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 ISAGRO USA, Inc. on DPR's Draft Human Exposure Assessment for Allyl Isothiocyanate as a Soil Fumigant

Background

This memorandum is prepared in response to comments submitted by ISAGRO USA, Inc. (ISAGRO, the registrant) on the draft allyl isothiocyanate (AITC) Exposure Assessment Document (EAD), Human Exposure Assessment for Allyl Isothiocyanate as Soil Fumigant prepared by the Human Health Assessment Branch (HHA) of the Department of Pesticide Regulation (DPR). DPR sent the 2020 draft EAD to ISAGRO in July, 2020 along with the draft AITC Risk Characterization Document (RCD) and received comments back from ISAGRO on October 5, 2020. This memorandum summarized DPR's responses to ISAGRO's comments on the draft AITC EAD in an itemized fashion. Corresponding revisions were also made to the final EAD and its appendices. Responses to comments pertaining to the Executive Summary, Toxicological Profile, and Risk Assessment sections of the RCD are covered in a separate memorandum.

Note that references cited in the ISAGRO review were not included in the reference section of this memorandum. Likewise, every effort has been made to ensure that any references to tables found in the draft or final RCD are clear. Tables specific to this memorandum are numbered independently of the EAD.

DPR sincerely appreciates the efforts taken made by the Registrant and its representatives to review the draft EAD. When appropriate, ISAGRO's comments were incorporated into the final EAD. Responses to specific comments are detailed below.

Responses to comments:

Comments by Mr. Frank Lequerica

Comment 1. Cover letter: Withdrawn the label for Dominus® 100 (which mistakenly included "use instructions" for this product intended solely for formulators.)

> **DPR Response:** In response to the withdrawal of the Dominus® 100 registration, DPR revised the exposure assessment document as well as the two appended memoranda. Accordingly, the revised exposure assessment is based on the only product with active registration application (Dominus®/IRF135, DPR Tracking ID: 280548-N, https://www3.epa.gov/pesticides/chem_search/ppls/089285-00002-20151228.pdf). All the exposure estimates for different scenarios and time periods were updated accordingly. Dominus® contains 96.3% AITC.

Comments by Dr. Beth E. Mileson

Comment 1. Appendix 1, Page 4 (full pdf page 105): "AITC has higher boiling point and lower vapor pressure than Pic and 1,3-D, suggesting that at the soil surface AITC may be less ready to volatize into air."

If pic and 1,3-D are used as surrogates for human exposure assessment of AITC (against the recommendation of Isagro), the higher boiling point and lower vapor pressure of AITC compared to pic and 1,3-D support adjustment of the data to account for these physical chemical differences. For example, estimation of worker exposure based on the 90th rather than the 95th percentile, as presented in Appendix 1 Tables 7 and 8, would still provide a conservative exposure estimate given the assumption of a lognormal distribution of sample measurements.

> **DPR Response:** DPR agrees that chemical-specific monitoring data are preferred for characterizing worker exposure to AITC. However, due to the lack of AITC-specific worker monitoring data, and after reviewing all the available information, DPR used monitoring data from chloropicrin (Pic) and 1,3-dichloropropene (1,3-D) as the surrogate data. The rationale for choosing 1,3-D and Pic as surrogate data for worker exposure assessment have been discussed in detail in VI. Exposure Appraisal, section A. Occupational handler exposure in the final EAD.
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> DPR acknowledges that 1,3-D and Pic are more volatile than AITC, but does not consider the need for using a lower percentile value in the estimation of exposure. First, as described in V. Exposure Assessment, section A. Exposure duration, DPR uses short-term exposure to "*represent the highest exposure an individual may realistically experience*", and DPR's

standard practice is to use 95th percentile values as the "*upper-bound exposures*" (Frank, 2009; Kwok, 2017). This practice of selecting the reasonable worst-case scenario from the proposed label has also been consistently used in exposure assessments for other pesticides. While this scenario is generally considered conservative and may not represent average air concentrations, it can represent high airborne concentrations that are possible based on the proposed applications. It can therefore represent an important scenario for DPR to capture in its exposure assessment. The evaluation of airborne concentrations and emissions can be further refined based on field data and reflected in future mitigation strategies.

