

May 28, 2024

Information Quality Guidelines Staff (Mail Code 28221T) U.S. Environmental Protection Agency (EPA) 1200 Pennsylvania Ave., NW Washington, DC 20460 E-mail at <u>quality@epa.gov</u>

Re: Demand for Correction 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

To Whom It May Concern:

Public Employees for Environmental Responsibility (PEER) hereby submits this 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.

For reasons detailed below, we demand the retraction of a research memo entitled "Verification Analysis for PFAS in Pesticide Products (ACB Project B23-05b)" dated May 18, 2023⁴ and the accompanying press release dated May 23, 2023.⁵

I. Challenged Material Is Subject to Information Quality Act

Factual Background: Dr. Lasee was a "participant" at the Great Lakes Toxicology and Ecology Division Laboratory (GLTED) lab from February 1, 2021 to February 1, 2023 as an Oak Ridge Institute for Science and Education (ORISE) "research fellow." In November of

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 <u>https://www.epa.gov/system/files/documents/2023-05/BEAD%20PFAS%20Study%20Results%202023.pdf</u>

⁵ EPA Completes Scientific Testing of Pesticide Products for PFAS | US EPA

2022, Dr. Lasee and other scientists published a study⁶ about the discovery of large amounts of PFOS (3.92 - 19.2 parts per million) in 6 out of 10 pesticides he studied. The work associated with is publication was done prior to Dr. Lasee's fellowship at GLTED, was not the subject of his fellowship, and did not involve any EPA employees.

On November 4, 2022, Dr. Yaorong Qian of EPA's Analytical Chemistry Branch (ACB) emailed Dr. Lasee, asking him if he could send "an aliquot of the pesticide products you tested and found PFAS." Dr. Qian also stated, "Any information you provided will remain confidential." Dr. Lasee made it clear in conversations with Dr. Qian that the manufacturers and brands of pesticides he tested should not be revealed due to safety concerns and the products tested were not new. Dr. Qian assured Dr. Lasee that this information would "not be revealed to outside parties without your explicit permission." Dr. Lasee sent the requested pesticides on or about January 17, 2023 and the EPA received the samples on January 19, 2023.

Prior to sending the pesticide samples to Dr. Qian, Dr. Lasee spiked the samples with a small, known concentration of PFOS, a standard practice (commonly referred to as a "Matrix Spike") that ensures the tests are working. Dr. Lasee did not originally tell Dr. Qian or anyone else at EPA that he had spiked the samples. According to the American Society for Testing and Materials (ASTM), "Matrix spiking is commonly used to determine the bias under specific analytical conditions..."⁷ Specifically, samples are spiked with a known concentration to gauge the quality of a lab's extraction and analytical technique (i.e., if you spike something with 100 and they come back and say they found 80, you know the method was 80% effective).

In this case, Dr. Lasee did not know the existing concentrations of PFAS in the samples he sent to EPA, so he chose to do a low spike to avoid damaging their instrument.

EPA ran initial tests on the pesticides for PFAS and told Dr. Lasee on February 10th that they did not find any PFAS. On February 23, 2023, Dr. Lasee informed Dr. Qian that he had spiked the samples, and since EPA did not find the PFAS from the spikes, they should run the tests again. On March 16, 2023, EPA used its newly developed method for finding PFAS in oily matrices – like pesticides - with their Sciex 6500+ on the pesticide samples. Dr. Lasee did not share the concentration of the spikes with the EPA, as the expectation is that they would tell him what the concentrations were (or at least give him a number above zero).

On May 18, 2023, EPA wrote a memo regarding their tests,⁸ and on May 30, 2023, they issued the memo with an accompanying press release.⁹ The press release stated:

"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 is confident in the results of this newly released method, which is specifically targeted to detect the presence of PFAS in pesticide products formulated with surfactants."

⁶ Targeted analysis and Total Oxidizable Precursor assay of several insecticides for PFAS - ScienceDirect

⁷ <u>D5810 Standard Guide for Spiking into Aqueous Samples (astm.org).</u> In addition, it is a quality control technique which EPA also employs.

⁸ See fn 4.

⁹ See fn 5.

Neither the memo nor the press release mentioned that the samples provided by Dr. Lasee had been spiked or that the EPA was unable to detect the spike. Moreover, EPA released all the names of the products, in violation of the agreement they had made with Dr. Lasee.

