Responses to Comments on the AIR MONITORING NETWORK RESULTS FOR 2018 - VOLUME 8

APPENDIX N

Responses to Comments on the AIR MONITORING NETWORK RESULTS FOR 2018 VOLUME 8

Number	Comment	Response	Action
1.	**From California Rural Legal Assistance Foundation (CRLAF), Natural Resources Defense Council (NRDC), Center for Environmental Health (CEH), Californians for Pesticide Reform (CPR), Pesticide Action Network (PAN):** **Executive Summary –** The description of Shafter air monitoring results in the Executive Summary should include two clarifying statements: 1) If the 2018 annual average 1,3-D air concentration of 1.53 ppb were to continue for 70 years it would exceed DPR's current regulatory target of 0.56 ppb for control of lifetime cancer risk; and 2) The 8 year average 1,3-D air concentration of 0.41 ppb already exceeds DPR's previous regulatory target of 0.14 ppb which OEHHA continues to support.	While DPR has used annual averages to compare to regulatory targets to assess lifetime exposures, in cases where longer term monitoring data is not available, shorter timeframes are less suitable for comparison to a 70-year target. Therefore if longer term monitoring data is available, use of a multi-year average value to approximate a lifetime cancer risk estimate is more accurate and the preferred DPR approach. All of the screening levels and regulatory targets for the various active ingredients and time periods were established by DPR in collaboration with OEHHA. The methodology used to compare measured air concentrations to DPR-established screening levels and regulatory targets in this report is consistent with previous DPR study publications.	No changes to report are needed.

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2.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Combined results for all pesticides and communities –** We remain concerned that beginning the report by quoting statistics that aggregate all the data conveys a false sense of security that does not reflect the air levels documented by the actual monitoring data. The statements in the report that 93.8% of analyses did not return a detectable concentration that 6.2% of analyses had at least one detectable pesticide concentration and that 1.3% of analyses had quantifiable detections are highly misleading because they ignore the realities of pesticide use patterns. In order to reach 100% detections (a total of 12,058 positive analyses), every pesticide tested for would have to be found on each of the days monitored at each of the air monitoring sites. In reality, use of most pesticides is concentrated in certain months. As pesticide use varies between crops and regions, not all of the pesticides monitored for are used near all of the monitoring sites. Therefore, using the total number of analyses for all pesticides at all locations as the denominator does not provide a meaningful context. Detection frequency should either be calculated based on what pesticides were used in the vicinity of a specific site, shortly prior to the sampling date, or should not be highlighted. When these concerns were raised two years ago at the August 18, 2017 PREC meeting, then Branch Chief Pam Wofford stated that DPR was conducting an uncertainty analysis of frequency of detections. Is this analysis still in process and if so when will it be completed?	DPR makes every attempt to convey all data and results obtained as part of the AMN in a clear and unbiased manner. The manner in which pesticide air concentrations are stated in this report, are consistent with previous DPR study publications. Pesticide concentrations measured in all eight of the AMN's sampling locations are listed in various tables throughout the report, and described in the report's text, Discussion, and Executive Summary. DPR believes that the sampling results are clearly and effectively presented throughout the report and thus no changes are required at this time. DPR posts all completed air monitoring reports including raw monitoring data. This information can be accessed at the following site: http://www.cdpr.ca.gov/docs/emon/airinit/air_network_data_analysis.htm On June 2018, DPR released the report titled "Air Monitoring Network Report: A Comprehensive Evaluation of Results (2011-2016)". This report includes a section titled: "Analysis of Sampling Frequency". In this section, DPR used several non-parametric statistical methods to evaluate the AMN data. Results from the sampling frequency analysis showed that the sampling was not equally distributed among all seven days of the week during the 2011–2016 sampling period, which led DPR to increase the randomization of the sampling start days to include Fridays to Sundays more consistently for sampling in 2018 and on. Additionally, based on the 2011-2016 AMN data, a lack of significant difference between days of a week and measured concentrations was observed. A linear regression model was used to establish that the percentage of quantifiable detections increases on average by 3.8 for every 100 additional collected samples. As a result of the analysis, although a larger sample size could result in more detections, the effect was determined to be relatively weak and DPR determined that based on limited resources, no major change to current sampling procedures were needed at the time.	No changes to report are needed.

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3.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Combined results for all pesticides and communities –** We note that Table 4 shows that there was an average of at least one pesticide detection in 86% of weekly sample sets collected at each monitoring site. This statistic should also be included in any discussion of aggregate findings in the report narrative.	DPR makes every attempt to convey all data and results obtained as part of the AMN in a clear and unbiased manner. The manner in which pesticide air concentrations are stated in this report, are consistent with previous DPR study publications. Additionally, DPR posts all AMN obtained results on the Pesticide Air Monitoring Results Database where all monitored results can be accessed. This information can be accessed at the following site: https://www.cdpr.ca.gov/docs/emon/airinit/pesticide_air_monitoring_database.htm.	No changes to report are needed.
4.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Combined results for all pesticides and communities –** The report states that there were 4 lost samples in 2018 including 3 summa canisters. The date and location of lost or otherwise invalidated samples should be provided in the report.	Comment acknowledged by DPR. 2018 AMN report was amended to include a detailed description of invalided air samples.	Changes to report were made
5.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Combined results for all pesticides and communities –** The tables in the Air Monitoring Study Results and 1,3-D Ambient Air Monitoring Results Presentations at the July 19th Pesticide Registration and Evaluation Committee (slides 13-15 and slides 26-27) that compile highest air concentrations and compare highest 1 day, 4 week or 13 week and annual average concentrations between sites for all pesticides with quantifiable detections are very helpful and informative. We strongly recommend including them in the report with 1,3-D results combined with other pesticide results.	Comment acknowledged by DPR. DPR will continue to evaluate changes to future air monitoring reports in an effort to improve transparency and help the reader better understand the air monitoring results.	No changes to report are needed.

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6.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Chloropicrin Acute Screening Level –** The acute regulatory target for chloropicrin of 73 ppb used in this report as a 24 hour average exposure target level was set in a Risk Management Directive (RMD) as an 8 hour average so at the very least it should be adjusted to 24.3 ppb as a 24 hour level. Furthermore, this 73 ppb target level was set over the objection of OEHHA. The chloropicrin TAC report and risk assessment, which are also supported by OEHHA, include a 24 hour reference level of 0.92 ppb for protection of children. The highest 24 hour level measured in Oxnard (0.8 ppb) reached 87% of this reference level and the highest level measured in Santa Maria (0.46 ppb) reached 50% of this level.	DPR devised regulatory targets based on complete assessments of possible health risks. As mentioned in the report, exceeding a regulatory target does not necessarily mean an adverse health effect occurs, but it does trigger a detailed evaluation and it may indicate that the restrictions on the pesticide use may need to be modified. DPR, as part of the AMN procedures, collects 24-hr air samples, which are compared with established acute screening levels or regulatory targets for individual pesticides. If any 24-hr air concentration exceeds its acute target, DPR conducts a detailed evaluation to determine if any unacceptable exposure may have occurred and if any additional restrictions on the use of the pesticide are needed. Comparing a measured 24-hr air concentration to the established acute regulatory target (8-hr, 24-hrs, or 72-hrs) as a trigger for further evaluation in the case of any exceedances is consistent with previous DPR protocols and studies. No changes to the report are deemed necessary.	No changes to report are needed.
7.	**From CRLAF, NRDC, CEH, CPR, PAN:** **MITC Acute Screening Level –** The acute regulatory target for MITC of 220 ppb used in this report as a 24 hour average exposure target level was set in a Risk Management Directive as an 8 hour exposure level so at the very least it should be adjusted to 73 ppb as a 24 hour exposure target level. Furthermore, this level was set over OEHHA's objections because 220 ppb was the "no effects" level in a toxicology study, leaving no margin of error. The DPR TAC report and risk assessment established an 8 hour reference level of 22 ppb for protection against irritation to the eyes and respiratory system which should be adjusted to 7.3 ppb as a 24 hour target exposure level. The highest 24 hour air level measured in Shafter (1.2 ppb) reached 16.4% of 7.3ppb, the reference level of 22 ppb, adjusted for 24 hour exposure. As you know, in the seasonal monitoring study conducted in Arvin in the summer of 2017 a peak 24 hour level of 4 ppb was measured with a month-long average air level of 1.03 ppb, exceeding the sub-chronic screening level of 1 ppb, set to prevent damage to the nasal cavity.	See response for Comment #6 above.	No changes to report are needed.

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8.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Use of 13-week Subchronic Screening Levels –** In 2017 DPR discontinued the practice of using a 4-week rolling average concentration to compare to chloropicrin and 1,3 D sub-chronic screening levels and began comparing to 90 day or 13 week rolling averages. This change was made after peak 4 week rolling averages were found to exceed the 4 week chloropicrin screening level at the Santa Maria air monitoring site in 2014 and 2015 and the peak 4-week 1,3-D air concentration for 2016 in Shafter reached 97.6% the 1,3-D sub-chronic screening level. DPR toxicologists claim these changes were justified because the toxicology studies used to set the sub-chronic screening levels were 90 days long for chloropicrin and 13 weeks long for 1,3-D. However, the revised averaging times have still not been reviewed by OEHHA and should be. We think it is more scientifically valid and health protective to continue to compare air levels of these fumigants to the peak 4-week rolling average concentration rather than a season long average concentration. While rhinitis was found in rats at the end of a 90-day chloropicrin inhalation study it may have developed earlier and humans may be more sensitive than rats. In addition, in reality people are exposed to varying levels of chloropicrin and 1,3-D over time and higher level short term exposures may cause more respiratory and nasal problems. If calculated as a 4 week rolling average, the highest sub-chronic chloropicrin air concentration in 2018 was 0.225 ppb at both the Oxnard and Santa Maria sites. This reaches 64% of the sub-chronic screening level of 0.35 ppb.	DPR disagrees with this comment. While, as a standard practice, we default to comparing calculated 4-week rolling average air concentrations against a 28-day time period as a Tier-I comparison for subchronic exposures for most pesticides included in the AMN. This practice is inappropriate for pesticides that have a specified subchronic time period established from available toxicological data. Therefore, in the absence of additional toxicological data, DPR will continue to use a 13-week time frame to estimate subchronic exposures to chloropicrin as stated in this report and consistent with previous DPR study publications.	No changes to report are needed.
9.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Contribution of Concentrations to Averages –** This report correctly reports that in 2018 the 1,3 D sub-chronic screening level averaged over 13 weeks was exceeded at the Shafter site. However, the statement that the exceedance of the sub-chronic 1,3 D screening level at the Shafter site was primarily driven by the 50.5 ppb level measured on January 22nd is misleading because levels in excess of 1 ppb were measured for several weeks after the January spike and a level of 4 ppb was measured in late October.	DPR makes every attempt to convey all data and results obtained as part of the AMN in a clear and unbiased manner. The detection of 50.5 ppb from the Shafter site was by far the largest observed value to date for that sampling site location. As such, it had the largest direct effect on the all average time frames for 2018 including sub-chronic and chronic average. While other smaller concentration peaks occurred throughout the year and they do contribute to the overall average concentration, they did not have the same statistical impact as the 50.5 ppb detection.	No changes to report are needed.

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10.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Use of the Phrase "Potential Carcinogens" –** The phrase "potential carcinogens" is not appropriate. The pesticides 1,3 D, chlorothalonil, DDVP, diuron, iprodione and propargite are classified as known carcinogens under Proposition 65 and as probable carcinogens by USEPA. In addition, studies are in process evaluating potential carcinogenicity of MITC and chloropicrin.	While DPR believes the use of the work "potential" is appropriate when addressing the list of pesticides as a whole, to avoid any mischaracterization, the sentence on Page 13 of the Report has been amended to read as "probable carcinogens."	Changes to report were made.
11.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Cancer Risk Level –** DPR has selected a cancer risk level of 1 in 100,000 as the regulatory target for 1,3 D but this level is not generally considered negligible. A cancer risk of 1 in 1 million is used as the level of negligible risk by DPR in risk assessments and considered by OEHHA and most public health entities as the limit for adequate health protection.	DPR disagrees with this comment. DPR's language for the selected cancer risk level is consistent with language previously published by the department. The statement is included in the report to provide the necessary context to the risk estimate calculations. Additionally, the provided range is in line with the range considered by other agencies, including US EPA and World Health Organization**,** to be "negligible" or "low-risk" (i.e. 10^{-5} to 10^{-6}).	No changes to report are needed.
12.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Cancer Risk Level (continued) –** The report should also note that DPR's 1,3 D risk assessment includes both the portal of entry and systemic cancer potency risk factors and that OEHHA maintains that the systemic cancer potency risk factor should continue to be used for adequate health protection. We note, as shown in slide 32 of the Air Monitoring Network results July 19, 2019 PREC meeting presentation, that 1,3 D cancer risk levels exceed 10^{-6} at the Shafter, Santa Maria and Watsonville sites using the portal of entry cancer potency factor. Utilizing the systemic cancer potency risk factor, risk exceeds 10^{-5} at the Shafter and Santa Maria sites. Further, at the Watsonville site, the average air concentration reached 0.1 ppb, the threshold level OEHHA supports to protect children from cancer.	DPR disagrees with this comment. The cancer risk estimate and interpretations included in this report are consistent with previous DPR study publications and follow the latest 2016 1,3-D Risk Management Directive. No changes to the report are deemed necessary	No changes to report are needed.
13.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Chloropicrin carcinogenicity –** The average annual concentration of chloropicrin in Chualar and Watsonville was 0.03 ppb (30 ppt) and was 0.04 ppb (40 ppt) in Santa Maria. If sustained over time, these concentrations all greatly exceed the reference concentration of 0.24 ppt for controlling cancer risk to the 1 in a million level that was established in the DPR Chloropicrin TAC and Risk Characterization documents as the negligible risk level and supported in review by OEHHA and the TAC Scientific Review Panel. DPR subsequently made a unilateral decision that chloropicrin cancer data was equivocal and that an additional study was needed to assess cancer risk. That study is not due to be submitted until December 31, 2021 so in the meantime we are left with great uncertainty about cancer risk from chloropicrin exposure due to this huge data gap.	Comment acknowledged by DPR. As stated in the comment, DPR is awaiting additional data submission on chloropicrin. Until the Department updates any of the regulatory targets for chloropicrin, monitored air concentrations will continue to be compared to previously established values in a manner that is consistent with previous DPR publications.	No changes to report are needed.

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14.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Results for Individual Communities –** We appreciate inclusion of a description of each community. An aerial view map of each monitoring site would also be helpful along with an assessment of proximity to agricultural fields. Carrots are an additional major crop in the Cuyama area. Carrot preplant fumigation may account for the high percentage (89%) of detections of MITC at the Cuyama site. The figures showing temporal trends in levels of individual pesticides detected at each monitoring site are very useful.	Comment acknowledged by DPR. The addition of carrots as a major crop in the Cuyama area has been included in the community description. While we agree that inclusion of pesticide use information will be greatly beneficial to frame a detailed picture of the typical use of pesticides near the monitored community, official PUR data for 2018 is not available as of this publication. We do intent on conducting relevant pesticide use and air concentration correlations in future analysis reports, but any such work is beyond the scope of this annual report.	Changes to report were made.

