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MEMORANDUM

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DATE: August 30, 2013

SUBJECT: COMMENTS ON THE DEPARTMENT OF PESTICIDE REGULATION'S CHLOROPICRIN MITIGATION PROPOSAL

The Office of Environmental Health Hazard Assessment (OEHHA) has reviewed the document, *Chloropicrin Mitigation Proposal, Control of Resident and Bystander Acute Exposure from Soil Fumigation Applications* ("Mitigation Proposal"), prepared by the Department of Pesticide Regulation (DPR) and dated May 15, 2013. As noted in your cover letter, the proposed mitigation measures are intended to reduce the health risk from acute exposure to chloropicrin following soil fumigation. Populations of potential concern are people who live and/or work (i.e., residential and occupational bystanders) near field fumigations. To address these risks, DPR is proposing several mitigation measures. Our comments regarding these measures are provided below.

Overall Evaluation of the Proposed Control Measures

OEHHA recognizes that most of the proposed mitigation measures are significantly more stringent than those currently required by the U.S. Environmental Protection Agency (U.S. EPA), and are anticipated to afford stronger health protection to potentially exposed populations. For example, current product labels allow applications on fields up to 160 acres, while DPR is proposing a 40 acre limit on field size. This proposal and other control measures that DPR has drafted were compared with current label requirements on page 2 of the "Summary of Proposed Control Measures for

Chloropicrin," attached to the Mitigation Proposal. To provide a more concise overview of these proposals, OEHHA suggests that DPR provide a table that compares current label restrictions with DPR's newly proposed restrictions. In general, OEHHA supports adoption of mitigation proposals that are more stringent than those currently required by U.S. EPA.

This memo provides several specific comments for your consideration, including the following:

- The two tables of buffer zone distances for untarped and standard tarped applications should not include any values less than the proposed 60-foot minimum.
- Additional justification for eliminating certain studies from the evaluation of flux rates should be provided.
- The uncertainties inherent in the buffer zone calculations should be described more clearly and completely.
- A statement that the target exposure concentration will not necessarily prevent the occurrence of eye and nose irritation in exposed populations should be included.
- A cost-benefit analysis of using Totally Impermeable Film (TIF) tarps should be added to the Mitigation Proposal. Since TIF tarps significantly reduce emissions and allow growers to use lower application rates, the potential public health benefits of requiring use of these tarps should also be discussed.
- Clearer justification for specifying a nine-day tarp cutting interval for TIF tarps should be provided.
- OEHHA does not concur with DPR's re-analysis of the weight of evidence for the carcinogenicity of chloropicrin presented in Appendix 3. OEHHA has concluded that chloropicrin is a genotoxic carcinogen. Support for this conclusion was provided in two recent DPR health risk assessments, as well as an independent peer review conducted by California's Scientific Review Panel (SRP) in 2010.

Calculation of Buffer Zone Distances

Much of the information provided in the Mitigation Proposal addresses the development of minimum buffer zone distances for different field sizes (5,10, 20, 30 and 40 acres) and fumigant application rates (100, 150, 300, 250, 300, and 250 pounds/acre). Minimum buffer zones were calculated for applications using any tarps that are not Totally Impermeable Film tarps ("non-TIF" tarps; Table 1) and untarped applications (Table 2). While the cover letter that was attached to the Mitigation Proposal indicates that DPR's proposed minimum buffer zone distances for non-TIF and untarped applications is 60 feet, both of these tables show values well below 60 feet, even as low as zero feet. OEHHA recommends that DPR revise these tables, replacing all values that are less than 60 feet with the default minimum and providing a footnote in each cell where the calculated value was replaced with the default minimum.

The technical basis for development of chloropicrin buffer zones is provided in Appendix 4 of the Mitigation Proposal. A key component of this analysis is the determination of flux estimates using data from 47 different chloropicrin application field studies that have been conducted over the past 17 years. For a variety of reasons, the number of studies from which usable data were derived was reduced from the original 47 applications (Appendix 1 of Appendix 4) to just 28 (Appendix 2 of Appendix 4). In some instances, justification for eliminating these studies was not provided. Furthermore, several of the studies that were eliminated showed very high flux rates (e.g., four of the six applications included in the 1996 investigation conducted by Beard et al.), while others showed very low flux estimates (e.g., the studies conducted in Bainbridge, GA and Hart, MI). One effect of eliminating extreme values from the pool of flux estimates is to narrow the width of the distribution of these values. Consequently, the upper percentile estimates of flux, as well as the upper percentile estimates of exposure (discussed below) are potentially lower than they would be if all the flux estimates were included in the analysis. Since the process of paring the data from the original 47 application studies to just 28 has the potential to significantly alter the conclusions of this evaluation, OEHHA recommends that DPR provide a more detailed analysis of the studies that were censored and clear justification for eliminating them. If justification for eliminating certain studies cannot be provided, they should be included in the analysis.

