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MEMORANDUM

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DATE: July 23, 2013

SUBJECT: COMMENTS ON THE DRAFT EXPOSURE ASSESSMENT DOCUMENT FOR PROPARGITE

The Office of Environmental Health Hazard Assessment (OEHHA) has reviewed the draft Exposure Assessment Document (EAD) for occupational and air exposure to propargite, prepared by the Department of Pesticide Regulation (DPR), dated February 21, 2012. Our comments are provided in the attachment. OEHHA reviews exposure assessments prepared by DPR under the authority of the Food and Agriculture Code section 11454.1.

OEHHA has several general comments on the exposure assessment methodology and conclusions of the draft EAD. These comments and our recommendations, as well as, suggested clarifications, additions and corrections, are contained in the attachment.

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

Attachment

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OEHHA's Comments on DPR's Draft Exposure Assessment Document for Propargite

The Office of Environmental Health Hazard Assessment (OEHHA) is responding to a request from the Department of Pesticide Regulation (DPR) to comment on the draft Exposure Assessment Document (EAD) for propargite. The document addresses occupational and ambient air exposures.

OEHHA reviews exposure assessments prepared by DPR under the authority of Food and Agricultural Code Section 11454.1, which requires OEHHA to conduct scientific peer reviews of exposure assessments conducted by DPR.

SUMMARY

The draft EAD for propargite assessed a wide range of occupational exposure scenarios of agricultural workers, including handlers and fieldworkers as well as bystander and resident exposure located close to fields being treated with propargite. The exposure scenarios covered include both inhalation and dermal exposure in agricultural settings and inhalation exposure in non-agricultural settings.

DPR initiated this review because of the history of pesticide illness reports from the use of propargite.

- OEHHA agrees with the use of more current information and assumptions including the latest exposure-related data.
- The EAD represents a large amount of work and DPR is to be commended for its effort on this exposure assessment.
- The propargite EAD thoroughly describes exposure scenarios for handler exposure from agricultural use, reentry exposure following agricultural use, and exposure from non-agricultural settings.
- OEHHA notes that the document was somewhat difficult to follow. There are a number of clarifications and contradictions in the document that need to be addressed. Thorough editing will improve the readability and clarity of the document.

OEHHA has several suggestions and comments below, including:

- using the most current Pesticide Use Report (PUR) data in assessing average exposure frequency;
- considering other pathways for exposure of children (e.g., at a minimum dermal exposure) in the context of aggregate exposure for bystanders;

- citing the studies on sensitization for a more complete picture of the toxicity of propargite, as mentioned in the RCD, including the nectarine harvesters' study;
- clarifying protective assumptions used for personal protective equipment in the dermal exposure estimates for workers.

GENERAL COMMENTS

The draft EAD describes the three product formulations of propargite adequately. The basic formulations/packaging categories are emulsifiable concentrate (EC) and water soluble bags (WSB), which account for the differences in clothing and PPE required to be used by handlers according to label specifications.

In the EAD, the "Usage in California" section reported the Pesticide Use Report (PUR) data for 2004-2008. However, in the "Exposure Frequency" section (page 39), 2000-2004 data were used to estimate the long-term exposures for handler and reentry exposure. The justification for use of the 2000-2004 PUR data was that the estimates were intended to represent an average exposure frequency rather than annual usage. However, it is not clear why the 2004-2008 data were not used. OEHHA suggests including the most current PUR data in assessing average exposure frequency. If this is not possible, there should be a clearer explanation of why the more recent data cannot be used.

OEHHA notes that the exposure assessment thoroughly describes exposure scenarios for handler exposure from agricultural use, reentry exposure following agricultural use, and exposure from non-agricultural settings. Nine worker categories were identified. A total of 19 sub-scenarios were further identified to cover all critical activities related to reentry exposure in fields treated with propargite.

OEHHA notes that the EAD does not cover all the same routes of exposure as detailed in the RCD. The EAD does not assess exposure from dermal contact or dietary exposure from food and drinking water, but these pathways are discussed in the RCD.

DPR used default average breathing rates of 0.59 cubic meters per kilogram body weight per day (m^3/kg-day) for children and 0.28 m^3/kg-day for adults to estimate human-equivalent exposure doses from experimental animal studies, and to calculate human exposure levels (in terms of mg/kg-day) from air concentrations. OEHHA recommends that DPR consider citing the breathing rates developed for the *Air Toxics Hot Spots Program Risk Assessment Guidelines: Technical Support Document (TSD) for Exposure Assessment and Stochastic Analysis* (OEHHA 2012). In OEHHA's TSD, the mean and 95th percentile daily breathing rates for infants are 0.66 and 1.09 m^3/kg-day, respectively; for adults the corresponding values are 0.19 and 0.29 m^3/kg-day.

