Julie Henderson
Director

Department of Pesticide Regulation

Gavin Newsom
Governor

Jared Blumenfeld
Secretary for Environmental Protection

M E M O R A N D U M

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 Office of Environmental Health Hazard Assessment on DPR's 2020 Draft Human Exposure Assessment for Allyl Isothiocyanate as a Soil Fumigant

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Background

At the request of the Human Health Assessment (HHA) Branch of the Department of Pesticide Regulation (DPR), the Office of Environmental Health Hazard Assessment (OEHHA) reviewed the July 2020 Draft Human Exposure Assessment for Allyl Isothiocyanate (AITC) as a Soil Fumigant. OEHHA was asked to respond to a series of charge questions covering the hazard identification, exposure assessment, risk characterization, and worker and bystander margins of exposure, and provided comments to DPR on October 28, 2020.

This memorandum summarizes DPR's responses to OEHHA's comments on the draft AITC EAD in an itemized fashion, and is divided into the following sections: Summary and Major Recommendations; Detailed Comments; Response to Charge Statements; and Minor Comments. Corresponding revisions were also made the final EAD and its appendices as appropriate. Responses specific to the hazard identification and risk characterization are detailed in a separate memorandum.

Note that references cited in this memorandum are specific to OEHHA comments or DPR's response, and not necessarily duplications of those in the draft or final EAD. Likewise, every effort has been made to ensure that any references to tables found in the draft or final EAD are clear. Tables specific to this memorandum are numbered independently of the EAD. All OEHHA comments in this memorandum are direct quotes from the documents, which can be found at https://oehha.ca.gov/media/downloads/pesticides/document/commentsaitc110320.pdf.

OEHHA Summary and Major Recommendations – Exposure Assessment

OEHHA Comment 1: There is a need to address data gaps in environmental fate information. Plant materials that release AITC and related isothiocyanates have been studied for decades as alternatives to chemical fumigants. However, soil fumigation with highly-purified AITC is a relatively new pest control approach. Consequently, the environmental fate data available for purified AITC are limited and most studies were performed under laboratory conditions (Borek et al., 1995; Pechacek et al., 1997). This lack of environmental fate data, such as degradation chemicals and soil half-life estimated from field studies, contributes substantially to the overall uncertainties in the AITC exposure estimates and potential health impacts. OEHHA suggests that DPR include an environmental fate section in the document, identify existing data gaps and discuss how this may limit the assessment.

> **DPR Response:** The Exposure Appraisal of the AITC Exposure Assessment Document (EAD) has been updated with a new Section C. Exposure to AITC Degradates to discuss possible human exposures to these compounds. For additional detail, please see the response to OEHHA's Detailed Comments on the environmental fate of AITC degradates, below.

OEHHA Comment 2: Greater transparency in data selection and clarity in statistics used would be useful. Because AITC has limited human exposure and field emission studies, DPR used data from various studies of surrogate chemicals to evaluate occupational and non-occupational exposures. Given the situation, OEHHA agrees with DPR's general approach of using data of surrogate chemicals. However, the reasons for selecting certain soil emission data and the rationale for applying certain statistics to summarize occupational and non-occupational exposures were not clearly stated in the draft EAD. OEHHA suggests that DPR clearly discuss and quantify if possible how (i) variation within the selected data of surrogate chemicals, and (ii) uncertainties of using surrogate data would impact the AITC exposure estimations.

> **DPR Response:** Each of three application scenarios, i.e., shallow shank without tarp, deep shank without tarp, and drip without tarp, were analyzed for the associated emission rates of either 1,3-dichloropropene (1,3-D) or chloropicrin (Pic). The study with the highest emissions was selected as surrogate data. This was purposefully conservative, with the highest values providing the bounding estimates of the emissions. The criteria of how the surrogate studies were selected can be found in the memorandum "Using allyl isothiocyanate (AITC)-specific and surrogate data to determine AITC soil emissions for residential and occupational bystander exposure assessments-revised," which is the Appendix 1 to the AITC EAD. Please also refer to DPR's response to OEHHA's detailed comment on emissions using surrogate data below for additional details.

OEHHA Comment 3: Only inhalation exposures were evaluated and the draft EAD did not include dermal exposure to AITC. AITC is a known skin irritant and sensitizer. This concern may be particularly relevant for pesticide handlers who could be dermally exposed to highly concentrated (e.g., > 96%) AITC soil fumigant products. AITC residues in soil could also affect post-application workers with limited or no PPE. OEHHA suggests DPR investigate this route of exposure.