Second, as discussed in VI. Exposure Appraisal, section A (Occupational handler exposure) of the final EAD, the emission rates of AITC were compared to 1,3-D or Pic for the specific application periods and also compared with in-field air concentrations measured during the time of application between AITC and 1,3-D or Pic. These comparisons, as detailed in Tables 21 and 22 in the final EAD and in Tables R-1 and R-2 below, indicate that AITC emission rates and air concentrations at the time of application are comparable to those from 1,3-D and Pic. This implies the potential for similar worker exposures. For broadcast shallow shank application with polyethylene (PE) tarp, AITC emission was lower than that of 1,3-D or Pic (see below). However, because of the limited AITC emission data available for this application method, the variations of emissions under different field, weather, and application conditions could not be evaluated. Therefore, based on comparability for other application methods, this assessment determined that 1,3-D and Pic data represented the best available information during the development of this exposure assessment and could be used to overcome the challenges from lacking AITC-specific monitoring data.

Table R-1. Comparison of soil emission rates between allyl isothiocyanate (AITC) and 1,3-dichloropropene (1,3-D) or chloropicrin (Pic) at the time of application

Application and tarp method	AITC emission[b] (µg/m²/s)	Range of 1,3-D or Pic emission (µg/m²/s)
Broadcast shallow shank w/ TIF[a] tarp	8.7	0.1-28.7
Broadcast shallow shank w/ PE tarp	0.7	5.2-57.0
Drip-TIF tarp	7.7	5.3-19.5[c]
Drip-PE tarp	54.9	23.0-86.8

Data was obtained from various sources (Knuteson and Dolder, 2000; van Wesenbeeck and Phillips, 2000; Rotondaro, 2004; Ajwa, 2008; Ajwa, 2009; Ajwa, 2010; Ajwa and Sullivan, 2010; Sullivan and Chellemi, 2010; Sullivan, 2012; Ajwa *et al.*, 2014; Ajwa, 2015).
a: TIF=totally impermeable film, PE=polyethylene;
b: the emission rates were normalized to 327 and 246 lbs/ac for shank and drip application respectively;
c: includes data from applications using virtually impermeable tarp.

Table R-2. Comparisons of air concentrations measured near the breathing heights of applicators during the time of applications

Application and tarp method	AITC[b] concentration[c] (μg/m^3)	Range of 1,3-D or Pic concentration (μg/m^3)
Drip-TIF[a] tarp	28.7	49.4-97.4[d]
Drip-PE tarp	317.9	254.5-996.4

Data was obtained from various sources (Knuteson and Dolder, 2000; van Wesenbeeck and Phillips, 2000; Rotondaro, 2004; Ajwa, 2008; Ajwa, 2009; Ajwa, 2010; Ajwa and Sullivan, 2010; Sullivan and Chellemi, 2010; Sullivan, 2012; Ajwa *et al.*, 2014; Ajwa, 2015).
a: TIF=totally impermeable film, PE=polyethylene;
b: AITC=allyl isothiocyanate, 1,3-D=1,3-dichloropropene, Pic=chloropicrin;
c: the emission rates were normalized to 327 and 246 lbs/ac for shank and drip application respectively;
d: includes data from applications using virtually impermeable tarp.

Comment 2. Appendix 1, Page 10 (full pdf page 111), Table 5: "*Table 5. Estimated AITC seasonal and annual use information based on 1,3-D use data retrieved from AGRIAN database in 2014-2018.*"

Table 5 indicates that there are deep shank handlers in the field 105 days out of the year in Fresno and that there are re-entry workers 157 days per year. That would mean that a handler is in the deep shank field every third day, and a worker is re-entering a treated field virtually every other day. Deep shank applications are typically used for planting trees and vines, which is done about once every 20 years. These are impossibly high exposure assumptions for AITC.

