



Department of Pesticide Regulation



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MEMORANDUM

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SUBJECT: RISK MANAGEMENT DIRECTIVE AND MITIGATION GUIDANCE FOR
CANCER RISK FROM 1,3-DICHLORPROPENE (1,3-D)

In December 2015, the Department of Pesticide Regulation (DPR) completed a Risk Characterization Document (RCD) for 1,3-D. This document outlines DPR's management decisions based upon the RCD to set the regulatory target concentration necessary to initiate and guide the development and adoption of mitigation measures to address cancer risk to bystanders (nearby workers and residential/public). Risk management decisions to address cancer risk to handlers of 1,3-D (workers involved in the application), as well as acute, seasonal, and chronic (non-cancer) exposures identified in the RCD will be issued at a later date after further analysis and consideration.

Background

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 in fruit and nut trees, strawberries, grapes, carrots, and a host of other food and non-food crops. It is commonly used as a pre-plant treatment that is injected into 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 cause human exposure through inhalation. Dermal exposure is expected to be minimal; therefore, use restrictions are aimed at mitigating risk from inhalation.

DPR and other agencies have evaluated the cancer risk potential of 1,3-D. In 1997, DPR assessed the risk and implemented mitigation measures. In 1986, the U.S. Environmental Protection Agency (U.S. EPA) issued a Special Review of 1,3-D based on cancer concerns for workers. This review involved a data call-in requiring additional residue chemistry, inhalation exposure, and environmental fate data. In December 1998, U.S. EPA published a Reregistration Eligibility Decision (RED) for 1,3-D. Following publication of this Reregistration Eligibility Decision, additional mitigation measures through label modifications were put in place including lower maximum application rates, closed loading requirements, additional personal protective equipment, an increased restricted entry interval, and a buffer from occupied structures.



U.S. EPA updated the human health assessment for 1,3-D in 2007, but no new mitigation measures specific to 1,3-D were required. In 2007, U.S. EPA classified 1,3-D as “likely to be carcinogenic to humans” based on animal studies. The International Agency for Research on Cancer categorized 1,3-D as a group 2B carcinogen (“possibly carcinogenic to humans”). 1,3-D is listed under Proposition 65 as a chemical known to the State of California to cause cancer.

1,3-D is listed as a Hazardous Air Pollutant under the Clean Air Act, and is therefore designated as a Toxic Air Contaminant in California.

Updated Cancer Risk Estimate and Goal

DPR scientists evaluated a range of scenarios for the 2015 estimates of cancer risk. In other words, DPR evaluated different assumptions about when and how people are exposed to 1,3-D as well as about 1,3-D’s cancer potency. Using this information, the scientists estimated the risk of people contracting cancer for each set of assumptions. This analysis indicated a need to implement certain risk management measures to reduce cancer risk in exposed populations. For this purpose, DPR concluded that a cancer risk goal of 1×10^{-5} for a 70-year lifetime exposure was a reasonable objective for mitigation. DPR used the same target in 2001 when it previously adopted mitigation measures for 1,3-D. A cancer risk goal of 1×10^{-5} for a 70-year lifetime exposure means that the risk of contracting cancer should be no more than 1 individual for every 100,000 people. The risk level and exposure period are consistent with the [Proposition 65](#) standards for notification of carcinogenic risk and with the U.S. EPA non-dietary cancer risk policy, which states that U.S. EPA will seek to reduce risks in the 10^{-4} to 10^{-6} range (Barolo D. Non-Dietary Cancer Risk Policy, Office of Pesticide Programs and Toxic Substances, U.S. EPA, August 14, 1996).