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15.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Discontinuation of Field Spikes –** We are concerned to note fairly low field spike percent recoveries for chlorothalonil (73%); chlorpyrifos (77%); malathion (72%); and MITC (78%) which suggest that reported values for these pesticides may be underestimates. We also strongly disagree with the Department's decision to discontinue use of field spikes at the end of 2018. It would seem appropriate to devote more resources to figuring out why these field spikes were low instead of discontinuing field spike measurements. Field spikes provide reliable data about how field conditions may be affecting sample recovery. While the field spikes have their challenges and the data from them have their limitations (as cited by DPR in the 2018 AMN update), discontinuing the practice of collecting field spikes would mean that no information would be collected about how field samples might have been affected by important environmental conditions (e.g., humidity, temperature, other environmental factors affecting samples). For example, a 2018 memo from CDFA regarding MITC stated "The low recovery for the blind spikes would indicate that the sampling, extraction and analysis of the samples the lab analyzed during 2017 are reporting findings that are lower than what is actually in the air during the sampling." MITC air monitoring studies conducted by academics have included fortified field spikes, in order to collect data about field conditions while conducting air sampling. DPR could potentially use information from field spikes to help determine whether losses in the field are the result of laboratory methods (as CARB determined for 2017 methyl bromide samples), or for other reasons. In the 1990s, low field spike recovery rates for methyl bromide contributed to a study being conducted that showed that recoveries were greatly improved if steel canisters were used, rather than charcoal air tubes. As a result, sampling methodologies were improved for DPR field sampling. Therefore, field spikes can be useful and indeed may play an important role in helping DPR assess whether screening thresholds are potentially being exceeded.	DPR disagrees with this comment. DPR performed an assessment on the need and value of fortified field spikes detailed in a memorandum released on November 9, 2018. Although fortified field spike samples provide some additional information on recovery from the sampling matrix, the value of these samples, as currently prepared and handled, in assessing any quality control aspect of the air monitoring studies conducted by DPR's Air Program are debatable. DPR will continue to use results from trapping efficiency studies, storage stability studies, laboratory field blanks, laboratory fortified matrix spikes, field blanks, and co-located samples to provide greater verifiable information. These quality control measures provide DPR confidence in the analytical method and resulting air concentrations.	No changes to report are needed.
16.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Historic Air Concentrations –** It would be better to place the historical air concentration analyses, which provide very useful background, in the "Results from individual communities" section after 2018 data for each community site. In the historic analyses, some of the table entries show 0 ppb with a value in ng/m3. A non-zero value should also be provided in ppb. Tables 10 and 11 for Santa Maria appear to have ppb to ng/m3 conversion or rounding errors for chloropicrin and malathion.	The intent of this report is to focus on the observed ambient air concentrations during the 2018 calendar year. Historical data for all air monitoring studies are available through the Pesticide Air Monitoring Results Database where all monitored results can be access and/or reviewed. This information can be accessed at the following site: https://www.cdpr.ca.gov/docs/emon/airinit/pesticide_air_monitoring_database.htm.	No changes to report are needed.

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17.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Historic Air Concentrations in Shafter –** The historical air concentration analysis shows that the Shafter annual air concentration for MITC (0.058 ppb) was higher in 2018 than any previous year. This should be mentioned earlier in the report.	DPR makes every attempt to convey all data and results obtained as part of the AMN in a clear and unbiased manner. As such, we attempt to follow a similar result reporting pattern for all sampling site locations. The manner in which the overall air concentrations for MITC in Shafter are stated are consistent with all other sampling locations.	No changes to report were made.
18.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Historic Air Concentrations from TAC Network Sites –** For Oxnard, Santa Maria and Watsonville more than 2 years of data are available for 1,3-D, methyl bromide and chloropicrin because these were previously TAC sites. That additional data should be included in historical analyses.	DPR disagrees with this comment. Although similar pesticides were sampled for, the TAC study and the AMN study differ in sampling protocol and sampling interval. The intent of this report is to focus on the observed ambient air concentrations during the 2018 calendar year. However, historical data for all air monitoring studies are available through the Pesticide Air Monitoring Results Database where all monitored results can be access and/or reviewed. This information can be accessed at the following site: https://www.cdpr.ca.gov/docs/emon/airinit/pesticide_air_monitoring_database.htm.	No changes to report are needed.
19.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Air Monitoring Database –** The Air Monitoring database is very well designed, user friendly and versatile. We greatly appreciate the inclusion of preliminary monitoring data and the ability to filter data by chemical, site and specific time periods and download filtered data into spreadsheets. It is unfortunate that Google will discontinue Google sheets at the end of the year, which means that the AMN data can no longer be organized using this system. We urge DPR to develop an alternative database that continues to be searchable and if possible is expanded to include mapping and graphing functions.	Comment acknowledged by DPR. DPR is currently working to provide a suitable alternative with similar functionality as the Google Fusion Tables interface. During this time, result from the Pesticide Air Monitoring Results Database will continue to be available for download as a .CSV file until a suitable Google Fusion Table replacement is determined.	No changes to report are needed.
20.	**From CRLAF, NRDC, CEH, CPR, PAN:** **Suggestions for Further Analysis –** Many of these monitoring sites are located at schools. We would recommend conducting an analysis to evaluate how the school buffer zone requirements may have impacted air levels measured at these sites. It also appears that 1,3- D and chloropicrin air levels have decreased at coastal sites in recent years. We recommend conducting an analysis that looks at whether there is any correlation between these fumigant air levels and the extent of use of TIF tarps surrounding the air monitoring sites.	This comment is beyond the scope of the "Air Monitoring Network Results for 2018 – Volume 8" draft document. Comment acknowledged by the Department. No response required.	No changes to report are needed.

21.	**From DAS:** 1,3-D Screening Levels and Regulatory Target – Alternative, refined derivations of 1,3-D acute, subchronic and chronic Human Equivalent Concentrations (HECs) and associated screening levels, and the "regulatory target" concentration (for lifetime exposure and risk evaluation) used for comparison to AMN measurements and modeled air concentrations, have been presented to DPR by DAS. Table 1 presents a comparison of screening level values currently recommended by DPR, versus those recommended by DAS. Detailed comments have been submitted to DPR. Further, an important consideration is the selection of an appropriate exposure metric (i.e., matching duration and time required for manifestation of the toxicological effect of interest), for comparison to alternative HECs and the resulting risk estimates (Margins of Exposure). In the case of the acute HEC recommended by DPR, while the values have been time-weighted to a 24 hour period based on Haber's Law (or Rule) (i.e., adjustment for concentration x time), the time to effect in the repeat dose study selected by DPR is 3 days (time and repeat dosing period required for statistically significant body weight decrement to be observed). Thus, the DPR acute screening level, should be compared to 72-hour time weighted average estimated exposure values (theoretical air concentrations assumed to be inhaled by bystanders for risk analysis). Further, an alternative to the repeat dose study used by DPR for the acute screening level derivation, is reliance on a 4-hour inhalation toxicology study and related benchmark response (BMR) of 10% body weight gain decrement, which reflects U.S. Environmental Protection Agency (U.S. EPA) and other guidance for selection of a biologically significant response. Differences in subchronic and chronic screening levels recommended by DAS, in comparison to DPR (see Table 1), relate to DAS's reliance on U.S. EPA's most recent guidance for derivation of inhalation reference concentrations (screening levels), and the use of a refined uncertainty factor that is consistent with that derived by the U.S. EPA. Detailed comments regarding DAS's recommendations have been submitted to DPR. <table 1> In the case of the acute screening level for 1,3-D, it is important to provide context to the point of departure, i.e., decrements in body weight gain. Body weight gain decrements have been used by multiple entities (DPR, U.S. EPA) as a point of departure and the basis for establishing permissible exposure limits to humans. However, upon closer examination of 1,3-D inhalation toxicology studies and the decrements in body weight observed in all of these studies, coupled with consideration of some key physiological and toxicokinetic measurements/indicators, it is clear that body weight, particularly after repeat dosing, e.g., 3 days, is not an optimal point of departure for use in acute (24 hrs or less) Human Equivalent Concentration (HEC) derivation. In fact, it appears body weight decrements resulting from inhalation exposure to 1,3-D are a secondary effect, resulting from primary effects on respiration rate, GSH depletion, and systemic over-exposure to the test material. A recent toxicokinetic study supports this reasoned conclusion and also raises significant questions about inhalation studies that are conducted above the kinetically-derived maximum dose and their use in risk assessment. As DPR considers risk mitigation measures for acute exposures to 1,3-D, it is imperative that a balanced discussion and reasoned conclusion, supported by the available science, be conducted. If a repeat dose study is used for the acute HEC (normalized to 24 hr exposure duration, i.e., per day exposure basis), as stated previously, it is imperative that it is compared to an appropriate exposure metric that matches the time to effects (3 days, or three 24 hr periods).	Development of the screening levels for 1,3-D, including information and justification of all data used to determine these levels, were detailed in the 2015 1,3-D Risk Assessment document. The use of human equivalent concentrations and uncertainty factors in establishing DPR screening levels is consistent with previous DPR study publications. No changes to the report are deemed necessary.	No changes to report are needed.

22.	**From DAS:** 1,3-D and Effects on Portal of Entry Tissues – Dichloropropene compounds, in general, have sensory irritation properties and this translates into portal of entry (in this case inhalation) effects involving the respiratory tract, which are considered a primary toxicological/irritancy effect in animals and humans. Body weight is typically a secondary effect from oral and inhalation exposures often resulting from an apical injury, stress, or other treatment-related factors that may directly affect food consumption or respirability (e.g., breathing rate). In fact, for 1,3-D, the U.S. EPA IRIS program/office used nasal histopathology for derivation of the BMD and while this was derived from a repeated dose and longer-term study, it shows the focus on portal of entry effects, which are a primary effect of exposure to 1,3-D. Consideration of body weight as the sentinel and appropriate endpoint of concern for establishing permissible exposure levels to humans, particularly from body weight decrements after 3 days of exposure (as used by DPR from Stott et al., 1984) is a toxicologically "blunt" and potentially irrelevant (relative to the toxicological profile and characteristics of 1,3-D) endpoint. If body weight is going to be used as a point of departure, particularly for acute exposures, available data for 4-hr exposures should be used, notably when body weight changes were reported. Finally, use of an acute exposure scenario such as 4-hours is far more appropriate when extrapolating to the human situation for protection of human health following acute exposures of this time duration. Humans are not continuously exposure to 1,3-D for 72 hours and therefore, there is no scientific or rational basis to use body weight decrements at 3 days for extrapolating to the acute (24 hrs or less) exposure scenario for humans.	Comment acknowledged by DPR. Comment is directed towards the established regulatory target concentration of 1,3-D and not specific to the Draft Air Monitoring Network Results For 2018 Report. No changes to the report are deemed necessary.	No changes to report are needed.

23.	**From DAS:** Review of Selected Inhalation Studies and Effects on Body Weight – Stott et al (1984) conducted a 13-week inhalation in rats and mice and at the two top concentrations (90 and 150 ppm) for both species, statistical decrements in body weight were recorded. In rats, the decrements for both sexes began on day 3 (first measurement) and continued for the duration of the study, while in male and female mice, statistically significant differences were not recorded at 90 ppm until day 59 and 45, respectively and at day 15 (males) and day 3 and 17 (females) for animals exposed to 150 ppm. In interpreting these effects for rats, Stott et al (1984) concluded that "As no histologically observable changes were noted in these tissues, the organ weight differences were not interpreted as being indicative of a specific target organ effect; but rather, represented an indirect, nonspecific result of TELONE II vapor exposure in these rats." For mice, Stott et al (2014) concluded that "The absence of any observable histological alterations in any of these organs indicated that the organ weight differences were a nonspecific result of exposure to TELONE II vapors (e.g. stress-induced atrophy of lymphoid elements)." For both species, there is a clear threshold for concentration dependent effects on body weight gain and for both, high concentrations of 1,3-D were required in order to elicit/manifest a decrement in weight gain. Additionally, it would appear that the absence of any histologically relevant changes in those organs/tissues evaluated support the interpretation that decrements in body weight gain are a result of non-specific secondary consequences to experimental stress or reduction in respiratory minute volume (discussed below), both of which could result in reduction in food consumption and hence declines in body weight gain. In the end, these results are consistent with exposure to excessive concentrations of 1,3-D and not the result of treatment-related target organ specificity and toxicity. A review of six different study types as noted by DPR in their 2015 Risk Characterization Document (RCD) for 1,3-D, Table IV, reveals a generally similar pattern in that body weight decrements, while recorded at various days (and again, multiple study types were involved), are concentration-dependent, but clearly threshold related. The studies ranged from a genotoxicity study to subchronic inhalation studies to 2-yr bioassays, and while we have not reviewed these studies for determination of the critical point of departure, it is likely that body weight decrements were not found to be the most sensitive driver in all cases for establishment of references values for permissible exposures to humans. In summary, a review of multiple studies shows body weight decrements to be a common occurrence resulting from repeated exposure to 1,3-D, a phenomenon which is concentration-dependent and for which a clear threshold exists. Table 2 presents Benchmark Concentrations (BMC10 for body weight decrement associated with a 10% response rate) and BMCL10 (lower confidence limit) based on body weight decrement for various 1,3 D repeat dose studies. In comparison, the BMCL10 derived by DAS for the Cracknell et al (1987) 4-hour inhalation exposure study (1,3 D at concentrations 0, 351, 572, 585, or 665 ppm) is 42 ppm. Moreover, the effects consistently resulted from exposure to high concentrations of 1,3-D, and certainly for animals from the repeat dose study conducted by Stott et al (1984), appear to be secondary effects owing to other experimental factors (e.g., stress, reduction in respiratory minute volume). If, as we believe, these effects are secondary to other experimental factors, then it is important to probe further for biological/physiological evidence as to why exposure to high concentrations of 1,3-D result in overall body weight declines, which is discussed next.	Comment acknowledged by DPR. Comment is directed towards the established regulatory target concentration of 1,3-D and not specific to the Draft Air Monitoring Network Results For 2018 Report. No changes to the report are deemed necessary.	No changes to report are needed.

24.	**From DAS:** **Drivers Behind Body Weight Decrements –** Several biological changes occur in animals upon repeated inhalation exposure to 1,3-D. These effects are physiological (respiration) as well as metabolic (glutathione depletion). Either or both of these effects could result in stress to rats or mice exposed to 1,3-D via inhalation. Changes in the respiratory patterns of rats or mice have been observed following 1,3-D exposures. Stott et al. report 26-47% decreases in respiratory minute volume (RMV) in rats acutely exposed for 3 hr to 1,3- D concentrations of 300 and 900 ppm (Stott and Kastl, 1986). Hotchkiss et al. also found a decrease in respiration of rats acutely exposed to 1,3-D for 6 hr, with 21 and 52% reductions in RMV at 60 and 150 ppm vs. 2.5 ppm (Hotchkiss et al., 2015). These up to two-fold decreases in total inhalation would impact normal physiology and as a result, food consumption and body weight. The metabolic fate of 1,3-D involves conjugation with glutathione (GSH) for all of the reported pathways observed in the rat and mouse (Bartels et al., 2004). These observations are consistent with the measured depletion of lung GSH levels upon repeated exposures, with decreases of ~40-50% at 1,3-D concentrations of 60 and 150 ppm (Stott et al., 2001). Depletion of GSH in the portal of-entry lung tissue is known to result in oxidative stress (Deneke et al., 1985; Rahman and MacNee, 2000) which could impact body weight gains (i.e., resulting in body weight decrements).	Comment acknowledged by DPR. Comment is directed towards the established regulatory target concentration of 1,3-D and not specific to the Draft Air Monitoring Network Results For 2018 Report. No changes to the report are deemed necessary.	No changes to report are needed.

