M E M O R A N D U M

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DATE: December 8, 2022

SUBJECT: EXPOSURE ESTIMATES, MARGINS OF EXPOSURE, AND CANCER RISK ESTIMATES FOR TARP CUTTERS EXPOSED TO 1,3-DICHLOROPROPENE

On September 12, 2022, the Department of Pesticide Regulation's (DPR) Human Health Assessment Branch (HHA) received a request from the Worker Health & Safety Branch (WHS) to review occupational exposures and risks from 1,3-dichloropropene for a class of handlers known as tarp cutters (see Appendix A). In response to that request, HHA calculated new and/or revised short-term, intermediate-term, and long-term exposure estimates and non-cancer and cancer risk estimates for handlers. These estimates are based on current product labels and incorporate new data, as appropriate, as well as current permit conditions and regulations.

Background

In 2015, HHA published a Risk Characterization Document (RCD) for 1,3-dichloropropene (1,3-D) which evaluated inhalation exposures and risks to workers and occupational and residential bystanders (DPR, 2015). Multiple exposure scenarios were evaluated for handlers and reentry workers. Occupational seasonal, annual, and lifetime human equivalent concentrations, margins of exposure, and air unit risks and cancer risk values were revised in 2017 (DPR, 2017). Neither the original RCD nor the subsequent memorandum specifically evaluated exposure or risk for a class of workers known as tarp cutters.

Tarp cutters/splitters, tarp punchers, and tarp removers are all considered pesticide handlers according to state and federal regulations and California permit conditions. Handlers are defined

in Title 3 of the California Code of Regulation (CCR) as those who adjust, repair, or remove treatment site coverings, which can be interpreted to include cutting, punching and repositioning tarps (3 CCR 6000(d)). At the federal level, tarp cutters are defined as handlers in the Worker Protection Standard (Title 40, Code of Federal Regulations, 40 CFR 170.3(1)(B)). The US Environmental Protection Agency (US EPA) expands on this definition in its Soil Fumigant Training for Certified Applicators (see Appendix B). In addition, California labeling and permit conditions define tarp cutters and punchers as handlers,[1] noting that the label definition of handler includes additional activities not listed in 3 CCR 6000.

Handler and reentry worker exposure estimates are found in Section B. Exposure Assessment, in the 2015 RCD. There were sixteen 1,3-D end-use products with active registrations in California at the time the exposure assessment was conducted. As stated in the RCD,

> "Five of the labels for active products (Telone II, Pic-Clor 60 EC, Trilone II, Telone EC, and Inline) for active products on the DPR product label database for 1,3-D allow for exposures without respiratory protection. As stated in all five of these product labels, from 1-5 days following application, a half-face respirator is required for the handler (e.g., tarp remover), entering the treated area. However, for three of these product labels (Telone II, Tri-Cal Trilone II, and Telone EC), there's no information on respirator requirements for handlers entering the treated area after the 5-day fumigation period. The other two labels (Pic-Clor 60 EC and Inline), state that the handler entering the treated area 5 days or more after the application doesn't have to don respiratory protection unless irritation of the eyes and nose, presumably due to the chloropicrin in the product mixture, occurs." (DPR, 2015, p. 136).

Therefore, the exposure assessment did not incorporate a respiratory protection factor into the exposure estimates for the tarp remover.

Revised and New Handler Exposure Estimates

At this writing, there are 16 products and 1 special local need (SLN) product registered in California containing 1,3-D, either as the sole active ingredient (AI) or in combination with other AIs. All conventional (Section 3) product labels have been updated since the 2015 RCD was published. Many label updates reflect a transfer of Dow/Corteva 1,3-D products to Salt Lake Holdings in 2020, and do not necessarily reflect changes to applications, uses, or personal protective equipment (PPE).

Table 1 lists the revised estimates for handler scenarios previously presented in the 2015 RCD as well as estimates for a new scenario, the tarp cutter. All estimates utilize the surrogate chloropicrin ratio approach previously described (DPR, 2015). The revised exposure estimates

[1] California Department of Pesticide Regulation, Soil Fumigant 2012 Labeling and Permit Conditions (ENF 13-09). Available at https://www.cdpr.ca.gov/docs/county/cacltrs/penfltrs/penf2013/2013009.htm.

trend lower than the 2015 estimates because the 1,3-D specific data used for estimating exposure utilized spillage controls (Houtman, 1993). Previously, 1,3-D specific non-spillage control data were used for these scenarios since no information specifically addressing the use of spillage controls was found in the chloropicrin studies (Beard, 1996; Rotondaro, 2004). However, subsequent review of the studies found the following statements:

> "…typical commercial application practices were followed" (Rotondaro, 2004), and
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> "…The application equipment used in the study was typical commercial equipment representative of the geographic region. It was maintained and operated according to standard commercial practices." (Beard, 1996).