Another variable in the buffer zone distance estimates is the modeled percentile of protection (80^{th}, 85^{th}, 90^{th} and 95^{th} percentile values). However, a clear rationale for providing alternative levels of protection was not stated. The Mitigation Proposal notes:

> *"DPR is reviewing various factors that assist in determining the need for appropriate buffer zones to protect bystanders and residents. The factors include the distances of proposed buffer zones, current use practices and existing buffer zones, the number of applications where no reported incidents occurred, and the number of reported incidents."*

Nevertheless, these alternative "levels of protection" are based on complex analysis of the 28 field studies, flux estimation calculations and air dispersion modeling, and there does not appear to be a clear technical basis for choosing one percentile value over the others. Furthermore, adopting an 80^{th} or even a 90^{th} percentile level of protection would be difficult to reconcile with the stated goal of protecting the health of residential and occupational bystanders. In effect, DPR would accept a specific frequency of "nonattainment" episodes where the buffer zone would not be sufficient to ensure that the downwind concentration would remain below the target exposure level. Selecting a lower percentile of protection also has the potential to increase the frequency of episodic peak exposures that exceed the target exposure standard by a substantial margin.

Additional uncertainties are associated with the adequacy of the 73 parts per billion (ppb) target exposure level that DPR identified to protect public health (discussed below). Another public health concern is fact that chloropicrin photodegrades to phosgene, which means that bystander populations downwind of application sites will potentially be exposed to a mixture of the two compounds, both of which are potent sensory irritants. DPR's 2010 Risk Management Directive for chloropicrin (Appendix 2) did not take combined exposure to chloropicrin and phosgene into consideration when the target exposure level for chloropicrin was established. Based on these considerations, OEHHA recommends that DPR adopt buffer zones that are consistent with an overarching goal of protecting the health of all residential and occupational bystanders, including sensitive sub-populations. This may require that buffer zones extend beyond the ranges specified in Tables 1 and 2, in order to attain exposure concentrations that are lower than the target exposure level of 73 ppb.

Target Exposure Level

The buffer zone calculations were based in part on a target exposure level of 73 parts per billion (ppb) as an eight-hour time-weighted average (TWA) exposure, as stipulated in DPR's Risk Management Directive (RMD) for chloropicrin (DPR, 2010; also attached to the Mitigation Proposal as Appendix 2). OEHHA provided comments to DPR on the scientific justification for this value shortly before the RMD was issued in December 2010, noting in particular that it probably is not adequate to protect children and individuals with pre-existing respiratory conditions such as asthma. Additionally, since the target exposure concentration is an 8-hour TWA value, excursions well above 73 ppb could occur for several hours and would still be permissible. For this reason, DPR's statement, "At this level [73 ppb], U.S. EPA does not expect eye or nose irritation, or upper respiratory changes" (page 3 of the Mitigation Proposal) does not accurately reflect the actual exposure scenario. The level of 73ppb is an 8-hour TWA concentration, not a ceiling concentration that cannot be exceeded. Therefore, excursions well into a concentration range sufficient to cause eye and nose irritation could occur, and this should be clearly stated in the document.

Other Application Variables Reduce Bystander Exposure

DPR's analysis of alternative mitigation measures focuses on preventing short-term exposure to chloropicrin by establishing buffer zones around the fumigated fields. Other application variables that could influence the likelihood of bystander exposure following field fumigation include the following:

- The application rate, in units of pounds (lbs) of active ingredient (AI) per acre of land (lbs AI/acre)
- The application method (shank injection and chemigation, for example)
- Soil type, soil organic content and soil moisture

- Method of application (bedded *vs.* broadcast *vs.* planting hole application)
- Size of the fumigated field (acres)
- Emission reduction strategies (irrigation to form water seals, thiosulfate treatment of soil)
- Tarped vs. untarped application
- Type of tarp, including virtually impermeable film (VIF) and totally impermeable film (TIF)
- Meteorological conditions

Therefore, in addition to increasing the size of buffer zones, other options for reducing the likelihood and magnitude of short-term exposure are available. These include increasing the duration that fields are tarped beyond the label-required five-day minimum, which would reduce emissions to ambient air and thereby reduce the size of the buffer zone. This strategy is supported by experimental results recently published by Gao et al. (2013), who evaluated the efficacy of TIF tarps and reported:

> *"The ambient air monitoring from the three fields with tarp-cutting after 5, 10, and 16-days indicated that 1,3-D [1,3-dichloropropene] and CP [chloropicrin] emissions were reduced by 78% and 88%, and their total emissions by 43% and 64%, respectively, by increasing the tarping duration from 5 to 10 days…All data indicate that extending TIF tarp-cutting to 10 days or longer can significantly reduce both the peak flux rate and the cumulative emissions of 1,3-D and CP."*

The Mitigation Proposal includes a provision for increasing the tarping duration from the label-mandated 5-day minimum to 9 days when TIF tarps are used, and OEHHA endorses this proposal. However, while Section IV of Appendix 4 analyzes differences in flux rates as a function of tarping duration, the analysis does not provide a clear conclusion. For this reason, we recommend that DPR provide clearer justification for specifying 9 days as the minimum tarping duration. The results published by Gao et al. suggest that a tarping duration of 10-15 days may be warranted in order to minimize emissions when the tarps are cut. OEHHA recommends that DPR provide a rationale for not specifying a longer tarping duration in the Mitigation Proposal.

