October 6, 2016

TO: Interested Parties

SUBJECT: COMMENTS ON THE DRAFT RISK MANAGEMENT DIRECTIVE FOR 1,3-DICHLOROPROPENE (1,3-D) AND RESPONSES

Food and Agricultural Code section 14023(f) requires that "For each pesticide identified by the director as a toxic air contaminant based on its listing as a hazardous air pollutant pursuant to Section 7412 of Title 42 of the United States Code for which a risk assessment has been completed, the director, in consultation with the Office of Environmental Health Hazard Assessment [OEHHA], the State Air Resources Board [ARB], and the air pollution control or air quality management districts in the affected counties, shall determine the need for and appropriate degree of control measures. Any person may submit written information for consideration by the director in making determinations on control measures. The director's written determination and any formal written comments made by the consulting agencies shall be made available to the public." The following are the comments from these agencies on the Department of Pesticide Regulation's (DPR's) 1,3-D risk management directive, and DPR's responses.

Monterey Bay Air Resources District Comments (September 9, 2016, on behalf of local air pollution control districts):

With respect to the air monitoring and modeling data, I don't understand how the one year measured concentrations may differ that much from a 70-year modeling data set. Wouldn't it depend on how much is measured from year to year? Empirical measurements could be above or below modeled concentrations. There were no attachments included with the document (Tao, Barry and Kwok) to help evaluate the reasoning in this section.

Please better explain the statement, "Computer modeling may not accurately estimate concentrations under calm conditions, so December air concentrations are more uncertain compared to other months." Most air dispersion models perform better using stable air conditions, provided that there is some minimal surface wind. Also, what evidence is used to support December as being the calmest month? Do you have application data by month?

DPR Response:
DPR did not state that December is the calmest month, but stated that the meteorological condition in December was calm. Additionally, the concentrations differ from year to year. DPR's evaluation of the modeling and the actual air monitoring data revealed those differences

as well. Critical evaluation of the modeling and actual air monitoring data also demonstrated that there are discrepancies between the modeled data and the actual monitoring data which were not fully understood and have not yet been resolved at this time. The discrepancies appeared to be most significant during the month of December apparently due in part to meteorological conditions. DPR does have application data by month and the data are being used to continue to analyze the discrepancies between modeling and monitoring. DPR used the monitored data because it may be more reliable than modeled data and because it is more health-conservative.

ARB Comments (September 14, 2016):

Comment 1:
Regulatory target concentration – As part of ARB's work plan to assess priorities for our Air Toxics Program, we will be reviewing all of our existing airborne toxic control measures to determine the need for future revisions or new control actions. One of the criteria used to determine whether future work is needed will be to use OEHHA's updated health risk methodology to ensure that people of all ages, especially children, are properly evaluated. In light of OEHHA's updated risk assessment procedures and the benefits to a uniform approach to risk assessment within Cal/EPA, we encourage DPR to ensure that the basis for your regulatory target concentration is consistent with OEHHA's new approach. (OEHHA released their final version of the document, Air Toxics Hot Spots Program Guidance Manual for the Preparation of Risk Assessments in February 2015. The Guidance Manual can be found at: <http://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0>.

DPR Response:
This comment addresses DPR's risk assessment of 1,3 D instead of the Risk Management Directive. The risk assessment is final and currently posted online at <http://www.cdpr.ca.gov/docs/risk/rcd/dichloro_123115.pdf>. Nonetheless, DPR's risk assessment process was reviewed by a committee of the National Academy of Sciences – National Research Council in 2015. The committee stated that "DPR's risk characterization documents are comprehensive and follow established risk assessment practices." However, the committee also recommended including the most up-to-date risk assessment methodologies in updating its risk assessment guidelines. DPR is in the process of revising its risk assessment process based on the recommendations which includes evaluating the utility of OEHHA's Air Toxic Hot Spots Program Guidance Manual and U.S. Environmental Protection Agency's (U.S. EPA's) most current Risk Assessment Guidelines for pesticide risk assessments <https://www.nap.edu/catalog/21664/review-of-californias-risk-assessment-process-for-pesticides>.

Comment 2:
Prohibition of 1,3-D applications during winter months – The draft risk management directive states that applications during December will be prohibited to address air concentration uncertainties and potentially high seasonal exposures. One of the references noted in the directive is a document by Tao. The Tao document contains a table of application scaling factors to account for different conditions that might lead to higher air concentrations in certain times of the year. That table has higher application factors for the months of December and January, compared with the rest of the year. This is consistent with the increased likelihood of nighttime surface-based inversions during the winter months, which can trap emissions and lead to higher air concentrations than would occur under meteorological conditions with more dispersion. Rather than prohibiting applications during key winter months (i.e., December and January, not just December), we suggest prohibiting applications during any winter months if the regional weather forecast calls for stagnant conditions for the days including and following an application. We leave it to DPR to determine this critical period of days following an application, based on prior monitoring studies that indicate the period of time that 1,3-D slowly escapes from the soil following an application.