25.	**From DAS:** **Toxicokinetic KMD –** The metabolic clearance of inhaled 1,3-D has been shown to saturate in the rat and mouse. Stott and Kastl found that 1,3-D blood levels became supralinear at or above 300 ppm (3 hr acute exposure) (Stott and Kastl, 1986). Similarly, blood levels of 1,3-D were shown to be supralinear in mice at or above 30 ppm (6 hr acute exposure) (Hackett, 2018). This nonlinearity in systemic exposure is consistent with test material-based GSH depletion (discussed above), and correlates with increases in 1,3-D blood levels following lung GSH depletion via diethylmaleate pretreatment in rats (Yang, 1989). Beyond saturation of metabolic clearance, the ratio of cis/trans 1,3-D isomers in mouse blood also changes substantially from ~0.13 to ~0.20 between the exposure concentrations of 40 and 60 ppm. These data indicate a substantial shift in one or more processes involved in metabolism of these two isomers at higher 1,3-D exposure levels. Several regulatory guidance documents describe a Kinetically-derived Maximum Dose (KMD) as a dose level or exposure concentration at which systemic exposures become non-dose proportional, due to saturation of one or more pharmacokinetic or metabolic processes (i.e., absorption, metabolism) (OECD, 2014; NRC, 2007). For example, as per OECD Guidance document 116: *"Although top dose selection based on identification of inflection points in toxicokinetic nonlinearity may result in study designs that fail to identify target organ or body weight effects, it must be appreciated that metabolic saturation in fact represents an equivalent indicator of biological stress. In this case, the stress is evidenced by appearance of non-linear toxicokinetics rather than appearance of histological damage, adverse changes in clinical chemistry, haematology parameters or decrease in body weight gain."* Based on this rationale, biological effects such as body weight gain decrements, seen only at or above the KMD, would be considered irrelevant for human health risk assessments.	Comment acknowledged by DPR. Comment is directed towards the established regulatory target concentration of 1,3-D and not specific to the "Air Monitoring Network Results for 2018 – Volume 8" draft document. No changes to the report are deemed necessary.	No changes to report are needed.

26.	**From DAS:** **Discussion and Recommendations –** Analysis of the scientific data presented above indicates that there is strong evidence that the body weight decrements that are often seen in toxicity studies in animals exposed to 1,3-D are not a direct result of treatment-related exposure (i.e., primary or apical effect), but rather an indirect effect resulting from key physiological and metabolic processes. This is supported by evidence that 1,3-D's primary effect following inhalation is on portal-of-entry effects (used by EPA's IRIS program for BMD calculations) and consistent evidence from numerous studies indicating that body weight decrements are a threshold-related phenomenon with decrements only occurring at higher doses/concentrations, ones at which systemic exposures become non-dose proportional owing to saturation of pharmacokinetic or metabolic processes. In fact, as discussed above, there is solid evidence that the higher concentrations associated with body weight decrements were associated with (a) reduced respiration which directly has relevance for reduced food consumption and body weight gain; (b) GSH depletion which in turn can be associated with oxidative stress and body weight decrements; and (c) test concentrations which exceeded the KMD for 1,3-D and therefore which are not relevant for human risk assessment. Body weight decrements resulting from high exposures to 1,3-D should not be used as the primary basis for HEC derivation and subsequent risk mitigation as it has clearly been shown that this effect is secondary to overexposure which has direct effects on physiological parameters such as respiration rate and resultant reduced body weight gain. If DPR decides to continue to use body weight decrease from the repeated exposure studies to derive an acute endpoint, several considerations should be recognized: 1) Body weight was evaluated following acute exposure in the Cracknell et al (1987) study, and the use of repeated exposure on the same endpoint and disregarding the existing acute exposure studies results in a more conservative acute screening level value. 2) DPR used the benchmark dose approach to generate BMCLs and used the 1 standard deviation (SD) as benchmark response (BMR). This is a default assumption / selection according to the Benchmark Dose Technical Guidance Document (External Review Draft): "for continuous data if no known biological significance, a change of 1SD may be applied as a default BMR." However, with respect to body weight change and to what degree or magnitude it is considered adverse, two guidance documents specifically point out that 10% decrease in body weight is generally recognized as biologically significant (USEPA 2003, and USEPA 2000). Consistent with this guidance, U.S. EPA's tier I risk assessment, Integrated Risk Information System (IRIS), and tier II risk assessment, Provisional Peer-viewed Toxicity Values (PPRTV) both utilize 10% body weight decrease as BMR. 3) Body weight decrease used to derive an acute reference concentration (RfC) is of minimal adversity when such effect is not accompanied with other toxicological correlates or toxicity indications from other endpoints including clinical chemistry, hematology, neurotoxicity, and histopathology in adult animals, or fetal and offspring effects in pre-, post-neonatal, or young animals. Thus, based on these considerations, reduced uncertainty factors may be warranted. Solecki et al (2005) in their publication on the establishment of acute reference doses for pesticides, specifically noted that "A reduced factor [safety] might be appropriate if the	Comment acknowledged by DPR. Comment is directed towards the established regulatory target concentration of 1,3-D and not specific to the "Air Monitoring Network Results for 2018 – Volume 8" draft document. No changes to the report are deemed necessary.	No changes to report are needed.

	endpoint used to derive an ARfD is of minimal adversity and the critical NOAEL is from a repeat dose study (e.g., reduced food consumption and body weight gain (i.e., observed in the first days) or increased organ weight with minimal pathological change. When considering body weight changes considerations need to be given to potential problems of palatability of the feed." This perspective is directly relevant to the case here in which inhalation of high concentrations of 1,3-D are affecting respiration and hence reduced food consumption. In conclusion, there is little support for the utilization of body weight decrement as an endpoint for establishing an acute HEC and if this practice continues, then there is strong recommendation for comparing the selected time domain of the acute HEC to a corresponding exposure period (i.e., 4 hr HEC compared to a 4 hr TWA inhalation exposure, or a 3-day HEC compared to a 3-day TWA inhalation exposure). For purposes of "acute" exposure, a more defensible and appropriate exposure period is 4- hours (or 24-hours), and not 3 days. The latter is clearly not acute and would be better described as short-term. Finally, there is sound scientific evidence that body weight decrements are secondary effects owing to a variety of 1,3-D-specific portal of entry effects, and related effects on physiology,), pharmacokinetics and metabolism, at sufficient doses (at and above the KMD).		

27.	**From DAS:** **AMN Program Overview –** Table 3 shows the years that monitoring was conducted and the total number of 24-h samples collected at each of the 17 locations that are currently, or were historically, in the AMN program. Extensive monitoring in areas of high 1,3-D use during 2018 showed that 88.9% of the samples had no detectable residues of 1,3-D (Report AIR 19-02). Targeted monitoring in the two high use areas (Delhi and Parlier) under Study 309 in 2018 showed that 1,3-D was detected in 68% and 84% of the samples, respectively (Report AIR 19-03). The highest 24-h concentration of 1,3-D in 2018 occurred in Shafter and although it did not exceed the acute screening level (110 ppb), it did result in exceedance of the 13 week rolling average (RA) concentration screening level (3 ppb). Dow AgroSciences (DAS) concurs with the Department's observation that the exceedance of the 13-week RA at the Shafter site was largely influenced by the single high 24-h 1,3-D concentration (50.5 ppb) that occurred at that site. The dominating effect of a single high concentration of 1,3-D on the 13-week RA and annual average concentration was also observed at the Parlier site in Study 309 (Report AIR 19-03) where a 1,3-D concentration of 111.3 ppb was measured in October 2018. Considering these exceedances of the subchronic screening level at the Shafter and Parlier locations, and the uncertainty associated with the 13- week RA concentration, DAS suggests some alternative approaches for determining annual average and RA concentrations, including the use of air dispersion modeling to account for missing and censored data, in subsequent sections of this document. The distribution of all the weekly 24-h 1,3-D concentrations measured in the AMN program to date (3,037 samples) are shown in Figure 1 and illustrate the highly skewed nature of the data, with the highest measured concentration (100th percentile) of 111.3 ppb, while the 99.9th percentile concentration falls to 10 ppb. This reflects the fact that most of the samples resulted in no detection of 1,3-D (ND) or low trace level detections, as was the case in the 2018, with 88.9% of samples containing no detectable level of 1,3-D. <table 3> <figure 1> The annual average 24-h 1,3-D concentration at each AMN location, for each year of monitoring, is shown in Table 4. Although 24-h 1,3-D concentrations have not exceeded the DAS-recommended acute screening level at any of the monitoring locations, the maximum value measured (see Figure 1, i.e., 111.3 ppb) slightly exceeds DPR's current acute screening level (110 ppb; see Table 4 below), and a small number of higher-level detections have resulted in an exceedance of the DPRs 13-week rolling average (RA) screening level (3 ppb) in Parlier and Shafter, and exceedance of the chronic screening level for 1,3-D (2 ppb) in Parlier in 2018. The DPR lifetime/cancer risk regulatory target of 0.56 ppb was exceeded in Parlier in 2017 and 2018, and Shafter in 2018. All other sites/years have annual average concentrations 10 to 20-fold below the chronic screening level (2 ppb). Table 4 also shows that when all weekly 24-h concentrations are averaged across the years sampled at a given location, the multi-year concentrations are also below the chronic screening level, ranging from 0.07-1.71 ppb. The average 24-h concentration at the Parlier site is based on just two years (2017/2018) of weekly 24-h 1,3-D data that contain a small number of exceptionally high 1,3-D concentrations that drive the rolling average and annual average 1,3-D concentration and is discussed in more detail below.	DPR disagrees with this comment. Every attempt is made by staff to convey the obtained results in clear and unbiased manner. The manner in which pesticide air concentrations are stated in this report, are consistent with previous DPR study publications. Pesticide concentrations measured in all AMN sampling locations are listed in various tables throughout the report, and described in the report's text, Discussion, and Executive Summary. DPR believes that the sampling results are clearly and effectively presented throughout the report and thus no changes are required at this time.	No changes to report are needed.

	Table 4 also shows that the average 24-h 1,3-D concentration across all AMN locations each year is less than the chronic screening level (2 ppb). The "Grand Mean" of 24-h concentrations from all sites/all years is 0.25 ppb, and suggests that on average, over the long-term California residents are not exposed to levels of 1,3-D exceeding the chronic screening level. It is appropriate to consider the "Grand Mean" concentration to infer potential long-term human exposure to CA residents, since it inherently considers population mobility. <table 4>		
28.	**From DAS:** **Parlier Site 2017-2018 –** Figure 2 is a time series plot of the weekly 24-h 1,3-D concentration at the Parlier AMN site for 2017 and 2018 and shows that a very small number of high concentrations control the 13-week RA concentrations (Figure 3), and the annual average concentration. The annual average concentration at the Parlier site in 2017 (0.62 ppb) was dominated by a single detection of 1,3-D (16 ppb) from a sample collected on Sept 19-20, 2017. Examination of the 1,3-D application records and weather conditions at the Parlier site during September 2017 showed that 1,3-D was applied at 33 gallons per acre (gpa), the tree and vine rate, to a 9-acre field within a few hundred feet of the AMN receptor. The weather data showed significant calm periods for several days following the application and during the sampling time. Calm conditions are known to cause elevated concentrations of ambient air concentrations of pesticides. The annual average concentration at the Parlier site in 2018 was dominated by a single detection of 1,3- D (111 ppb) occurring on October 9, 2018. Just prior to that sample event, 5 applications of 1,3-D had been made to fields ranging from 1.5 to 2 acres in size. All fields were within one mile of the AMN receptor, and two were within about 500 feet of the receptor. Averaging this single 24-h detection with the 51 other weekly 24-h samples resulted in an annual average concentration of 2.94 ppb, exceeding both the chronic screening level and lifetime/cancer risk regulatory target of 0.56 ppb. <figure 2>	Comment acknowledged by DPR. Comment is not directed toward the "Air Monitoring Network Results for 2018 – Volume 8" draft document. No changes to the report are deemed necessary.	No changes to report are needed.

29.	**From DAS:** **Shafter Site 2018 –** In contrast to previous years of AMN results for Shafter, where maximum measured concentrations were well below screening levels, in 2018 a single high 24-h concentration (50.5 ppb) was measured at the Shafter receptor, though not exceeding the acute screening level, which resulted in an exceedance of the 13-week RA and annual average screening levels when averaged with weekly 24-h 1,3-D concentrations for the rest of 2018. Figure 4 shows a time series plot of the 24-h 1,3-D concentrations at the Shafter AMN site plotted weekly for 2018. The single high concentration of 1,3-D (50.5 ppb) detected at the site on January 23-24, 2018 dominates the 13-week rolling average (RA) concentration which peaks at 5.6 ppb (Figure 5) and exceeds the subchronic screening level of 3 ppb. Examination of the 1,3-D application records and weather conditions at the Shafter site during January 2018 showed that 1,3-D was applied at 30 gpa to a 25-acre field within a few hundred feet of the AMN receptor, two days prior to the sample event. The weather data showed significant stable air (calm periods) for several days following the application and during the sampling event. Calm conditions are known to cause elevated concentrations of pesticides in ambient air. The SOFEA model was parameterized with product use data (from PUR database) and weather data from the area and which simulated 24-h 1,3-D concentrations of 50 ppb between the 95th and 99th percentile, suggesting a concentration of that magnitude is a low probability occurrence and is driven by the close proximity of the field to the receptor, and wind direction. It should be noted that 1,3-D applications to tree and vine crops occur only once every 20-30 years depending on the lifespan of the orchard. Furthermore, for a human to potentially be exposed at those sub-chronic and chronic levels of 1,3-D would require that they be co-located with that receptor for 13 weeks or 52 weeks, or in the case of the lifetime/cancer risk regulatory target, for 70 years. National and California specific population mobility surveys indicate that humans are very mobile and the assumption that they remain in a fixed location for 13 weeks, let alone a year, is extremely rare and adds significant conservatism to the risk assessment (Driver et al. 2016a, 2016b). Figure 5 shows that the 13-week RA 1,3-D concentration begins to rise in late January 2018 (after the 50.5 ppb 24-h detection on Jan 23), exceeding the 13-week RA screening level (3ppb) in February 2018, and reaching a maximum (5.6 ppb) approximately 13 weeks later (April 24, 2018). After the 13-week RA peaks on April 24, it drops precipitously, reflecting the low 24-h weekly concentrations occurring throughout the remainder of the year at the Shafter site. <figure 4> <figure 5>	Comment acknowledged by DPR. No response is required.	No changes to report are needed.

30.	**From DAS:** **Study 309 AMN Sites in Delhi and Parlier –** DPR initiated monitoring at two additional sites (Delhi and Parlier) in late 2016 as part of Study 309. The goal of that air monitoring study is to evaluate the effectiveness of the current 1,3-D township cap and permit conditions promulgated as a result of DPR's 2016 RCD that became effective in January 2017. The new permit conditions allow annual application of 136,000 pounds of 1,3-D per township, ban December applications, and eliminate the 'banking' system. To monitor the effect of these changes in 1,3-D product use, DPR selected two communities characterized by relatively high historical 1,3-D use which were not already included in monitoring conducted by DPR or the California Air Resources Board (ARB). DPR staff collected weekly 24-h air samples to monitor 1,3-D in the communities of Delhi (Merced County) and Parlier (Fresno County) beginning in November 2016. Weekly 24-h 1,3-D samples have been collected since then, and a complete weekly time series for these communities is available for January 1, 2017 through December 31, 2018. Since the measured concentration at a receptor is more greatly affected by the proximity and source strength of a 1,3-D application, and less by the total number of applications, or total mass applied in a 6x6 mile township, it is erroneous to assume that the observation of a single high 24-h 1,3-D concentration means that a particular mitigation is not effective. It could simply mean that a single application of 1,3-D was made very close to the receptor at a time when meteorological conditions favored movement to that receptor location. DPR has shown in multiple analyses with several active ingredients, that correlation between the AMN concentration at a receptor and the mass of chemical applied in the township(s) surrounding the receptor is very weak. This is because parameters such as weather and proximity to the AMN receptor have a major effect on the measured concentration causing it to vary significantly from year to year. Therefore, multiple years of monitoring are needed to visualize and quantify the effect of mitigations that reduce the mass of 1,3-D applied annually in a township. The weekly 24-h AMN data is perhaps more useful for assessing mitigations that reduce 1,3-D use during certain times of year (e.g. the December ban). The 1,3-D concentration data collected from the new site in Delhi for example show that the 2016 RCD mitigation banning December applications has been successful in reducing historically high 1,3-D concentrations resulting from calm conditions that are prevalent at that time of year, as is discussed in detail below.	Comment acknowledged by DPR. Comment is not directed toward the "Air Monitoring Network Results for 2018 – Volume 8" draft document. No response is required.	No changes to report are needed.

