Gavin Newsom, Governor Yana Garcia, Secretary for Environmental Protection David Edwards, Ph.D., Acting Director

MEMORANDUM

- TO:Carol Perkins
Manager, CalEPA Scientific Peer Review Program
Office of Research, Planning, and Performance
California State Water Resources Control Board
- **FROM:** Kannan Krishnan, Ph.D. Acting Deputy Director for Scientific Programs

Krishnan (Sep 20, 2024 12:24 PDT)

- DATE: September 20, 2024
- **SUBJECT:** Request for External Scientific Peer Review of the Scientific Basis of OEHHA Memorandum: "Update to the Health-Based Recommendations to Mitigate Cancer Risk of Occupational Bystander Exposure to 1,3-Dichloropropene" and its associated documents

Title of Proposal for Review

This request is regarding the Office of Environmental Health Hazard Assessment (OEHHA) memorandum whose subject is "Update to the Health-Based Recommendations to Mitigate Cancer Risk of Occupational Bystander Exposure to 1,3-Dichloropropene," its attachment, and a supplemental document titled "Estimation of Lifetime Exposure for Occupational Bystanders When Regularly Working at the Edge of 1,3-Dichloropropene Treated Fields" that supports the memorandum. These documents were prepared for the Department of Pesticide Regulation (DPR) pursuant to the joint and mutual provisions outlined in Food and Agricultural Code sections 12980 and 12981 to address potential cancer risks to occupational bystanders from the use of the fumigant 1,3-dichloropropene (1,3-D).

OEHHA staff request that you initiate the process to identify external scientific peer reviewers for this document, per the requirements of California Health and Safety Code section 57004.

Purpose of Review

Food and Agricultural Code sections 12980 and 12981 mandate that development of regulations relating to pesticides and worker safety be the joint and mutual responsibility of DPR and OEHHA, and any regulations related to health effects be based on OEHHA's recommendations.



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OEHHA has prepared health-based recommendations for DPR to address potential cancer risks to occupational bystanders from the use of the fumigant 1,3dichloropropene (1,3-D). These recommendations, submitted to DPR as a memorandum with an attachment and a supplemental document containing clarifications, and additions to the attachment, will be the health basis for regulations to mitigate potential cancer risks to occupational bystanders from the use of 1,3-D and require peer review in accordance with Health and Safety Code section 57004.

When References will be Available at the FTP Site

References were uploaded to the FTP site as of September 20, 2024.

Requested Review Period

We request that scientific peer review be accomplished within 30 days.

Necessary Areas of Expertise for Reviewers

We estimate that a total of three reviewers will be adequate to cover the areas of expertise needed to review the conclusions detailed in Attachment 2. We would like all three reviewers to review all parts of the documents, but each expert described below should place more emphasis on the conclusions listed for their expertise. We request selection of reviewers with expertise in the following areas:

<u>Cancer risk assessment</u>. We are looking for expertise in cancer risk assessment to evaluate our estimation of an acceptable air concentration of 1,3-D to reduce the risk to occupational bystanders of developing cancer based on calculations using an OEHHA-derived cancer potency factor. [Conclusion 1]

<u>Occupational bystander exposure to pesticides</u>. We are also looking for someone familiar with farmworker activity practices in California, specifically activities that do not involve fumigant application or handling, such as harvesting, pruning, and weeding, to evaluate our assumptions related to work hours and activity patterns by crop, season, and field fumigation method, underlying the assessment of occupational bystander exposure to 1,3-D. [Conclusions 2 and 3]

<u>Exposure assessment</u>. Expertise is needed in exposure assessment of air toxics, preferably with knowledge of fumigants, to evaluate our estimates of occupational bystanders' exposure to 1,3-D, including assumptions made, methods used, and conclusions about 1,3-D air concentration estimates. [Conclusions 1, 2, and 3]

Contact Information

Dr. Ouahiba Laribi is the project manager: Ouahiba.Laribi@oehha.ca.gov, (510) 622-2070.