DPR Response: DPR revised the method to categorize different application methods and updated Table 4 (the original Table 5) of the final EAD. Estimated AITC seasonal and annual use information is based on 1,3-D use data retrieved from AGRIAN database in 2014-2018. Specifically, the revisions consider the fact that different crops may be planted in fields with different fumigation methods, and the work crews involved in these activities may differ as well. Hence, use data of broadcast and bed/strip applications are analyzed separately in the updated table. The table was also updated to reflect that now there is only one product submitted to DPR for registration (Dominus®/IRF135, https://www3.epa.gov/pesticides/chem_search/ppls/089285-00002-20151228.pdf, US EPA Reg. No. 89285-2, December 28, 2015) whose proposed label only allows deep shank injection to be used via broadcast application. Therefore, only the use data of broadcast deep shank applications were considered and analyzed.

DPR revised the column title "Application days in a year" to "Days of exposure in a year" to avoid misunderstanding. DPR also revised the paragraph prior to Table 4 for further clarification. "Seasonal application rate (lbs/ac)," which was used to estimate intermediate-term (seasonal) exposures, was derived from the median application rate within the use season. Information in the column "Days of exposure in a year," which was used to estimate long-term (annual) exposures, was derived from the number of application days within a year. For handlers, information in the columns “Seasonal application rate (lbs/ac)” and “Days of exposure in a year” were summarized from the highest-use company in the highest-use county and also assumed within one company all the applications within the same county and using the same application method were performed by the same applicator crew. For re-entry workers, these two types of information were summarized from the highest-use county. In contrast to handlers, re-entry workers are not likely to enter all fumigated fields within one county. Accordingly, using the number in the column “Days of exposure in a year” may overestimate the long-term exposures for re-entry workers. However, re-entry workers could enter the same fumigated field(s) multiple times within a year. Currently there are no data that track re-entry worker activity patterns. Because of this, further refinement of the method described in Table 4 of the updated EAD could not be performed. It is noteworthy that the “Days of exposure in a year” was only used for calculating long-term exposures, not short- and intermediate-term exposures.

Comment 3. Appendix 1, Page 11 (full pdf page 112), paragraph 1: “The product labels state that workers performing tarp cutting, punching and removing are required to “wear long-sleeved shirt, long pants and gloves.”

Protective respirator is not required for tarp cutter, remover, and puncher. It is possible that a respirator could be required if needed for the tarp cutter, puncher and remover.

DPR Response: DPR appreciates the recommendations from ISAGRO to mitigate workers exposures via various measures including the use of respirator. However, the worker exposure assessment was based on the original Dominus® label dated December 28, 2015 submitted to DPR with the registration application. Additional changes to PPE requirements or other possible mitigation measures are beyond the scope of the exposure assessment and will be addressed during product registration.

Comment 4. Appendix 1, Page 13 (full pdf page 114): “In the absence of experimental data, the inhalation exposure was characterized using a default inhalation absorption rate of 100% (Frank, 2008).”

The inhalation toxicology studies that provide the endpoints for the AITC risk assessments result in points of departure for external exposures, not internal or “absorbed” doses. The utility of converting the external exposures of workers to internal doses is not clear. At best the exposure characterizations based on the calculated absorbed doses are only relative measures of exposure and cannot be related to the Reference Concentrations (RfCs) or Human Equivalent Concentrations (HECs).

DPR Response: Text was added in IV. INHALATION ABSORPTION to clarify and avoid misunderstanding. The inhalation absorption rate was used to calculate human internal exposures, and was not incorporated in the calculations of external air concentrations as summarized in Appendix 3: Summary of air concentration tables that was used to calculate margin of exposures.