DPR Response: Personal protective equipment (PPE) requirements of Dominus® are provided in III. FACTORS CONSIDERED TO DEVELOP EXPOSURE SCENARIOS, section C. Label precaution and PPE requirement of the exposure assessment document. The product requires all handlers "*when performing activities with the potential for liquid contact*" to use coveralls in addition to long-sleeved shirt and long pants. While the cloth penetration factor of AITC is not available, DPR by default assumes each layer of coverall or long-sleeved work clothing provides 90% protection from pesticide exposure (Thongsinthusak *et al.*, 1993). Therefore, considering the PPE requirement and the volatile property of AITC, this assessment determined the primary route of AITC exposure is through inhalation.

OEHHA Detailed Comments – Exposure Assessment

1. Environmental Fate of AITC – Degradants

In aqueous solutions, Pechacek et al (1997) demonstrated that 24-50% of AITC was transformed into allylamine and 11-26% was transformed to carbon disulfide. Both chemicals are highly volatile at ambient temperature and pressure. Allylamine could cause eye and respiratory tract irritation. Carbon disulfide is listed as a reproductive toxicant under Proposition 65.
OEHHA suggests that DPR discuss if soil emissions of carbon disulfide, allylamine, or other AITC degradants are possible under field conditions, and if these chemicals, which are not evaluated in the draft EAD, can potentially pose a health hazard to handlers and bystanders.

DPR Response: A new section titled "Exposure to AITC degradates" has been added to the exposure appraisal portion of the AITC EAD to discuss possible human exposures to AITC degradates. This assessment did not estimate worker exposures to AITC degradates, as there is no study that monitored worker exposures to AITC degradates. In addition, there is no information on soil emission rates of AITC degradates under label-described application methods. Accordingly, the quantitative assessment of bystander exposures to AITC degradates could not be performed.

The degradation pathway of AITC has been discussed previously (Borek *et al.*, 1995; Pechacek *et al.*, 1997; USEPA, 2013). In soils with pH ranging from 4.4 to 9.1, the half-lives of AITC were between 20-60 hr, and at near neutral pH (6-8), the primary degradates in aqueous solutions were allyl thiocyanate (ATC), allylamine (AA), carbon disulfide (CDS), allyl dithiocarbamate sodium salt (ADTC) and diallylthiourea (DATU) (Borek *et al.*, 1995; Pechacek *et al.*, 1997). For applicators and loaders with exposures occurring at the time of applications, they are not likely exposed to AITC degradates except ATC, as it is an isomerization product of AITC and that may exist in commercially prepared AITC products. Bystander exposures to ATC are also possible but the exposures are expected lower than AITC as ATC is more reactive than AITC in the environment. Bystanders may also be exposed to volatile AA and CDS. Although the quantitative assessment of these exposures is not feasible due to the lack of data, the exposures are not expected to be high as both AA and CDS rapidly react with photochemical radicals after releasing into the atmosphere (USEPA, 2013).

2. Occupational Exposure of On-site Workers

a. Exposure Scenarios: DPR used data from surrogate chemicals and product label to define exposure scenarios… OEHHA agrees with these scenarios for on-site workers. Off-site workers are discussed in the bystander section below.

DPR Response: No response necessary

b. Surrogate Data: Breathing level air concentrations of MITC (methyl isothiocyanate), a structural analog of AITC, have been measured for some application methods. However, unlike AITC, a precursor chemical (metam sodium or metam potassium) is first applied to the soil and then converts into MITC over the next 2-24 hours. For this reason, DPR stated that MITC studies are less likely to be relevant to AITC applicator exposure scenarios compared to 1,3-D or chloropicrin studies. OEHHA agrees with this assumption and the use of 1,3-D and chloropicrin as surrogate chemicals in estimating occupational exposures for on-site workers.

DPR Response: No response necessary

c. Re-entry Interval: The proposed re-entry interval (REI) is 5 days following application, with or without tarp. Due to limited field data, it has not been demonstrated if all the applied AITC would be depleted after 5 days. In a field data study presented by the registrant, the peak emission rate of AITC when the PE tarp was cut after Day 5 was as high as 80% of the highest peak emission rate observed (Ajwa et al., 2014). This suggests that if a certain set of environmental conditions increases the soil half-life of AITC, a significant percentage of the applied chemical could still be present after 5 days, which could lead to higher than expected soil emission following the expiration of REI.

DPR Response: Text was added to the exposure appraisal of the EAD in Section A, Occupational Handler Exposure, to discuss the uncertainty in tarp cutter/remover/puncher exposure assessment. DPR agrees that for tarped fields, applied AITC may not completely dissipate from soil before tarp-cut (for shank applications) or tarp-punch (for drip applications). To assess post-application exposures after the REI expires, tarp cutter/remover/puncher exposure scenarios were included in this assessment.