Extending the tarping duration also might make possible a significant reduction in chloropicrin application rates while maintaining the required level of pesticidal activity. In this regard, Gao et al. (2013) concluded:

> *"This study also provided soil-air concentration data that can be used to evaluate the potential for reducing fumigant application rates under TIF, which has shown a large improvement of fumigant diffusion resulting in a more uniform fumigant distribution in surface soils and the root zone of annual crops."*

In addition, Fennimore and Ajwa (2011) compared strawberry fruit yield per plant under two application scenarios, one that utilized standard high density polyethylene (HDPE) tarps and the other TIF tarps. The fruit yield that was obtained using 100 pounds of chloropicrin per acre (lbs/acre) in combination with TIF tarps was essentially identical to the yield obtained using 300 lbs/acre in combination with standard tarps (Fennimore and Ajwa, 2011; Figure 2). The authors noted that this result was likely due to higher fumigant concentrations being held for a longer period of time under TIF than under the more per standard films. If application rates of chloropicrin can be reduced, the opportunities for exposure of off-site residents and bystanders – as well as applicators and tarp cutters – would likely be reduced as well.

Analysis of Costs and Benefits of Totally Impermeable Film (TIF) Tarps

In addition to facilitating less use of chloropicrin, TIF tarps can provide economic benefits to the growers by increasing yields. Therefore the extra cost associated with use of TIF can be at least partially offset by increased production per acre as well as savings from a substantial reduction in the amount of chloropicrin applied per acre.

The Mitigation Proposal's focus on buffer zone estimates appears to provide a narrow range of options for growers. A wider range of alternative application strategies should be evaluated with an overarching goal of providing economic benefits to growers as well as reducing the potential for bystander exposure. OEHHA recommends that DPR provide technical information to stakeholders that would allow them to make an impartial assessment of alternative fumigant application strategies, weighing the economic costs and benefits to growers and the potential for reduced exposure of occupational or residential bystanders.

Re-Assessment of the Weight of Evidence of Chloropicrin's Carcinogenicity

Appendix 3 of the Mitigation Proposal is an April 23, 2013 memorandum from DPR Assistant Director Marylou Verder-Carlos to Chief Deputy Director Chris Reardon. The subject of the memo is "The Risk Management Directive (RMD): Reconsideration of the Carcinogenicity of Chloropicrin." Since the express purpose of the proposed control measures is to protect against acute sensory effects (eye and respiratory irritation) of chloropicrin, and since cancer is generally associated with long-term exposure to concentrations well below the threshold for acute toxicity, it is unclear why this memo was included with the Mitigation Proposal.

The stated purpose of this memorandum was to reassess the weight of evidence for the carcinogenicity of chloropicrin. Even though DPR recently completed two human health risk assessments (DPR, 2010 and 2012) which concluded that chloropicrin is carcinogenic and likley has a genotoxic mode of action, the April 23 memorandum concluded that the evidence for the carcinogenicity of chloropicrin is equivocal and that

a genotoxic mode of action is unlikely because postive results from several *in vitro* genotoxicity assays were not replicated in two *in vivo* assays.

For reasons discussed in previous correspondence with DPR (OEHHA, 2009a,b; 2012), OEHHA disagrees with the evaluation presented in this DPR memo. OEHHA's conclusions regarding the weight of evidence for the carcinogenicity of chloropicrin are supported not only by the two DPR risk assessments cited above, but also by the findings of the Scientific Review Panel (SRP; 2010) that independently evaluated the weight of evidence and concluded that "The weight of the available evidence...supports classifying chloropicrin as a genotoxic cancer-causing substance warranting cancer risk estimations." A point-by-point discussion of the issues raised in this DPR memo can be found in the above-referenced OEHHA memos.

Thank you for providing this document for our review. If you have any questions regarding OEHHA's comments, please contact Dr. Charles Salocks at (916) 323-2605 or Dr. Anna Fan at (510) 622-3200.

References

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Office of Environmental Health Hazard Assessment (2012). Memo from Anna M. Fan, Ph.D. (OEHHA) to Gary Patterson, Ph.D. (DPR) summarizing OEHHA's comments on DPR's 2011 draft Risk Characterization Document for chlropicrin. October 15, 2012; pages 1-2.

Scientific Review Panel (April 1, 2010). *Findings of the Scientific Review Panel on "Evaluation of Chloropicrin as a Toxic Air Contaminant" as adopted at the Panel's February 24, 2010 Public meeting.* Attachment to a letter from John Froines, Chair of the Scientific Review Panel, to Mary-Ann Warmerdam, Director of the Department of Regulation.

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