Office of Inspector General
U.S. Environmental Protection Agency
At a Glance

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Why We Did This Evaluation

We performed this evaluation to examine the extent to which the U.S. Environmental Protection Agency followed policies and procedures in developing the cancer assessment for the 1,3-Dichloropropene pesticide-registration-review decision to prevent unreasonable adverse effects on human health. We initiated this evaluation based on multiple complaints submitted to the Office of Inspector General Hotline.

The Federal Insecticide, Fungicide, and Rodenticide Act requires the EPA to review every pesticide registration no later than 15 years after the active ingredient's initial registration to determine whether the pesticide continues to meet the statutory standard—that is, whether the pesticide performs its intended function without unreasonable adverse effects on human health and the environment. When registered pesticides are reviewed as part of the 15-year registration review process, the EPA does not typically initiate a new cancer assessment unless requested by the registrant through the Pesticide Registration Improvement Act.

This evaluation supports an EPA mission-related effort:

- *Ensuring the safety of chemicals.*

This evaluation addresses these top EPA management challenges:

- *Ensuring the safe use of chemicals.*
- *Safeguarding scientific integrity.*

Address inquiries to our public affairs office at (202) 566-2391 or OIG_WEBCOMMENTS@epa.gov.

List of OIG reports.

The EPA Needs to Improve the Transparency of Its Cancer-Assessment Process for Pesticides

What We Found

Deficiencies and a lack of transparency in the 1,3-D pesticide cancer-assessment process has undermined scientific credibility and public confidence.

The EPA did not adhere to standard operating procedures and requirements for the 1,3-Dichloropropene, or 1,3-D, pesticide cancer-assessment process, which undermines public confidence in and the transparency of the Agency's scientific approaches to prevent unreasonable impacts on human health. Specifically, the EPA used two scientific approaches, kinetically derived maximum dose and weight-of-evidence, in its cancer-assessment process for 1,3-D, even though it did not have guidance outlining how to use those approaches. The EPA also did not adhere to docketing and transparency requirements to provide the public and stakeholders with information that may have influenced the EPA's cancer-assessment decision. Further, the EPA did not follow its literature-search procedures and neglected to document its review of all health effects data that may have impacted the results of the 1,3-D draft human health risk assessment, which is informed by the cancer assessment. The EPA's Cancer Risk Assessment Committee did not adhere to the EPA's *Peer Review Handbook* and the Office of Management and Budget's guidance on peer review in the areas of composition, independence, and expertise. These deficiencies undermined the scientific credibility of the 1,3-D cancer assessment, which led to questioning by multiple stakeholders. An external peer review would have improved the credibility of the 1,3-D cancer assessment.

Recommendations and Planned Agency Corrective Actions

We make nine recommendations to improve the transparency of the 1,3-D cancer-assessment process and restore the scientific credibility of the Agency's 1,3-D cancer classification. These recommendations address the lack of guidance for the EPA's use of the kinetically derived maximum dose and weight-of-evidence approaches, an incomplete public docket, an incomplete literature search, noncompliance with internal peer review standards, and the need for an external peer review. These recommendations will also improve the EPA's cancer-assessment process for pesticides more broadly.

The EPA was not in full agreement with Recommendations 1, 2, and 8, which remain unresolved. We are in discussions with the EPA on the unresolved recommendations. The EPA generally agreed with Recommendations 3–7 and 9, which are resolved with corrective actions pending.