A. Challenged Material Is "Information" Subject to the IQA

By its terms, EPA's Information Quality Act Guidelines apply to "information" which "generally includes any communication or representation of knowledge such as facts or data, in any medium or form... to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position."¹⁰

The challenged material unquestionably constitutes "information" for purposes of the IPA. As stated in EPA's accompanying press release, the purpose of the material was to represent an EPA viewpoint or position, in this case in the form of "scientific research to fill gaps in understanding of PFAS, to identify which PFAS may pose human health and ecological risks at which exposure levels and develop methods to better test and measure them."¹¹

B. Challenged Information Was Publicly Disseminated by EPA

EPA Guidelines also specify that "EPA initiates a distribution of information... if EPA indicates in its distribution that the information supports or represents EPA's viewpoint...or other Agency decision or position.¹²

In this instance, EPA issued the May 23rd press release to announce its findings, analysis, and posture with respect to the presence of PFAS in pesticides.¹³ In addition, EPA also distributed the memo and press release to state pesticide regulators across the county.¹⁴

C. Parties Have Standing to Challenge the Information

The EPA Guidelines state that any "affected individual" (a term defined broadly) may challenge information disseminated by an agency by filing a demand for correction.¹⁵

Dr Steven Lasee is an affected individual as the lead author of the peer-reviewed study critiqued in the challenged EPA research memo. Dr. Lasee was not consulted before EPA issued a press release announcing its research memo nor was he offered an opportunity to respond to the memo's contents.

¹⁴ See, for example, https://acrobat.adobe.com/id/urn:aaid:sc:US:fb5f6b84-7182-42ff-a19d-d0fa6ab329e9

¹⁰ EPA Guidelines 5.2

¹¹ See fn 5.

¹² EPA GUIDELINES 5.3.

¹³ EPA's May 23, 2023 press release garnered much media attention as well as attention in the environmental regulatory community. It has also confused the press and the public alike. For example, E&E News published an article claiming that EPA had found there were no PFAS in pesticides, conflating this issue with the leaching of PFAS from fluorinated containers into pesticides.

¹⁵ EPA GUIDELINES A3.7, 8.2.

PEER, a nonprofit organization chartered in the District of Columbia with members throughout the country, is an affected individual for multiple reasons:

a) PEER discovered the presence of PFAS in Anvil 10+10, the pesticide used in the aerial spraying programs of Massachusetts, Florida, New York and an estimated 25 other states, finding that were later corroborated by EPA.¹⁶

b) For more than 30 years, PEER has been a leading advocate for scientific integrity within EPA.¹⁷ Our mission is to hold government agencies accountable for enforcing environmental laws, maintaining scientific integrity, and upholding professional ethics. The subject matter of this complaint represents a significant breach of EPA scientific integrity which directly affects our work in this field.

c) PEER supporters, staff, and board members are at risk for ingestion of PFAS contaminated foodstuffs due to the presence of PFAS in commercial pesticides.

D. Press Release Is Also Covered

The EPA Guidelines do not typically apply to "information of an ephemeral nature, such as press releases..."¹⁸ However, in this instance the EPA press release went beyond the mere announcement of the availability of the challenged research memo. The press release recounted other steps the agency was taking on the issue and touted its "ongoing efforts to better understand and manage, when necessary, pesticide formulations that contain PFAS to ensure enduring and protective solutions."¹⁹ In addition to announcing the release of the research memo, this press release was a document used in support of an agency position." As such, it is also covered by the EPA Guidelines.

II. Challenged Material Is Categorized as "Influential" and Thus Subject to Most Rigorous Scientific Standards

The EPA Information Quality Guidelines state that "Disseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity."²⁰ In this instance, the challenged material must be held to higher than a 'basic" standard of scientific integrity.

The challenged research memo 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."²¹ 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,

¹⁶ See <u>https://peer.org/epa-confirms-pfas-in-aerial-pesticides/</u>

¹⁷ See <u>https://peer.org/epa-fears-empowering-own-scientists/</u>

¹⁸ EPA GUIDELINES 5.4.

¹⁹ *Supra* at 5.5.

²⁰ Supra at 3.

