M E M O R A N D U M

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SUBJECT: ANALYSIS OF THE SUFFICIENCY OF ACUTE MEASURES TO MITIGATE CANCER RISK TO NON-OCCUPATIONAL BYSTANDERS FROM 1, 3-DICHLOROPROPENE

Summary

The Department of Pesticide Regulation (DPR) is under court order to submit proposed regulations addressing potential cancer risks to bystanders from the use of 1,3-Dichloropropene (1,3-D) to the Office of Administrative Law by November 9, 2022. (*Vasquez v. Department of Pesticide Regulation* (2021) 68 Cal.App.5th 672.) The current primary measure to mitigate cancer risk to non-occupational bystanders is a "township cap" that limits the use of 1,3-D on an annual basis within each township (6 x 6-mile area) so that the air concentration will not exceed the regulatory target concentration of 0.56 parts per billion (ppb) over a 70-year lifetime average. This was the mitigation challenged in the *Vasquez* case.

DPR is currently developing regulations to mitigate potential short-term, 72-hour acute air concentration exposure to non-occupational bystanders from the use of 1,3-D to 55 ppb or less. The proposed regulations include setbacks between occupied structures and 1,3-D applications, as well as new fumigation methods and higher field soil moisture that will significantly reduce 1,3-D emissions as compared with current use. This includes a proposed requirement to use lower emission fumigation methods for applications to fields for tree orchards or grape vineyards.

This memorandum analyzes the effect of the proposed regulatory requirements on potential air concentrations of 1,3-D by evaluating historic use, including townships with the highest use in recent State history (i.e., annual use in townships where cap exceedance through banking was allowed). Using the proposed acute mitigation measures and updates to DPR's analytic methods

and data, DPR calculates the highest estimated one-year average 1,3-D air concentration as 0.35 ppb. This estimated concentration is based on data from 2013-2017, when use of 1,3-D was historically high due to DPR granting use waivers and DPR does not expect use to exceed the amount of use during 2013-2017. The estimated concentration is well below DPR's regulatory target concentration of 0.56 ppb for cancer risk. Therefore, the acute mitigation measures proposed in the regulations by themselves meet DPR's regulatory target concentration for cancer risk of 0.56 ppb as a 70-year average and sufficiently mitigate 1,3-D cancer risk to non-occupational bystanders.

Background

1,3-D is a fumigant used to control nematodes, insects, and disease organisms in the soil. 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 result in human exposure through inhalation.

1,3-D is currently listed as a restricted material and the purchase and use of 1,3-D for agricultural production purposes are allowed only under a restricted materials permit from the local county agricultural commissioner (CAC). Before issuing a permit, the CAC must evaluate the permit application to determine whether the intended use may cause a substantial adverse environmental impact based on local conditions at the application site. Depending on the results of this review, the CAC may deny the permit or impose permit conditions including the use of specific mitigation measures. As part of the permit for any restricted material, applicators must provide a notice of intent to the CAC before any application. The notice of intent includes application-specific information, such as the number of acres being treated and date the application is intended to commence.

In August 2015, DPR released a draft 1,3-D risk assessment, known as the risk characterization document. DPR received comments on the draft risk characterization document from Dow AgroSciences (DAS), U.S. Environmental Protection Agency (U.S. EPA), the Office of Environmental Health Hazard Assessment (OEHHA), and several scientists coordinated through the University of California for peer review. DPR scientists considered and responded to the comments and on December 31, 2015, DPR published a final risk characterization document titled, *1,3-Dichloropropene Risk Characterization Document, Inhalation Exposure to Workers, Occupational and Residential Bystanders and the General Public* (DPR, 2015b).

The Risk Characterization Document evaluates the toxicity and oncogenic effects from inhaling 1,3-D, including but not limited to oncogenic effects, and assesses the levels at which such effects occur, how much 1,3-D human exposure occurs under different scenarios, uncertainties in available data, and the levels at which harmful effects are not expected to occur. The scientific analysis in the Risk Characterization Document reflects the fact that an individual's exposure risk from 1,3-D varies depending on whether the individual lives near a field treated with 1,3-D (i.e., residential/non-occupational bystander), works near a field treated with 1,3-D (i.e., occupational bystander), or works with, directly handles, or otherwise works in and about a field treated with 1,3-D (i.e., a worker).