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Attachments

Attached please find:

- 1. Attachment 1: Plain English Summary.
- 2. Attachment 2: Scientific Assumptions, Findings, and Conclusions to Review.
- 3. Attachment 3: Individuals who Participated in the Development of the Proposal.
- 4. Attachment 4: References Cited.
- cc: Ouahiba Laribi, Ph.D., Chief Pesticide Exposure Evaluation and Medical Education Section Office of Environmental Health Hazard Assessment

Attachment 1: Plain English Summary

1,3-dichloropropene (1,3-D) (CAS # 542-75-6, molecular formula C₃H₄Cl₂) is one of the most widely used fumigants in California, with over 11 million pounds used in 2021. It is used as a pre-plant control for parasitic nematodes and other soil pests on a wide variety of crops and ornamentals. It was added to California's Proposition 65 list as a carcinogen in 1989. 1,3-D is a toxic air contaminant and a "restricted material" that requires a permit from the county agricultural commissioner prior to its application.

DPR and OEHHA are jointly developing regulations to address potential cancer risks to occupational bystanders from the use of 1,3-D. OEHHA submitted a memorandum to DPR on June 11, 2024, outlining its updated health-based recommendations to mitigate the cancer risk of occupational bystanders (i.e., those working in fields adjacent to fumigated fields and/or those working in an area where 1,3-D is routinely applied), consistent with the joint and mutual provisions outlined in Food and Agricultural Code sections 12980 and 12981.

OEHHA based its recommendations on a cancer risk level of one per one hundred thousand (10⁻⁵) and determined that occupational bystander exposure to an average air concentration of 0.21 parts per billion (ppb) or below over a working lifetime of 40 years would be associated with this acceptable risk level. OEHHA further outlined some mitigation measures that could be applied to achieve the 1,3-D air concentration for acceptable risk. These include changes to application methods, restrictions on proximity of occupational bystanders to fields after 1,3-D application, and controlling application conditions.

Attachment 2 Scientific Assumptions, Findings, and Conclusions to Review

Attachment 2: Scientific Assumptions, Findings, and Conclusions to Review

Reviewers are asked to determine whether the scientific work product is "based upon sound scientific knowledge, methods, and practices."

OEHHA requests that you make this determination for the estimations provided in the memorandum whose subject is Update to the Health-Based Recommendations to Mitigate Cancer Risk of Occupational Bystander Exposure to 1,3-Dichloropropene, and its supporting documents (attachment to the memorandum and the supplement to the attachment, titled "Estimation of Lifetime Exposure for Occupational Bystanders When Regularly Working at the Edge of 1,3-Dichloropropene Treated Fields"). An explanatory statement is provided below for focusing the review.

Assumptions, Findings, and Conclusions

OEHHA performed detailed modeling and analyses to develop health-based recommendations to reduce occupational bystanders' cancer risk when working at the edge, or in the vicinity, of 1,3-D treated fields. OEHHA's health-based recommendations to mitigate the cancer risk of occupational bystander exposure to 1,3-D were developed using a cancer potency value of 0.057 ppm⁻¹ (per 1 part per million), equivalent to an inhalation cancer slope factor of 0.19 (mg/kg-day)⁻¹. The derivation of this cancer slope factor was previously peer-reviewed by California's Carcinogen Identification Committee, which is composed of scientific and health professionals serving as the State's Qualified Experts in determining that a chemical has been clearly shown to cause cancer. OEHHA applied the cancer potency in the process outlined below to develop recommendations to mitigate the cancer risk to occupational bystanders exposed to 1,3-D.

1. Estimation of an acceptable air concentration.

OEHHA estimated that the acceptable air concentration experienced by occupational bystanders over their working lifetime that is associated with a risk of 1 in 100,000 (target risk value) for developing cancer is 0.21 ppb.

The sections of the product that pertain to this conclusion include:

- Scientific Basis (Memo pg. 3)
- Acceptable cancer risk (Memo attachment pg. 1-2)
- Cancer potency factor (Memo attachment pg. 8)
- Average air concentration experienced by occupational bystanders over their working lifetime (Memo attachment pg. 8)
- 2. Estimation of occupational bystanders' exposure from working in close proximity to treated fields without (i.e., at the edge of the field) and with (i.e., at 100 ft buffer zone) mitigation measures.