²¹ *Supra* at 6.2.

local or tribal governments" and "have the potential to result in major cross-Agency or cross-media policies." $^{\rm 22}$

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."²³ 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.

III. Egregious EPA Misconduct Demonstrates Significant Departures from accepted scientific practices

In this instance, EPA is guilty of numerous departures from both accepted scientific and ethical practices.

Following the issuance of EPA's May 23, 2023 press release, PEER submitted a FOIA request on Dr. Lasee's behalf for EPA's test results. Although the challenged research memo discussed two tests run on the pesticides, the FOIA yielded results from four tests. Surprisingly, the third test (Sciex 6500+ LC/MSMS), which the EPA stated were representative of the quantification of their newly developed method, found PFAS in the pesticides they tested.

By all appearances, EPA engaged in a pattern of conduct that provided misinformation to a national audience and intentionally damaged Dr. Lasee, by doing the following:

1) EPA 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) In the EPA's quality assurance documentation, they 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."

This is a false statement by the EPA's own data. 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.

3) 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. EPA concluded in its memo that:

²² *Supra* at 6.2.

²³ *Supra* at 6.3.

"Furthermore, since low amounts of PFAS are readily observed in the environment, incorrectly interpreted background data could be multiplied by a large dilution factor (if dilution was used as sample preparation), resulting in reporting of an overexaggerated concentration of a background PFAS or a false-positive identification. These large dilution factors utilized by Lasee et al. could have contributed to the high results obtained in that study."

Had EPA reported Dr. Lasee's method blank instead of removing it, it would have showed that Dr. Lasee did not have background contamination. Removing the method blank from the data they presented is a serious scientific integrity violation.

4) 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.

5) The memo states that 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" – in other words, that ACB's methods were better than Dr. Lasee's. What EPA did not report is that their 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.

6) 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 they would not release this information without Dr. Lasee's explicit permission. Dr. Lasee never gave them that permission.

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

In short, EPA's ACB coerced Dr. Lasee into cooperation with the promise of anonymity of the products he tested, only to betray this trust, publicly, in their memo; deliberately removed data from Dr. Lasee's work when they wrote their memo; failed to reveal that Dr. Lasee spiked the samples with PFOS (given that their tests did not find the spiked PFOS concentrations, this indicates that these tests were not sensitive or accurate); and purposefully lied about their results, which did not corroborate Dr. Lasee's exact findings, but did confirm his conclusion that there are PFAS in pesticides.

These actions fly in the face of EPA's own Information Quality Act guidelines which purport to "to ensure and maximize the quality, including objectivity, utility and integrity, of disseminated information" by the agency.²⁴ They also arguably constitute false official statements within the meaning of 18 U.S.C.§ 1001, a felony.

²⁴ EPA GUIDELINES 5.1.

IV. Challenged Materials Violated Procedures for Maximizing Information Quality

EPA Information Quality Act Guidelines lay out an "Agency-wide Quality System" that is designed to "ensure that EPA organizations maximize the quality of environmental information."²⁵ That System includes steps the agency should take before disseminating scientific or technical information, especially influential information.

In this instance, EPA took none of the quality ensuring steps.

A. No External Peer Review

The Guideline invoke "EPA's Peer Review Policy" which "provides that major scientifically and technically based work products... should be peer-reviewed...or those work products that are intended to support the most important decisions or that have special importance in their own right, <u>external peer review is the procedure of choice</u>"²⁶ (emphasis added).

In this instance, there was no external peer review before EPA issued a press release based solely upon an internal review announcing what it claimed were important new results.

B. Black Box Development Circumventing "Action Development Process"

The EPA Guidelines also strongly encourage periodic circulation of information product development within the agency "at key decision milestones to facilitate the consideration of a broad range of regulatory and non-regulatory options and analytic approaches... before the release of substantive information..."²⁷

In this instance, there was no discernible attempt to seek out different internal viewpoints. Instead, the research memo was apparently developed by one unit of the agency in an opaque "black box" process that invited no critical review.

C. No Pre-Dissemination Review

The Guidelines direct each "EPA Program Office" to "incorporate the information quality principles "into their existing pre-dissemination review procedures" in order "to facilitate implementation of consistent cross-Agency pre-dissemination reviews by establishing a model of minimum review standards based on existing policies …that may occur at many steps in development of information, not only at the point immediately prior to the dissemination of the information."²⁸

Needless to elaborate, but EPA seemingly completely bypassed any of the recommended pre-dissemination review steps prior to rushing to publication and web-posting a research memo dated May 18th less than a week later on May 23rd.