Regulatory Target Concentration to Address Cancer Risk

DPR needs to establish a regulatory target concentration to achieve the 1×10^{-5} risk goal. However, there are uncertainties in estimating the air concentration that meets this risk level including the following:

- *Mode of action*: The 2015 RCD indicates that 1,3-D may cause cancer by two possible mechanisms: portal of entry or systemic modes of action. DPR scientists evaluated both mechanisms and concluded that the weight of the evidence favored a portal of entry mode of action based on currently available studies.
- *Residency duration and time away from residence (mobility)*: People generally do not live in one place throughout their lifetimes, and if they do, school, work, and other activities occur away from their residence. The 2015 risk document considered several options to estimate

years of residency in one place and time spent away from a residence. DPR concluded that a low-mobility scenario and 70-year lifetime exposure would be health protective in this case.

- *Additional uncertainty factor for age sensitivity:* The draft RCD was sent for peer review to the Office of Environmental Health Hazard Assessment (OEHHA). One of their comments addressed the variations of human sensitivities based on age as recommended in U.S. EPA and OEHHA guidance documents for carcinogens. DPR scientists favored not including an additional uncertainty factor for age sensitivity because a direct portal of entry mechanism bypasses the metabolic differences that can result in increased sensitivity in early life. However, DPR scientists recognized that there is remaining uncertainty involving age-related sensitivity due to other potential susceptibilities such as the rapid growth and development of the lung in early life, and the longer latency period during which cancer could develop. For this reason, DPR will use an age sensitivity factor to derive a concentration level that will trigger additional evaluation and consideration of further mitigation.

To account for the uncertainties and achieve a risk goal of 1×10^{-5} , DPR will set a regulatory target concentration of 0.56 parts per billion (ppb). This concentration is a 70-year average that should be achieved at least 95 percent of the time, and is based upon:

- the conclusion that the mode of action is portal of entry,
- assumption of 70-year residency time, and
- assumption of low mobility.

The 95 percent probability of protection is consistent with previous risk management directives. This means that DPR will implement limits on use and other restrictions so that there is at least a 95 percent probability that the average air concentrations for 70 years will not exceed 0.56 ppb. Although the RCD did not consider the age sensitivity factor necessary, adding an additional uncertainty factor to account for age sensitivities can be considered a health protective goal. This additional factor would result in an average lifetime target concentration of 0.27 ppb. As described below, if any one-year average concentration reaches this level, DPR will require additional evaluation. The 0.27 ppb trigger recognizes that science evolves and provides an expedited process to implement more stringent mitigation measures if they become necessary.

The regulatory target concentration of 0.56 ppb is higher than the previous target of 0.14 ppb. The target is higher because DPR has determined that it is appropriate to use a portal of entry mechanism as opposed to the systematic mechanism that was selected previously. This resulted in the use of differences in lung surface area instead of body weight to extrapolate data from animal studies to humans.

Measures to Achieve Regulatory Target Concentration

After several revisions, the following control measures have been in effect since 2002 with the goal of achieving the 2001 regulatory target concentration of 0.14 ppb. DPR has required Dow AgroSciences (1,3-D manufacturer and registrant) to limit the use in each township (6 x 6 mile area). Under this township cap program, each township was allocated 90,250 adjusted total pounds¹ of 1,3-D per year. If less than 90,250 adjusted total pounds was used in the township during the year, the excess was placed in a “bank” for future use in that township. If a sufficient amount was available in the bank, up to 180,500 adjusted total pounds could be used in a township during a year.

Concerns were raised, however, about the “bank” for both scientific and practical reasons. The bank was based in part on the fact that 1,3-D had not been used in California from 1991-1995. Since 1,3-D is now used regularly in California, there is a concern that high use, potentially up to double the cap, would result in one-year concentrations above the proposed regulatory concentration levels. Additionally, the banking system requires a level of recordkeeping that is disproportionate to any benefit it may confer.

DPR will revise the township cap program to meet the new regulatory target concentration of 0.56 ppb. While this is a 4x increase of the 2001 regulatory target concentration, the township cap will not increase by 4x because DPR has acquired additional data and developed more refined methods to relate air concentrations with use levels. DPR staff developed two methods to determine the township cap level.