31.	**From DAS:** **Effectiveness of December Ban using Delhi AMN data –** The AMN receptor in Delhi is in the same township (Merced 06S11E) as the DAS receptor that was used to collect continuous 72-h 1,3-D concentrations from October 2010-January 2012. The AMN and DAS receptors were about 2 miles apart, located in section 8 and section 16 of Merced 06S11E, respectively. The close spatial proximity of the receptors allows comparison of 1,3-D concentrations observed in December both before and after the ban on December applications in 2016. Figure 6 (see subfigures A and B) show the 72-h 1,3-D concentrations at the DAS monitor near the Delhi site in 2011, prior to the ban on December applications, with a peak concentration of 61 ppb occurring in December of that year (highlighted in red). The annual average concentration at that receptor was 1.02 ppb in 2011. Removing the December 2011 data from the annual average calculation reduces the annual average concentration to 0.11 ppb (~ 10-fold reduction, Fig. 5B) and is similar to the annual average concentrations of 0.13 and 0.2 ppb observed at the AMN Delhi receptor in 2017 (Fig. 5C) and 2018 (Fig. 5D) respectively, measured after the ban on December applications. <figure 6> This comparison of monitoring data collected in Merced, one of the highest 1,3-D use areas in California, shows that historically high 1,3-D concentrations occurring in December have been significantly mitigated by the ban on applications in December.	Comment acknowledged by DPR. Comment is not directed toward the "Air Monitoring Network Results for 2018 – Volume 8" draft document. No response is required.	No changes to report are needed.
32.	**From DAS:** **Impact of Township Cap Set at 136,000 Pounds 1,3-D per Year –** The impact of setting the township allocation at 136,000 pounds 1,3-D per year could take more time to show up in the AMN monitoring results since the 1,3-D levels in air are primarily dependent on whether an application occurs close to and upwind of the receptor, or under stable air conditions. Changes in township allocation limits will likely be observed in the AMN dataset after the new township cap limit has been in place for several more years. Possibly the best way to assess the effect of the change in California-wide 1,3-D township allocation (cap) is to look at the trend in annual average concentration obtained at all AMN sites over time. DAS agrees with DPRs acknowledgement that a single high 24-h concentration can dominate the 13-week RA and the annual average concentration, which can result in an exceedance of a trigger. This suggests that additional years of monitoring are required before the full impact of mitigations are reflected in the ambient 1,3-D concentrations.	Comment acknowledged by DPR. Comment is not directed toward the "Air Monitoring Network Results for 2018 – Volume 8" draft document. No response is required.	No changes to report are needed.

33.	**From DAS:** **Calculation of Rolling Average (RA) Concentrations –** As shown earlier, a single 24-hour 1,3-D concentration can dominate the calculation of the 13-week RA concentration each year, and raises the question of the representativeness of that RA. This is further exacerbated by the uncertainty introduced by the 85% missing data in the dataset and suggests that the longest time series of weekly 24-h data available should be used to calculate moving averages and annual averages for the purpose of characterizing potential exposure and risk. Figure 7 shows the weekly 24-hour 1,3-D concentration for the Shafter AMN receptor from the start of monitoring in 2011 through the end of 2018, the last full year of data, resulting in an 8-year time series of weekly 24-h concentrations (416 values). The highest measured 24-h concentration (~50 ppb) at the Shafter AMN site occurred on Jan 21, 2018 and is highlighted in red in Figure 6. DAS recommends using all the available AMN data at each site to calculate all the potential 13-week RA concentrations for the eight year period that the AMN receptor at Shafter has been monitored (Figure 6A). This requires the same assumption discussed above, that each 'weekly' average concentration is characterized by the single 24-h sample collected during that week. The number of 13 week rolling average concentrations (n) that can be calculated from eight continuous years of weekly monitoring data is 403 (n=8*52-13) and are shown in Figure 6B. These 403 estimates form a probability distribution function (PDF) of 13-week RA concentrations at the Shafter AMN site (Figure 7) and allow the risk manager to select an appropriate percentile concentration to use in the risk assessment. Figure 8 shows that the 13-week RA concentration spanning the 50 ppb 24-h detection that occurred on January 21, 2018 is the highest RA concentration (5.6 ppb) ever measured at Shafter over eight years. This is not surprising since 50 ppb is the highest 24-h concentration of 1,3-D ever measured at the Shafter AMN location between 2011 and 2018, and clearly dominates the 13-week RA calculation in early 2018. For comparison, the 90th and 95th percentile 13-week RA concentrations are 1 ppb and 2 ppb, respectively when the entire 8-year time series of weekly 1,3-D concentrations is considered. <figure 7> <figure 8> Here again, the missing data come into play because a true 13-week rolling average would require averaging 91 consecutive days of concentration data, but since there is only a single 24-h sample collected each week, that concentration is necessarily assumed to represent exposure for that entire week (i.e.. the same concentration applies for all seven days of the week). Depending on the local weather and product use near the receptor, this could result in an over- or under- estimation of the weekly and rolling average concentrations and underscores the value of using an air dispersion model (e.g. SOFEA) to simulate 1,3-D concentrations in ambient air based on known mass of 1,3-D applied, location and timing of the applications, and local weather (wind speed, direction, etc.).	The manner in which pesticide air concentrations are stated in this report, are consistent with previous DPR study publications. The use of 13-week rolling averages for 1,3-D are clearly explained in the report. Furthermore, all tables in the report where the use of 13-week average concentrations are included contain a footnote that reads: "These concentrations represent the highest 13-week rolling average." DPR believes that the sampling results are clearly and effectively presented throughout the report and thus no changes are required at this time.	No changes to report are needed.

34.	**From DAS:** **General Discussion of AMN data utility –** The collection and analysis of air samples is very resource intensive and taking continuous measurements for an extended time period is typically not feasible. For this reason, only a single 24-h sample is collected from each AMN site each week. The weekly 24-hour 1,3-D concentrations are very useful for characterizing potential acute exposure to 1,3-D, however the utility of the AMN data for quantifying short-term, sub-chronic, and chronic (annual or lifetime) exposure and risk is not as straightforward for two reasons. First, only a single 24-h sample is collected each week and therefore 6 out of 7 days (>85%) have no data. This results in the need to assume a 1,3-D concentration on the non-sampled days. DPR assumes that the measured concentration persists for the entire week which they acknowledge could result in either an over- or under-prediction of the weekly average concentration. Secondly, the AMN dataset is typically highly censored due to many samples where the concentration is less than the analytical Limit of Detection (LOD) or Minimum Detection Limit (MDL). DPR assumes that samples that show no detection (ND) are equal to one-half of the MDL or LOD, which could also result in an over- or under-prediction of the weekly concentration. Both issues add uncertainty when monitoring data is used to assess potential sub-chronic, chronic and lifetime exposure and risk, and point to the value of air dispersion modeling to fill in gaps in the monitoring data.	Comment acknowledged by DPR. No response is required.	No changes to report are needed.
35.	**From DAS:** **Use of Air Dispersion Modeling to Supplement AMN Data –** A cost-effective and scientifically sound approach to supplementing monitoring data is to use a validated air dispersion model such as the SOil Fumigant Exposure Assessment (SOFEA) model. SOFEA can be parameterized with pesticide use data (volume applied; date applied etc.) obtained from DPR's Pesticide Use Reporting (PUR) database and when combined with local meteorological data, has been shown to accurately simulate the timing and magnitude of 1,3-D concentrations in ambient air (van Wesenbeeck et al., 2016) as well as the overall PDF of 1,3-D concentrations in air. SOFEA also simulates air concentrations on an hourly time step and can therefore be used to characterize acute, subchronic and chronic exposures ranging from 1 hour to several years, or a human lifetime. The use of a modeling tool such as SOFEA is a logical complement to monitoring datasets and can be used to fill in data gaps with reasonable certainty, especially when local product use information and weather data are available. Ultimately the use of a model significantly reduces the need for arbitrarily conservative assumptions to deal with missing and censored data, and decreases the uncertainty associated with many monitoring datasets.	Comment acknowledged by DPR. Comment is not directed toward the "Air Monitoring Network Results for 2018 – Volume 8" draft document. No response is required.	No changes to report are needed.
36.	**From CARB:** **Significance of undetected pesticides –** The executive summary and the body of the report note that of the 36 pesticides monitored, eight were not detected. This implies that those pesticides do not become airborne. We suggest noting that one reason for not detecting some of the pesticides is that they were not used in the vicinity of the monitoring sites.	DPR disagrees with this comment. Official 2018 pesticide use information has not been released by the Department as of this report's publication. Therefore, it would be inappropriate for DPR to make the claim that no pesticide use occurred in the vicinity of the monitoring sites as suggested without having use data for the time period in question.	No changes to report are needed.

Responses to Comments on the AIR MONITORING NETWORK RESULTS FOR 2018 - VOLUME 8

37.	**From CARB:** **Page numbers –** Although the table of contents lists page numbers, there are no page numbers in the body of the report.	Comment acknowledged by DPR. Page numbers have been added to the report.	Changes to report were made.
38.	**From CARB:** **References to CARB** – On page 5 and throughout the report, the California Air Resources Board is referenced as ARB. We officially now go by CARB, not ARB.	Comment acknowledged by DPR. All references to the California Air Resources Board throughout the report have been updated from ARB to CARB as requested.	Changes to report were made.
39.	**From CARB:** **Reason for community selection –** On page 5, the section titled "Number of Communities Monitored" states that four communities were selected based on nearby use of four soil fumigants. Fumigants listed include methyl isothiocyanate (MITC) and MITC-generators. MITC is not an applied fumigant; it breaks down from metam sodium and metam potassium. We suggest deleting MITC and just describing this as MITC-generators.	Comment acknowledged by DPR. The sentence on Page 5 has been updated to read as "MITC-generators" instead of "MITC" as suggested.	Changes to report were made.
40.	**From CARB:** **Pesticides monitored –** On page 6, the section titled "Pesticides Monitored" indicates that "DPR monitored 31 pesticides and 5 breakdown products." This should be DPR and CARB. In addition, it may be useful to include a description of which pesticides were analyzed by the CARB lab and which were analyzed by the CDFA lab.	Comment acknowledged by DPR. Page 6 has been edited to include "DPR and CARB" as requested.	Changes to report were made.
41.	**From CARB:** **Discussion –** On page 15, the last sentence states that "DPR is in the process of developing regulations to reduce exposures to 1,3-D in ambient air." This implies that there is no current mitigation for 1,3-D, which is incorrect. We suggest rewording this sentence to make it clear that the DPR effort will modify existing mitigation measures to further reduce exposures to 1,3-D.	Comment acknowledged by DPR. The sentence on Page 15 has been updated to read as follows: "DPR is in the process of developing additional regulations to further reduce exposures to 1,3-D in ambient air."	Changes to report were made.

Responses to Comments on the AIR MONITORING NETWORK RESULTS FOR 2018 - VOLUME 8

Attachments: Comments Correspondence

August 29, 2019

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RE: Comments on Draft Air Monitoring Report for 2018

Dear Dr. Pham:

Thank you for the opportunity to comment on this draft report. We appreciate all the hard work that went into conducting the air monitoring and compiling the report and the detailed presentation of air monitoring results. We offer the following recommendations to improve data presentation and correct a few errors we noted.

We commend the Department on improvements to the air monitoring program such as the development of the air monitoring database, which we find very well designed and useful. However, the presentation of air monitoring results in the annual report continues to be misleading, incomplete and, in some instances, inaccurate in its description of health threats from airborne pesticides. We strongly urge the Department to revise the draft report to provide a more comprehensive description of the air monitoring data

Comments on data presentation in the draft report

Executive Summary
The description of Shafter air monitoring results in the Executive Summary should include two clarifying statements:
1) If the 2018 annual average 1,3-D air concentration of 1.53 ppb were to continue for 70 years it would exceed DPR's current regulatory target of 0.56 ppb for control of lifetime cancer risk; and
2) The 8 year average 1,3-D air concentration of 0.41 ppb already exceeds DPR's previous regulatory target of 0.14 ppb which OEHHA continues to support.

Combined results for all pesticides and communities
We remain concerned that beginning the report by quoting statistics that aggregate all the data conveys a false sense of security that does not reflect the air levels documented by the actual monitoring data.

The statements in the report that 93.8% of analyses did not return a detectable concentration, that 6.2% of analyses had at least one detectable pesticide concentration and that 1.3% of analyses had quantifiable detections are highly misleading because they ignore the realities of pesticide use patterns. In order to reach 100% detections (a total of 12,058 positive analyses), every pesticide tested for would have to be found on each of the days monitored at each of the air monitoring sites. In reality, use of most pesticides is concentrated in certain months. As pesticide use varies between crops and regions, not all of the pesticides monitored for are used near all of the monitoring sites. Therefore, using the total number of analyses for all pesticides at all locations as the denominator does not provide a meaningful context.

Detection frequency should either be calculated based on what pesticides were used in the vicinity of a specific site, shortly prior to the sampling date, or should not be highlighted. When these concerns were raised two years ago at the August 18, 2017 PREC meeting, then Branch Chief Pam Wofford stated that DPR was conducting an uncertainty analysis of frequency of detections. Is this analysis still in process and if so when will it be completed?

We note that Table 4 shows that there was an average of at least one pesticide detection in 86% of weekly sample sets collected at each monitoring site. This statistic should also be included in any discussion of aggregate findings in the report narrative.

The report states that there were 4 lost samples in 2018 including 3 summa canisters. The date and location of lost or otherwise invalidated samples should be provided in the report.

The tables in the Air Monitoring Study Results and 1,3-D Ambient Air Monitoring Results Presentations at the July 19th Pesticide Registration and Evaluation Committee[1] (slides 13-15 and slides 26-27) that compile highest air concentrations and compare highest 1 day, 4 week or 13 week and annual average concentrations between sites for all pesticides with quantifiable detections are very helpful and informative. We strongly recommend including them in the report with 1,3-D results combined with other pesticide results.

Acute Screening Levels

Chloropicrin

The acute regulatory target for chloropicrin of 73 ppb used in this report as a 24 hour average exposure target level was set in a Risk Management Directive (RMD)[2] as an 8 hour average so at the very least it should be adjusted to 24.3 ppb as a 24 hour level. Furthermore, this 73 ppb target level was set over the objection of OEHHA.[3] The chloropicrin TAC report[4] and risk assessment[5], which are also supported by OEHHA[6], include a 24 hour reference level of 0.92 ppb for protection of children. The highest 24 hour level measured in Oxnard (0.8 ppb) reached 87% of this reference level and the highest level measured in Santa Maria (0.46 ppb) reached 50% of this level.

MITC

The acute regulatory target for MITC of 220 ppb used in this report as a 24 hour average exposure target level was set in a Risk Management Directive[7] as an 8 hour exposure level so at the very least it should be adjusted to 73 ppb as a 24 hour exposure target level. Furthermore, this level was set over OEHHA's objections [8] because 220 ppb was the "no effects" level in a toxicology study, leaving no margin of error. The DPR TAC report[9] and risk assessment[10] established an 8 hour reference level of 22 ppb for protection against irritation to the eyes and respiratory system which should be adjusted to 7.3 ppb as a 24 hour target exposure level.

[1] DPR Pesticide Registration and Evaluation Committee Air Monitoring Results and 1,3-D Ambient Air Monitoring Results Presentation. July 19, 2019

[2] https://www.cdpr.ca.gov/docs/emon/pubs/chloropicrin/directive.pdf

[3] https://oehha.ca.gov/media/downloads/pesticides/report/chloropicrinmitigationmemooehha2013.pdf

[4] DPR Toxic Air contaminant Assessment for Chloropicrin. February 2010

[5] DPR Risk Characterization Document (For chloropicrin exposure of Workers and the General Public) November 2012

[6] https://www.cdpr.ca.gov/docs/risk/rcd/oehha_comments.pdf

[7] https://www.cdpr.ca.gov/docs/emon/pubs/mitc/dirctv120202.pdf

[8] OEHHA Memorandum to Charles Andrews of CDPR. Comments on DPR's Proposed Mitigation Strategy for MITC. May 5, 2006.

