address the following five deficiencies identified in our demand for correction:

1) EPA falsely stated in their memo that "[n]one of the 29 PFAS compounds…was detected in any of the samples above the instrument's background levels." This is patently untrue. EPA's Sciex 6500+ LC/MSMS test found evidence of 14 PFAS, including PFOS, in the pesticides.

2) EPA deliberately omitted from its report that Dr. Lasee's method blank contained no PFAS, as it voided their argument that he had background contamination. Aliquots sent by Dr. Lasee were about 1 mL in volume, meaning EPA would not have been able to complete the extractions they claimed to have done.

3) The memo states that the Analytical Chemistry Branch's (ACB's) method "involves a more intense extraction and clean up procedure to isolate PFAS compounds from the sample matrix before instrumental analysis, thus reducing matrix interference which results in better/more accurate detection limits." Yet, EPA did not report that ACB's methods had substantial contamination. The results from the Sciex 6500+ LC/MSMS instrument, the instrument the EPA used to quantify their new method, showed background contamination for most PFAS analyzed.

4) EPA cited a table with all the product names, claiming it was from Dr. Lasee's paper. It was not, and in fact, Dr. Lasee had told EPA representative in a conversation that the names of the products could not be released, and EPA had assured him (through email and their representative's word) they would not release this information without Dr. Lasee's explicit permission.

5) Dr. Lasee used mass labeled internal standards for quantification as documented in his publication, but the memo implied that he did not.

The failure by AA Freedhoff to address these specific issues suggest that they are not in dispute. These departures from accepted scientific practices should result in EPA withdrawing this material from the public domain.

2. Ignored the Identified Violations of Procedures for Maximizing Information Quality

Our demand for correction pointed out that EPA violated its own Information Quality Act Guidelines for an "Agency-wide Quality System" to "ensure that EPA organizations maximize the quality of environmental information."[4] Specifically, EPA engaged in no external peer review. It circumvented all of the steps in the agency's "Action Development Process." It conducted no pre-dissemination review. Finally, it did not employ any integrated error correction process.

AA Freedhoff did not address any of these issues in her response. These steps are the ones EPA itself identifies as important for ensuring quality of scientific information it disseminates. The fact that EPA did not follow its own recommended guidelines suggest a lapse in due diligence.

3. Improperly Failed to Apply the Standard of Review for Influential Information

The EPA Information Quality Guidelines state that, "Disseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity." In this instance, the challenged material must be held to higher than a 'basic" standard of scientific integrity.

Our demand for correction pointed out that the challenged material is influential scientific information as defined by EPA guidelines. The EPA considers information to be "influential" when the "dissemination of the information will have or does have a clear and substantial impact … on important public policies or private sector decisions." The EPA Guidelines list documents such as studies, and guidance in support of "top Agency actions" as influential. According to the EPA, "top Agency actions usually have potentially great or widespread impacts on the private sector, the public or state, local or tribal governments" and "have the potential to result in major cross-Agency or cross-media policies."

As influential material, the EPA Guidelines specify that it subject to a higher degree of quality" as well as a "higher degree of transparency about data and methods." This higher level of scientific scrutiny would dictate that any significant departure from accepted or recommended practice should result in the correction or removal of the materials as failing to meet the EPA Guidelines.

In response, AA Freedhoff's letter, without explanation stated:

> "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."

As noted above, scientific material need not be a part of formal rulemaking to be considered influential. The test is the *importance* of the information. In this instance, EPA believed that it was important enough to merit a nationwide press release and widespread distribution to state regulatory agencies.

[4] *Supra* at 4.1

Further, under EPA's Information Quality Guidelines the influential classification is supposed to trigger a higher level of scrunty and transparency. AA Freedhoff's cursory conclusion that this material was not influential can be read as a tacit admission that the challenged material does not attain this higher level of quality assurance.

4. Did Not Address Threat to Public Health Caused by EPA's Violations

AA Freedhoff's response also did not address the public health implications flowing from this material. In this instance, the public health implications are profound. Specifically:

- Increased PFAS exposure to Americans through the consumption of PFAS contaminated food;
- Since immunotoxicity is potentially the most potent adverse effect to humans from exposure to certain PFAS, human immune response can be compromised, making Americans more susceptible to illness and pandemics;
- Permanent PFAS contamination of agricultural fields and their associated drainage water bodies (i.e., water contamination, including drinking water);
- Drastic increase in PFAS exposure potential for agricultural workers;
- Potential long-term health risks to humans and wildlife from repeated applications of persistent PFAS into the environment;
- An increase of total organic fluorine load in the environment and biota; and
- Costs of these health impacts and mitigation of PFAS contamination (i.e., water filtration, contaminated agricultural land, etc.).

Conclusion

Per the EPA Information Quality Guidelines, this appeal contains all the requisite elements of our identity, address, contact information, prior correspondence, as well as specific reasons that justify this appeal. For that reason, we repeat our demand for correction that EPA take the following steps:

1) Publicly rescind the May 18, 2023, research memo and retract the May 18, 2023 press release.

2) Issue a public statement, posted on official websites and accompanied by an EPA press release, that the research memo has been withdrawn from publication due to violations of the Information Quality Act; and

3) Issue an apology to the Journal study's authors, posted prominently on EPA's website, and distributed to every state pesticide control agency.

We look forward to the EPA timely decision on this appeal.

Sincerely,

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December 30, 2024

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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,[1] 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).[2] 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*).[5] 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.[6] 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[7] 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.[8] 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%202023.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&dgcid=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 Administrator[5] to which EPA fully responded.[6] Responsive FOIA documents are accessible to the public by visiting the EPA FOIA Reading Room[12] 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.

Sincerely,

Michal Freedhoff

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*.