Attachment 2 Scientific Assumptions, Findings, and Conclusions to Review

For each region (i.e., California coastal and inland regions), OEHHA estimated the average air concentration experienced by occupational bystanders over their working lifetime. DPR provided to OEHHA the modeled 1,3-D air concentrations at the edge of the field without a buffer zone and with a buffer zone of 100 feet from the field for 48 hrs, 5 days, and 7 days using American Meteorological Society/Environmental Protection Agency Regulatory Modeling system (AERMOD)¹. OEHHA used these modeling results and pesticide use data provided by DPR to estimate air concentrations that occupational bystanders may be exposed to at the edge of a treated field over a working lifetime of 40 years using various scenarios that account for different field fumigation methods, seasons, and regions.

Considering the data gaps in estimating how frequently a fieldworker might be present at the edge of a treated field during the time 1,3-D is being released into the air, OEHHA had to make a number of assumptions to estimate lifetime exposure of occupational bystanders. OEHHA is aware that some of its assumptions may overestimate exposure while others may underestimate it. But OEHHA believes the applied parameters (i.e., edge of field, hours per day, not accounting for background, frequency of exposure) and other modeling assumptions overall balance each other out.

The sections of the product that pertain to this conclusion include:

- Population of focus (Memo attachment pg. 3)
- Key variables on frequency and duration of exposure used to estimate lifetime 1,3-D exposure of occupational bystanders (Memo attachment pg. 3–5)
- Use of modeling to estimate average air concentrations (Memo attachment pg. 5–7)
- Occupation bystander exposure in California coastal and inland regions (Memo attachment pg. 9)
- Controlled application conditions (Memo attachment pg. 10)
- DPR modeled 1,3-D air concentrations¹ (Memo attachment appendix A pg. 13)
- Seasonal distribution of applications per Inland or Coastal Region (Supplemental document pg. 6–7)
- 3. Estimation of occupational bystanders' exposure from working in the general vicinity of treated fields (i.e., not in close proximity to treated fields).

OEHHA recognizes that occupational bystanders might also be exposed by working in the vicinity of treated fields. That is why OEHHA recommended ongoing assessment of 1,3-D through the evaluation of use, and measurement and modeling of air concentrations to ensure that occupational bystanders remain protected. If resulting annual ambient concentrations experienced by occupational bystanders working in the general vicinity of treated fields in high 1,3-D use areas fall significantly above 0.21 ppb,

¹The methodology used for these estimates has already been peer-reviewed for DPR's residential regulations.

Attachment 2 Scientific Assumptions, Findings, and Conclusions to Review

OEHHA also recommended that DPR develop and adopt additional mitigation measures to reduce localized exposure.

The section of the product that pertain to this conclusion include:

• Other Considerations: Occupational Bystanders Working in the Vicinity of Treated Fields (Memo attachment pg. 11-12)

In its recommendation for close proximity to field mitigation (as described in section 2), OEHHA assumed that strawberry fieldworkers were the most affected population and that their typical workday was 8 am–4 pm. Though this workday assumption might be valid for strawberry fieldworkers, it might not apply to other types of fieldworkers. Indeed, since the update to the health-based recommendations were provided to DPR, OEHHA was made aware through its various consultations that fieldworkers working with other crops (e.g., lettuce, spinach, canning tomatoes, onions, garlic, wine grapes, and sweet corn) might be harvesting during nighttime, at dawn, or at dusk (WCAHS, 2019). This is particularly important because air concentrations vary significantly between night and day, where nighttime concentrations tend to be higher. These differences are affected by season and region. Most of these activities require mechanical labor and happen infrequently, limiting the overall time spent at the edge of treated fields. However, exposure to ambient air might be significantly impacted by the working hours. Therefore, OEHHA is now suggesting that 0.21 ppb be considered in the context of localized agricultural practices and work shifts other than 8 am to 4 pm.

OEHHA also suggests mitigating total exposure from combined air concentrations from near-field and ambient air. However, there is no standard methodology available at this stage. DPR and OEHHA are working to develop a methodology to support this analysis.

Attachment 3 Individuals who have Participated in the Development of the Proposal

Attachment 3: Individuals who have Participated in the Development of the Proposal

For the sake of completeness, OEHHA has taken a special effort to identify all staff involved in the process of developing the health-based recommendations.

Section A. Office of Environmental Health Hazard Assessment Staff

Ph.D.,
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Acting Deputy Director for Scientific Programs:	Kannan Krishnan, Ph.D.
Acting Director:	David Edwards, Ph.D.
Director:	Lauren Zeise, Ph.D. (retired)

Attachment 4 References Cited

Attachment 4: References Cited

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