[9] DPR Toxic Air Contaminant Report for MITC. August 2002

[10] DPR Risk Characterization for MITC. July 2003

DPR Risk Characterization for Metam Sodium. July 21, 2004
https://www.cdpr.ca.gov/docs/risk/rcd/metam.pdf

The highest 24 hour air level measured in Shafter (1.2 ppb) reached 16.4% of 7,.3ppb, the reference level of 22 ppb, adjusted for 24 hour exposure. As you know, in the seasonal monitoring study conducted in Arvin in the summer of 2017 a peak 24 hour level of 4 ppb was measured with a month-long average air level of 1.03 ppb, exceeding the sub-chronic screening level of 1 ppb, set to prevent damage to the nasal cavity.

Sub-Chronic Screening Levels
Chloropicrin and 1,3-D

In 2017 DPR discontinued the practice of using a 4-week rolling average concentration to compare to chloropicrin and 1,3 D sub-chronic screening levels and began comparing to 90 day or 13 week rolling averages.[11] This change was made after peak 4 week rolling averages were found to exceed the 4 week chloropicrin screening level at the Santa Maria air monitoring site in 2014 and 2015[12] and the peak 4-week 1,3-D air concentration for 2016 in Shafter reached 97.6% the 1,3-D sub-chronic screening level.[13] DPR toxicologists claim these changes were justified because the toxicology studies used to set the sub-chronic screening levels were 90 days long for chloropicrin and 13 weeks long for 1,3-D. However, the revised averaging times have still not been reviewed by OEHHA and should be.

We think it is more scientifically valid and health protective to continue to compare air levels of these fumigants to the peak 4-week rolling average concentration rather than a season long average concentration. While rhinitis was found in rats at the end of a 90-day chloropicrin inhalation study it may have developed earlier and humans may be more sensitive than rats. In addition, in reality people are exposed to varying levels of chloropicrin and 1,3-D over time and higher level short term exposures may cause more respiratory and nasal problems.

If calculated as a 4 week rolling average, the highest sub-chronic chloropicrin air concentration in 2018 was 0.225 ppb at both the Oxnard and Santa Maria sites. This reaches 64% of the sub-chronic screening level of 0.35 ppb.

This report correctly reports that in 2018 the 1,3 D sub-chronic screening level averaged over 13 weeks was exceeded at the Shafter site. However, the statement that the exceedance of the sub-chronic 1,3 D screening level at the Shafter site was primarily driven by the 50.5 ppb level measured on January 22nd is misleading because levels in excess of 1 ppb were measured for several weeks after the January spike and a level of 4 ppb was measured in late October.

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[11] DPR Memorandum to Shelley DuTeaux. Calculation of Intermediate Term Residential Exposures Using Measured Air Concentrations from the Ambient Air Monitoring Network. August 9, 2016 https://www.cdpr.ca.gov/docs/hha/memos/intermediate_term_exposure_calculations.pdf
[12] DPR Report on Methyl bromide, 1,3-D and Chloropicrin Air Monitoring Results for 2010-2015. November 3, 2016
[13] DPR Air Monitoring Network Results for 2016. Volume 6. December 2017

Lifetime exposure: Cancer risk estimates
The phrase "potential carcinogens" is not appropriate. The pesticides 1,3 D, chlorothalonil, DDVP, diuron, iprodione and propargite are classified as known carcinogens under Proposition 65 and as probable carcinogens by USEPA. In addition, studies are in process evaluating potential carcinogenicity of MITC and chloropicrin.

DPR has selected a cancer risk level of 1 in 100,000 as the regulatory target for 1,3 D but this level is not generally considered negligible. A cancer risk of 1 in 1 million is used as the level of negligible risk by DPR in risk assessments and considered by OEHHA and most public health entities as the limit for adequate health protection.

The report should also note that DPR's 1,3 D risk assessment includes both the portal of entry and systemic cancer potency risk factors and that OEHHA maintains that the systemic cancer potency risk factor should continue to be used for adequate health protection. We note, as shown in slide 32 of the Air Monitoring Network results July 19, 2019 PREC meeting presentation, that 1,3 D cancer risk levels exceed 10^{-6} at the Shafter, Santa Maria and Watsonville sites using the portal of entry cancer potency factor. Utilizing the systemic cancer potency risk factor, risk exceeds 10^{-5} at the Shafter and Santa Maria sites. Further, at the Watsonville site, the average air concentration reached 0.1 ppb, the threshold level OEHHA supports to protect children from cancer.

Chloropicrin carcinogenicity
The average annual concentration of chloropicrin in Chualar and Watsonville was 0.03 ppb (30 ppt) and was 0.04 ppb (40 ppt) in Santa Maria. If sustained over time, these concentrations all greatly exceed the reference concentration of 0.24 ppt for controlling cancer risk to the 1 in a million level that was established in the DPR Chloropicrin TAC and Risk Characterization documents as the negligible risk level and supported in review by OEHHA and the TAC Scientific Review Panel. DPR subsequently made a unilateral decision that chloropicrin cancer data was equivocal and that an additional study was needed to assess cancer risk. That study is not due to be submitted until December 31, 2021[14] so in the meantime we are left with great uncertainty about cancer risk from chloropicrin exposure due to this huge data gap.

Results for individual communities
We appreciate inclusion of a description of each community. An aerial view map of each monitoring site would also be helpful along with an assessment of proximity to agricultural fields. Carrots are an additional major crop in the Cuyama area. Carrot preplant fumigation may account for the high percentage (89%) of detections of MITC at the Cuyama site.

The figures showing temporal trends in levels of individual pesticides detected at each monitoring site are very useful.

[14] Ann Prichard, communication by email

Field spike recoveries

We are concerned to note fairly low field spike percent recoveries for chlorothalonil (73%); chlorpyrifos (77%); malathion (72%); and MITC (78%) which suggest that reported values for these pesticides may be underestimates. We also strongly disagree with the Department's decision to discontinue use of field spikes at the end of 2018. It would seem appropriate to devote more resources to figuring out why these field spikes were low instead of discontinuing field spike measurements.

Field spikes provide reliable data about how field conditions may be affecting sample recovery. While the field spikes have their challenges and the data from them have their limitations (as cited by DPR in the 2018 AMN update)[15], discontinuing the practice of collecting field spikes would mean that *no* information would be collected about how field samples might have been affected by important environmental conditions (e.g., humidity, temperature, other environmental factors affecting samples). For example, a 2018 memo[16] from CDFA regarding MITC stated "The low recovery for the blind spikes would indicate that the sampling, extraction and analysis of the samples the lab analyzed during 2017 are reporting findings that are lower than what is actually in the air during the sampling."

MITC air monitoring studies conducted by academics[17] have included fortified field spikes, in order to collect data about field conditions while conducting air sampling. DPR could potentially use information from field spikes to help determine whether losses in the field are the result of laboratory methods (as CARB determined for 2017 methyl bromide samples), or for other reasons. In the 1990s, low field spike recovery rates for methyl bromide contributed to a study being conducted that showed that recoveries were greatly improved if steel canisters were used, rather than charcoal air tubes. As a result, sampling methodologies were improved for DPR field sampling. Therefore, field spikes can be useful and indeed may play an important role in helping DPR assess whether screening thresholds are potentially being exceeded.

[15] DPR Air Program Updates and Quality Control Discussion (Edgar Vidrio).
Memo from CDFA to DPR. Field Spikes for Air Monitoring Studies. November 2, 2018.
[16] CDFA memo to DPR: Addressing the recovery of MITC from charcoal tubes, June 14, 2018.
https://www.cdpr.ca.gov/docs/emon/airinit/cdfa_memoranda_mitc_field_spike.pdf#page=4

[17] Woodrow, James E., et al. "Determination of Methyl Isocyanate in Outdoor Residential Air near Metam-Sodium Soil Fumigations." *Journal of Agricultural and Food Chemistry* 62, no. 36 (September 10, 2014): 8921–27. https://doi.org/10.1021/jf501696a.

Littke, Matt H, et al. "Comparison of Field Methyl Isothiocyanate Flux Following Pacific Northwest Surface-Applied and Ground-Incorporated Fumigation Practices: Comparison of Field Methyl Isothiocyanate Flux Following Different Fumigation Practices." *Pest Management Science* 69, no. 5 (May 2013): 620–26. https://doi.org/10.1002/ps.3414.

Historical air concentration analyses
It would be better to place the historical air concentration analyses, which provide very useful background, in the "Results from individual communities" section after 2018 data for each community site. In the historic analyses, some of the table entries show 0 ppb with a value in ng/m3. A non-zero value should also be provided in ppb. Tables 10 and 11 for Santa Maria appear to have ppb to ng/m3 conversion or rounding errors for chloropicrin and malathion.

The historical air concentration analysis shows that the Shafter annual air concentration for MITC (0.058 ppb) was higher in 2018 than any previous year. This should be mentioned earlier in the report.

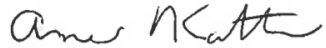
For Oxnard, Santa Maria and Watsonville more than 2 years of data are available for 1,3-D, methyl bromide and chloropicrin because these were previously TAC sites. That additional data should be included in historical analyses.

Air Monitoring Database
The Air Monitoring database is very well designed, user friendly and versatile. We greatly appreciate the inclusion of preliminary monitoring data and the ability to filter data by chemical, site and specific time periods and download filtered data into spreadsheets. It is unfortunate that Google will discontinue Google sheets at the end of the year, which means that the AMN data can no longer be organized using this system. We urge DPR to develop an alternative database that continues to be searchable and if possible is expanded to include mapping and graphing functions.

Suggestions for further analyses
Many of these monitoring sites are located at schools. We would recommend conducting an analysis to evaluate how the school buffer zone requirements may have impacted air levels measured at these sites. It also appears that 1,3- D and chloropicrin air levels have decreased at coastal sites in recent years. We recommend conducting an analysis that looks at whether there is any correlation between these fumigant air levels and the extent of use of TIF tarps surrounding the air monitoring sites.

Please contact us if you have any questions about these comments. Thank you again for your hard work maintaining the Air Monitoring Network and database and preparing these reports.

Sincerely,



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Dow AgroSciences Comments on
DPR's Draft Air Monitoring Network Results for 2018

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Introduction

The California Department of Pesticide Regulation's (DPR) Air Monitoring Network (AMN) has been in operation since 2010 and has developed a database of 24-h concentrations of 31 pesticide products, including 1,3-D, measured at receptors located in intensive agricultural areas in CA. A 24-h sample is collected on a randomly assigned day, once per week, at each AMN site for an entire year. Data exists for 17 sites, although since 2010, new sites have been added and some sites have been retired. Dow AgroSciences (DAS) recognizes that some of the sites are part of the Toxic Air Contaminant (TAC) or Study 309 programs, however the data are collectively referred to as "AMN" results in this review. A total of 3037 samples have been analyzed to date. Sites in Delhi and Parlier were introduced in 2016 under "Study 309" and are in townships with historically high 1,3-D demand and use (Merced and Fresno, respectively). The primary objective of monitoring at these sites under Study 309 is to evaluate the effectiveness of township use restrictions and a ban on December applications of 1,3-D.

DPR issued two draft reports, "AIR MONITORING NETWORK RESULTS FOR 2018 Volume 8- Report AIR 19-02" and "Monitoring of 1,3-Dicloropropene in Merced and Fresno Counties-Results for 2018: Volume 2-Report AIR 19-03" in July 2019. Results from both reports are reviewed in this document.

In addition, DAS has provided detailed comments to DPR regarding refined derivations of acute, subchronic and chronic screening levels and the regulatory target concentration value for 1,3-D. This is summarized further below. Finally, the regulatory target concentration derivation should be revised to address recent documentation of 1,3-D's Kinetically-derived Maximum Dose (KMD). Studies and related evaluations have been provided to DPR regarding the threshold-based KMD for 1,3-D and its role in refinement of chronic and lifetime exposure and risk estimation.

Evaluation of 1,3-D Screening-Levels and Regulatory Target

Alternative, refined derivations of 1,3-D acute, subchronic and chronic Human Equivalent Concentrations (HECs) and associated screening levels, and the "regulatory target" concentration (for lifetime exposure and risk evaluation) used for comparison to AMN measurements and modeled air concentrations, have been presented to DPR by DAS. Table 1 presents a comparison of screening level values currently recommended by DPR, versus those recommended by DAS. Detailed comments have been submitted to DPR. Further, an important consideration is the selection of an appropriate exposure metric (i.e., matching duration and time required for manifestation of the toxicological effect of interest), for comparison to alternative HECs and the resulting risk estimates (Margins of Exposure).

In the case of the acute HEC recommended by DPR, while the values have been time-weighted to a 24 hour period based on Haber's Law (or Rule)[1] (i.e., adjustment for concentration x time), the time to effect in the repeat dose study selected by DPR is 3 days (time and repeat dosing period required for statistically significant body weight decrement to be observed). Thus, the DPR acute screening level, should be compared to 72-hour time weighted average estimated exposure values (theoretical air concentrations assumed to be inhaled by bystanders for risk analysis). Further, an alternative to the repeat dose study used by DPR for the acute screening level derivation, is reliance on a 4-hour inhalation toxicology study

[1]F. J. Miller; P. M. Schlosser; D. B. Janszen (August 14, 2000). "Haber's rule: a special case in a family of curves relating concentration and duration of exposure to a fixed level of response for a given endpoint". *Toxicology*. **149** (1): 22–34.

and related benchmark response (BMR) of 10% body weight gain decrement, which reflects U.S. Environmental Protection Agency (U.S. EPA) and other guidance for selection of a biologically significant response. Differences in subchronic and chronic screening levels recommended by DAS, in comparison to DPR (see Table 1), relate to DAS's reliance on U.S. EPA's most recent guidance for derivation of inhalation reference concentrations (screening levels), and the use of a refined uncertainty factor that is consistent with that derived by the U.S. EPA. Detailed comments regarding DAS's recommendations have been submitted to DPR.

Table 1. Comparison of Alternative Screening Levels			**DPR Values**			**DAS Recommended Values**		
Exposure Duration	RGDR	HEC (ppm)	UFs	Screening Level (ng/m^3)	RGDR	HEC (ppm)	UFs	Screening Level (ng/m^3)
Acute	1	11	100	505, 000	1	42	30	6,342,000[c]
Sub-chronic	0.115	0.3	100	14,000[a]	1	2.6	30	394,110[b]
Chronic	0.198	0.2	100	9,000[a]	1	0.99	30	149,490[b]

[a] Based on EPA 1994: Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry Data.

[b] Based on EPA 2012: Advances in Inhalation Gas Dosimetry for Derivation of a Reference Concentration (RfC) and Use in Risk Assessment.

[c] Based on selection of 4-hr study and 10% BW gain decrement for the BMR.

In the case of the acute screening level for 1,3-D, it is important to provide context to the point of departure, i.e., decrements in body weight gain. Body weight gain decrements have been used by multiple entities (DPR, U.S. EPA) as a point of departure and the basis for establishing permissible exposure limits to humans. However, upon closer examination of 1,3-D inhalation toxicology studies and the decrements in body weight observed in all of these studies, coupled with consideration of some key physiological and toxicokinetic measurements/indicators, it is clear that body weight, particularly after repeat dosing, e.g., 3 days, is not an optimal point of departure for use in acute (24 hrs or less) Human Equivalent Concentration (HEC) derivation. In fact, it appears body weight decrements resulting from inhalation exposure to 1,3-D are a secondary effect, resulting from primary effects on respiration rate, GSH depletion, and systemic over-exposure to the test material. A recent toxicokinetic study supports this reasoned conclusion and also raises significant questions about inhalation studies that are conducted above the kinetically-derived maximum dose and their use in risk assessment. As DPR considers risk mitigation measures for acute exposures to 1,3-D, it is imperative that a balanced discussion and reasoned conclusion, supported by the available science, be conducted. If a repeat dose study is used for the acute

HEC (normalized to 24 hr exposure duration, i.e., per day exposure basis), as stated previously, it is imperative that it is compared to an appropriate exposure metric that matches the time to effects (3 days, or three 24 hr periods).