Chloropicrin (Pic) monitoring data from broadcast shank with polyethylene (PE) tarp applications were used to estimate exposures for tarp cutter/remover/puncher. The table below compares the fumigant emission rates before and after tarp-cut (or tarp-punch) with comparisons for all available AITC data and the surrogate Pic data mentioned above. For all AITC applications, the maximum AITC emissions after tarp-cut (or tarp-punch) always occurred within one day after tarp-cut (or tarp-punch) and were all lower than the maximum emissions before tarp-cut (or tarp-punch). The highest ratio of emissions between before and after tarp-cut (or tarp-punch) was 77%, which is comparable or lower than ratios from the Pic study used to assess tarp cutter/remover/puncher exposures. The lower AITC emissions after tarp-cut indicates tarp cutter/remover/puncher exposures to AITC are expected lower than the exposures to Pic.

Table R-1. Comparison of maximum fumigant emission rates before and after tarp cutting

Fumigant[a]	Application method	Maximum emission rate[b] (μg/m²/s)		
		Before tarp-cut	After tarp-cut	Ratio[c]
AITC	Shank with TIF tarp[d]	8.9	0.5	5%
	Drip with TIF tarp	34.8	0.09	<1%
	Shank with PE tarp	9.9	7.6	77%
	Drip with PE tarp	65.6	6.0	9%
Pic	Shank with PE tarp	23.3	70.4	302%
		57.8	47.8	83%

Information was summarized from Ajwa et al. (2014), Beauvais (2010) and Beard et al. (1996).
a: AITC=allyl isothiocyanate, Pic=chloropicrin;
b: the emission rates from those studies were used directly without application rate adjustments;
c: ratio of emissions between before and after tarp-cut (or tarp-punch);
d: TIF=totally impermeable film, PE=polyethylene.

For fields without tarp, the dissipation of AITC from soils are expected faster than in tarped field, as AITC more readily escapes from soil without tarp cover. Correspondingly, the re-entry worker exposures are expected to be even lower.

d. Statistics: Two surrogate fumigant chemicals, 1,3-D and chloropicrin, were used to estimate occupational exposure to AITC. For a given worker exposure scenario, a wide range of breathing zone air concentrations of 1,3-D or chloropicrin were obtained from field studies at different locations, using different application methods, and under different environmental conditions.

DPR reported the 95th percentiles of the exposure data when multiple studies were available. The 95th percentile calculation in the draft EAD (DPR EAD-95th) cited the method introduced in a DPR memo, which is different from the 95th percentile commonly used in statistical analysis (DPR, 2009). The commonly known 95th percentile is a type of non-parametric summary of the sampling data. The DPR method calculates the mean and standard deviation of the natural logarithms of the sampling data, uses two estimated statistics to determine a hypothetical log normal distribution, and then estimates the 95th percentile of the hypothetical distribution as DPR EAD-95th (DPR, 2009). This method relies on two assumptions: (1) the true exposure data has a log-normal distribution; (2) the measured exposure samples are representative and therefore their statistics can be used to determine the log-normal distribution of the exposure data. DPR EAD-95th can generate a reasonable high-end estimation that usually cannot be achieved from the small sample numbers typically collected in field studies. The draft EAD did not provide the necessary analysis to show these two assumptions were met in the calculation of the DPR EAD-95th for applicators during shank and drip applications (Pages 15 - 20 the draft EAD). OEHHA suggests DPR provide the necessary supporting information for these assumptions.

For each scenario of loader, tarp-cutter, and re-entry workers, the draft EAD only provided one data point, instead of statistics. OEHHA suggests DPR clarify what the nature of the "data point" is (e.g., 77021 μg/m^3 in footnote of Table 17, Page 21, Draft EAD; 4117 μg/m^3 in footnote of Table 18, Page 22, Draft EAD; and 173 μg/m^3 in footnote of Table 19, Page 22, Draft EAD).

DPR Response: DPR has revised the EAD which now includes a table that describes the statistics of exposure data used for exposure estimates for each assessed scenario. In addition, DPR used 95th percentile values throughout the entire document to assess short-term exposures.