Comment 5. Appendix 1, Page 16, (full pdf page 117), Table 7: "*Table 7. Summary statistics of chloropicrin air concentrations (µg/m^3) measured from applicators using broadcast and bed shank applications with tarp.*"

As noted above, if pic is used as a surrogate for human exposure assessment of AITC (against the recommendation of Isagro), the higher boiling point and lower vapor pressure of AITC compared to pic supports adjustment of the data to account for these physical chemical differences. In this case estimation of worker exposure based on the 90th rather than the 95th percentile, would still provide a conservative exposure estimate given the assumption of a lognormal distribution of sample measurements.

The Broadcast & Bed shank average concentration is 467 µg/m^3 the 95th percentile is 1759 µg/m^3, and the range is 25 to 1383 µg/m^3. Increased variability appears to be added to the Broadcast exposure estimate as a function of adding the lower "Bed" concentrations to the higher "Broadcast" concentrations and creating added variability that results in an increase in the estimated AITC applicator exposure identified in Table 8 [of the draft EAD]. Broadcast and Bed estimates could be kept separate to reduce uncertainty in the estimates.

DPR Response: Please see the responses to Comments 1 and 2 from Dr. Beth E. Mileson about revisions to the method of categorizing application methods. In the updated exposure assessment document, worker exposures for broadcast and bed/strip applications are estimated separately.

Comment 6. Appendix 1, Page 17 (full pdf page 118), Table 10: "*Table 10. Summary statistics of air concentrations (µg/m3) measured from applicator breathing zones using broadcast and bed shank applications.*"

The Broadcast & Bed measured concentrations for 1,3-D appear to include an outlier (18,328 µg/m^3) that is more than 8 times higher than the highest measured Pic concentration (2,143 µg/m^3). This would seem to be a case where the high value could be deleted if it is an outlier, based on standard outlier analysis rules. In any case, as described above in the first comment for Appendix 1, the concentration used to estimate worker exposure should be based on the 90th percentile rather than the 95th percentile, given the higher boiling point and lower vapor pressure of AITC compared to the surrogates Pic and 1,3-D.

DPR Response: Please see the responses to Comments 1 and 2 from Dr. Beth E. Mileson about revisions to the method of categorizing application methods. In the updated exposure assessment document, worker exposures for broadcast and bed/strip applications are estimated separately. In addition, for each assessed scenario, 95th percentile value of monitored worker exposures was used to estimate short-term exposures in the final EAD.

Comment 7. Appendix 1, Page 18 (full pdf page 119), Table 11: "*Table 11. Estimated applicator exposure to allyl isothiocyanate using shallow shank applications without tarp.*"

The footnotes of table 11 indicate that the highest air concentration measured from applicator breathing zones (18,328 µg/m^3; Table 10) was used to derive the short-term daily dose (STADD). In contrast, the footnotes of Table 8 indicate that the 95th percentile concentration (1,759 µg/m^3; Table 7) was used to derive the STADD. While we believe the actual number used should be the 90th percentile based on the different characteristics of AITC compared to pic and 1,3-D, a value higher than the 95th percentile should not be applied to AITC.

DPR Response: See Responses to Comments 1 5, and 6 from Dr. Beth E. Mileson for more details. In the final EAD, worker exposures in bed/strip and broadcast applications are assessed separately. In addition, in the updated exposure assessment document, for each assessed scenario, 95th percentile value of monitored worker exposures was used to estimate short-term exposures.

<u>Comments by Dr. Dan Chellemi</u>

Comment 1. ISAGRO USA recommends that DPR use the data from the Ajwa et al. study to set the maximum soil emission value for AITC.