The Risk Characterization Document then goes on to classify exposure risks for workers, occupational bystanders, and residential/non-occupational bystanders based on assumptions about the different durations of exposure to 1,3-D experienced by each group. Occupational lifetime exposure estimates in the Risk Characterization Document for both workers and occupational bystanders are based on the assumption that workers and occupational bystanders will potentially be exposed to 1,3-D over the course of an 8-hour workday, and—in the long-term—over a 40-year period spent working, out of an average lifespan of 75 years. In contrast, the Risk Characterization Document defines residential/non-occupational bystanders as nearby residents—including children—with 24-hour/7-day-a-week exposure to 1,3-D in the ambient air over the course of 30, 50, and 70 years living in a high 1,3-D use area.

In addition to duration of exposure, the Risk Characterization Document classifies risks based on how potential exposures occur. Residential/non-occupational and occupational bystander exposures occur as a result of off-site movement of 1,3-D from a treated field into ambient air. Unlike workers working in and about the treated area, residential/non-occupational bystanders and occupational bystanders will not be exposed directly to 1,3-D emerging from the soil where the product is applied. Rather, residential/non-occupational bystanders and occupational bystanders may be exposed to 1,3-D over the course of their lifetime when the pesticide enters ambient air and moves away from the application site as the result of drift or wind events. Accordingly, the RCD assesses the potential concentration of 1,3-D in the ambient air resulting from off-site movement using air dispersion models and monitoring data.

Worker exposures occur on the 1,3-D application site as the direct result of application and handling activities. With respect to worker exposure, the Risk Characterization Document's exposure assessment further distinguishes between different types of workers and the type of work performed. Generally, a worker handling the pesticide or moving in and about the treated field may be exposed directly to high concentrations of 1,3-D that emerge from the soil where the product is applied. Thus, worker exposure scenarios in the Risk Characterization Document include an analysis of short-term, seasonal, annual, and lifetime exposures for different types of field workers. These include the pesticide applicator, the handlers who remove tarps from fumigated fields, the workers who load fumigants for the application, and the reentry worker who enters the treated field following a restricted entry interval. In 2016, in response to information in the Risk Characterization Document regarding the ways in which 1,3-D exposure was understood to cause cancer, DPR issued a *Risk Management Directive and Mitigation*

Guidance for Cancer Risk from 1,3-D (Marks, 2016), which directed DPR staff "to initiate and guide the development and adoption of mitigation measures to address cancer risks to bystanders" so that there is "at least a 95 percent probability that the average air concentrations for 70 years will not exceed [a regulatory target concentration of] 0.56 ppb." The regulatory target concentration is based on analytic assumptions that apply only to non-occupational bystanders, including infants and children, specifically, 24-hour/7-day-a-week exposures in ambient air over a 70-year residency. These assumptions were consistent with the Risk Characterization Document's analysis of exposures to residential/non-occupational bystanders.

To mitigate its potential cancer risk to residential/non-occupational bystanders, DPR currently limits the use of 1,3-D on a regional basis (township cap). The current township cap is 136,000 "adjusted" total pounds (ATP) during a calendar year in any township[1]. Adjusted pounds refer to the amount of 1,3-D active ingredient used multiplied by an application factor (AF) to account for differences in air concentrations due to differences in emissions by fumigation method, as well as differences in weather conditions by region and season of application. To enforce the township cap, use of 1,3-D is tracked on a real-time basis and applications are not allowed once the cap is reached[2].

For each township and calendar year:
Adjusted total pounds (ATP) = sum of (pounds used × application factor (AF) for each application).

The current township cap program is enforced through a memorandum of understanding between DPR and the 1,3-D registrant, and permit conditions issued by CACs. In 2017, California Rural Legal Assistance successfully challenged the township cap program. (*Vasquez v. Department of Pesticide Regulation* (2021) 68 Cal.App.5th 672.) The court ordered DPR to submit proposed regulations addressing potential cancer risks to bystanders from the use of 1,3-D to the Office of Administrative Law by November 9, 2022.