1,3-D and Effects on Portal of Entry Tissues

Dichloropropene compounds, in general, have sensory irritation properties and this translates into portal of entry (in this case inhalation) effects involving the respiratory tract, which are considered a primary toxicological/irritancy effect in animals and humans. Body weight is typically a secondary effect from oral and inhalation exposures often resulting from an apical injury, stress, or other treatment-related factors that may directly affect food consumption or respirability (e.g., breathing rate). In fact, for 1,3-D, the U.S. EPA IRIS program/office used nasal histopathology for derivation of the BMD and while this was derived from a repeated-dose and longer-term study, it shows the focus on portal of entry effects, which are a primary effect of exposure to 1,3-D. Consideration of body weight as the sentinel and appropriate endpoint of concern for establishing permissible exposure levels to humans, particularly from body weight decrements after 3 days of exposure (as used by DPR from Stott et al., 1984) is a toxicologically "blunt" and potentially irrelevant (relative to the toxicological profile and characteristics of 1,3-D) endpoint. If body weight is going to be used as a point of departure, particularly for acute exposures, available data for 4-hr exposures should be used, notably when body weight changes were reported. Finally, use of an acute exposure scenario such as 4-hours is far more appropriate when extrapolating to the human situation for protection of human health following acute exposures of this time duration. Humans are not continuously exposure to 1,3-D for 72 hours and therefore, there is no scientific or rational basis to use body weight decrements at 3 days for extrapolating to the acute (24 hrs or less) exposure scenario for humans.

Review of Selected Inhalation Studies and Effects on Body Weight

Stott et al (1984) conducted a 13-week inhalation in rats and mice and at the two top concentrations (90 and 150 ppm) for both species, statistical decrements in body weight were recorded. In rats, the decrements for both sexes began on day 3 (first measurement) and continued for the duration of the study, while in male and female mice, statistically significant differences were not recorded at 90 ppm until day 59 and 45, respectively and at day 15 (males) and day 3 and 17 (females) for animals exposed to 150 ppm. In interpreting these effects for rats, Stott et al (1984) concluded that "As no histologically observable changes were noted in these tissues, the organ weight differences were not interpreted as being indicative of a specific target organ effect; but rather, represented an indirect, nonspecific result of TELONE II vapor exposure in these rats." For mice, Stott et al (2014) concluded that "The absence of any observable histological alterations in any of these organs indicated that the organ weight differences were a nonspecific result of exposure to TELONE II vapors (e.g. stress-induced atrophy of lymphoid elements)." For both species, there is a clear threshold for concentration-dependent effects on body weight gain and for both, high concentrations of 1,3-D were required in order to elicit/manifest a decrement in weight gain. Additionally, it would appear that the absence of any histologically relevant changes in those organs/tissues evaluated support the interpretation that decrements in body weight gain are a result of

non-specific secondary consequences to experimental stress or reduction in respiratory minute volume (discussed below), both of which could result in reduction in food consumption and hence declines in body weight gain. In the end, these results are consistent with exposure to excessive concentrations of 1,3-D and not the result of treatment-related target organ specificity and toxicity.

A review of six different study types as noted by DPR in their 2015 Risk Characterization Document (RCD) for 1,3-D, Table IV, reveals a generally similar pattern in that body weight decrements, while recorded at various days (and again, multiple study types were involved), are concentration-dependent, but clearly threshold-related. The studies ranged from a genotoxicity study to subchronic inhalation studies to 2-yr bioassays, and while we have not reviewed these studies for determination of the critical point of departure, it is likely that body weight decrements were not found to be the most sensitive driver in all cases for establishment of references values for permissible exposures to humans.

In summary, a review of multiple studies shows body weight decrements to be a common occurrence resulting from repeated exposure to 1,3-D, a phenomenon which is concentration-dependent and for which a clear threshold exists. Table 2 presents Benchmark Concentrations (BMC10 for body weight decrement associated with a 10% response rate) and BMCL10 (lower confidence limit) based on body weight decrement for various 1,3-D repeat dose studies. In comparison, the BMCL10 derived by DAS for the Cracknell et al (1987) 4-hour inhalation exposure study (1,3-D at concentrations 0, 351, 572, 585, or 665 ppm) is 42 ppm.

Moreover, the effects consistently resulted from exposure to high concentrations of 1,3-D, and certainly for animals from the repeat dose study conducted by Stott et al (1984), appear to be secondary effects owing to other experimental factors (e.g., stress, reduction in respiratory minute volume). If, as we believe, these effects are secondary to other experimental factors, then it is important to probe further for biological/physiological evidence as to why exposure to high concentrations of 1,3-D result in overall body weight declines, which is discussed next.

Table 2. Summary of BMC10 and BMCL10 for eight repeat-toxicity studies

Study	Dose levels (ppm)	Exposure duration	BMC10	BMCL10
Rat dominant lethal	0, 10, 60, 150	7	167	137
Rat 2-year	0, 5, 20, 60	6	63 (M) 81 (F)	61 (M) 75 (F)
Rat 13-week	0, 10, 30, 90, 150	3	148 (M) 169 (F)	117 (M) 134 (F)
Rat developmental (full)	0, 20, 60, 120	4 (gestation day-9)	188	146
Mouse 2 year	0, 5, 20, 60	7	109 (M) 102 (F)	81 (M) 81 (F)
Rabbit developmental (full)	0, 20, 60, 120	3 (gestation day-9)	No dose response	
Rat developmental (probe)	0, 50, 150, 300	3 (gestation day-8)	274	165

Rabbit developmental (probe)	0, 50, 150, 300	3 (gestation day-8)	203	105

Drivers Behind Body Weight Decrements

Several biological changes occur in animals upon repeated inhalation exposure to 1,3-D. These effects are physiological (respiration) as well as metabolic (glutathione depletion). Either or both of these effects could result in stress to rats or mice exposed to 1,3-D via inhalation.

Changes in the respiratory patterns of rats or mice have been observed following 1,3-D exposures. Stott et al. report 26-47% decreases in respiratory minute volume (RMV) in rats acutely exposed for 3 hr to 1,3-D concentrations of 300 and 900 ppm (Stott and Kastl, 1986). Hotchkiss et al. also found a decrease in respiration of rats acutely exposed to 1,3-D for 6 hr, with 21 and 52% reductions in RMV at 60 and 150 ppm vs. 2.5 ppm (Hotchkiss et al., 2015). These up to two-fold decreases in total inhalation would impact normal physiology and as a result, food consumption and body weight.

The metabolic fate of 1,3-D involves conjugation with glutathione (GSH) for all of the reported pathways observed in the rat and mouse (Bartels et al., 2004). These observations are consistent with the measured depletion of lung GSH levels upon repeated exposures, with decreases of ~40-50% at 1,3-D concentrations of 60 and 150 ppm (Stott et al., 2001). Depletion of GSH in the portal-of-entry lung tissue is known to result in oxidative stress (Deneke et al., 1985; Rahman and MacNee, 2000) which could impact body weight gains (i.e., resulting in body weight decrements).

Toxicokinetic KMD

The metabolic clearance of inhaled 1,3-D has been shown to saturate in the rat and mouse. Stott and Kastl found that 1,3-D blood levels became supralinear at or above 300 ppm (3 hr acute exposure) (Stott and Kastl, 1986). Similarly, blood levels of 1,3-D were shown to be supralinear in mice at or above 30 ppm (6 hr acute exposure) (Hackett, 2018). This nonlinearity in systemic exposure is consistent with test material-based GSH depletion (discussed above), and correlates with increases in 1,3-D blood levels following lung GSH depletion via diethylmaleate pretreatment in rats (Yang, 1989).

Beyond saturation of metabolic clearance, the ratio of cis/trans 1,3-D isomers in mouse blood also changes substantially from ~0.13 to ~0.20 between the exposure concentrations of 40 and 60 ppm. These data indicate a substantial shift in one or more processes involved in metabolism of these two isomers at higher 1,3-D exposure levels.

Several regulatory guidance documents describe a Kinetically-derived Maximum Dose (KMD) as a dose level or exposure concentration at which systemic exposures become non-dose proportional, due to saturation of one or more pharmacokinetic or metabolic processes (i.e., absorption, metabolism) (OECD, 2014; NRC, 2007). For example, as per OECD Guidance document 116:

"Although top dose selection based on identification of inflection points in toxicokinetic nonlinearity may result in study designs that fail to identify target organ or body weight effects, it must be appreciated that

metabolic saturation in fact represents an equivalent indicator of biological stress. In this case, the stress is evidenced by appearance of non-linear toxicokinetics rather than appearance of histological damage, adverse changes in clinical chemistry, haematology parameters or decrease in body weight gain."

Based on this rationale, biological effects such as body weight gain decrements, seen only at or above the KMD, would be considered irrelevant for human health risk assessments.

Discussion and Recommendations

Analysis of the scientific data presented above indicates that there is strong evidence that the body weight decrements that are often seen in toxicity studies in animals exposed to 1,3-D are not a direct result of treatment-related exposure (i.e., primary or apical effect), but rather an indirect effect resulting from key physiological and metabolic processes. This is supported by evidence that 1,3-D's primary effect following inhalation is on portal-of-entry effects (used by EPA's IRIS program for BMD calculations) and consistent evidence from numerous studies indicating that body weight decrements are a threshold-related phenomenon with decrements only occurring at higher doses/concentrations, ones at which systemic exposures become non-dose proportional owing to saturation of pharmacokinetic or metabolic processes. In fact, as discussed above, there is solid evidence that the higher concentrations associated with body weight decrements were associated with (a) reduced respiration which directly has relevance for reduced food consumption and body weight gain; (b) GSH depletion which in turn can be associated with oxidative stress and body weight decrements; and (c) test concentrations which exceeded the KMD for 1,3-D and therefore which are not relevant for human risk assessment. Body weight decrements resulting from high exposures to 1,3-D should not be used as the primary basis for HEC derivation and subsequent risk mitigation as it has clearly been shown that this effect is secondary to overexposure which has direct effects on physiological parameters such as respiration rate and resultant reduced body weight gain.

If DPR decides to continue to use body weight decrease from the repeated exposure studies to derive an acute endpoint, several considerations should be recognized:

1) Body weight was evaluated following acute exposure in the Cracknell et al (1987) study, and the use of repeated exposure on the same endpoint and disregarding the existing acute exposure studies results in a more conservative acute screening level value.

2) DPR used the benchmark dose approach to generate BMCLs and used the 1 standard deviation (SD) as benchmark response (BMR). This is a default assumption / selection according to the Benchmark Dose Technical Guidance Document (External Review Draft): "for continuous data if no known biological significance, a change of 1SD may be applied as a default BMR." *However, with respect to body weight change and to what degree or magnitude it is considered adverse, two guidance documents specifically point out that 10% decrease in body weight is generally recognized as biologically significant (USEPA 2003, and USEPA 2000).* Consistent with this guidance, U.S. EPA's tier I risk assessment, Integrated Risk

Information System (IRIS), and tier II risk assessment, Provisional Peer-viewed Toxicity Values (PPRTV) both utilize 10% body weight decrease as BMR.

3) Body weight decrease used to derive an acute reference concentration (RfC) is of minimal adversity when such effect is not accompanied with other toxicological correlates or toxicity indications from other endpoints including clinical chemistry, hematology, neurotoxicity, and histopathology in adult animals, or fetal and offspring effects in pre-, post-neonatal, or young animals. Thus, based on these considerations, reduced uncertainty factors may be warranted. Solecki et al (2005) in their publication on the establishment of acute reference doses for pesticides, specifically noted that "A reduced factor [safety] might be appropriate if the endpoint used to derive an ARfD is of minimal adversity and the critical NOAEL is from a repeat dose study (e.g., reduced food consumption and body weight gain (i.e., observed in the first days) or increased organ weight with minimal pathological change. When considering body weight changes considerations need to be given to potential problems of palatability of the feed." This perspective is directly relevant to the case here in which inhalation of high concentrations of 1,3-D are affecting respiration and hence reduced food consumption.

In conclusion, there is little support for the utilization of body weight decrement as an endpoint for establishing an acute HEC and if this practice continues, then there is strong recommendation for comparing the selected time domain of the acute HEC to a corresponding exposure period (i.e., 4 hr HEC compared to a 4 hr TWA inhalation exposure, or a 3-day HEC compared to a 3-day TWA inhalation exposure). For purposes of "acute" exposure, a more defensible and appropriate exposure period is 4-hours (or 24-hours), and not 3 days. The latter is clearly not acute and would be better described as short-term. Finally, there is sound scientific evidence that body weight decrements are secondary effects owing to a variety of 1,3-D-specific portal of entry effects, and related effects on physiology,), pharmacokinetics and metabolism, at sufficient doses (at and above the KMD).

AMN Program Overview

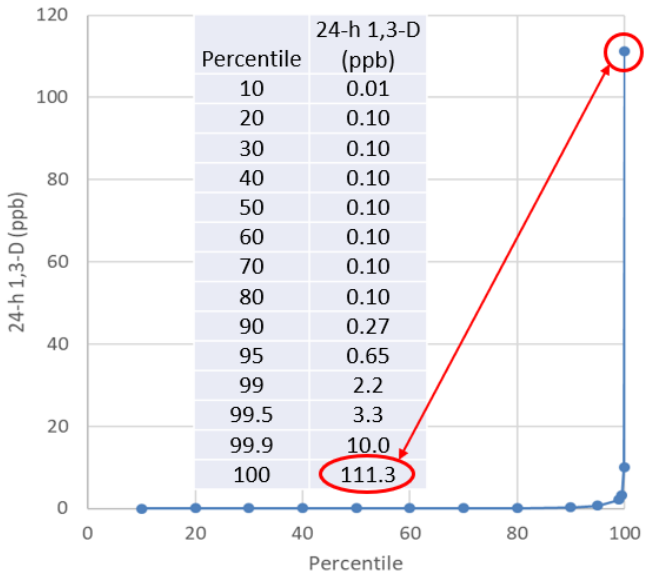
Table 3 shows the years that monitoring was conducted and the total number of 24-h samples collected at each of the 17 locations that are currently, or were historically, in the AMN program. Extensive monitoring in areas of high 1,3-D use during 2018 showed that 88.9% of the samples had no detectable residues of 1,3-D (Report AIR 19-02). Targeted monitoring in the two high use areas (Delhi and Parlier) under Study 309 in 2018 showed that 1,3-D was detected in 68% and 84% of the samples, respectively (Report AIR 19-03). The highest 24-h concentration of 1,3-D in 2018 occurred in Shafter and although it did not exceed the acute screening level (110 ppb), it did result in exceedance of the 13-week rolling average (RA) concentration screening level (3 ppb). Dow AgroSciences (DAS) concurs with the Department's observation that the exceedance of the 13-week RA at the Shafter site was largely influenced by the single high 24-h 1,3-D concentration (50.5 ppb) that occurred at that site. The dominating effect of a single high concentration of 1,3-D on the 13-week RA and annual average concentration was also observed at the Parlier site in Study 309 (Report AIR 19-03) where a 1,3-D concentration of 111.3 ppb was measured in October 2018. Considering these exceedances of the sub-chronic screening level at the Shafter and Parlier locations, and the uncertainty associated with the 13-week RA concentration, DAS suggests some alternative approaches for determining annual average and RA concentrations, including the use of air dispersion modeling to account for missing and censored data, in subsequent sections of this document.

The distribution of all the weekly 24-h 1,3-D concentrations measured in the AMN program to date (3,037 samples) are shown in Figure 1 and illustrate the highly skewed nature of the data, with the highest measured concentration (100th percentile) of 111.3 ppb, while the 99.9th percentile concentration falls to 10 ppb. This reflects the fact that most of the samples resulted in no detection of 1,3-D (ND) or low trace level detections, as was the case in the 2018, with 88.9% of samples containing no detectable level of 1,3-D.

Table 3. Monitoring years and number of 24-h 1,3-D samples collected at AMN each site.