All studies used in this assessment were evaluated and fumigant applications in these studies followed label instructions. The application methods complied with California use conditions and were also similar to AITC application methods. All worker exposures monitoring data were collected when they were performing routine work activities. Therefore, DPR considers that the data used are representative of each assessed scenario. In addition, Shapiro-Wilk tests were conducted to test the data distribution assumption used to derive 95th percentile values. Additional explanation has been added to the table footnotes throughout the EAD. The exposure data followed a log-normal distribution for all assessed scenarios, with the exception of the data for loaders, which included one "outlier." As there is no justification to reject that value (that is, it is a true data point), it was included in calculating the 95th percentile value of loaders. It is noteworthy that including this outlier shifted the distribution to the upper-end, this generating a higher 95th percentile value.

e. Combining data from studies of two different chemicals and two application methods: Data from two surrogate chemicals, chloropicrin and 1,3-D (Table 10, Page 17, draft EAD) or from two different application conditions, drip applications with and without tarp (Table 14, Page 20, draft EAD), were combined to derive summary statistics (i.e. average, standard deviation, DPR EAD-95th, and range) (Table A). This approach may not be justified because of two issues:

1) Datasets from different application methods (e.g., tarped and un-tarped) or chemicals (e.g., chloropicrin and 1,3-D) should not be combined. Their emission rates and emission profiles are likely to be very different.

2) The combined data may not meet the distribution assumption required for the calculation of DPR EAD-95th as described in the previous comment. For example, the average air concentrations of chloropicrin and 1,3-D measured from applicator breathing zones using broadcast and bed shank application (shown in Table 10 of the draft EAD) are 366 μg/m^3 and 3,238 μg/m^3, respectively. This suggest the combined dataset of chloropicrin and 1,3-D is likely to have a bimodal distribution, not log-normal.

OEHHA suggests that DPR revise this approach or discuss its limitations.

> **DPR Response:** Additional text was added to the exposure appraisal in the final EAD (see Section A. Occupational Handler Exposure) to clarify the points above. This assessment considered exposure data from both 1,3-D and Pic as surrogates for AITC. For each of the assessed scenarios, exposure data are available from either 1,3-D or Pic, with the exception of broadcast shallow shank application without tarp. In that scenario, both 1,3-D and Pic data are available for the applicators. Permutation tests revealed a significant ($p < 0.05$) difference in emissions between 1,3-D and Pic. Nevertheless, the application method is considered the major factor in determining applicator pesticide exposures. Also as discussed in Appendix 1 of the EAD, when 1,3-D and Pic were simultaneously applied to the same fields, their emission rates were comparable (Jiang, 2021). Therefore, for the broadcast shallow shank application without tarp, this assessment combined 1,3-D and Pic exposure data together to estimate applicator exposures to AITC.
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> In the final EAD, worker exposures were assessed for tarped and non-tarped applications separately with two exceptions: 1) Loaders, for which all the used exposure data were obtained from non-tarped applications; and, 2) Applicators in drip applications, for which permutation test shows the applicator exposures were comparable (i.e., no statistically significant difference) between tarped and non-tarped applications. Therefore, data from both tarp types were combined. This increased the number of available exposure data to generate average and 95th percentile values. Additional explanation was added to the loader and drip applicator sections of the EAD (V. Exposure Assessment) to clarify.

f. Uncertainties in estimating the number of AITC exposure days per year: Both 1,3-D and AITC applications are intended to target soil nematodes, so it is reasonable to derive the application days of AITC in a year (same as the worker exposure days in a year) estimates from 1,3-D data. For 1,3-D, the annual worker exposure days estimates are significantly lower in the 2014-2018 period compared to those from the 2010-2014 period and we believe this could be due to the implementation of a ban on December application since 2016. The total annual amount of 1,3-D used actually went up from the 2010-2014 period to the 2014-2018 period. The draft EAD used the 2014-2018 data for deriving estimates of annual worker exposure days for AITC. As of now, AITC usage is not subject to any restrictions and the label allows for more than one application per year. OEHHA is concerned that using the 1,3-D data from the 2014-2018 period may under-estimate workers' annual and lifetime exposures to AITC. Therefore, OEHHA recommends DPR discuss the limitations of the approach used and investigate other approaches to better estimate the workers' exposure days per year.

DPR Response: Text in Section III-D of the revised EAD (Factors considered to develop exposure scenarios: Projected AITC use in California) was revised and discussions were added to explain potential uncertainties associated with the use of 1,3-D data as surrogate.

This assessment analyzed 1,3-D use data from the most recent five years (2014-2018), which covers the period when DPR began restricting December applications in 2017 (DPR, 2016; DPR 2017). For each application scenario in Table 4, this assessment chose use data from the year that generate the greatest worker exposure estimates. As shown in the table below, data from 2016 were used for shallow broadcast shank and deep broadcast shank applications. These data were obtained before the revised permit conditions were imposed for 1,3-D (DPR, 2017). Use data from 2017 for shallow bed/strip shank and drip applications were used in the calculations, however, the number of days with exposures in 2017 was higher than in the previous years. Therefore, the new permit conditions did not affect 1,3-D use information cited in this assessment (i.e., annual number of 1,3-D applications), nor the resulting AITC long-term exposure estimates (annual and life-time).