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[1] A township is a 6×6 mi^2 area as defined by the Public Land Survey System (PLSS). Each PLSS township is identified by its "meridian" (Humboldt, Mount Diablo, or San Bernardino), "township" (sequential number north or south of the meridian), and "range" (sequential number east or west of the meridian), and is referred to as MTR. Each township contains 36 1×1 mi^2 "sections," identified by number and is referred to as MTRS. Example: For MTR M15S22E, "M" refers the Mount Diablo Meridian, "15S" refers to 15th township south of the meridian, and "22E" refers to the 22nd range east of the meridian. For MTRS M15S22E03, "03" refers to the 3rd section within the township.

[2] Use of 1,3-D is tracked using information from notices of intent and pesticide use reports (PURs). California has a comprehensive reporting system that requires applicators to submit information on every agricultural pesticide application. Each PUR includes date and time of application, location by MTRS, crop treated, number of acres or other units treated, product applied, amount of product applied, and other information.

DPR's continued monitoring and data analyses for 1,3-D indicated that additional mitigation measures were needed to address short-term acute exposures to non-occupational bystanders, including infants and children. To assist in developing the mitigation measures to mitigate acute exposures to non-occupational bystanders, DPR conducted a pilot project in 2020-2021 to evaluate potential new fumigation methods that would achieve emissions reductions comparable to totally impermeable film (TIF) tarping.

In 2021, DPR issued a *Risk Management Directive and Mitigation Guidance for Acute, Non-Occupational Bystander Exposure from 1,3-Dichloropropene* (Henderson, 2021), which directed DPR 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." The acute Risk Management Directive also instructed staff to "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."

Changes to the Methods for Determining the Township Cap and Estimated Cap Amount

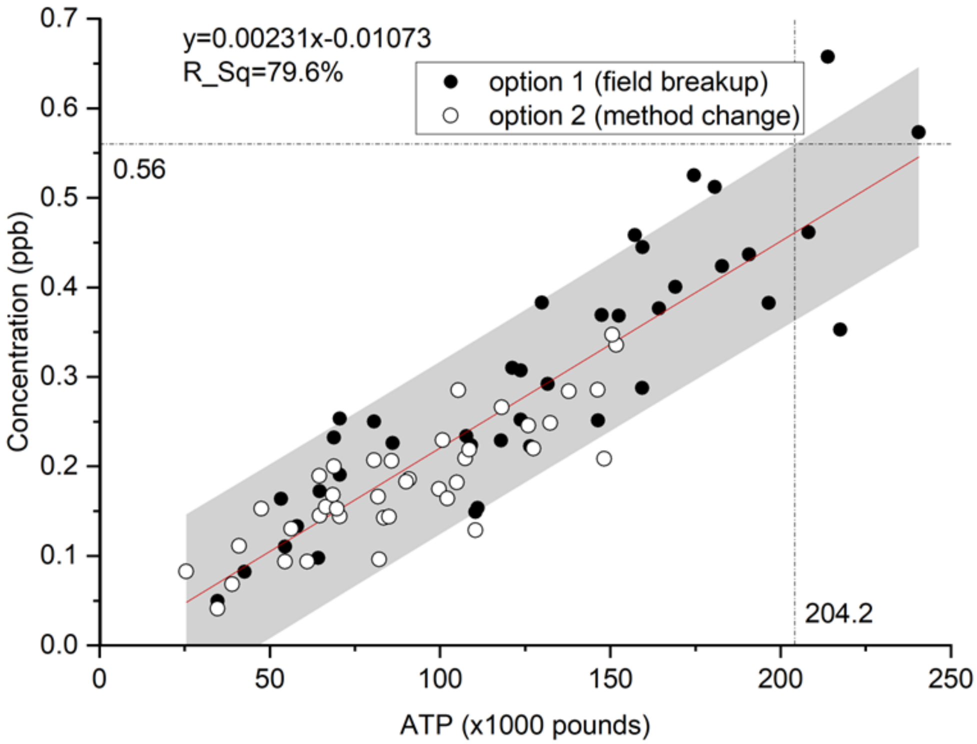
DPR's proposed mitigation for managing acute risks to non-occupational bystanders from 1,3-D significantly drive down emissions and exposure scenarios for both acute and cancer risks, whereby the need for a township cap to protect against long-term cancer risks to non-occupational bystanders no longer exists. This is due in part to several changes in the data and DPR's methods to determine the township cap. First, the proposed regulations requiring setbacks between occupied structures and 1,3-D applications, fumigation method changes, and increased soil moisture from a minimum of 25 percent of field capacity to a minimum of 50 percent of field capacity just prior to fumigation, will decrease overall exposure to non-occupational bystanders from the use of 1,3-D.

