



October 17, 2022

Elissa Reaves, Ph.D., Director
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: Comments on the Revised Proposed Interim Decision for 1,3-Dichloropropene for Registration Review; EPA-HQ-OPP-2013-0154.

Dear Dr. Reaves:

Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (EPA's) revised proposed interim decision (PID) for 1,3-Dichloropropene (1,3-D) (aka Telone), posted on August 18, 2022, in the Federal Register. 1,3-D is a soil fumigant registered to control plant-feeding nematodes, wireworms, and symphylans in soils. It is registered for food and feed crops (the main agricultural crop 1,3-D is used on potatoes), and for non-food and nursery crops. EPA downgraded its prior cancer classification of 1,3-D from 'likely to be carcinogenic to humans' to 'suggestive evidence of carcinogenic potential' and is seeking comments on this downgrade, among other things. PEER is opposed to this new cancer classification, for the reasons set forth below.

Background. On February 25, 2021, Public Employees for Environmental Responsibility (PEER) filed an Office of Inspector General (OIG) [complaint](#) on 1,3-D. In this complaint, PEER alleged that EPA improperly downgraded its prior cancer classification of 1,3-D from 'likely to be carcinogenic to humans' to 'suggestive evidence of carcinogenic potential.' Specifically, PEER stated that misrepresentations and omissions by EPA officials:

- Resulted in the 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.

EPA issued a September 26, 2019, cancer review memo that became the basis of the Agency's decision to downgrade 1,3-D's cancer classification.

The OIG Report. On July 20, 2022, the OIG issued a [report](#) that validated virtually all of PEER’s concerns. Specifically, the OIG found that:

- The Office of Pesticide Programs (OPP) had not published guidance on how to use the novel Kinetically Derived Maximum Dose (KMD), nor did it publish guidance on using and applying a weight-of-evidence approach in cancer risk assessments. Despite this lack of guidance, EPA used these approaches to downgrade 1,3-D’s cancer classification.
- The OPP did not comply with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements to place certain information in the public docket when the Agency meets with “individuals that are not government employees” regarding pesticide-registration reviews; specifically, EPA met with the registrant “at least five times” but there were no list of attendees or meeting minutes provided.
- The OPP did not comply with its own literature-search procedures for the 1,3-D cancer-assessment review by not using the proper search terms, which resulted in only eight studies being used, rather than the 100 found by OIG.
- CARC did not have adequate oversight to confirm adherence to the standards for internal peer review.
- CARC used KMD—a novel, precedent-setting, and controversial approach—without an external peer review.

According to the OIG, all of these failures and lack of transparency undermined public confidence in the Agency’s scientific approaches to prevent unreasonable impacts on human health. Despite these findings, EPA disagreed with three of the OIG’s nine recommendations. The recommendations rejected by EPA were:

- A request to issue guidance on when and how to conduct the kinetically derived maximum dose approach in cancer-risk assessments for pesticides;
- A request to issue guidance on using and applying a weight-of-evidence approach in cancer-risk assessments for pesticides; and
- A request to conduct an external peer review on the 1,3-D cancer-risk assessment.

By failing to accept the OIG’s recommendations on issuing guidance on how to conduct, use, and apply these two approaches, the public does not know if these approaches were

applied properly. In addition, failure to have a proper external peer-review on a cancer classification is troubling, especially since these approaches are novel and precedent-setting.

Accepted OIG recommendations have been delayed, and therefore proceeding with the cancer classification downgrade is premature. Although EPA agreed with the OIG’s recommendation to “[c]onduct a comprehensive literature search that identifies all published scientific studies concerning the potential carcinogenicity of 1,3-Dichloropropene, including a methodology to reconcile inconsistencies in the scientific data, and publish the results of the literature search and reconciliations” by March 31, 2023, this proposed interim decision was issued without consideration of a critical study that was initially missed due to the faulty literature search.

Specifically, the correct literature search results identified a critical 2015 study that demonstrates the genotoxicity of 1,3-D in an in vivo Comet assay which reported that 1,3-D induced DNA damage in liver cells. Because of this omission, positive evidence of genotoxicity in vivo was not included in the risk assessment of 1,3-D. In this proposed interim decision, EPA maintains that the classification of “Suggestive Evidence of Carcinogenic Potential” is most appropriate for 1,3-D, and is standing by its cancer classification downgrading. By issuing this proposed interim decision ahead of the publication of a proper literature search, EPA is deliberately ignoring a study that indicates 1,3-D induces DNA damage in vivo. As such, the cancer classification remains flawed.

In addition, PEER believes that 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. Despite this, EPA continues to dismiss studies that included epichlorohydrin, stating:

As noted previously, some of the toxicology studies that were previously used to evaluate the carcinogenic potential of 1,3-D contained epichlorohydrin, a known carcinogen, as a stabilizer. Since the previous cancer classification, additional toxicology studies have been submitted that did not contain epichlorohydrin and were considered adequate for assessing 1,3-D's carcinogenic potential. Those most recent studies did not observe all of the tumor types that were previously observed in the older carcinogenicity studies containing epichlorohydrin. Therefore, these older studies were not discussed in the *1,3-Dichloropropene: Report of the Cancer Assessment Review Committee* and the Agency maintains its decision.



PEER urges EPA to consider the tumors unique to 1,3-D, despite the fact that the formulation in those studies includes epichlorohydrin.

The unresolved OIG recommendations and delayed accepted recommendations go to the heart of 1,3-D's cancer classification. EPA's failures in the cancer classification of 1,3-D are not merely paper violations. Indeed, the flawed literature search and failure to include appropriate studies in the risk analysis led EPA to an incorrect cancer classification. Given the widespread use of 1,3-D, together with its potential to harm human health and the environment, it is incumbent on EPA to remedy the flaws in its cancer classification before developing a proposed interim decision. To do otherwise is nonsensical.

Conclusion. PEER urges EPA to withdraw this proposed interim decision pending completion of the OIG's full recommendations. Thank you for consideration of this matter.

Sincerely,

Timothy Whitehouse, Executive Director
Public Employees for Environmental Responsibility

cc: OIG