DPR Response: AITC data from Ajwa et al. (2014) has already been incorporated in this assessment. Among the five application scenarios assessed by DPR for bystander exposures, AITC soil emission data is available for two of them, i.e., shallow shank with polyethylene (PE) tarp and drip with PE tarp. These emission data from Ajwa et al. (2014), as well as the emission rates (once adjusted for the maximum application rate on the Dominus® label), were used for assessing bystander exposure. Surrogate data from 1,3-D and Pic were only used for the three scenarios that lacked AITC data, i.e., shallow shank without tarp, deep shank without tarp, and drip without tarp. Detailed discussions are provided in the revised soil emissions memorandum appended to the final EAD.

Comment 2. Rather than using a chemical with extended soil persistence and higher vapor pressures, ISAGRO USA recommends that DPR consider MITC as a surrogate for AITC. The timing of peak emissions under MITC is different that AITC due to that lag period required for hydrolysis of metam sodium or metam potassium to MITC but this can be accounted for by shifting the peak curves up in the model.

DPR Response: For worker exposure assessments, please see the response to Comment 1 from Dr. Beth E. Mileson for more detail about why 1,3-D and Pic data were chosen as surrogate data. The primary factor determining the worker exposures is the application method. Most of the assessed AITC worker exposure scenarios occur during the time of Dominus® application. For MITC-compounds (metam-sodium and metam-potassium), most of the application methods (e.g., drench, flood, etc.) are different from those of AITC. Hence, the MITC emission data cannot be used for AITC worker exposure assessment. Detailed discussions are also provided in the Exposure Appraisal section of the final EAD.

For bystander exposure assessment, the decision to choose 1,3-D and Pic as surrogate compounds rather than MITC is detailed in the memorandum "Using allyl isothiocyanate-specific and surrogate data to determine AITC soil emissions for residential and occupational bystander exposure assessments-revised" which is appended to the final EAD. Briefly, most MITC emission data were generated from application methods different than those proposed for AITC. For those methods that are comparable to AITC, AITC-specific emission data already exist. Hence, there is no need to use surrogate data.

DPR does not necessarily agree with the suggested "*shifting the peak curves*" to address the possible difference of emission patterns between MITC and AITC. First, there is only one set of AITC emission data for one application and tarp method, making the diurnal pattern of field emissions and the timing of the peak emission unclear. Second, the time and magnitude of fumigant soil emissions are an integrated outcome of fumigant properties, application methods, field and weather conditions. So, it is not appropriate to arbitrarily shift the peak curves to a different time other than its original time of occurrence and assume the emission rates are unchanged.

Comments by Dr. Rick Reiss:

Comment 1: The California Department of Pesticide Regulation (DPR) used very conservative methods to estimate bystander exposure for ally isothiocyanate (Jiang, 2020). DPR estimated air concentrations using AERMOD, the EPA's preferred dispersion modeling software. While AERMOD is a sound tool for air dispersion modeling, it is not sufficient for fumigant modeling. AERMOD outputs concentrations at the upper-end of the concentration distribution and, in DPR's case, only the maximum concentration was output over a 5-year simulation period. Typically, dispersion models like AERMOD are run for industrial sources that are continually emitting. Also, in regulatory applications, a 5-year meteorological file is used in the model to simulate the range of air concentrations that could occur given the wide range of meteorological variability that exists. However, fumigants are typically only used once per year, or less. When running AERMOD, DPR assumed that the fumigant was applied on each day of the 5-year simulation to generate a maximum concentration. While the estimated maximum concentration could theoretically occur, fumigant modeling has typically used different, probabilistic methods.

Both the EPA and DPR have used the Probabilistic Exposure and Risk model for FUMigants (PERFUM) to estimate a probabilistic distribution of air concentrations and buffer zones. For example, DPR used the PERFUM model to estimate buffer zones for chloropicrin several years ago. In this instance, DPR used the 95th percentile of the maximum concentration distribution within PERFUM. Using PERFUM allows the user to avoid the selection of the maximum concentration from AERMOD, which may, or even likely, would occur in a simulation day where there was no actual fumigant application. The current version of PERFUM embeds the EPA's AERMOD dispersion model to drive the dispersion modeling calculations, but provides a probabilistic estimate of exposure and required buffer zones. The recently released Version 3 includes a Graphical User Interface (GUI) to make running the model easier. DPR should use PERFUM to estimate buffer zones for allyl isothiocyanate. It could use an upper percentile (e.g., the 95th percentile as it did for chloropicrin), which would yield a health-protective buffer zone without having to base the buffer zone on maximum concentration over a 5-year simulation, where the maximum concentration may occur on a day where there were no actual application.

