Department of Pesticide Regulation

Julie Henderson
Director

Gavin Newsom
Governor

Jared Blumenfeld
Secretary for Environmental Protection

MEMORANDUM

TO: Karen Morrison, PhD
Acting Chief Deputy Director

FROM: Weiying Jiang, PhD, Staff Toxicologist *[original signed by W. Jiang]*
Eric Kwok, PhD DABT, Senior Toxicologist *[original signed by E. Kwok]*
Shelley DuTeaux, PhD MPH, Branch Chief *[original signed by S. DuTeaux]*
Human Health Assessment Branch

DATE: December 16, 2021

SUBJECT: Response to Comments by the US Environmental Protection Agency on the DPR's Draft Human Exposure Assessment for Allyl Isothiocyanate as a Soil Fumigant

---

Background

At the request of the Department of Pesticide Regulation (DPR), the Health Effects Division (HED) of US Environmental Protection Agency's (US EPA) Office of Pesticide Programs reviewed the July 2020 Draft Exposure Assessment Document (EAD) for Allyl Isothiocyanate (AITC). HED was asked to comment on a series of charge questions covering the hazard identification, exposure assessment, risk characterization, and worker and bystander margins of exposure, and provided comments in a letter submitted to DPR on October 8, 2020.

Responses to specific comments received on the charge questions related to the exposure assessment are detailed below. Response to the remaining charge questions are detailed in a separate memorandum. DPR sincerely appreciates HED's review. We consider comments by other regulatory agencies to be helpful in the development of technically complex, science-based regulatory documents. When appropriate, HED's comments were incorporated into the final EAD.

Note that references cited in the HED comments are not included in the reference section of this document; table references within DPR's responses correspond to tables in this memorandum and not those in the draft or final RCD unless otherwise specified.

Responses to Exposure Assessment Charge Questions

DPR Charge Question 5. Due to a lack of AITC exposure monitoring data, worker exposures to AITC were estimated using exposure monitoring data from 1,3-dichloropropene (1,3-D) and chloropicrin.

HED Comment: HED's assessment of worker exposures for soil fumigants is typically conducted with the use of required, chemical- and use pattern-specific exposure data and would be HED's recommendation for DPR. These data would most accurately represent the use pattern, chemical properties of AITC, and the potential exposures that may occur under a variety of use conditions, specifically the required tarp type/category. If DPR opts to proceed with the assessment of worker exposures for AITC without these data, HED concurs that the occupational handler use pattern for methyl isothiocyanate (MITC) does not align with AITC. Therefore, the use of 1,3-dichloropropene (1,3-D) and chloropicrin (Pic) data, which more closely match use pattern-specific exposure data, are a reasonable surrogate. Additionally, HED notes that the MITC exposure data are based on agricultural practices or application technology that have changed since the data were submitted. HED supports that the use pattern argument is stronger than the physical chemical argument described for use of these data.

DPR Response: No response necessary.

HED Comment, continued: HED notes that DPR applied an exposure adjustment ratio to account for the physical chemical properties between 1,3-D and Pic. Since HED typically uses chemical- and use-pattern specific exposure data, an adjustment ratio is not required and adjustment methods have not been previously evaluated. Further, HED notes that the ratio approach as described does not account for several application factors which could introduce uncertainty, including the tarp type used for the individual studies and the numbers (n) of study participants, and impact potential exposures for workers performing tasks such as tarp cutting or removal. Ultimately, HED recommends for the use of AITC-specific data since these data most accurately represent the behavior of AITC under varying handler exposure scenarios and eliminates the inherent uncertainties associated with the use of surrogate exposure data.

DPR Response: Similar to HED, DPR prefers using active ingredient (AI)-specific data to conduct exposure assessment when available. In the past when no AI-specific data were available, DPR had used surrogate data from other pesticides with similar physiochemical properties and application methods. For worker exposures, there is no AITC exposure monitoring available at all, so monitoring data from 1,3-dichloropropene (1,3-D) and chloropicrin (Pic) were used as surrogates. DPR used available but limited AITC data (soil emission and air concentration data measured during applications) to confirm the worker exposures were not underestimated with the use of 1,3-D and Pic surrogate data. Discussions are provided in detail in Exposure Appraisal of the AITC Exposure Assessment Document, as well as the Method Appraisal of Appendix 1 of the AITC EAD.

Details in the Exposure Appraisal of the AITC EAD have been clarified to explain that an exposure adjustment ratio, while used previously for 1,3-D, could not be used for the AITC exposure assessment because no AITC exposure monitoring data were available from which to derive an exposure adjustment ratio. Instead, exposure data from the surrogate fumigants 1,3-D and Pic were only corrected for appropriate application rates, assuming that the application rate, application method, and handler exposures are similar to AITC.

DPR Charge Question 6: DPR estimated bystander exposures to AITC using an air dispersion model (AERMOD). Occupational bystander exposures were estimated at the field edge, and residential bystander exposures were estimated at 25 and 100 ft from the field edge.

