January 18, 2023

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Re: Proposed rulemaking on the Health Risk Mitigation and Volatile Organic Compound Emissions Reduction for 1,3-Dichloropropene (1,3-D)

Salt Lake Holding LLC, a wholly owned subsidiary of The Dow Chemical Company (Dow), (here after referenced as Dow) appreciates the opportunity to provide comments on the Department of Pesticide Regulation's (DPR) proposed rulemaking on the Health Risk Mitigation and Volatile Organic Compound Emissions Reduction for 1,3-Dichloropropene (1,3-D), which was published on November 18, 2022.
DPR has a responsibility to protect human health and the environment and should continue to evaluate all current data related to the impact of this product. Dow has a strong interest in ensuring that the new proposed regulations are developed through a comprehensive, consistent, and rigorous analysis of all available toxicology, exposure, and risk-assessment science, while implementing the best available application processes to allow the agricultural industry to thrive. The protection of bystanders is a top priority to Dow and we continuously enhance our product stewardship program for 1,3-D. We are committed to ensuring these products are safe, including being used in a safe manner as well as a commitment to Product Stewardship by our distributors and the growers, while at the same time protecting food security through use of 1,3-D as a fumigant.

Soil fumigation is an integral part of farming operations throughout California and is fundamental to sustaining the state's agricultural economy. 1,3-D has been used in agriculture since the 1950s and has been extensively studied by various agencies worldwide. It is the active ingredient in soil fumigants that control nematodes, fungi, and other pests that otherwise would damage root structures of new plants. This not only helps boost crop yields, but also allows for more efficient use of water, fertilizers, and nutrients and less reliance on other pesticide products. As DPR has previously acknowledged, there is no commercially viable alternative to 1,3-D for pre-plan nematode control. With this in mind, we offer the following comments in response to the proposed regulations.

OEHHA Agreement Regarding DPR's Development of a Regulation to Mitigate Risks to Non-occupational Bystanders from 1,3-D Use

Dow appreciates the transparency of DPR by including the communication between OEHHA and DPR under "Documents Relied Upon". These letters help clarify each Agency's role in the development of this rulemaking which is designed solely to mitigate acute and cancer risks from non-occupational/residential bystanders from exposure to 1,3-D and further elaborate that this rulemaking is not subject to the Food and Agriculture Code. This is clear and understood by Dow.

Acute and Cancer Risks to Non-Occupational Bystanders from the Use of 1,3-D

Dow has previously provided DPR with scientific opinion, supporting white papers, and peer-reviewed publications to substantiate that there is limited scientific support for utilization of body weight (BW) decrement as an endpoint for establishing either acute or short-term HECs. There is sound scientific evidence that BW decrements are *threshold-based, adaptive, reversible,* and secondary effects attributable to impacts on physiology, pharmacokinetics and metabolism (Juberg et al., 2020). Moreover, the minimal decrements in BW used for HEC derivation occurred *at repeat dose concentrations related to, approaching or above the Kinetically Derived Maximum Tolerated Dose (KMD) for 1,3-D,* exposure levels that are not comparable or directly relevant to intermittent, low-level exposures potentially experienced by human bystanders (Bartels et al., 2019). Dow maintains there is undue conservatism embedded in the risk assessments for 1,3-D, specifically, there is a scientific basis for concluding that a 1X (versus 2X) pharmacokinetic uncertainty factor (PK UF) is both appropriate and health protective (see Juberg et al., 2019a) and that there is no need for an age-sensitivity factor (ASF) of 3X based on numerous scientific bases (see Juberg et al., 2019b).

Dow believes that DPR's evaluation of cancer risk fails to recognize or include updated scientific information which undermine its cancer risk assessment for 1,3-D. Badding et al. (2020) evaluated the mutagenic potential of 1,3-D in a state-of-the-art study and the results support the conclusion that 1,3-D does not pose a mutagenic hazard or risk. In an extensive review of both genotoxicity and carcinogenicity data for 1,3-D, Yan et al (2020) demonstrated that 1,3-D is a threshold carcinogen for both oral and inhalation routes of exposure and as such, a threshold approach for cancer risk assessment is scientifically appropriate (which EPA agrees with and DPR opposes). Additionally, an independent panel of experts concluded that a cancer weight of evidence classification of "not likely to be carcinogenic to humans" is best supported for 1,3-D. (Hays et al., 2021).

In closing, we would strongly encourage DPR to revisit and reconsider these peer-reviewed publications and the multiple sets of comments submitted by Dow as they represent new and compelling scientific evidence that Dow believes are critical to an objective and accurate risk assessment for 1,3-D.

Section 1 - Setback Distance

DPR used the HYDRUS modeled 1,3-D emission profiles for each FFM to run AERFUM for 100-, 200- and 500-foot buffers for a range of field sizes up to 80 acres, shown in Section 3 of the proposed regulation. Dow suggests that the modeled setbacks shown in Section 3 could be more granular and should include acceptable field sizes and application rates for 300- and 400-foot setbacks. This would allow greater flexibility for growers, while maintaining acceptable bystander exposure.