Second, DPR updated the method to calculate AFs based on the proposed regulatory requirements. Current AFs are based on emission estimates from 1,3-D application-site air monitoring studies. These studies estimated 1,3-D emissions using measured air concentrations from monitoring sites near specific applications and the data represent point estimates of emissions for the location and conditions of the application site. The updated AFs incorporate emission estimates from the soil to the atmosphere using the HYDRUS computer model. This model can estimate 1,3-D emissions based on its chemical properties (e.g., soil adsorption), characteristics of the soils where applications occur (e.g., water content), and characteristics of methods of application (e.g., depth of fumigant injection below the soil surface). The HYDRUS model enables DPR to estimate emissions for a wider variety of fumigation methods and under a wider variety of soil conditions rather than relying on the limited number of application-site monitoring studies. For example, HYDRUS indicates that higher field soil moisture will substantially reduce emissions. Brown (2022) and Luo and Brown (2022) give detailed descriptions of the updated 1,3-D emission estimates using HYDRUS.

Third, DPR used air dispersion modeling instead of community air monitoring data to estimate 1,3-D air concentrations under the proposed regulations. DPR used a second computer model, American Meteorological Society/Environmental Protection Agency Regulatory Model (AERMOD) to estimate 1,3-D air concentrations. AERMOD estimates air concentrations based on two key data inputs: emissions and weather conditions. DPR used the 1,3-D emissions estimated from HYDRUS, and historical weather data from several California locations as the AERMOD inputs. The AERMOD model enables DPR to estimate air concentrations for a wider variety of locations and weather conditions rather than relying on the limited community air monitoring data. Additionally, AERMOD can account for other proposed requirements to mitigate acute risk to non-occupational bystanders, such as setbacks around occupied structures where 1,3-D applications are prohibited. The setback distance varies with fumigation method, season, application rate, and size of area fumigated. The setbacks will cause changes to the sizes of fumigations and/or changes to fumigation methods with lower emissions. Luo (2022) describes the AERMOD modeling methods to determine the township cap, including those to account for the proposed mitigation measures.

With the updates to the data and methods described above, Luo (2022) determined what the new annual township cap amount would need to be so that air concentrations do not exceed 0.56 ppb over a 70-year average using a regression of 1,3-D ATP and estimated air concentrations (Figure 1). Based on the regression analysis, a new annual township cap could be set at 204,200 ATP.

Figure 1. Linear regression (solid line) and prediction interval (shaded area) of estimated 1,3-D ATP and the 95th percentile of the one-year average air concentration within a township. The potential township cap amount was determined from the upper prediction interval.



Luo (2022) also described several uncertainties in the township cap estimate. One uncertainty is that the 1,3-D ATP used for the regression is based on adjustments to the historical 1,3-D use data for the highest recent years (2013-2017), and while the historical use data are accurate, there are uncertainties in adjusting historical use data to estimate future ATP. In particular, under the proposed setback requirements, future applications, particularly those with methods resulting in higher emissions such as those without a tarpaulin, will generally have two options to comply: 1) break up larger fields into smaller blocks and fumigate them sequentially over several days (Option 1 – Field Breakup), or 2) shift to a fumigation method with lower emissions (Option 2 – Method Change). Luo (2022) describes the method to estimate which 2013-2017 fumigations would have been impacted by the proposed setback requirements and for the impacted fumigations, the two methods to estimate the changes in use and resulting ATP that are incorporated into the regression analysis shown in Figure 1.

