February 25, 2021

U.S. Environmental Protection Agency
Office of Inspector General Sean W. O'Donnell
1200 Pennsylvania Avenue, N.W. (2410T)
Washington, DC 20460

RE: Request for Review of Fraud by the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) for Misrepresenting/Omitting Facts in a Risk Assessment of 1,3-Dichloropropene (Telone), a Soil Fumigant and Nematicide

Dear Inspector General O'Donnell:

I am writing on behalf of Public Employees for Environmental Responsibility (PEER) to request that your office review alleged false or misleading representations, failure to use the best scientific information in decision-making, and omissions of known facts by senior U.S. Environmental Protection Agency (EPA) officials in the human health risk assessment of 1,3-dichloropropene (1,3-D) - commonly known by the brand name Telone - a soil fumigant and nematicide.[1] Specifically, EPA downgraded its prior cancer classification of 1,3-D from 'likely to be carcinogenic to humans' to 'suggestive evidence of carcinogenic potential.'

Misrepresentations and omissions by EPA officials –

- Resulted in improper exclusion of relevant peer-reviewed science of 1,3-D;
- Resulted in an updated cancer classification that ignored the genotoxicity of 1,3-D; and
- Puts applicators of the fumigant and the public at grave risk, given that 1,3-D is one of the nation's most-used pesticides.

[1] Note that 1,3-D is used in other pesticide formulations, but Telone is a commonly used brand.

EPA's September 26, 2019 cancer review memo was the basis of the Agency's decision to not use a linear low-dose approach for the quantification of cancer risk for the widely used fumigant, 1,3-D. This change in approach allows higher amounts of the chemical in the air, without being considered a risk to human health.

PEER is a valid Complainant. According to the Office of Inspector General website, "Complaints and requests may be submitted by anyone, including … organizations and members of the public."[2] PEER is submitting this complaint as a non-profit organization and member of the public.

PEER's allegations are under the purview of the Inspector General: The Office of the Inspector General (OIG) is charged with investigating "complaints of fraud, waste, abuse and mismanagement in agency programs and operations, and violations of law, regulations and policies by EPA … employees …"[3] While the OIG cannot investigate all complaints presented, it prioritizes issues relating to the "effectiveness of agency programs…[m]ismanagement … of EPA resources…[m]isconduct by EPA …employees, and [m]atters of high public … interest."[4] PEER's allegations involve all of these topics, and more importantly, are resulting in risks to human health and the environment.

PEER's allegations fall under the definition of fraud. The OIG defines fraud as "a false representation about a material fact. It is any intentional deception designed to … secure from the United States, or the EPA, for an individual, a benefit, privilege, allowance or consideration to which he or she is not entitled."[5] In this case, PEER is alleging that senior managers in EPA's Office of Pesticide Programs (OPP) failed to consider studies and information related to the positive genotoxicity of 1,3-D in both its cancer report and human health risk assessment. This resulted in a benefit to the manufacturer of Telone, Dow AgroSciences (hereinafter "Dow") – specifically, the downgrading of the cancer designation of 1,3-D – which in turn generates revenue to Dow to which it should not be entitled.

The OIG states that examples of fraud indicators include "[i]nadequate or missing documentation," "[f]alse or misleading information," "[m]anagement override of key internal controls."[6] PEER believes that all three of these indicators were present in the finalization of the human health risk assessment for 1,3-D. Specific examples are set forth below.

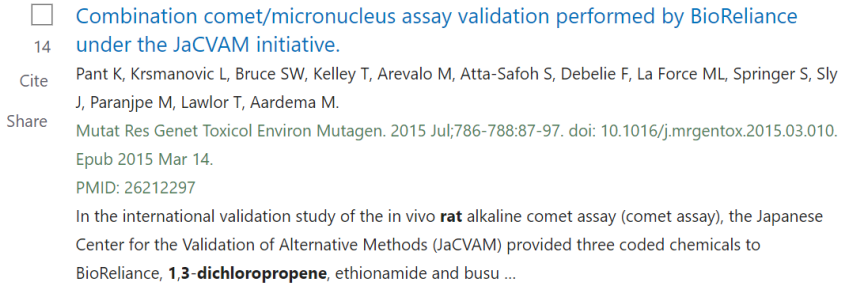
> Inadequate or missing documentation. PEER believes that EPA incorrectly concluded that 1,3-D was *not* genotoxic in the recent Cancer Assessment Review Committee (CARC) report, based on insufficient analysis. In Appendix B of the 2020 Draft Human Health Risk Assessment for 1,3-D, EPA states it used the literature search terms: "((Telone) OR (Telone 1,3-D)) AND (rat OR mouse OR dog OR rabbit OR monkey OR mammal)." Using this approach, EPA only identified eight studies.[7] However, the search