Moreover, TriClor is listed among the products in the studies. A search for TriClor product labels in the US EPA's Pesticide Product and Label System website[2] resulted in labels registered as early as 1994 and 1995 with language requiring the use of spillage control techniques when applying the fumigant. For this updated exposure analysis, the assumption was made that spillage control techniques were utilized in both studies.

Short-term air concentrations for each handler scenario were calculated in the same manner as in the 2015 RCD, using the 95th percentile of the natural logarithms of the air concentration data (Frank, 2009). The exposure estimates in Table 1 are the highest of those calculated for each exposure scenario using the current product labels and permit conditions. Of the 15 active end-use product labels which were reviewed, six of the labels (Pic-Clor 60 EC, Tri-Cal Trilone II, Tri-Cal Tri-Form 80 EC, Telone II, Telone EC, and InLine) do not require handlers to start work wearing a respirator when entering the field after 5 days post-application. Handlers potentially impacted by this issue include the tarp cutter and tarp remover. The exposure estimates for these scenarios were generated without incorporating the protection factor for a respirator. The seasonal, annual, and lifetime air concentrations for all handler scenarios were calculated utilizing the associated seasonal application rates and number of application days used in the 2015 RCD (DPR, 2015)

Several of the exposure estimates exceed the 8-hr time-weighted-average (TWA) 1,3-D air concentration of 1 ppm. However, 3 CCR 6780 General Fumigant Safe Use Requirements (a) states, "When fumigant concentrations cannot be controlled and an employee's exposure exceeds the Permissible Exposure Limit (PEL) as specified in Title 8, California Code of Regulations, Section 5155, Airborne Contaminants, or more stringent requirements by product labeling, the employer shall provide and require the employee to wear approved respiratory protective equipment." Title 8 CCR 5155 lists the chemical "Dichloropropene" in Table AC-1 as having a PEL of 1 ppm. Assuming this is 1,3-dichloropropene, the exposure estimates above 1 ppm would require the use of approved respiratory protective equipment. However, since the regulation does

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[2] US Environmental Protection Agency Pesticide Product and Label System. https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1 Accessed September 23, 2022.

not specify the type of respiratory protection (e.g., half-face or full-face respirator), respiratory protection factors for the tarp remover and tarp cutter exposure scenarios were not incorporated.

Table 1. New and Revised Handler Exposure Estimates

Exposure Scenario[a]	STAC[b]	SAC[c]	AAC[d]	LAC[e]
	(all values in ppm)			
Applicator (drip w/o tarp)	0.13	0.017	0.0058	0.0031
Applicator (drip w/ tarp)	0.10	0.0080	0.0027	0.0014
Applicator (injection auger)	0.45	n/a	n/a	n/a
Tarp Remover (shallow shank)	14	1.7	0.55	0.29
Tarp Remover (deep shank)	14	3.7	2.3	1.2
Tarp Remover (drip)	14	1.1	0.38	0.20
Tarp Cutter (shallow shank)	12	1.4	0.44	0.24
Tarp Cutter (deep shank)	12	3.0	1.9	0.99
Tarp Cutter (drip)	12	0.92	0.31	0.16

[a] Exposure estimates for the applicator using the drip application method and injection auger application method incorporate the 90% protection factor for a half-face respirator. The exposure estimates for the tarp remover and tarp cutter do not incorporate this protection factor.

[b] Short-Term Air Concentration (STAC): The estimated 8-hr time-weighted average (TWA) 1,3-D breathing-zone air concentration of the handler. This estimate consists of the 95th percentile of the natural logarithms of the air concentration data (Frank, 2009) corrected for recovery, adjusted to the maximum application rate, and, if applicable, for the use of a respirator.

[c] Seasonal Air Concentration (SAC): This estimate is the daily 8-hr TWA 1,3-D breathing-zone air concentration that the handler is anticipated to breathe over the course of the use season. The estimate consists of the mean value of the air concentration data corrected for recovery, adjusted to the appropriate seasonal application rate, and, if applicable, for the use of a respirator.