DPR Response:
Setting criteria for meteorological conditions that would be considered for before an application would be allowed would be impractical even if DPR could develop scientifically-supported criteria because the height above ground level of an inversion layer can be very difficult to predict at a local level. In addition to the technical difficulties, any meteorological guidance would be difficult to verify and enforce. Nonetheless, since calm winds and low-inversions have been contributing factors in pesticide illnesses, DPR will continue to consider developing guidance for adverse weather conditions. In the meantime, the higher application factors used to calculate the adjusted total pounds (ATP) for January applications takes into account the potential effects of the meteorological conditions. Moreover, the monitoring data indicates that additional restrictions in January are not needed. DPR will continue to conduct monitoring and can revise the requirements if needed.

OEHHA comments (September 20, 2016)

DPR General response to OEHHA comments:
Many of OEHHA's comments would best be addressed using computer modeling to estimate air concentrations. Unfortunately, 1,3-D air concentrations estimated using computer modeling are inconsistent and lower compared to measured air concentrations. Instead, DPR relied on air monitoring and use data to determine a health-conservative township cap.

OEHHA compared annual concentrations to the regulatory target concentration of 0.56 ppb, which is a 70-year average concentration. DPR's use of annual data for a 70-year regulatory target concentration is health-conservative. Additionally, DPR made the health-conservative

assumptions that samples with no detectable 1,3-D had concentrations of one-half the minimum detection level even when there was no use, and calculated 1-year average concentrations instead of 1-year median values.

DPR used all currently available data to determine the township cap. These included modeling and air monitoring data. Initial analysis to determine a direct correlation between use and air concentrations indicated an uncertain relationship most likely due to the many factors other than amount of use that can influence air concentrations, such as locations of applications relative to the monitoring location, weather conditions, application methods, and variations in sizes of butter zones. Therefore, to account for the uncertainty due to these other factors, DPR relied on a near worst-case (95th percentile) assumption regarding the relationship between use and air concentration. That is, DPR assumed that a low amount of 1,3-D causes a high concentration. This assumption is a reasonable surrogate for the inability to monitor or model at all possible locations under all possible conditions, and presents a health-conservative approach.

DPR Responses to specific comments follow.

Comment 1:
The cap was calculated using the annual average air concentration of 1,3-D at one point in a township and ATP of 1,3-D used annually in that 36 square-mile township. The implicit assumption is that 1,3-D use is roughly uniform throughout the township. However, the application of 1,3-D is not uniform; some areas receive more treatment than others and many areas receive none as they are not farmland. Residents who live close to a field treated with higher than the average amount may be exposed to higher air concentrations of 1,3-D than the measured level at the monitor.

DPR response:
The analysis reflects 1,3-D concentration and its use in 36 miles around the sampling site. The air monitoring data used for the analysis is based on measured concentrations that reflect the actual use patterns near the monitoring stations, so there is no assumption that use is uniform throughout a township. Air concentrations are also affected by different factors such as application methods, meteorological conditions and other factors in addition to amount of pesticides used. DPR chose to use the air monitoring data instead of the modeling data because it is the best available science to manage the possible cancer risk of 1,3 D to residents and bystanders. Determining the township cap based on the 95th percentile should account for residents who live close to a treated field. It also provides a more health-conservative approach in comparison with the township cap presented by the modeling approach. However, DPR will continue to evaluate the air monitoring data in comparison with the modeling methods to ensure the use of the best available science.

Comment 2:
The calculation is also based on the implicit assumption that annual average air concentration of 1,3-D is roughly uniform throughout a township. However, we know that air contaminants exhibit high spatial variability depending on factors such as proximity to the source, wind direction and velocity, other weather phenomena, and local topography. Residents who live close and downwind from a field treated may be exposed to higher concentrations of 1,3-D than the measured level at the monitor.

DPR response:
The analysis does not assume that air concentrations are uniform throughout a township. DPR agrees that different locations will have different air concentrations and they will vary with several factors. In this analysis, single data points were not considered to represent all the concentrations everywhere within a township. Township is a spatial unit that DPR used to manage the use, but the intent of the monitoring is not to represent the township where the sampling sites are located. The air monitoring provides a distribution of concentrations. By selecting the 95th percentile of the distribution, DPR accounts for residents who live close and downwind from a field. DPR will continue air monitoring and can revise the township cap if higher air concentrations are detected.

To estimate spatial variation, DPR used computer modeling to estimate 70-year average air concentrations at 1,296 locations in a township using historical weather data and hypothetical use patterns. The 95th percentile of the 1,296 modeled locations would be a township cap of approximately 200,000 adjusted pounds and allow December applications. Instead of computer modeling, DPR relied on 1-year air monitoring and actual use data to determine a more health-conservative township cap of 136,000 adjusted pounds and prohibit December applications.

