

Department of Pesticide Regulation

Gavin Newsom Governor

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MEMORANDUM

Jared Blumenfeld Secretary for Environmental Protection

TO: Karen Morrison Assistant Director and Acting Chief Deputy Director

> Nan Singhasemanon Assistant Director

FROM: Julie Henderson Acting Director 916-445-4000

DATE: October 19, 2021

SUBJECT: RISK MANAGEMENT DIRECTIVE AND MITIGATION GUIDANCE FOR ACUTE, NON-OCCUPATIONAL BYSTANDER EXPOSURE FROM 1,3-DICHLOROPROPENE (1,3-D)

This document outlines the Department of Pesticide Regulation's (DPR's) risk management decision based on the December 2015 Risk Characterization Document (RCD) for 1,3-D. Specifically, this decision sets the regulatory target concentration necessary to initiate and guide the development and adoption of mitigation measures to address acute, non-occupational exposures to bystanders from 1,3-D identified in the RCD. In 2016, DPR issued a risk management decision regarding the potential cancer risk to non-occupational bystanders from 1,3-D; however, air monitoring results showing detections of 1,3-D in ambient air at or near health screening levels highlights the need to address a gap in regulatory requirements to address potential acute, non-occupational bystander exposures.

Prior to finalizing this decision, DPR consulted with the Office of Environmental Health Hazard Assessment, the California Air Resources Board, and air pollution control districts or air quality management districts in the affected counties in accordance with Food and Agricultural Code section 14023(f). DPR also consulted with the California Department of Food and Agriculture. Comments received from the consulting agencies on the proposed decision and DPR's responses are enclosed.

1,3-D is a fumigant used to control nematodes, insects, and disease organisms in the soil. 1,3-D has major uses in California on fruit and nut trees, strawberries, grapes, carrots, and several other food and non-food crops. It is commonly used as a pre-plant treatment that is injected into the soil. It may also be applied through drip irrigation. Regardless of the application method, the possibility of offsite transport of this fumigant due to volatilization may subsequently result in acute human exposure through inhalation; dermal exposure is expected to be minimal. Current label requirements aimed at mitigating the acute risk to bystanders from inhalation are largely limited to a 100-foot buffer zone, regardless of application rate or field size.

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The 2015 RCD identified nine inhalation animal studies that reported effects that could be used to assess acute risks because effects occurred after only a few doses were administered to the test animals. Acute inhalation effects included irregular breathing, closed eyes, and lung congestion. The most common and sensitive effects in these studies were reductions in body weight and/or body weight gain, as observed in rats, mice, and rabbits. Comparable concentrations of 1,3-D in different species elicited comparable decrements in body weight or weight gain. The critical study (Stott *et al.*, 1984) was conducted in rats and showed a weight gain decrement after only 3 days of exposure. The regional gas dose ratio approach was used to adjust the benchmark concentration to a human exposure concentration of 11 parts per million (ppm) for acute, nonoccupational exposure scenarios. Reference concentrations, which are estimates of inhalation exposures to humans that are likely to be without appreciable risk of deleterious effects, were calculated for acute and/or short-term (up to 7 days) non-occupational scenarios. DPR's 2015 RCD calculated an acute, non-occupational bystander reference concentration of 110 parts per billion (ppb) for children and 367 ppb for adults. In order to account for uncertainties in the intraspecies pharmacokinetic data, the Office of Environmental Health Hazard Assessment (OEHHA) recommended acute, non-occupational bystander reference concentrations of 55 ppb for children and 184 ppb for adults.

DPR performs pesticide air monitoring in various California communities to identify pollutants, including 1,3-D, and support measures to mitigate human health exposures, if deemed necessary. DPR's evaluation of the 2017–2019 results from pesticide air monitoring and computer modeling indicates that observed levels of 1,3-D could result in acute health effects to children. This includes several elevated readings at air monitoring stations in Parlier and Shafter, California, including a 24-hour reading of 111 ppb.

DPR is selecting a 55 ppb acute, non-occupational bystander reference concentration for 1,3-D. This decision is based on:

- (1) Substantial evidence in the 2015 RCD of acute risks;
- (2) The uncertainty in the adequacy of animal models to determine acute risks from 1,3-D (intraspecies pharmacokinetics);
- (3) Scientific support for different cancer modes of action for 1,3-D. Importantly, in evaluating cancer risks, DPR identified evidence demonstrating that both portal of entry and systemic exposures may be operative in producing lung tumors in mice, and;
- (4) Recent elevated air monitoring readings providing evidence of acute exposures at or near health screening levels.

Following a health-protective approach, DPR determined that the factors above warrant the selection of 55 ppb as the relevant reference concentration.

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DPR finds that additional control measures are necessary to sufficiently reduce exposures to this level. Please direct staff to develop proposed regulatory language to establish control measures that mitigate the effects of acute risks to non-occupational bystanders associated with 1,3-D by limiting the 72-hour acute exposure to non-occupational bystanders to 55 ppb or less. Please also have staff evaluate the impact acute control measures may have on DPR's existing mitigation to address cancer risk to non-occupational bystanders from 1,3-D.

DPR hosted a workshop in October 2019 which indicated that the use of totally impermeable film (TIF) tarpaulins, or measures providing a comparable degree of protection, would be required to reduce exposures to this target concentration. DPR's 1,3-D pilot project in the Central Valley is currently underway to assess the viability of mitigation measures that could achieve emissions reductions comparable to TIF tarping. Subject to all prerequisite consultation requirements, please direct staff to incorporate the results of the 1,3-D pilot projects as they begin the development of mitigation measures for 1,3-D. Staff should also explore the suitability of regional or local control measures to limit acute, non-occupational bystander exposure to 1,3-D.