Table R-2. Number of 1,3-dichloropropene applications per year in 2014-2018

Application method	Number of exposures per year				
	2014	2015	2016	2017	2018
Handler					
Shallow broadcast shank	76	85	95[a]	94	61
Shallow bed/strip shank	41	45	47	61	63
Deep broadcast shank	105	84	75[b]	58	61
Drip	41	43	49	49	46
Re-entry worker					
Shallow broadcast shank	76	85	95	94	63
Shallow bed/strip shank	41	45	47	61	63
Deep broadcast shank	157	163	142[b]	122	93
Drip	56	47	56	59	47

a: values selected in AITC exposure assessment are highlighted in grey;
b: 2016 use data were used because the seasonal application rate in 2016 is higher than in 2014, thus using 2016 data generates the highest estimations for intermediate-exposures.

3. Off-site Workers and Residential Bystanders

a. Exposure scenarios: The product labels for AITC prohibit application within 25 feet of any occupied structure and the registrant's training material recommends no application be done within 100 feet of any sensitive site. Therefore, for each application method, DPR estimated exposure for off-site workers at the field edge and for residential bystanders (children and adults) at 25 and 100 ft from the field edge. OEHHA agrees with these scenarios for off-site workers and residential bystanders.

DPR Response: No response necessary

b. Emission using surrogate data: As shown in Table 11 (Page 56, draft EAD) and reference list, there are various studies of 1,3-D and chloropicrin for some application method. It is unclear how the surrogate numbers in Table E1 (Page 39, draft EAD) were selected from multiple studies. OEHHA recommends that DPR describe how emission rate data were selected and why a particular study was chosen.

DPR Response: Criteria of selecting surrogate studies are stated in Appendix 1 of the EAD. To avoid underestimating the emissions, for each of the three application scenarios without AITC-specific emission data (shallow shank without tarp, deep shank without tarp, and drip without tarp), this assessment selected surrogate 1,3-D or Pic study that showed the highest soil emission rate.

c. Peak emission period of shallow shank with tarp: Emission data used by DPR was summarized for the first 5 days after application (Page 45-46, Appendix 1). Based on the data used by DPR, shallow shank with tarp was estimated to have maximum 2% daily mass loss due to soil emission in the first 5 days post application; therefore, the total soil emission over 5 days would cause <= 10% mass loss. Assuming AITC degradation half-life in soil is 2.5 days (USDA, 2014; US EPA, 2013), degradation could cause about 75% mass loss over the first 5 days. Considering both degradation and emission of AITC in soil in the first 5 days, 15% of AITC application amount could still be available and be released if tarp cutting occurs on the 6th day. OEHHA recommends that DPR analyze the environmental fate of AITC and evaluate the emission profile for at least 6 days to cover the tarp-cutting period.

DPR Response: Text was added into the title of Figure 1 in Appendix 1 of the EAD to clarify and provide better interpretation of the data. In the study from Ajwa et al. (2014), the emission rates were provided for different number of days for different application and tarp methods. As such, the Figure 1 in Appendix 1 only shows the emissions within the first 5 days to facilitate comparisons. DPR analyzed the entire emission profile, which extended from the start of application to 2 days after tarp cutting (for shank applications) or punching (for drip applications). For all four application and tarp methods, the highest emission rates occurred within the first five days. The restricted entry interval required on the Dominus® product label is also 5 days.

In regards to AITC's environmental fate, please see DPR's response to OEHHA's comment on Environmental Fate of AITC – Degradants, earlier in this document as well as the new Section C. (Exposure to AITC Degradates) in the final EAD for discussion of possible human exposures to AITC degradates.

d. Modeling bystander exposure with AERMOD: DPR modeled six 4-hr periods, three 8-hr periods, and one 24-hr period for each day over a 5 year period and used the maximum air concentrations of all modeling periods, all modeled counties, and the 5 years of weather conditions for bystanders' exposure assessment. DPR explained that using the maximums of the 5-year weather data was intended to compensate for the uncertainty in the emission data. However, using weather data for multiple years and multiple locations to characterize various dispersion conditions on the predicted air concentrations cannot compensate for the uncertainty in the emission rates.

Estimation of soil emission and air dispersion are two separate steps needed to predict air concentration and off-site workers and residential bystanders' inhalation exposures. OEHHA recommends DPR carefully evaluate soil emission rates and select the most appropriate dataset(s) and statistics for air dispersion modeling.

DPR Response: Text in the exposure appraisal section of the final EAD has been added to clarify the purpose of conducting multiple-year, multiple-location AERMOD modeling.

Of the five assessed application and tarp methods, three lacked AITC-specific data (shallow shank without tarp, deep shank without tarp, and drip without tarp). Therefore, 1,3-D or Pic surrogate data were used. For each application type, multiple sets of 1,3-D or Pic emission data are available. Data with the highest emission rates were selected as surrogate for purposes of estimating bystander exposures in this assessment.