Section 1 - Maximum Application Rate

Dow suggests that the modeled application rates shown in Section 3 of the proposed regulation (100, 110, 125, 150, 200, 250, 300, 332 lbs/ac) could be more granular (e.g., application rates in 25 lbs/ac increments from 150-300 lbs/ac). This would also allow greater flexibility for growers, while maintaining acceptable bystander exposure. Dow requests that DPR include guidance for growers that need to apply rates of 1,3-D that fall between the currently listed application rates.

Section 1 – Soil Moisture Requirements

Dow contends that "Option 1" would not be practical for many (or most) soils in CA since it would make the soil too wet to conduct fumigation activities and overapplication of irrigation water would be a misuse of a valuable natural resource. Dow agrees that the methods proposed in Options 2 and 3 would allow growers and their irrigation specialists to deliver the precise amount of water needed to meet the requirement of 50% of field capacity soil water content and would be a more efficient use of the limited water supply in CA than would Option 1. Thus, we suggest that Option 1 is removed from the regulation.

General comments on DPR's modeling approach

Dow agrees with DPR's modeling approach for setting an allowable annual "township cap" for 1,3-D that relies on the simulation of 1,3-D concentrations in ambient air in lieu of simulating exposure, thus obviating the need for demographic and age and gender specific parameters to assess risk. DPR's "target concentration based" modeling shows that the proposed maximum allowed use of 1,3-D per township (township cap) combined with the mitigations recommended to reduce acute exposure (50% FC soil moisture and setbacks) will ensure that non-occupational bystanders will not be exposed to annual average 1,3-D concentrations exceeding 0. 56 ppb, in fact the maximum annual average concentration predicted under maximum allowed 1,3-D use is 0.35 ppb. Dow also agrees that the target concentration-based approach allows DPR to more readily evaluate the effectiveness of the numerous mitigations in the proposed regulations using the ambient air samples collected in DPR's Air Monitoring Network (AMN) and by conducting air dispersion modeling using the actual 1,3-D application information collected in Pesticide Use Reports (PURs) through the county agriculture commissioner's permitting process.

DPR's modeling approach contains many areas of conservativism, including the assumption that people live, work and travel within the same high use township (6x6 mile area) for 70 years, and the use of a single weather dataset (Parlier) that generates the highest 1,3-D concentrations in ambient air of the ten weather stations (four coastal, two inland) that DPR evaluated across the state. While the conservative assumptions applied in both the emission modeling (HYDRUS) and air dispersion modeling (AERFUM) result in a significant level of safety for non-occupational bystanders, Dow suggests that DPR evaluate opportunities to refine the modeling by using more representative local or county-based weather data rather than developing regulations for all fumigations across the state based on the worst-case weather data in the entire state.

Annual DPR report

DPR (2022) states the following "*The proposed regulations require an annual DPR report that includes an evaluation of the highest-use townships and monitoring locations that exceed specified threshold concentrations. The evaluation will include estimates of peak and one-year average air concentrations to ensure that the regulations continue to achieve the regulatory target concentrations specified by the acute and cancer risk management directives for non-occupational bystanders. After the acute mitigation measures go into effect, the annual evaluations will be able to use actual ATP data to estimate air concentrations rather than using estimated ATP data as described above*".

Further, the modeling report by Luo, Yuzhou (2022c) states the following "*When the GIS data for field boundaries become available, the actual coordinates of treated fields can be modeled by AERFUM and the results for township cap modeling are expected to be similar to these with source randomization*". Currently the 1,3-D source randomization in DPR's AERFUM modeling is based on the Public Land Survey System (PLSS) Section (1x1 mile area) where the application was made, as reported in the PUR. Clearly DPR assumes that in the future, 'actual coordinates' of treated fields will be available. Is it stated clearly in the new regulations to require growers to report GPS coordinates for each fumigated field?

To enhance transparency, Dow requests that DPR share the proposed modeling approach or protocol that will be used to conduct the annual review of mitigations in DPR's annual report. Additionally, DPR should specify who will be responsible for collecting the information that DPR will be evaluating.