Site	Years monitored	No. of Samples
Santa Maria	2010-2018	519
Shafter	2011-2018	413
Oxnard	2011-2018	450
Watsonville	2011-2019	428
Ripon	2011-2016	306
Salinas	2011-2016	306
Parlier	2017-2018	108
Delhi	2017-2018	109
Camarillo	2010-2011	65
Chualar	2017-2018	100
Tulelake	2017	25
San Joaquin	2018	36
Macdoel	2017	32
Dorris	2017	35
Lindsay	2018	35
Weed	2017	35
Cuyama	2018	35
TOTAL 1,3-D analyses		**3037**

Figure 1. Probability distribution of all 3,037 24-h 1,3-D concentrations measured in the AMN program since 2010.



The annual average 24-h 1,3-D concentration at each AMN location, for each year of monitoring, is shown in Table 4. Although 24-h 1,3-D concentrations have not exceeded the DAS-recommended acute screening level at any of the monitoring locations, the maximum value measured (see Figure 1, i.e., 111.3

ppb) slightly exceeds DPR's current acute screening level (110 ppb; see Table 4 below), and a small number of higher-level detections have resulted in an exceedance of the DPRs 13-week rolling average (RA) screening level (3 ppb) in Parlier and Shafter, and exceedance of the chronic screening level for 1,3-D (2 ppb) in Parlier in 2018. The DPR lifetime/cancer risk regulatory target of 0.56 ppb was exceeded in Parlier in 2017 and 2018, and Shafter in 2018. All other sites/years have annual average concentrations 10 to 20-fold below the chronic screening level (2 ppb).

Table 4 also shows that when all weekly 24-h concentrations are averaged across the years sampled at a given location, the multi-year concentrations are also below the chronic screening level, ranging from 0.07-1.71 ppb. The average 24-h concentration at the Parlier site is based on just two years (2017/2018) of weekly 24-h 1,3-D data that contain a small number of exceptionally high 1,3-D concentrations that drive the rolling average and annual average 1,3-D concentration and is discussed in more detail below.

Table 4 also shows that the average 24-h 1,3-D concentration across all AMN locations each year is less than the chronic screening level (2 ppb). The "Grand Mean" of 24-h concentrations from all sites/all years is 0.25 ppb, and suggests that on average, over the long-term California residents are not exposed to levels of 1,3-D exceeding the chronic screening level. It is appropriate to consider the "Grand Mean" concentration to infer potential long-term human exposure to CA residents, since it inherently considers population mobility.

Table 4. Average of all 24-h 1,3-D concentrations (ppb) collected at AMN sites from 2010-2018

Site	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**Average (All years)**
Camarillo	0.359	0.255								**0.285**
Chualar								0.096	0.044	**0.069**
Cuyama									0.100	**0.100**
Delhi							0.277[a]	0.134	0.198	**0.170**
Dorris								0.100		**0.100**
Lindsay									0.100	**0.100**
Macdoel								0.100		**0.100**
Oxnard		0.100	0.236	0.209	0.136	0.254	0.156	0.159	0.108	**0.181**
Parlier							0.433[a]	0.617	2.945	**1.708**
Ripon		0.542	0.100	0.234	0.071	0.074	0.089			**0.178**
Salinas		0.532	0.113	0.176	0.012	0.048	0.045			**0.150**
San Joaquin									0.105	**0.105**
Santa Maria	0.270[a]	0.209	0.228	0.226	0.157	0.153	0.159	0.119	0.108	**0.179**
Shafter		0.464	0.132	0.607	0.204	0.179	0.346	0.110	1.554	**0.452**
Tulelake								0.100		**0.100**
Watsonville		0.118	0.205	0.171	0.134	0.157	0.117	0.117	0.084	**0.144**
Weed								0.100		**0.100**
AVERAGE (All Sites)	**0.314**	**0.317**	**0.169**	**0.271**	**0.119**	**0.144**	**0.203**	**0.159**	**0.535**	**0.248**

[a]Partial Year

Table 5. DPRs acute, subchronic, and chronic screening levels and lifetime cancer risk regulatory target.

Exposure	Exposure Period	Screening Level (ppb)	Potential Health Effect
Acute	72 hour	110	Change in body weight
Subchronic	90 day	3	Tissue damage in nose and lung
Chronic	1 year	2	Tissue damage in nose and lung
Lifetime/Cancer Risk*	70 years	0.56	Cancer

*Regulatory target rather than a screening level

Parlier Site 2017-2018

Figure 2 is a time series plot of the weekly 24-h 1,3-D concentration at the Parlier AMN site for 2017 and 2018 and shows that a very small number of high concentrations control the 13-week RA concentrations (Figure 3), and the annual average concentration.

The annual average concentration at the Parlier site in 2017 (0.62 ppb) was dominated by a single detection of 1,3-D (16 ppb) from a sample collected on Sept 19-20, 2017. Examination of the 1,3-D application records and weather conditions at the Parlier site during September 2017 showed that 1,3-D was applied at 33 gallons per acre (gpa), the tree and vine rate, to a 9-acre field within a few hundred feet of the AMN receptor. The weather data showed significant calm periods for several days following the application and during the sampling time. Calm conditions are known to cause elevated concentrations of ambient air concentrations of pesticides.

The annual average concentration at the Parlier site in 2018 was dominated by a single detection of 1,3-D (111 ppb) occurring on October 9, 2018. Just prior to that sample event, 5 applications of 1,3-D had been made to fields ranging from 1.5 to 2 acres in size. All fields were within one mile of the AMN receptor, and two were within about 500 feet of the receptor. Averaging this single 24-h detection with the 51 other weekly 24-h samples resulted in an annual average concentration of 2.94 ppb, exceeding both the chronic screening level and lifetime/cancer risk regulatory target of 0.56 ppb.

Figure 2. Weekly time series of 24-h 1,3-D concentration at the Parlier AMN site from 2017-2018

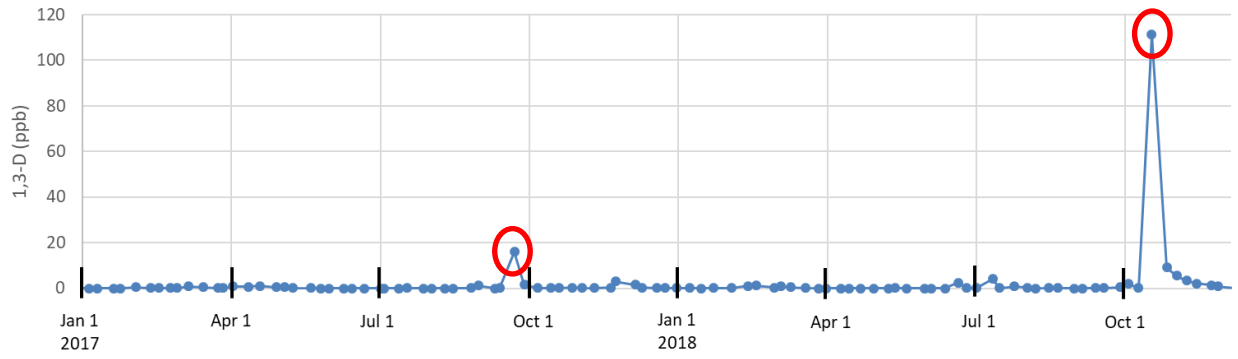
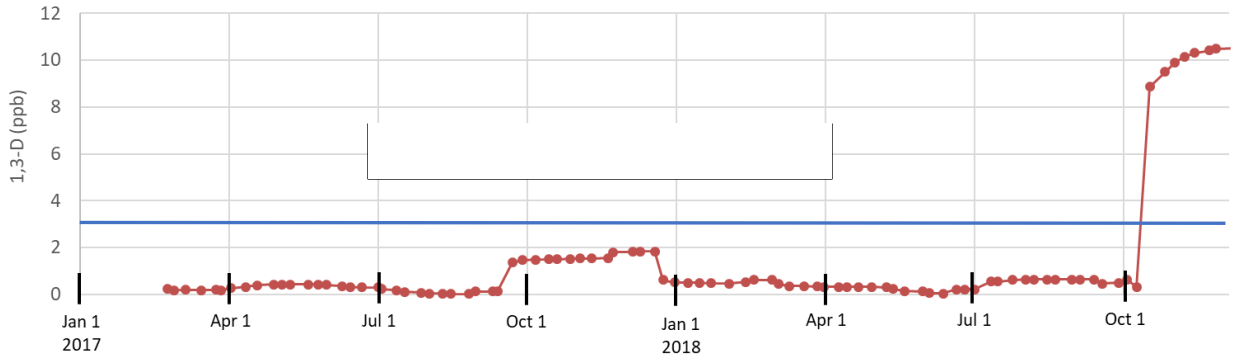


Figure 3. Weekly time series of 13-week RA 1,3-D concentration at the Parlier AMN site 2017-2018



Shafter Site 2018

In contrast to previous years of AMN results for Shafter, where maximum measured concentrations were well below screening levels, in 2018 a single high 24-h concentration (50.5 ppb) was measured at the Shafter receptor, though not exceeding the acute screening level, which resulted in an exceedance of the 13-week RA and annual average screening levels when averaged with weekly 24-h 1,3-D concentrations for the rest of 2018.

Figure 4 shows a time series plot of the 24-h 1,3-D concentrations at the Shafter AMN site plotted weekly for 2018. The single high concentration of 1,3-D (50.5 ppb) detected at the site on January 23-24, 2018 dominates the 13-week rolling average (RA) concentration which peaks at 5.6 ppb (Figure 5) and exceeds the subchronic screening level of 3 ppb.

Examination of the 1,3-D application records and weather conditions at the Shafter site during January 2018 showed that 1,3-D was applied at 30 gpa to a 25-acre field within a few hundred feet of the AMN receptor, two days prior to the sample event. The weather data showed significant stable air (calm periods) for several days following the application and during the sampling event. Calm conditions are known to cause elevated concentrations of pesticides in ambient air. The SOFEA model was parameterized with product use data (from PUR database) and weather data from the area and which simulated 24-h 1,3-D concentrations of 50 ppb between the 95th and 99th percentile, suggesting a concentration of that magnitude is a low probability occurrence and is driven by the close proximity of the field to the receptor, and wind direction.

It should be noted that 1,3-D applications to tree and vine crops occur only once every 20-30 years depending on the lifespan of the orchard. Furthermore, for a human to potentially be exposed at those sub-chronic and chronic levels of 1,3-D would require that they be co-located with that receptor for 13 weeks or 52 weeks, or in the case of the lifetime/cancer risk regulatory target, for 70 years. National and California specific population mobility surveys indicate that humans are very mobile and the assumption that they remain in a fixed location for 13 weeks, let alone a year, is extremely rare and adds significant conservatism to the risk assessment (Driver et al. 2016a, 2016b).

Figure 5 shows that the 13-week RA 1,3-D concentration begins to rise in late January 2018 (after the 50.5 ppb 24-h detection on Jan 23), exceeding the 13-week RA screening level (3ppb) in February 2018, and

reaching a maximum (5.6 ppb) approximately 13 weeks later (April 24, 2018). After the 13-week RA peaks on April 24, it drops precipitously, reflecting the low 24-h weekly concentrations occurring throughout the remainder of the year at the Shafter site.

Figure 4. Weekly time series of 24-h 1,3-D concentration at the Shafter AMN site in 2018

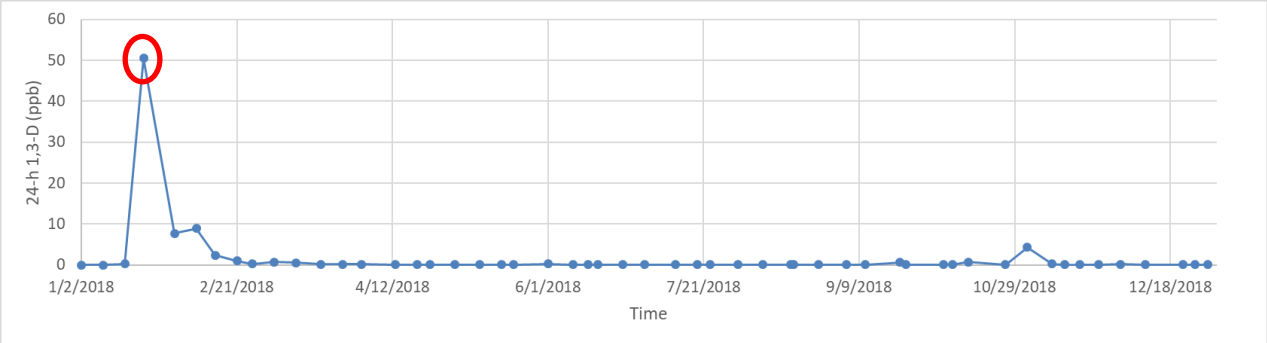
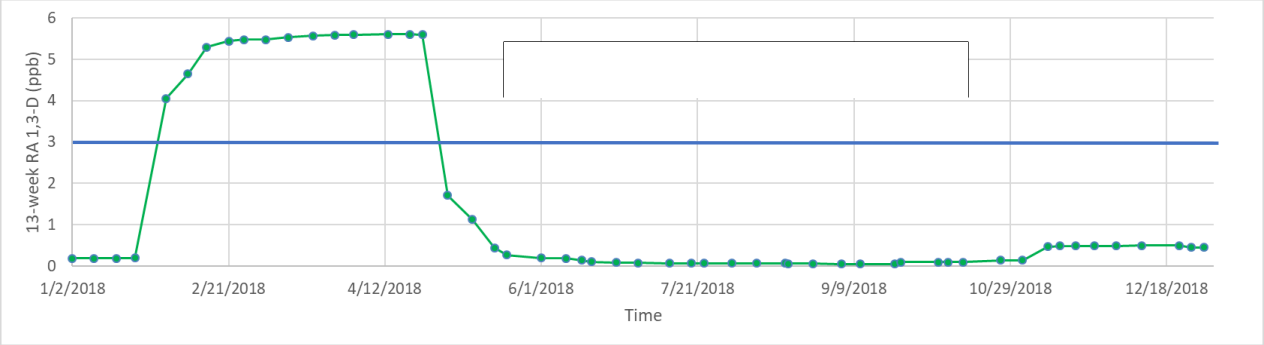


Figure 5. Weekly time series of 13-week RA 1,3-D concentration at the Shafter AMN site in 2018.



Figures 2-5 clearly show the impact that a single high 24-h concentration has on RA and annual average concentrations. Additional discussion of calculation of RA's, and potential ways to refine these values using all the available AMN data is given in a later section of this document.

Study 309 AMN Sites in Delhi and Parlier

DPR initiated monitoring at two additional sites (Delhi and Parlier) in late 2016 as part of Study 309. The goal of that air monitoring study is to evaluate the effectiveness of the current 1,3-D township cap and permit conditions promulgated as a result of DPR's 2016 RCD that became effective in January 2017. The new permit conditions allow annual application of 136,000 pounds of 1,3-D per township, ban December applications, and eliminate the 'banking' system.

To monitor the effect of these changes in 1,3-D product use, DPR selected two communities characterized by relatively high levels of historical 1,3-D use which were not already included in monitoring conducted by DPR or the California Air Resources Board (ARB). DPR staff collected weekly 24-h air samples to monitor 1,3-D in the communities of Delhi (Merced County) and Parlier (Fresno County) beginning in November 2016. Weekly 24-h 1,3-D samples have been collected since then, and a complete weekly time series for these communities is available from January 1, 2017 through December 31, 2018.

Since the measured concentration at a receptor is more greatly affected by the proximity and source strength of a 1,3-D application, and less by the total number of applications, or total mass applied in a 6x6 mile township, it is erroneous to assume that the observation of a single high 24-h 1,3-D concentration means that a particular mitigation is not effective. It could simply mean that a single application of 1,3-D was made very close to the receptor at a time when meteorological conditions favored movement to that receptor location. DPR has shown in multiple analyses with several active ingredients, that correlation between the AMN concentration at a receptor and the mass of chemical applied in the township(s) surrounding the receptor is very weak. This is because parameters such as weather and proximity to the AMN receptor have a major effect on the measured concentration causing it to vary significantly from year to year. Therefore, multiple years of monitoring are needed to visualize and quantify the effect of mitigations that reduce the mass of 1,3-D applied annually in a township.