For the remaining two application types (shallow shank with PE tarp and drip with PE tarp), AITC-specific emission data were used. However, because there was only one set of AITC emission data available for each of the two application types, the variability of emission rates caused by different field conditions (soil type, weather, application equipment, etc.) is not known. This suggest that the characterization of bystander exposures may not be adequate. To account for the variability of bystander exposures under different meteorological and field conditions, and for the short-term exposure assessment purpose, bystander exposures were estimated by extracting maximum emission rates from the AITC emission profiles and conducting AERMOD modeling in six different regions around the state. For each selected region, daily modeling was performed for five years and the upper-end values from the modeling results (i.e., maximum of daily 95th percentile value from all six regions and five years) were used to estimate the bystander exposures for purposes of this assessment.

e. Annual and long-term exposure: The seasonal, annual and lifetime doses were not estimated for residential bystanders and off-site workers. Because fumigation of a field may not happen all at once and a worker can work in multiple fields in the same area or across counties, it is possible for an off-site workers to be exposed to AITC many times a year. It is also possible that several AITC applications could occur sequentially near the same location and result in residential bystander exposure that lasts more than a few days. Lastly, the draft EAD notes that the DOMINUS® product can be used for end-of-season post-plant crop termination applications. OEHHA suggests DPR consider including seasonal, annual and lifetime exposure estimates for residential bystanders and off-site workers.

DPR Response: Text was added in the exposure appraisal of the final EAD to clarify (see Section B. Occupational and Residential Bystanders). This assessment only estimated short-term bystander exposures, which are considered as the highest exposure among all three exposure periods (short-, intermediate- and long-term). As AITC has not yet been registered in California as a fumigant, environmental monitoring data and use data in California are not available. It is unreasonable to assume bystanders are next to fumigated field on a daily basis (thereby assuming that the fumigant would also be used daily). Consequently, the intermediate- and long-term bystander exposures were not assessed in this document, but they are expected lower than short-term exposures.

f. Pesticide-related illness: The Isagro AITC products have been used outside of California for several years since US EPA approval in 2014. The Sentinel Event Notification System for Occupational Risk (SENSOR) program at NIOSH may have reports of pesticide illness related to AITC use in the 13 other participating states. OEHHA suggests that DPR consult the SENSOR program at NIOSH and ask if any AITC-related illnesses associated with soil fumigation have been reported in the US.

Secondly, California does have many reports of MITC-related illnesses and injury that were associated with bystander or re-entry worker exposure. MITC is regulated as a toxic air contaminant. Because AITC and MITC share similar chemical structures and many chemical properties as well as some application methods, there is a concern that AITC may pose a similar health hazard. OEHHA recommends that DPR evaluate this possibility in the draft EAD.

DPR Response: As discussed in Appendix 1 of the EAD, MITC compounds (e.g., metam sodium and metam potassium) are often applied using methods different of AITC. In addition, available MITC data often showed maximum MITC emissions at night, which is different from available AITC emission data which show maximum emissions during the day. As application methods and soil emission are major causes of bystander exposures, DPR does not agree with analyzing MITC-related illness cases as an estimate of possible AITC illness. The remainder of the comment is addressed in a separate memorandum on responses to the Risk Characterization Document.

Comments on Charge Statements – Exposure Assessment

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.

OEHHA Comment: OEHHA verified all of the AITC dose calculations for occupational exposures, but has not verified that the breathing-level air concentrations from the 1,3-D and chloropicrin were correctly reported from the registrant studies. OEHHA agrees that, in general, these estimates are reasonable and health-protective. However, OEHHA has some concerns about certain instances where disparate datasets were pooled. For example, Table 14 (page 20, draft EAD) shows that use of PE tarps reduced average breathing zone air concentrations by 44% (6 applicators) compared to un-tarped applications (6 applicators). The pooled-value exposure concentration is lower than if the un-tarped value were calculated separately. OEHHA recommends that exposure estimates from tarped and un-tarped applications be calculated separately so that the exposure from un-tarped applications will not be underestimated.

The draft EAD did not discuss environmental fate processes (soil dissipation, adsorption, chemical reactivity with soil constituents an aqueous-phase degradation) that reduce AITC levels in soil and ultimately impact the amount of AITC soil emissions. Laboratory studies reveal that the soil half-life of AITC can vary 3-fold due to factors such as soil type, temperature, pH and moisture levels (Borek et al., 1995). A longer soil half-life (60+ hours) would result in higher than expected emissions during and shortly after tarp cutting. In addition, high levels of soil residues could potentially cause dermal exposure of re-entry workers (soil shapers and pipe layers) who are not required to use any personal protective equipment (PPE) following expiration of the 5-day REI. We note that the Dominus product label suggests that growers test AITC-treated soil for phytotoxic residues “after a minimum of 7 days after application".