Additional uncertainties are associated with the regression analysis. First, an alternative regression method recommended by the Office of Environmental Health Hazard Assessment (OEHHA) resulted in a higher township cap amount (Luo, 2022). Second, both DPR's and

OEHHA's methods to determine the township cap amount rely on estimating one-year average 1,3-D air concentrations and one-year use amounts to achieve 0.56 ppb as a one-year average concentration. However, the risk management directive for cancer risk establishes a regulatory target concentration of 0.56 ppb as a 70-year average. DPR chose to use one-year estimates instead of attempting to estimate 70-year air concentrations because using one-year estimates is more health-protective.

Estimated Maximum Use and Maximum Air Concentrations of 1,3-D

The regression shown in Figure 1 is based on 80 data points representing:

- 8 townships (Oxnard, two near Parlier, Ripon, Santa Maria, two near Shafter, Watsonville)
- 5 years of 1,3-D PUR and weather data for the highest recent use years (2013-2017)
- 2 scenarios for acute mitigation (break up of fields into smaller blocks and shifting to lower emission fumigation method)

The eight townships selected are among the highest for 1,3-D use and ATP. The five years of 1,3-D PUR data used in the modeling includes four years (2013-2016) when DPR granted waivers to exceed the township cap. These townships and years indicate the likely highest possible use of 1,3-D and associated highest possible air concentrations. Figure 1 and Table 1 show the following for the 40 township and year combinations modeled:

1) two had estimated 1,3-D air concentrations that exceeded 0.56 ppb as a one-year average;
2) four had 1,3-D use that exceeded the proposed township cap of 204,200 ATP; and
3) all exceedances of 0.56 ppb or 204,200 ATP assumed that all fumigations complied with the proposed setback requirements by breaking up the field into smaller blocks and fumigating sequentially using higher emission methods (Option 1).
4) All four townships had predicted one-year air concentrations well below 0.56 ppb when fumigations complied by switching to lower emission methods (Option 2).

Table 1a. Highest township and year combinations under field breakup option (Option 1, solid black points in Figure 1) during 2013-2017. These township and year combinations exceeded the proposed township cap of 204,200 ATP.

City	Township	Year	Estimated ATP Using Field Breakup	Estimated Air Concentration (ppb)
Parlier	M15S22E	2016	240,581	0.57
Ripon	M02S08E	2015	217,544	0.35
Parlier	M14S18E	2013	213,873	0.65
Shafter	M24S26E	2015	208,220	0.46

Table 1b. Estimated ATP and air concentrations under the fumigation method change option (Option 2, white or open points in Figure 1) for the highest township and year combinations shown in Table 1a.

City	Township	Year	Estimated ATP Using Fumigation Method Change	Estimated Air Concentration (ppb)
Parlier	M15S22E	2016	137,800	0.28
Ripon	M02S08E	2015	148,263	0.21
Parlier	M14S18E	2013	127,477	0.22
Shafter	M24S26E	2015	100,814	0.23

Table 1a lists four township and year combinations that exceeded the 204,200 ATP. Tree orchards and grape vineyards fumigated using variations of 18-inch injection depth fumigation methods accounted for all 1,3-D use in the given township/year (appendix). An addendum to the economic impacts analysis for the proposed regulations (Mace, 2022) indicates that nearly all tree and grape fumigations would shift from 18-inch depth methods to 24-inch depth methods with lower emissions (Option 2) to comply with the proposed setback requirements. To ensure that the 0.56 ppb regulatory target concentration is not exceeded, even for a one-year average, the proposed regulations will require all tree and grape fumigations to use 24-inch depth fumigation methods, or other fumigation methods with lower emissions. This analysis demonstrates that shifting to fumigation methods with lower emissions will reduce 1,3-D emissions from tree and grape fumigations to levels well below the proposed township cap and regulatory target concentration even for the townships with highest 1,3-D use.

Since all tree and grape fumigations will be required to shift to 24-inch depth methods, a different set of townships were predicted to have the highest 1,3-D ATP (Table 2), and that the estimated air concentrations are significantly lower in comparison to Table 1a. The highest townships are township S11N35W near Santa Maria for 2013 and 2014. Figure 1 and Table 2 show that these two township and year combinations had estimated 1,3-D use of approximately 151,000 ATP and air concentrations of approximately 0.35 ppb for fumigation method changes (Option 2).