²⁵ *Supra* at 4.1

²⁶ *Supra* at 4.2.

²⁷ *Supra* at 4.3.

²⁸ Supra at 7.1.

D. No Integrated Error Correction Process

The Guidelines also advocate utilization of an "Integrated Error Correction Process" by which "members of the public can notify EPA of a potential data error in information EPA distributes or disseminates." The idea is that "EPA reviews the error notification and assists in bringing the notification to resolution with those who are responsible for the data within or outside the Agency, as appropriate."²⁹

In this instance, the Error Correction Process could clearly have been aided by contacting Dr. Lasee to allow him to review the research memo and associated data which reviewed his work prior to publication. That obviously was not done.

Further, in a March 4, 2024 letter from PEER to EPA Administrator Michael Regan, the agency was put on notice of the need to correct the error.³⁰ EPA's response was a memo dated April 22, 2024 authored by Anne Overstreet, Director of EPA's Biological and Economic Analysis Division [ATTACHMENT I].³¹ This memo, however, is replete with factual and analytic inaccuracies detailed in ATTACHMENT II.

Thus, the only effort to identify errors in which EPA engaged was to ask the very officials involved in committing these errors to defend themselves.

V. EPA's Results Are Not Being Reproduced by Independent Researchers

In addition, PEER will be submitting a new peer-reviewed article that has been accepted (but not yet published) detailing the vast number of pesticides with PFAS, either from active ingredients, inert ingredients, contamination from fluorinated containers, or unknown sources. Moreover, PEER understands that other scientists have been finding issues with EPA's new oily matrix method of detecting PFAS in pesticides, and potential publications may be following. While the PFOS concentrations found by Dr. Lasee have not been replicated, numerous scientists have been finding PFAS in pesticides. This new research indicates that EPA's work falls well below the high standards imposed on influential information.

VI. Demand for Prompt Correction to Minimize Public Health Threat

These challenged materials relate to a matter of serious public health concern. The presence of PFAS in pesticides points to an appalling regulatory breakdown by EPA. The work of Dr. Lasee and other scientists demonstrate that PFAS is found in many pesticides, and it flies in the fact of EPA's statement that they did not detect any PFAS in the pesticides tested. Moreover, if EPA's new method for detecting PFAS in oily matrices like pesticides is not sensitive or accurate enough to detect those PFAS, it can lead to critical human health threats.

²⁹ *Supra* at 4.4.

³⁰ See March 4, 2023 "Demand for Retraction and Apology" letter from PEER Executive Director Tim Whitehouse to EPA Administrator Michael Regan.

³¹ Based upon records obtained under the Freedom of Information Act, Ms. Overstreet was a principal official involved in this attempt to attack the quality of Dr. Lasee's published research.

The presence of PFAS in pesticides does not spring solely from contaminated barrels (yet another major EPA regulatory and enforcement failure) but from the ingredients of the pesticides themselves, possibly added as dispersants to aid in the even spreading of the agents on plant surfaces. If the source of the PFAS observed was container contamination, the primary PFAS constituent would be PFPeA, as per the EPA container contamination report. This was not observed in any of the results the EPA obtained.

Rather than using this research as the basis for immediate protective action, EPA has deceptively tried to discredit these findings and falsely portray itself as an effective regulatory agency. At the very least, EPA should acknowledge that it has spread the dangerously false message that, in the self-congratulatory words of its May 2023 press release, the agency has taken effective steps to "proactively stop PFAS chemicals from entering the environment."

As outlined above, the challenged material should also be retracted because they violate EPA Guidelines for Information Quality. Accordingly, Dr. Lasee and PEER ask that the EPA take the following steps to comply with the Information Quality Act:

- 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 receiving your response at the contact information heading this stationery within 90 days, as specified within the EPA Information Quality Guidelines,³² if not sooner, given the adverse public health consequences stemming from EPA's misconduct.

Thank in advance for your prompt attention to this complaint.

Sincerely,

Steven Lasee, MS, PhD Environmental Toxicologist LaseeConsulting.com

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³² EPA GUIDELINES A55.