OEHHA suggests DPR expand the environmental fate discussion in the RCD including how variation in environmental conditions may affect emission rate at the time of tarp cutting and influence inhalation exposure of workers and nearby residents.

DPR Response: Responses to issues surrounding worker exposures, including potential exposure to AITC degradates and potential underestimation of exposure have been addressed earlier in the responses to OEHHA Major Comment 2 (page 2), OEHHA Detailed Comment 1 (page 3) and 2.e (page 6). The EAD was revised accordingly to address these points. Considering the volatility of AITC, for post-application workers, their AITC exposures through dermal route is expected minimal and much lower than through inhalation. For occupational and residential bystanders, please refer to the previous response to OEHHA Detailed Comment 3.d (page 10) for details. In general, the bystander exposures are not expected to be underestimated.

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.

OEHHA Comment: DPR used the AERMOD model to estimate inhalation exposure for occupational bystanders (i.e., off-site workers) at the field edge and for residential bystanders (children and adults) at 25 and 100 ft from the field edge… However, the draft EAD did not describe the data selection process. OEHHA suggests that DPR provide reasons and justifications for selecting the specific surrogate chemical studies to estimate emission rates in some bystander exposure scenarios.

Recently DPR used the HYDRUS model to estimate 1,3-D soil emissions when developing mitigation measures for all the application methods of 1,3-D. Since AITC field data are limited, OEHHA suggests DPR consider a similar approach or at least compare HYDRUS-derived results with available AITC field studies to evaluate this approach in AITC exposure assessment.

DPR Response: Please refer to responses to criteria of selecting surrogate studies, above. In addition, Appendix 1 of the EAD has been updated to explain the process by which DPR avoided underestimating emissions for application scenarios that lacked AITC-specific data. Those updates include a new section in the Appendix 1 that compares emissions estimated by HYDRUS. To provide support for the use of the surrogate data method, some modeling results from the two-dimensional version of the HYDRUS (i.e., HYDRUS-2D) on AITC applications were made available to the Human Health Assessment Branch by the Environmental Monitoring Branch (EM) at DPR. Details on the HYDRUS-2D settings and validations will be provided elsewhere by EM. As shown in the newly added Tables 11 and 12 in EAD Appendix 1, these comparisons demonstrate that using 1,3-D or Pic as surrogate meets the need of AITC exposure assessment and the surrogate emission rates are comparable or higher than the rates generated by HYDRUS-2D. Among the scenarios analyzed, both overestimation and underestimation of the modeled emission rates occurred, suggesting that further investigation is needed for assessing the advantage of HYDRUS-2D over surrogate data approach for assessing the AITC bystander exposures.

Comments on Charge Questions – Worker and Bystander Margins of Exposure

Charge Question 8. Risks to on-site workers were estimated for acute (short term), subchronic (seasonal) and chronic (annual, lifetime) exposures.

OEHHA Comment: OEHHA agrees with the chosen durations to estimate occupational risks of on-site workers in the draft RCD, and noted that many occupational exposure scenarios are far below DPR's target MOE of 30. As noted in the Risk Characterization section, OEHHA suggests a target MOE of 600.

> **DPR Response:** See responses to OEHHA comments on Extrapolation, Variability and Uncertainty in a separate memorandum on responses to the RCD for further discussion.

Charge Question 9. Risk to off-site workers and residential bystanders were estimated for acute exposures.

OEHHA Comment: Based on the proposed uses of AITC and its toxicological properties, OEHHA recommends estimates for seasonal, annual, and lifetime exposures of off-site workers and residential bystanders be included in the assessment. It is of concern to OEHHA that all the acute exposure scenarios for off-site workers and residential bystanders, including children, were below the draft RCD's target MOE of 30, and would be well below OEHHA's suggested target MOE of 600.

> **DPR Response:** As mentioned earlier in this document, the exposure assessment only estimated short-term bystander exposures, which are considered as the highest exposure among all three exposure periods (short-, intermediate- and long-term). As the fumigant use of AITC has not been registered in California yet, its environmental monitoring data and use data in California is not available. It is unreasonable to assume bystanders are next to fumigated field on a daily basis. Consequently, the intermediate- and long-term bystander exposures were not assessed in this document, but they are expected lower than short-term exposures. In regards to the target MOE, see responses to OEHHA comments on Extrapolation, Variability and Uncertainty in a separate memorandum on responses to the RCD for further discussion.