HED Comment: As described above for the occupational handler assessment, HED typically conducts bystander exposure assessment with use of chemical-specific soil emission flux data. Consistent with the above response, the use of surrogate data likely introduces uncertainties which may impact estimated bystander risks. Further, HED employs the PERFUM 3 (note: PERFUM 2 was used in previous soil fumigant assessments, PERFUM 3 will be used going forward) model for assessment of bystander risks with use of chemical-specific soil emission flux data. It is unclear to HED why DPR opted to use AERMOD modeling since this is not described in the DPR draft risk characterization assessment. While AERMOD is a component of PERFUM 3, HED is unsure of the impact from the use of AERMOD vs PERFUM 3 modeling. Further, HED notes that DPR contributed funding to the development of PERFUM 3 and has been closely involved in its development, including recent upgrades. If DPR opts to rely on AERMOD, HED recommends that DPR describe the reasoning for its use in lieu of PERFUM 3 and discuss what impacts or uncertainties may occur from its use.

DPR Response: A new section titled "Comparison with PERFUM3" has been added to the memorandum "Determination of allyl isothiocyanate air concentrations around fields fumigated using shank or drip applications-revised" which is appended to the final EAD. This new section discusses PERFUM3 and compares modeling results between PERFUM3 and the results of the AITC assessment. PERFUM3 uses air concentration estimates from the entire modeling period (i.e., 5 years) to calculate the 95th percentile value. Therefore, DPR concluded that PERFUM3 could not meet the purpose of this AITC analysis as short-term exposure is defined as exposures "*lasting seven days or less*" (Kwok, 2017). However, DPR adopted the concept used in PERFUM3 and used 95th percentile values of air concentrations instead of maximum concentrations to evaluate bystander exposures. DPR conducted additional AERMOD runs with updated model inputs, and also revised the post-AERMOD processing methods to generate revised air concentrations outputs. In addition to the updates to the appended memorandum, DPR also revised all relevant bystander exposure assessment tables in the exposure assessment document for use in calculating margins of exposure (MOEs) for all target populations.

This assessment used AERMOD View™, which employs the same modeling engine (AERMOD) as PERFUM3. PERFUM3 includes several pre- and post-modeling features and is capable of generating different percentile rank (e.g., 95th percentile) values of air concentrations, which are generated by combining modeling results from all receptors at the same distance and from all modeled days (e.g., 5 years). However, short-term exposures may occur from as few as one application, so the percentile rank values should be generated only using air concentrations from the same day. For that purpose, this assessment set AERMET View™ to output daily air concentration values for each receptor, and the 95th percentile value of each day was estimated using air concentrations from all the receptors on the same distance and at the same sampling height. To the best of our knowledge, similar results cannot be obtained from PERFUM3.

DPR originally used maximum air concentrations instead of the 95th percentile values to estimate bystander exposures to expedite our modeling process and to maximize computing efficiency. Updating the bystander exposure assessments with the use of 95th percentile values agrees with DPR's practice as the 95th percentile values are considered as the "*upper-bound estimates*" and should be used for short-term exposure assessments (Frank, 2009; Kwok, 2017). This also consistent with values used for other short-term scenarios in the AITC exposure assessment. Table R-1 below used a 40-ac shallow shank with polyethylene (PE) tarp scenario as an example to compare the estimated bystander exposures using the current method and the previous maximal method. Compared to the previous values, applying the 95th percentile values in the current assessment will only cause less than 10% difference for the occupational bystander values, and less than 20% difference for the residential bystander values.

Table R-1. Comparison of select bystander exposures estimated using the current method (using 95th percentile values) or the previous method (using maximum values)

Exposure scenario	STADD[a] (µg/kg/d)		
	Previous method (using maximum values)	Current method (using 95th %ile values)	Difference
Occupational bystander			
0 ft[b], adult	185	175	6%
Residential bystander			
25 ft, adult	112	98	14%
25 ft, child	272	238	14%
100 ft, adult	92	79	16%
100 ft, child	203	175	16%

a: short-term absorbed daily dose;
b: distance from the field edge.

DPR used all available AITC data and only used surrogate data when data gaps were identified. As discussed in the emissions memorandum "Using allyl isothiocyanate (AITC)-

specific and surrogate data to determine AITC soil emissions for residential and occupational bystander exposure assessments-revised" (Appendix 1 of the final EAD), AITC soil emissions data are only available for two of the five assessed application scenarios (shallow shank with polyethylene (PE) tarp and drip with PE tarp). These two sets of emission data are already used in this assessment to estimate air concentrations for bystander exposure assessment. DPR also compared these two AITC datasets with 1,3-D and Pic emission data which showed their emission rates were comparable. With that, for the remaining three scenarios without AITC data (shallow shank without tarp, deep shank without tarp and drip without tarp), 1,3-D and Pic data were used as surrogate for air concentration estimations. We direct HED to the updated and appended memoranda in the AITC EAD for additional discussion.

References:

Frank, J. 2009. Policy memorandum-Method for calculating short-term exposure estimates. HSM 09004. Sacramento, CA: Worker Health and Safety Branch, Department of Pesticide Regulation, California Environmental Protection Agency. https://apps.cdpr.ca.gov/whsrpts/hsmemo/hsmem_hsmno_action.cfm.

Kwok, E. 2017. Human health assessment branch policy on the estimation of short-term, intermediate-term (seasonal), and long-term (annual or lifetime) exposures. Sacramento, CA: Human Health Assessment Branch, Department of Pesticide Regulation, California Environmental Protection Agency. https://www.cdpr.ca.gov/docs/hha/memos/hha_expo_interval_memo_012517.pdf