[2] https://www.epa.gov/office-inspector-general/epa-oig-hotline#file_now
[3] Id.
[4] Id.
[5] Id.
[6] https://www.epa.gov/sites/production/files/2016-03/documents/oig_fraud_booklet_3-30-16.pdf
[7] Note that if you run that search today, nine studies appear because one additional study has been added since the publication of the Draft Human Health Risk Assessment.

terms did not include the full name of the pesticide at issue: 1,3-dichloropropene. Using the active ingredient name instead of the trade name, "Telone," 100 relevant articles are produced. While the first seven of these are new since the Risk Assessment was finalized, the other 93 are not.

The expanded search results identified a critical 2015 study that demonstrates the genotoxicity of 1,3-D in a Comet assay (see Figure 1, below). The assay reported that 1,3-D induced DNA damage in liver cells.

Figure 1



Therefore, one of the key studies that was not considered given this incomplete search was a 2015 peer-reviewed study which found that "…1,3-dichloropropene induced DNA damage … in liver cells at all three test article doses."[8] Because of this omission, positive genotoxicity data were not included in the risk assessment of 1,3-D. This flawed literature search resulted in missing documentation in a human health risk assessment.

False or Misleading Information. The Cancer Assessment Review Committee (CARC) report incorrectly concluded that the lung tumors observed in mice following inhalation exposures at the highest treated dose (60 ppm) should be excluded, because they occurred at a dose that exceeded the "kinetically derived maximum tolerated dose." The approach of using a kinetically derived maximum dose has *not* been accepted by the broader scientific community. There also are concerns about using this approach to conclude that "there were no treatment-related tumors in male mice via the inhalation route at concentrations below the kinetically derived maximum dose" given: 1) the positive DNA damage assay; and 2) the lack of data on the mode of action (MOA) for the lung tumors.

Moreover, the decision to not include the National Toxicology Program (NTP) 1,3-D study in the CARC report based on the fact that the formulation contained epichlorohydrin was misleading. While the presence of epichlorohydrin in the formulation could result in confounding effects, EPA had previously concluded that it was possible to consider the tumors that were unique to 1,3-D. It is worth noting that the studies that were considered in the CARC report did not dose the mice to the levels that caused urinary bladder and lung tumors in female mice in the NTP study, tumors that have not been linked to epichlorohydrin.

[8] https://www.sciencedirect.com/science/article/abs/pii/S1383571815000595

Inappropriate statistical modeling. The authors assume a mathematical model with a piecewise form and then use regression analysis to empirically fit the model parameters using the data. They then apply a biological interpretation to the point where the two piecewise functions meet. This is incorrect, and is explained more fully below:

- The mathematical model used is continuous but not differentiable at every point in its domain; this type of behavior is rarely encountered in biological systems and casts doubt on how well this mathematical description represents the underlying biological processes.
- Absorption, distribution, metabolism, and elimination (ADME) processes in particular do not show abrupt transitions, unlike (for example) neuron polarization. Hence, any piecewise description of ADME processes is more for simplicity and convenience than it is an accurate mathematical description of the underlying biological processes.
- While there is a biological basis for proportionality between blood concentration and exposure, there is no biological basis for an abrupt transition into a supra-linear power law relationship at higher levels of exposure.
- Given there is no biological basis for using two-piecewise functions, there can be no biological interpretation for the point at which the piecewise functions meet. Therefore, it may be more appropriate to do a weighted non-linear least-squares regression on the untransformed data rather than an ordinary least-squares regression on the log-transformed data. This would provide a continuous equation to better describe the biological phenomenon.

Management override of key internal controls. PEER urges OIG to investigate whether senior management was aware of the Comet assay, the NTP 1,3-D study, and any other relevant information, before finalizing the CARC report. PEER suspects that senior management were aware of the information, and yet declined to include it, and we urge the OIG to examine any meeting minutes, videos, notes, or other contemporaneous documentation of the CARC meeting to determine why this critical study was not considered.