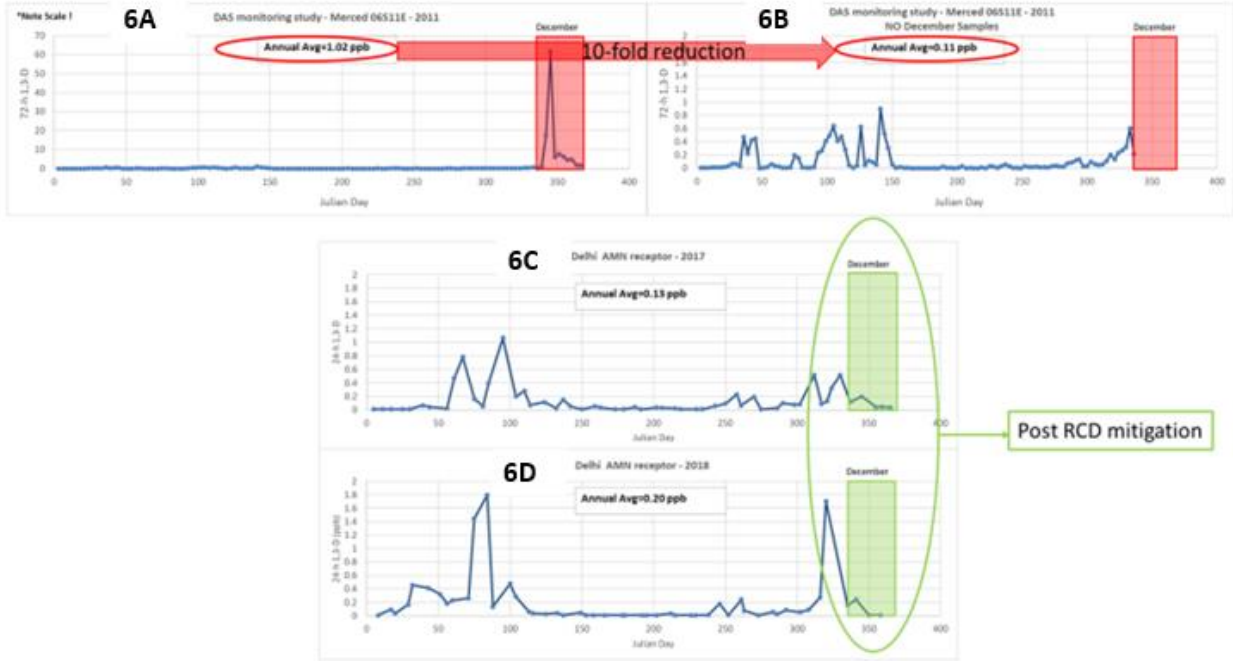
The weekly 24-h AMN data is perhaps more useful for assessing mitigations that reduce 1,3-D use during certain times of year (e.g. the December ban). The 1,3-D concentration data collected from the new site in Delhi for example show that the 2016 RCD mitigation banning December applications has been successful in reducing historically high 1,3-D concentrations resulting from calm conditions that are prevalent at that time of year, as is discussed in detail below.

Effectiveness of December Ban using Delhi AMN data

The AMN receptor in Delhi is in the same township (Merced 06S11E) as the DAS receptor that was used to collect continuous 72-h 1,3-D concentrations from October 2010-January 2012. The AMN and DAS receptors were about 2 miles apart, located in section 8 and section 16 of Merced 06S11E, respectively. The close spatial proximity of the receptors allows comparison of 1,3-D concentrations observed in December both before and after the ban on December applications in 2016.

Figure 6 (see subfigures A and B) show the 72-h 1,3-D concentrations at the DAS monitor near the Delhi site in 2011, prior to the ban on December applications, with a peak concentration of 61 ppb occurring in December of that year (highlighted in red). The annual average concentration at that receptor was 1.02 ppb in 2011. Removing the December 2011 data from the annual average calculation reduces the annual average concentration to 0.11 ppb (~ 10-fold reduction, Fig. 5B) and is similar to the annual average concentrations of 0.13 and 0.2 ppb observed at the AMN Delhi receptor in 2017 (Fig. 5C) and 2018 (Fig. 5D) respectively, measured after the ban on December applications.

Figure 6. Impact of 2016 ban on December applications in Merced township 06S11E (Delhi).



This comparison of monitoring data collected in Merced, one of the highest 1,3-D use areas in California, shows that historically high 1,3-D concentrations occurring in December have been significantly mitigated by the ban on applications in December.

Impact of Township Cap Set at 136,000 Pounds 1,3-D per Year

The impact of setting the township allocation at 136,000 pounds 1,3-D per year could take more time to show up in the AMN monitoring results since the 1,3-D levels in air are primarily dependent on whether an application occurs close to and upwind of the receptor, or under stable air conditions. Changes in township allocation limits will likely be observed in the AMN dataset after the new township cap limit has been in place for several more years.

Possibly the best way to assess the effect of the change in California-wide 1,3-D township allocation (cap) is to look at the trend in annual average concentration obtained at all AMN sites over time. DAS agrees with DPRs acknowledgement that a single high 24-h concentration can dominate the 13-week RA and the annual average concentration, which can result in an exceedance of a trigger. This suggests that additional years of monitoring are required before the full impact of mitigations are reflected in the ambient 1,3-D concentrations.

Calculation of Rolling Average (RA) Concentrations

As shown earlier, a single 24-hour 1,3-D concentration can dominate the calculation of the 13-week RA concentration each year, and raises the question of the representativeness of that RA. This is further exacerbated by the uncertainty introduced by the 85% missing data in the dataset and suggests that the

longest time series of weekly 24-h data available should be used to calculate moving averages and annual averages for the purpose of characterizing potential exposure and risk.

Figure 7 shows the weekly 24-hour 1,3-D concentration for the Shafter AMN receptor from the start of monitoring in 2011 through the end of 2018, the last full year of data, resulting in an 8-year time series of weekly 24-h concentrations (416 values). The highest measured 24-h concentration (~50 ppb) at the Shafter AMN site occurred on Jan 21, 2018 and is highlighted in red in Figure 6.

DAS recommends using all the available AMN data at each site to calculate all the potential 13-week RA concentrations for the eight-year period that the AMN receptor at Shafter has been monitored (Figure 6A). This requires the same assumption discussed above, that each 'weekly' average concentration is characterized by the single 24-h sample collected during that week. The number of 13-week rolling average concentrations (n) that can be calculated from eight continuous years of weekly monitoring data is 403 (n=8*52-13) and are shown in Figure 6B. These 403 estimates form a probability distribution function (PDF) of 13-week RA concentrations at the Shafter AMN site (Figure 7) and allow the risk manager to select an appropriate percentile concentration to use in the risk assessment.

Figure 8 shows that the 13-week RA concentration spanning the 50 ppb 24-h detection that occurred on January 21, 2018 is the highest RA concentration (5.6 ppb) ever measured at Shafter over eight years. This is not surprising since 50 ppb is the highest 24-h concentration of 1,3-D ever measured at the Shafter AMN location between 2011 and 2018, and clearly dominates the 13-week RA calculation in early 2018. For comparison, the 90th and 95th percentile 13-week RA concentrations are 1 ppb and 2 ppb, respectively when the entire 8-year time series of weekly 1,3-D concentrations is considered.

Figure 7. Weekly time series of 24-h 1,3-D concentration (A) and 13-week RA (B) from 2011-2018 at the Shafter AMN receptor

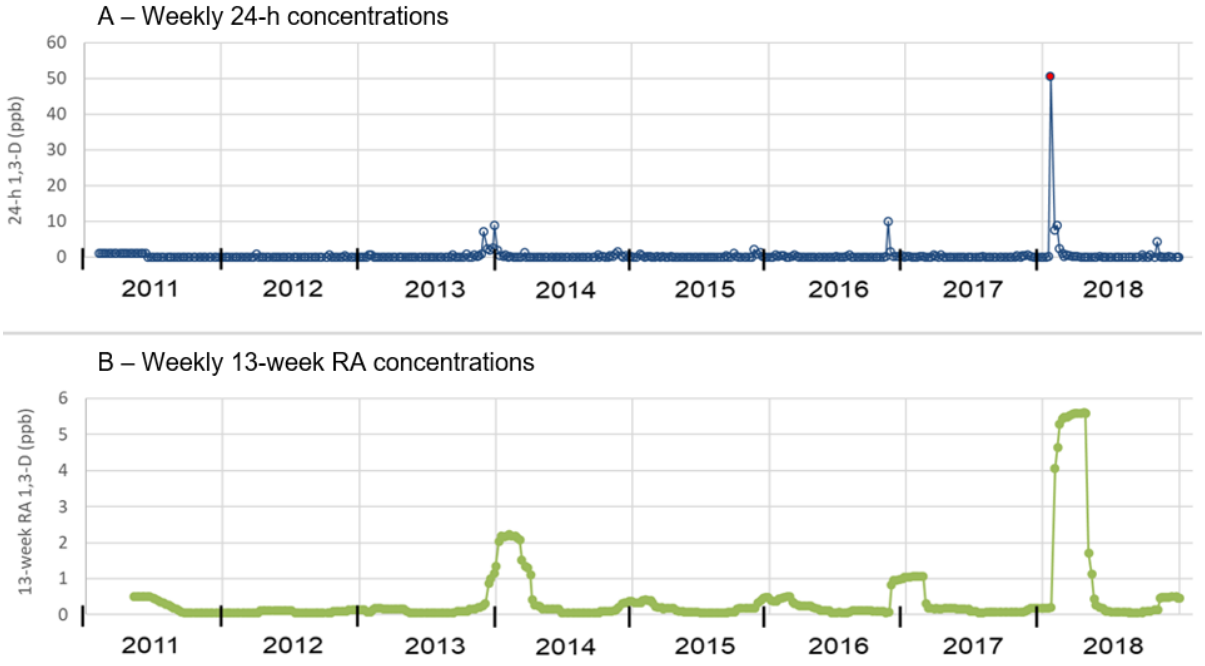
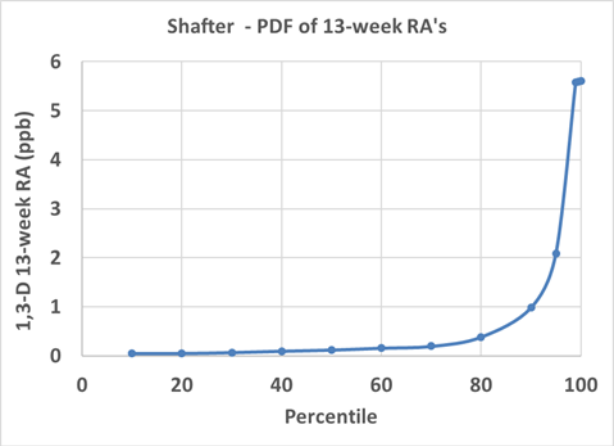


Figure 8. Shafter PDF of 13-week RA from 8-year dataset.



Here again, the missing data come into play because a true 13-week rolling average would require averaging 91 consecutive days of concentration data, but since there is only a single 24-h sample collected each week, that concentration is necessarily assumed to represent exposure for that entire week (i.e.. the same concentration applies for all seven days of the week). Depending on the local weather and product use near the receptor, this could result in an over- or under- estimation of the weekly and rolling average concentrations and underscores the value of using an air dispersion model (e.g. SOFEA) to simulate 1,3-D concentrations in ambient air based on known mass of 1,3-D applied, location and timing of the applications, and local weather (wind speed, direction, etc.).

General Discussion of AMN data utility

The collection and analysis of air samples is very resource intensive and taking continuous measurements for an extended time period is typically not feasible. For this reason, only a single 24-h sample is collected from each AMN site each week. The weekly 24-hour 1,3-D concentrations are very useful for characterizing potential acute exposure to 1,3-D, however the utility of the AMN data for quantifying short-term, sub-chronic, and chronic (annual or lifetime) exposure and risk is not as straightforward for two reasons. First, only a single 24-h sample is collected each week and therefore 6 out of 7 days (>85%) have no data. This results in the need to assume a 1,3-D concentration on the non-sampled days. DPR assumes that the measured concentration persists for the entire week which they acknowledge could result in either an over- or under-prediction of the weekly average concentration. Secondly, the AMN dataset is typically highly censored due to many samples where the concentration is less than the analytical Limit of Detection (LOD) or Minimum Detection Limit (MDL). DPR assumes that samples that show no detection (ND) are equal to one-half of the MDL or LOD, which could also result in an over- or under-prediction of the weekly concentration. Both issues add uncertainty when monitoring data is used to assess potential sub-chronic, chronic and lifetime exposure and risk, and point to the value of air dispersion modeling to fill in gaps in the monitoring data.

Use of Air Dispersion Modeling to Supplement AMN Data

A cost-effective and scientifically sound approach to supplementing monitoring data is to use a validated air dispersion model such as the SOil Fumigant Exposure Assessment (SOFEA) model. SOFEA can be parameterized with pesticide use data (volume applied; date applied etc.) obtained from DPR's Pesticide Use Reporting (PUR) database and when combined with local meteorological data, has been shown to accurately simulate the timing and magnitude of 1,3-D concentrations in ambient air (van Wesenbeeck et al., 2016) as well as the overall PDF of 1,3-D concentrations in air. SOFEA also simulates air concentrations on an hourly time step and can therefore be used to characterize acute, subchronic and chronic exposures ranging from 1 hour to several years, or a human lifetime.

The use of a modeling tool such as SOFEA is a logical complement to monitoring datasets and can be used to fill in data gaps with reasonable certainty, especially when local product use information and weather data are available. Ultimately the use of a model significantly reduces the need for arbitrarily conservative assumptions to deal with missing and censored data, and decreases the uncertainty associated with many monitoring datasets.

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From: Baker, Lynn@ARB <lynn.baker@arb.ca.gov>
Sent: Tuesday, August 13, 2019 10:45 AM
To: Pham, Minh@CDPR <Minh.Pham@cdpr.ca.gov>
Cc: Guerrero, Joe@ARB <joe.guerrero@arb.ca.gov>
Subject: Comments on 2018 air monitoring network report

Minh,

Following the July 2019 presentation at DPR's PREC meeting regarding your air monitoring network report for 2018, I reviewed the draft report and have the following comments.

1. Significance of undetected pesticides – The executive summary and the body of the report note that of the 36 pesticides monitored, eight were not detected. This implies that those pesticides do not become airborne. We suggest noting that one reason for not detecting some of the pesticides is that they were not used in the vicinity of the monitoring sites.
2. Page numbers – Although the table of contents lists page numbers, there are no page numbers in the body of the report.
3. References to CARB – On page 5 and throughout the report, the California Air Resources Board is referenced as ARB. We officially now go by CARB, not ARB.
4. Reason for community selection – On page 5, the section titled "Number of Communities Monitored" states that four communities were selected based on nearby use of four soil fumigants. Fumigants listed include methyl isothiocyanate (MITC) and MITC-generators. MITC is not an applied fumigant; it breaks down from metam sodium and metam potassium. We suggest deleting MITC and just describing this as MITC-generators.
5. Pesticides monitored – On page 6, the section titled "Pesticides Monitored" indicates that "DPR monitored 31 pesticides and 5 breakdown products." This should be DPR and CARB. In addition, it may be useful to include a description of which pesticides were analyzed by the CARB lab and which were analyzed by the CDFA lab.
6. Discussion – On page 15, the last sentence states that "DPR is in the process of developing regulations to reduce exposures to 1,3-D in ambient air." This implies that there is no current mitigation for 1,3-D, which is incorrect. We suggest rewording this sentence to make it clear that the DPR effort will modify existing mitigation measures to further reduce exposures to 1,3-D.

Please contact me if you have any questions about these comments.

Lynn

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