DPR Response: A new section "Comparison with PERFUM3" has been added into the appended memorandum "Determination of allyl isothiocyanate air concentrations around fields fumigated using shank or drip applications-revised" to discuss PERFUM3 and compare modeling results between PERFUM3 and this assessment. PERFUM3 uses air concentration estimates from the entire modeling period (i.e., 5 years) to calculate the 95 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 assess bystander exposures. DPR conducted additional AERMOD runs with updated model inputs and also revised the post-AERMOD processing methods to generate air concentrations. Accordingly, the entire memo mentioned above was revised, and the bystander exposure assessment tables in the exposure assessment document were updated as well.

This assessment used AERMOD View^{TM}, 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^{TM} 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 height above ground. To the best of our knowledge, similar results cannot be obtained from PERFUM3.

DPR originally used the maximum air concentrations instead of the 95th percentile values to estimate bystander exposures. That method was adopted in order to expedite our modeling process and also to maximize computing efficiency. In the updated memorandum "Determination of allyl isothiocyanate air concentrations around fields fumigated using shank or drip applications-revised", DPR revised the bystander exposure assessments with the use of 95th percentile values. This 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). Table R-3 below used 40ac shallow shank with PE tarp scenario as an example and compared the bystander exposures estimated using the current method and the previous method. Using the current method with 95th percentile values provided refined exposure estimations compared to the previous values, and the difference is < 10% for occupational bystander and < 20% for residential bystander.

Table R-3. Comparison of selective 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	Current method	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.

Comment 2: Another conservative aspect of DPR's modeling is that it assumed the same flux for each hour of the day. The available data, which DPR summarizes, shows that there are often dramatic differences in the day-night flux values for allyl isothiocyanate. Generally, conditions are less conducive for dispersion during nighttime hours than during the day. Therefore, assuming fluxes at night that are the same as during the day will result in higher downwind concentrations than otherwise would occur. DPR should consider using the ratio of the daytime and nighttime fluxes in the existing studies to modify the flux profiles. As an example, we considered an alternative shallow shank with no tarp scenario with a 2X difference between day and nighttime fluxes. Therefore, instead of assuming 82.9 μg/m^2/sec for each hour, we assumed 55.3 μg/m^2/sec for the nighttime hours and 110.6 μg/m^2/sec for the daytime hours. This results in the same mass loss over 24 hours as assuming the constant flux rate, while providing a realistic day-night difference. However, the PERFUM results showed that there was an additional 20-30% reduction in the concentrations depending on the downwind distance.

DPR Response: The previous method with constant 24 hr-average hourly rates was chosen as a time-efficient way (saving ~80% of modeling time) to expedite the modeling process, as the adjustments for different application scenarios could be processed after AERMOD modeling with a nominal emission rate. As shown in the comparison table (Table R-3) above, using scenario-specific hourly emission rates as direct AERMOD inputs, together with using 95th percentile values instead of the maximum, result in refined residential bystander exposures are < 20% different from the previous estimates.

DPR updated the modeling inputs, and the scenario-specific hourly emission rates were directly input into AERMOD for each application scenario to generate the air concentrations. These changes are reflected in the memorandum “Determination of allyl isothiocyanate air concentrations around fields fumigated using shank or drip applications-revised” that is appended to the final EAD. Appropriate changes have also been incorporated into the bystander exposure assessment section of the final EAD.

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