[d] Annual Air Concentration (AAC): This estimate represents the breathing-zone air concentration of the handler amortized over the full year. It is equal to the SAC multiplied by the ratio of the annual number of application days to the number of days in the year (i.e., 365).

[e] Lifetime Air Concentration (LAC): This estimate represents the working environment breathing-zone air concentration of the handler amortized over a lifetime. The LAC is equal to the AAC multiplied by the assumed number of years worked over a lifetime (i.e., 40 years), divided by the assumed lifespan (i.e., 75 years).

Calculation of Non-Cancer and Cancer Risk Estimates

Non-cancer risk estimates from exposure to 1,3-D were expressed as margins of exposure (MOE). The MOE is a quantitative tool used by DPR to determine the potential risk arising from exposure to a pesticide. It is defined as the ratio of the point of departure (or a human equivalent concentration for inhaled chemicals) to an estimated exposure. The exposure estimates are adjusted to account for PPE described on the label. Risks from 1,3-D are from inhalation, so the exposure values are expressed as air concentrations in parts per million (ppm).

$$\text{Margin of Exposure (MOE)} = \frac{\text{Human Equivalent Concentration (HEC) (ppm)}}{\text{Estimated Exposure (ppm)}}$$

The resulting value is compared to the acceptable or target MOE. Values at or above the target MOE are generally considered protective for all relevant populations regardless of exposure conditions. A a target MOE of 30 is considered protective of human health for 1,3-D (DPR, 2015). The target MOE is equivalent to the total uncertainty factor (UF_{TOTAL}), which is the product of an uncertainty factor of 3x that accounts for pharmacodynamic differences between laboratory animals and humans and an uncertainty factor of 10x that accounts the range of sensitivity within the human population (UF_{TOTAL} = (3x10) = 30).

To calculate new risk estimates for tarp cutters and revised risk estimates for other handler classes, the MOEs were calculated on a duration basis using the exposure estimates in Table 1. For short-term risks, a HEC of 33 ppm was used (DPR, 2015). For seasonal and annual risks, HECs of 1.26 ppm and 0.82 ppm, respectively, were applied (DPR, 2017). Lifetime cancer risks were estimated using the same method as described in the 2015 RCD, assuming both a portal of entry and systemic mode of action (MOA) (DPR, 2015). The risk values were calculated using the upper confidence limit air unit risk (AUR) value generated from linearized multistage cancer modeling as described in DPR, 2015 and 2017. HHA uses an acceptable negligible cancer risk value of 1×10^{-6}, which represents a single increased incidence of cancer among a population of 1 million individuals exposed in a similar manner. The new non-cancer and cancer risk estimates for select handler classes including tarp cutters are in Table 2, below.

Table 2. Margins of exposure (MOEs) and cancer risk values calculated using revised and new handler exposure estimates

	Short term[a]		Seasonal[b]		Annual[c]		Lifetime[d]		
Exposure scenario	**STAC** (ppm)	**MOE**	**SAC** (ppm)	**MOE**	**AAC** (ppm)	**MOE**	**LAC** (ppm)	**Elevated Cancer Risk** (Portal of Entry MOA)	**Elevated Cancer Risk** (Systemic MOA)
Applicator (drip w/o tarp)	0.13	254	0.017	74	0.0058	141	0.0031	1.30×10^{-05}	4.50×10^{-05}
Applicator (drip w/ tarp)	0.1	330	0.008	158	0.0027	304	0.0014	5.88×10^{-06}	2.03×10^{-05}
Applicator (injection auger)	0.45	73	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Tarp remover (shallow shank)	14	2	1.7	1	0.55	1	0.29	1.22×10^{-03}	4.21×10^{-03}
Tarp remover (deep shank)	14	2	3.7	< 1	2.3	< 1	1.2	5.04×10^{-03}	1.74×10^{-02}
Tarp remover (drip)	14	2	1.1	1	0.38	2	0.2	8.40×10^{-04}	2.90×10^{-03}
Tarp cutter (shallow shank)	12	3	1.4	1	0.44	2	0.24	1.01×10^{-03}	3.48×10^{-03}
Tarp cutter (deep shank)	12	3	3	< 1	1.9	< 1	0.99	4.16×10^{-03}	1.44×10^{-02}
Tarp cutter (drip)	12	3	0.92	1	0.31	3	0.16	6.72×10^{-04}	2.32×10^{-03}

Abbreviations: AAC, annual average concentration; AUR, air unit risk; HEC, human equivalent concentration; LAC, lifetime average concentration; MOA, cancer mode of action; MOE, margin of exposure; POE, portal of entry; ppm, parts per million; SAC, seasonal average concentration; STAC, short term average concentration; n/a, not applicable

Highlighted cells indicate and excess risk to handlers for either non-cancerous effects (below target MOE of 30) or cancer (population incidence above 1 in a million (10^{-6})).