Product Stewardship

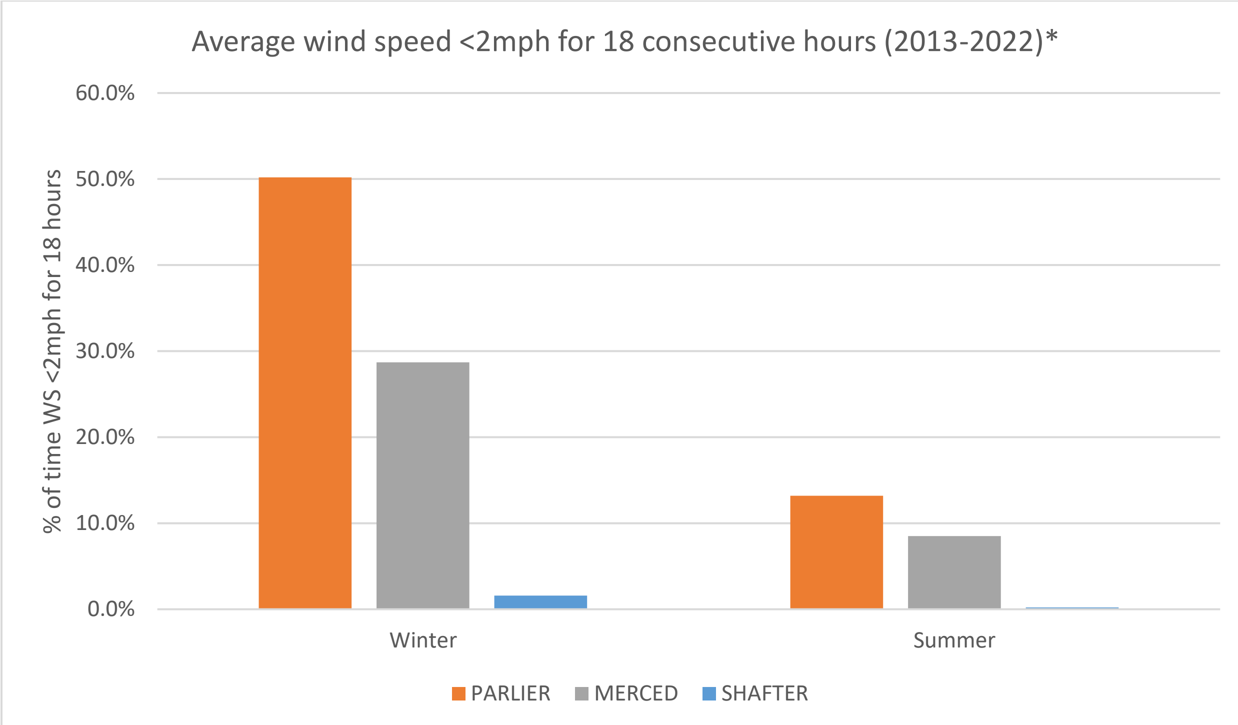
For future consideration, Dow would like to work with DPR to strengthen the label language related to unfavorable weather conditions for use of 1,3-D in California. While we believe the current label is satisfactory, Dow believes adding this type of language for 1,3-D products is good product stewardship. We understand that changes to the label are not necessarily part of this rule, but we wanted to offer the suggestion as an opportunity to work with DPR to craft new language sometime in the near future.

Seasonal and Regional Application Approach

Dow suggests that DPR consider the dramatic differences in regional weather patterns encountered in CA when developing the setbacks for each FFM. California is a large and geographically diverse state with numerous distinct microclimates that have different effects on the magnitude of 1,3-D concentration in ambient air that could occur after a fumigation. Figure 1 shows a comparison of the percent of time that average hourly wind speeds are <2mph for 18 consecutive hours at California Irrigation Management System (CIMIS) weather stations located in Shafter (Kern Co.), Parlier (Fresno Co.) and Merced (Merced Co.). Figure 1 indicates that the prevalence of long periods of low wind speed (i.e., calm) conditions varies significantly by region, even within the central valley, and were the most common in Parlier and over an order of magnitude less common in Shafter. This corroborates the conclusion reached by DPR (Yuo, 2022c) that of the ten weather stations in high fumigant use areas in CA that were used to model 1,3-D concentrations in ambient air, the weather data from Parlier resulted in the highest AERFUM modeled concentrations of 1,3-D in ambient air, thus DPR chose to use Parlier weather to conduct the setback modeling for the entire state.

Although the use of the Parlier weather data to model setback distances across the state of CA does add an additional layer of conservatism to the modeled setback's, it also results in setbacks in some areas of the state that are much larger than are required to protect human health and would be challenging for some growers to implement. The difference in the percent of time that low wind speeds occur in the three CIMIS stations examined by Dow reflect the diversity in microclimates within the central valley of CA. Given the variability of geography and microclimates across the state of California, Dow suggests that DPR refine the setback modeling using weather data that is more relevant to the local county/geography where the 1,3-D is being applied.

Figure 1. Percent of time that average wind speed is <2mph for 18 consecutive hours.



**Based on CIMIS station #39 (Parlier), #148 (Merced) and #5 (Shafter)*

Dow also suggests that DPR continue to evaluate the seasonal approach proposed in the rule to allow for more flexibility in application months which would increase opportunities for growers to rely on natural rainfall in lieu of irrigation to meet the 50% field capacity soil moisture requirement. The CIMIS hourly wind speed data used to generate Figure 1 also suggests that extended low wind conditions and the potential for inversions and excessive concentration of 1,3-D in ambient air are significantly diminished by February and we encourage DPR to evaluate the inclusion of February with the "March-October" application season. Inclusion of February in that season, and the resulting smaller setback requirement would enable more growers to take advantage of the soil moisture accumulated over the preceding winter months and reduce reliance on irrigation to meet the soil water content mitigation requirement in the proposed regulation.

Thank you for considering our comments. Should you need to reach out and discuss the comments with us, please contact Stephanie Burt at sburt3@dow.com.

Documents relied upon by Dow for these comments.
Dow can make the following documents available to DPR upon request. Please email sburt3@dow.com.

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