Composition of the Cancer Assessment Review Committee (CARC): PEER urges the OIG to examine the composition of the CARC for the assessment of 1,3-D in order to ensure that the committee members had the experience necessary to properly address the unique technical challenges posed by this particular pesticide. Moreover, the CARC is clearly not utilizing the best available science, and therefore there is serious doubt that they are fulfilling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food Quality Protection Act (FQPA), the Scientific Integrity Presidential Memorandum of 2009, and the Information Quality Act. The work in OPP is at high risk for harming the public, which makes it all the more critical that the CARC address these issues comprehensively.

Relevant name(s) of all parties involved, including witnesses and other contacts. PEER suggests that the OIG ask OPP for the list of attendees at the May 22, 2019 CARC meeting to discuss the final risk assessment. In particular, OIG should interview people who presented at

this meeting, and get copies of all draft reports and assessments, and any recordings, presentations, or meeting notes, if available.

The OIG should make sure to interview Gregory Akerman, Acting Associate Director of OPP. Dr. Akerman was one of the managers who signed the September 26, 2019 CARC report on 1,3-D.[9] In addition, Anwar Dunbar also signed the CARC report, and should be interviewed.[10] It may also be of interest that Dr. Akerman has been accused of having a conflict of interest with pesticide companies in the past.[11]

Dates and times of the events or issues that you are identifying. The CARC meeting was May 22, 2019, and the CARC report was finalized September 26, 2019. OIG should also look for meetings between EPA staff and Dow regarding 1,3-D, and all documents regarding the cancer classification of 1,3-D.

The location of the issue or the area that it impacts. Telone has been used in the United States since 1954,[12] and is the "the most commonly used fumigant in plasticulture and bare ground production systems in the Southeastern U.S."[13] PEER is unaware of the use of other formulations containing 1,3-D, but the popularity and widespread use of Telone by itself is of concern. Therefore, the incorrect risk assessment conducted on 1,3-D puts millions of people in the southeastern United States at risk.

Any additional pertinent information you have concerning the issue. A collation of eight Attorneys General urged EPA to revise its draft human health risk assessment due to the fact that it "dangerously ignores science and downplays the risks individuals face when they are exposed to 1,3-D."[14] Moreover, the state of California wrote to EPA on and stated that its determination to downgrade 1,3-D from 'likely to be carcinogenic to humans' to 'suggestive evidence of carcinogenic potential' "runs counter to the determination of various regulatory agencies and is unsupported by the agency's exclusive reliance on the 2019 Cancer Assessment Review Committee (CARC) findings."[15] California also stated that, "A consequence of this downgrade is that USEPA's cancer guidelines allow a decision not to estimate plausible cancer risks, leaving the public insufficiently informed about the carcinogenicity of 1,3-D and laying the groundwork for less health-protective regulatory controls."[16]

Conclusion. PEER believes that the downgrading of 1,3-D from its prior cancer classification of 'likely to be carcinogenic to humans' to 'suggestive evidence of carcinogenic potential' was due to fraudulent activity at EPA. Specifically, a flawed literature search resulted in eliminating

[9] https://yosemite.epa.gov/sab/sabproduct.nsf/E035B3D665F05A5685258581003AFC3F/$File/EPA-HQ-OPP-2013-0154-0104.pdf
[10] Id.
[11] https://www.baumhedlundlaw.com/blog/2017/march/epa-official-helped-monsanto-kill-glyphosate-stu/
[12] https://www.farmprogress.com/regulatory/california-dpr-caps-telone-fumigant-use-jan-1
[13] https://extension.uga.edu/publications/detail.html?number=B1502
[14] https://www.law.nyu.edu/centers/state-impact/press-publications/press-releases/telone-draft-risk-assessment
[15] https://peermd.sharepoint.com/:b:/s/all-staff/EYGfYny4-z5KueiboD6ZEQABcBkHRf8tQ6cC9KUDJbAh0w?e=YulgLh
[16] Id.

critical studies from consideration – especially the 2015 Comet assay - together with the use of the kinetically derived maximum dose, which is not widely accepted, the exclusion of the NTP study, and the inappropriate statistical modeling, lead us to believe that fraud occurred. Moreover, since senior management at EPA signed off on the flawed CARC report, we believe management may have overridden key internal controls. Finally, we believe it is worth examining the composition of the CARC for 1,3-D, for its composition may have deliberately included staff unprepared to address the unique technical aspects of 1,3-D.

Thank you for your attention to this matter. Please do not hesitate to contact us if you have any questions.

Sincerely,

Timothy Whitehouse, Executive Director
Public Employees for Environmental Responsibility