Comment 3:
Furthermore, the use of the proposed township cap to regulate 1,3-D use is also based on the idea that the amount of 1,3-D applied in a 36 square-mile area correlates well with the annual average air concentration of 1,3-D within the township. However, based on past monitoring data and application information presented in the DPR report, OEHHA does not see a correlation between these two parameters; there is not a significant relationship between pounds applied and air concentration. Also of note, a township in Merced received 167,175 ATP of 1,3-D in 2011 (23 percent higher than the proposed cap of 136,000 ATP) and measured an annual average air concentration of 1.92 ppb (more than three-fold higher than the target concentration of 0.56 ppb). Even if 1,3-D use had been at the proposed cap of 136,000 ATP, it appears likely that the annual average air concentration in that township would have well exceeded the target concentration.

DPR response:
The analysis does not assume that there is a correlation between air concentrations and use within a 6 x 6 mile area. DPR calculated the ratio of air concentrations to 6 x 6 mile use for

31 site-year combinations, sorted the ratios from highest to lowest, and selected the 95th percentile. This sorting procedure accounts for the range of air concentrations and use amounts. The 1.92 ppb detected in the Merced township was due to high concentrations detected in December. By prohibiting December applications, the concentration and use for this site would be 0.27 ppb and 70,298 adjusted pounds. Moreover, the 0.56 ppb regulatory target concentration is a 70-year, not a 1-year average. Using 1-year data to estimate 70-year averages is health-conservative.

Comment 4:
OEHHA does not agree with DPR's selection of a "portal-of-entry effect" as the preferred Mode of Action for 1,3-D. As explained in the attachment, OEHHA believes the available information supports use of a Mode of Action based on systemic effects, which under DPR's calculations would produce a target air concentration of 0.16 ppb, rather than the proposed concentration of 0.56 ppb. Additional consideration should be given to the potential for the increased sensitivity of children to carcinogenic effects.

DPR Response:
The oncogenic risk calculations are provided in the risk characterization document (RCD) for both portal of entry and systemic modes of action. However, based on the available evidence, DPR's position is that portal of entry is the more plausible mode of action for the 1,3-D-induced bronchioloalveolar adenomas in mice. Extensive discussions of new data and the weight of evidence for each mode of action can be found in the revised RCD (pages 117-118) and in the DPR response to OEHHA comments (p. 3-5).
<http://www.cdpr.ca.gov/docs/risk/rcd/dichloro_123115.pdf>
<http://www.cdpr.ca.gov/docs/hha/memos/13-d-dpr_hhab_resp_to_oehha_080516_final.pdf>
Regarding cancer risk, DPR used the linearized multistage algorithm to estimate potency. This is considered to be a health conservative approach to cancer risk estimation because it extrapolates risk to dose levels lower than the biologically observed effect range. DPR's view is that the weight of evidence does not currently support the use of age sensitivity factors (ASFs) to further adjust the cancer risk for 1,3-D. The reasons are presented in the DPR response to OEHHA comments (p. 9-11). These include (1) lack of data showing increased cancer susceptibility for portal of entry-based tumor formation by the inhalation route, and (2) lung-specific data showing no apparent increased susceptibility by the oral route. DPR will re-evaluate the ASF issue if new data becomes available. In the meantime, DPR used an ASF to derive a target concentration of 0.27 ppb that, if exceeded, will trigger additional evaluation and consideration of further mitigation.

Comment 5:
Many 1,3-D formulations also contain chloropicrin in significant amounts. Just like 1,3-D, chloropicrin also caused lung cancer in test animals but with a much higher potency. The Risk

Management Decision should address the likelihood that many bystanders exposed to 1,3-D will simultaneously be exposed to chloropicrin.

DPR Response:
Conducting pesticide risk assessments on cumulative effects of carcinogens and non-carcinogens is outside the scope of this process, and, moreover, it is neither standard practice nor a statutory requirement. However, DPR is initiating a process to update its risk assessment guidance and will consider the utility of OEHHA's Air Toxic Hot Spots Program Guidance Manual and U.S. EPA's most current Risk Assessment Guidelines for pesticide risk assessments in addressing risks due to cumulative exposures to multiple carcinogens.

DPR and U.S. EPA do not classify chloropicrin as a carcinogen, and a review of data presented by the National Toxicology Program also concludes that the results of the animal studies are inconclusive. After evaluating all available information on the carcinogenic potential of chloropicrin and the differing scientific opinions on this subject, the issue appears to be equivocal at this time. However, DPR has required the registrants to conduct studies to address this issue. For further information, see DPR's risk management directive for chloropicrin at <http://www.cdpr.ca.gov/docs/emon/pubs/chloropicrin/directive.pdf>

Sincerely,

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