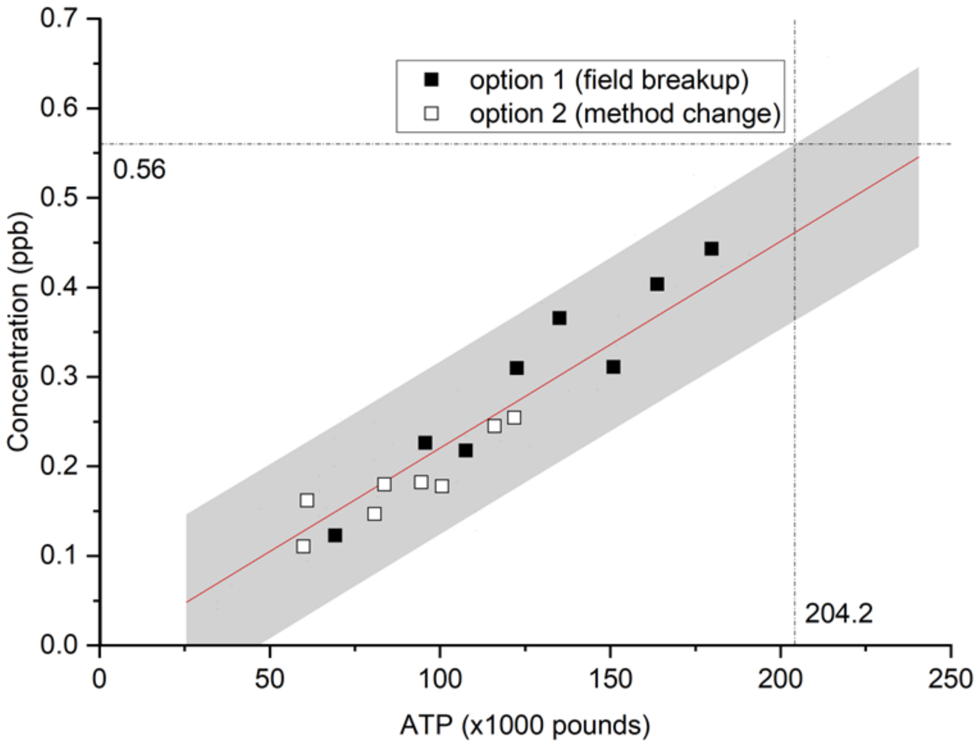
Table 2. Highest township and year combinations based on historic use under proposed regulations using the fumigation method change option (Option 2, white or open points in Figure 1) during 2013-2017.

City	Township	Year	Estimated ATP Using Fumigation Method Change	Estimated Air Concentration (ppb)
Santa Maria	S11N35W	2013	151,735	0.34
Santa Maria	S11N35W	2014	150,609	0.35
Ripon	M02S08E	2015	148,263	0.21
Watsonville	M12S02E	2014	146,269	0.29

The appendix shows that most 1,3-D use in township S11N35W near Santa Maria is for strawberries. Fumigant products used for strawberries usually contain a combination of 1,3-D and chloropicrin. Prior to 2015 most fumigation methods for strawberries used a standard polyethylene tarpaulin with drip chemigation. Product label changes for chloropicrin requested by DPR, including larger buffer zones, went into effect in September 2017. The appendix shows that in 2017 all strawberry fumigations used TIF tarpaulins, which have much lower emissions than standard tarpaulins.

Based on the available data, almost all growers and applicators in the townships with the highest historical 1,3-D use will be required to shift to fumigation methods with lower emissions or have already shifted. With the proposed acute mitigation measures, the highest estimated one-year average 1,3-D air concentration is approximately 0.35 ppb. Moreover, the 70-year average specified by the risk management directive will be even lower than the highest one-year value. This is illustrated in Figure 2 that shows the highest estimated five-year average 1,3-D air concentration indicated by the white or open squares is 0.25 ppb (township M15S22E near Parlier) using the fumigation method change option (Option 2).