Minor Comments – Exposure Assessment

B. Draft EAD

1. Definition of Buffer Zone: The buffer zone defined in this document refers to what is known as a setback, which is the distance between a treated field and any occupied structure. However, the most commonly recognized definition of buffer zone is a distance between the application site (i.e., edge of field) and any bystander, residential or occupational. Therefore, as mentioned in the US EPA factsheet on buffer zones, "all non-handlers including field workers, nearby residents, pedestrians, and other bystanders must be excluded from the buffer zone during the buffer zone period, except for people in transit" (US EPA, 2012b).

OEHHA believes the use of the term buffer zone in this document is misleading and should be consistent with the way DPR uses this term when doing mitigations.

> **DPR Response:** Instead of defining a buffer zone distance, Dominus® only requires a minimum of 25 feet from "*any occupied structure, such as a school, daycare, hospital, retirement home, business or residence*", and based on this, occupational bystanders are not subject to the 25 ft requirement. This is the reason why in this assessment, residential bystander exposures were assessed at 25 ft from the field edge, while occupational bystander exposures were assessed at 0 ft (at field edge). Section III-C of the AITC EAD (Factors considered to develop exposure scenarios: Label precaution and PPE requirement) was revised to reflect this detail.

2. There are inconsistencies in the Maximum TWA emission values for AITC shank applications presented in:

- Table 26 (page 30, draft EAD) – Typo – Emission rates for AITC (shallow shank) should be consistent with other values in these documents
- Table E1 (page 39, Appendix 1, draft EAD), Table 9 (page 52, Appendix 1, draft EAD), and Table 11 (page 56-57, Appendix 1, draft EAD) appear to be correct, however it would be more informative to consistently indicate TIF or PE tarp instead of study field number (Table D).

OEHHA suggests that DPR revise the main draft EAD document so that those values match up with the values in the supporting documents and that Table 9 in Appendix 1 be revised for clarity.

> **DPR Response:** DPR updated the EAD and associated appendices. All the emission values were checked for consistency and the application and tarp information were added for all cited studies. Table footnotes were revised to clarify. For tarp scenarios, emission data were obtained from applications using PE tarp, as the emission rates are higher than those from TIF tarp applications.

3. There are inconsistencies in the application rate and maximum TWA emission values for AITC Drip application. OEHHA suggests that DPR review and revise all the numbers as necessary

- The concentrations of drip application were generally normalized to the rate of 246lbs/ac in the draft EAD; but several places in the Appendix used 245 lbs/ac (TableE1, Page 39; Table 9 – 10, Page 52-53; Figure 4, Page 54).
- In Table 5 (page 46, Appendix 1, draft EAD) and Table 11 (pages 56-57, Appendix1, draft EAD), the maximum TWA emissions for drip application values were normalized to an application rate of 340 lbs/acre.
- As shown in Table E, the maximum TWA emissions values vary from table to table for drip application. The values in table 11 are about 40% higher than the other tables.

- Also, please provide consistent tarp and treatment information instead of field number.

DPR Response: DPR updated the drip applications to 246 lbs/ac in the EAD and both appendices. Emission rates were normalized to the same application rates (327 lbs/ac for broadcast shank, or 246 lbs/ac for drip and bed/strip shank), unless otherwise specified. In addition, Appendix 1 of the EAD now specifies the application and tarp information for all cited studies. Note that these applications may be different in the final approved label.

4. The draft EAD listed Oakland as the upper air station for the modeling site at Siskiyou County, which is not the appropriate air station for this location (Table 2, Page 70,draft EAD). The correct upper air station for Siskiyou County should be KMFR at Medford, OR.

DPR Response: AERMOD modeling in Siskiyou County was re-conducted using KMFR as the source of upper-air data. All the air concentration and exposure assessment tables were updated correspondingly when necessary.

5. Figure 3 (Page 49, draft EAD) – These 4 graphs show MITC emission rates under a variety of conditions (shank, drip and 3 tarp options). However, the graphs are not labeled to clearly show which conditions apply to each, so the information cannot not be easily compared to the AITC study data.

DPR Response: This figure was updated and the application method for each sub-graph was added to clarify.

6. Typos in Page 29-30. (Appraisal B, draft EAD):

- Page 29, last line – typo – should be "AITC" instead of MITC,
- Page 30, line 4 – typo – should be "Table 26" instead of Table 27

DPR Response: Typos were corrected in the updated exposure assessment document.

References:

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DPR 2016. Changes in the management of 1,3-D. California Department of Pesticide Regulation. https://www.cdpr.ca.gov/docs/whs/pdf/1_3_d_faq.pdf

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USEPA. 2013. Biopesticides registration action document. Oil mustard and ally isothiocyanate (AITC). https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0658-0006.