- Using air monitoring and pesticide use data, DPR staff evaluated the relationship between the amount of 1,3-D applied and air concentrations, and arrived at a use level that would meet the 0.56 ppb regulatory target concentration. See attached [Tao document](#).
- Using the SOil Fumigant Exposure Assessment (SOFEA) computer model that has been developed and refined over a number of years, the 0.56 ppb regulatory target concentration would be met at levels inconsistent and usually higher than the ones estimated using air monitoring and use data. See attached [Barry and Kwok document](#).

There are several possible reasons why the two methods produce different township cap levels. One reason is the difference in time periods of the evaluations. The air monitoring data could only be evaluated as one-year average air concentrations, while the SOFEA modeling estimated 70-year average air concentrations. Using one-year data instead of 70-year data results in a lower

¹ 1,3-D allocations and use are “adjusted total pounds” using application factors that vary from 0.3x to 2.3x of pounds applied depending on fumigation method, month, and region. The application factors account for differences in emissions and air concentrations associated with different application methods, field conditions, and weather conditions.

township cap. Another possible reason is uncertainty in estimating December air concentrations. Monitoring data shows higher air concentrations during December than other months. The higher December concentrations are likely due to long periods of calm conditions at night. Computer modeling may not accurately estimate concentrations under calm conditions, so December air concentrations are more uncertain compared to other months. Additionally, the December monitoring data potentially indicates unacceptable seasonal exposures compared to the subchronic reference concentration in the 2015 RCD. DPR selected the air monitoring and pesticide use data method, which results in a township cap that is lower than the SOFEA method.

Effective January 1, 2017, DPR staff will make the following revisions to the township cap program to achieve the regulatory target concentration of no more than 0.56 ppb.

- The township cap will be 136,000 adjusted total pounds each year, based on 1,3-D air monitoring and use data described in the attached [Tao document](#).
- The banks of unused 1,3-D for all townships will be discontinued due to the potential for repeated high air concentration over several years.
- 1,3-D applications during December will be prohibited to address air concentration uncertainties and potentially high seasonal exposures.

These restrictions mean that if:

- 100,000 people lived in a 6 x 6 mile township for 70 years; and
- 136,000 adjusted pounds of 1,3-D were applied in the township every year for 70 years; then
- there is less than a 5 percent chance that 1 person in the township would develop cancer from exposure to 1,3-D.

DPR has determined that this will reduce emissions sufficiently so that the public will not be exposed to levels that may cause or contribute to significant adverse health effects.

Continued Evaluation of Mitigation Measures

To verify that the regulatory target concentration is achieved 95 percent of the time, DPR will continue to evaluate the effectiveness of the township cap and other mitigation measures, including the following.

- *Continue air monitoring:* As specified in the Budget Act for 2016-2017, DPR and the Air Resources Board (ARB) will continue to expand the air monitoring network by conducting year-round monitoring for 32 pesticides (including 1,3-D) in eight communities. The eight communities will include the top three regions for 1,3-D use, or DPR and/or ARB will conduct additional monitoring to capture the top three regions.
- *Continue to evaluate computer model:* DPR will continue to evaluate the SOFEA model. The modeled air concentrations will be compared to the air monitoring data network of DPR and

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ARB to verify that the SOFEA model can accurately simulate long-term air concentrations in all high-use areas.

While the regulatory target concentration is a 70-year average, DPR will measure the effectiveness of its mitigation measures on an annual basis as an additional margin of safety. Monitoring that shows one-year average air concentrations less than 0.27 ppb will indicate that no changes are needed to the revised mitigation measures. DPR will evaluate and consider more stringent mitigation measures if air monitoring shows one-year average air concentrations that are between 0.27 and 0.56 ppb. The evaluation will include an analysis of measured air concentrations relative to 1,3-D use near the monitoring stations. The mitigation measures that DPR will evaluate and consider include, but are not limited to, a lower township cap amount, different township cap amounts in different regions, additional application date restrictions, additional application method restrictions, application factor revisions, and larger buffer zones. DPR will implement more stringent mitigation measures if one-year average air concentrations exceed 0.56 ppb.

Attachments