Figure 2. The estimated 1,3-D ATP and air concentrations (as the 95th percentile of the five-year average concentrations over a township) for the modeled townships and scenarios (squares). The regression line (solid) and the prediction intervals (shaded) are taken from Figure 1.



Conclusions and Activities to Ensure Effectiveness of Mitigation Measures

Based on the data for all 1,685 township-year combinations with 1,3-D use during 2013-2017, which considers the likely highest 1,3-D use in the State, the highest estimated average one-year 1,3-D air concentration is approximately 0.35 ppb. This is 63 percent of the 0.56 ppb regulatory target concentration for non-occupational bystander cancer risk. Therefore, the proposed acute mitigation measures will lower 1,3-D emissions and annual air concentrations well below the amounts necessary to address cancer risk to non-occupational bystanders, thereby eliminating the need for a township cap. Moreover, estimated five-year concentrations are significantly lower than the highest one-year value. The DPR risk management directive specifies a 70-year average risk for cancer risk to bystanders which provides an additional margin of safety.

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. If new data indicates additional mitigation is needed after the regulations are in effect, that new data will help determine which additional mitigation measures (e.g., more stringent setbacks, fumigation method changes, township cap other use limit) will be most effective in reducing exposures.

Citations

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Tao, Jing. 2016. “Analysis of Agricultural Use and Average Concentrations of 1,3-Dichloropropene in Nine Communities of California in 2006 – 2015, and Calculation of a Use Limit (Township Cap),” Department of Pesticide Regulation Report, October 6, 2016.

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Appendix

Table 3. Use of 1,3-D by crop and fumigation method for the four township and year combinations that exceeded the proposed township cap of 204,200 ATP during 2013-2017 when the modeling assumed the field breakup option.

Township-Year Community	**Crop**	**Amount of Unadjusted 1,3-D (pounds) by Fumigation Method and Method Code**			
		Untarped 18-inch Broadcast (code 1206)	**Tarped 18-inch Broadcast (code 1207)**	**Untarped 18-inch Strip (code 1210)**	**Total**
M15S22E-2016 Parlier	Almond	96,475		7,037	103,511
	Cherry	2,081			2,081
	Grape	15,203			15,203
	Grape, raisin	6,680			6,680
	Peach	8,652	4,658		13,310
	Plum	13,033	8,959		21,992
	Preplant	6,680			6,680
	Walnut			12,101	12,101
	Total	148,804	13,618	19,138	181,559
M02S08E-2015 Ripon	Almond	48,243		16,077	64,321
	Preplant	9,185	30,060	18,543	57,788
	Walnut	38,076			38,076
	Total	95,504	30,060	34,621	160,184
M14S18E-2013 Parlier	Grape, raisin	52,327			52,327
	Preplant	71,299			71,299
	Total	123,626			123,626
M24S26E-2015 Shafter	Preplant	109,048		33,310	142,359
Total		844,916	87,355	140,827	1,073,097

Table 4. Use of 1,3-D by crop and fumigation method for township S11N/35W near Santa Maria during 2013-2017. Estimated ATP and air concentrations for this township are also shown.

Crop	**Fumigation Method and Method Code**	**Amount of Unadjusted 1,3-D (pounds)**				
		2013	**2014**	**2015**	**2016**	**2017**
Brussels sprout	Untarped, 12-inch (1201)				357	515
	Untarped, 18-inch (1206)				991	
Carrot	Untarped, 18-inch (1206)		18,464		11,923	
Cauliflower	Untarped, 18-inch (1206)				10,426	
Raspberry	TIF, 18-inch (1247)		3,379			
Strawberry	Tarp, drip (1209)	125,191	106,443	68,911	34,158	
	TIF, 12-inch (1242)	7,326	7,791	6,450	12,568	16,676
	TIF, 18-inch (1247)		280			
	TIF, drip (1259)	8,756	19,384	65,398	88,319	110,183
	Other (1290)			4,938		
Total unadjusted pounds		141,274	155,742	145,697	158,743	127,375
Estimated ATP		*151,735*	*150,609*	*118,104*	*104,938*	*54,502*
Estimated 1-yr air concentration (ppb)		***0.34***	***0.35***	***0.27***	***0.18***	***0.09***