[a] Short Term Risk Estimate: MOE = (short-term HEC)/Estimated Exposure (ppm) = 33 ppm/(values from Table 1) (DPR, 2015)

[b] Seasonal Risk Estimate: MOE = (seasonal HEC)/Estimated Exposure (ppm) = 1.26 ppm/(values from Table 1) (DPR, 2017)

[c] Annual Risk Estimate: MOE = (seasonal HEC)/Estimated Exposure (ppm) = 0.82 ppm/(values from Table 1) (DPR, 2017)

[d] Lifetime cancer risk estimate assuming portal of entry (POE) mode of action: the upper confidence limit air unit risk generated from linearized multistage cancer modelling (BMCS version 2.6) = 0.0042 ppm^{-1} (DPR, 2017); assuming systemic mode of action: the upper confidence limit air unit risk generated from linearized multistage cancer modelling (BMCS version 2.6) = 0.0145 ppm^{-1} (DPR, 2017)

Conclusions

Exposure estimates for select classes of 1,3-D handlers, including tarp cutters, were revised or newly calculated using current labels, regulations and permit conditions. These estimates were then used to calculate short-term, seasonal and annual risks for non-cancer effects and lifetime cancer risks. Importantly, some of the product labels do not require the handler entering the treated field after 5 days post-application to start work wearing a respirator. This can include the tarp remover and tarp cutter. Our findings indicate elevated risks for non-cancer effects for tarp cutters and removers for all durations analyzed, as well as elevated cancer risks.

References

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APPENDIX A.

REQUEST TO CALCULATE TARP CUTTER EXPOSURE ESTIMATES AND CANCER RISKS FOR 1,3-DICHOLOROPROPENE

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SUBJECT: REQUEST TO CALCULATE TARP CUTTER EXPOSURE ESTIMATES AND CANCER RISKS FOR 1,3-DICHOLOROPROPENE

As part of the Worker Health and Safety Branch's (WHS) review of occupational exposures for 1,3-dichloropropene (1,3-D) identified in the risk characterization document (RCD), it was determined that exposure estimates for the tarp remover scenario did not include tarp cutter activities. Field observations have shown that tarp cutting and tarp removing are specific activities, each with a potentially different level of exposure.

To ensure potential 1,3-D exposures to tarp cutters are also considered, WHS requests that the Human Health Assessment Branch staff calculate short-term, intermediate-term, long-term, and lifetime exposure estimates, as well as cancer risks for this scenario.

APPENDIX B.

CATEGORIZATION OF TARP CUTTERS AS FUMIGATION HANDLERS

(40 CFR Part 170)

Fumigation Handlers

The following activities are prohibited from being performed by anyone other than persons who have been appropriately trained and equipped as handlers in accordance with the requirements in WPS (40 CFR Part 170):

- Monitoring fumigant air concentrations;
- Cleaning up fumigant spills (this does not include emergency personnel not associated with the application);
- Handling or disposing of fumigant containers;
- Cleaning, handling, adjusting, or repairing the parts of application equipment that may contain fumigant residues; and
- Performing any handling tasks as defined by the WPS (40 CFR 170).

The following activities are prohibited from being performed in the application block from the start of the application until the entry-restricted period ends and in the buffer zone during the buffer zone period by anyone other than persons who have been appropriately trained and equipped as handlers in accordance with the requirements in WPS (40 CFR Part 170). (Note: persons repairing and monitoring tarps are considered handlers for the duration listed below). Prohibited activities (except for trained and equipped handlers) include:

- Participating in the application as supervisors, loaders, drivers, tractor co-pilots, shovelers, cross ditchers, or as other direct application participants;
- Installing, repairing, operating, or removing irrigation equipment;
- Performing scouting, crop advising, or monitoring tasks;
- Installing, perforating (cutting, punching, slicing, poking), or removing tarps; and
- Repairing or monitoring tarps until 14 days after application is complete if tarps are not perforated and removed during those 14 days.

Note: Highlighting added