OEHHA recommends using also the most recent guidelines (OEHHA 2012, OPP 2012) for breathing rates, exposure durations, and other exposure assumptions.

OEHHA notes that the risk-reduction value used of 90% for use of gloves only applies to the hand portion of dermal absorption. This assumes the use of adequate PPE and that it is used properly. There is no additional accounting of clothing other than the gloves. It is unclear from the text if the Pesticide Handler Exposure Data (PHED) data accounts for the reduction in exposure from PPE for other parts of the body. What is the specific degree of protection that the clothing affords? It is unclear how assumptions of protection by PPE for the dermal calculations were used other than 90% for gloves.

The bystander exposure of non-users (residential or bystander) is limited to "infants" for 1-hour and 24-hour ADDs. Other potential scenarios are possible for swimmers, take-home and other indoor exposure, and dermal contact from drift. OEHHA suggests considering other scenarios including children in the context of an aggregate exposure.

OEHHA agrees with the use of the PHED surrogate data, which are appended to the end of the document as Appendix III. OEHHA acknowledges the amount of work described there and agrees with having the data available and shown in the appendices.

OEHHA notes that there are a number of clarifications and contradictions that need to be addressed in the document. In addition, some issues of synchronization between the RCD and EAD are noted. Please refer to the specific comments section for specific examples. Furthermore, for many of the explanations the reader is referred to other documents and reviews for a number of assumptions and calculations, which makes the report difficult to understand. Finally, the document needs editing for clarity and succinctness. In many places, there are run-on sentences, incorrect grammar and words used inappropriately. This also made the document difficult to understand and review.

SPECIFIC COMMENTS

Abstract

The EAD's "Abstract" (page i) could be improved as it does not provide a clear summary of the EAD and the results of the exposure assessment. It gives the highest values of ADDs (page i, lines 22-27) for aerial applicators, field workers, and infant bystanders, but does not mention which scenarios are covered in the document, the routes of exposure considered (inhalation and dermal) or the types of exposure that are evaluated in the document. No information is given regarding dermal and inhalation absorption or pharmacokinetics.

In addition, OEHHA suggests correcting a minor contradiction. In the EAD's "Abstract" (page i, line 11), the author defined skin irritation cases to be "slightly over 65%", based on pesticide illness reports, whereas in the "Reported Illness" section (page 5, line 5), the number was reported as 67%.

Introduction

DPR states, "Accordingly, this pesticide exposure assessment revision is written not only as a stand-alone document but also as an integral part of the RCD" (page 1, line 25). The EAD does not assess dietary exposure from food and drinking water, but these pathways are developed in the RCD (Lewis 2004; Lewis 2012). OEHHA suggests that the scope of the document (e.g. residential, bystander and occupational) be adequately described at the beginning of the EAD's Abstract (page i) or in the EAD's Introduction (page 1) in order to distinguish the scope of the EAD from the RCD.

Exposure Related factors

Usage in California

As mentioned in the general comments section in the EAD, the "Usage in California" section reported the PUR data for 2004-2008 (page 4, line 27). However, in the "Exposure Frequency" section (page 39), the 2000-2004 data were used to estimate the long-term exposures for handler and reentry exposure. The justification for use of the 2000-2004 PUR data was explained as follows in Appendix IV (page 94), "The temporal use patterns summarized in Tables IV-A through IV-D below were based on the 2000-2004 annual PUR (Pesticide Use Report) data provided by this Department (DPR 2011). They were not updated with the latest available PUR data because the estimates were each intended to represent an average exposure frequency that is much more specific to a particular handler task than to the annual usage in a particular year. The PUR data were available by year, month, county, crop/site, poundage, acreage, air *vs.* ground equipment, etc." It is not clear from the description why the older PUR data had to be used. Perhaps the 2004-2008 data were not sufficient to estimate average exposure frequency for a particular handler task. OEHHA suggests, if possible, utilizing the most current PUR data in assessing average exposure frequency. If the 2004-2008 PUR data are insufficient for the task, it should be clearly explained in Appendix IV, first paragraph, page 94, as well as Appendix V, page 98.

Pages 4, 20 and 24 have inconsistent dates for the latest PUR data. The latest PUR data available is defined as being for 2004 to 2008 on page 4, and for 2000 to 2004 on pages 20 and 24. OEHHA suggests clarifying these discrepancies.

Reported Illnesses

As described on page 6, the 1995 outbreak followed use of propargite at an application rate of 6.25 pounds of active ingredient per acre (lb AI/acre) and the 1999 episode followed an application at the rate of 7 lb AI/acre (although it was complicated by the concomitant misapplication of a pyrethroid). OEHHA notes that both outbreaks followed applications that exceeded current label amounts. Did the label amount change since the outbreaks and did it result in lowering the application rate?

Based on the pesticide illness reporting system, the EAD (page 5) states that skin irritation represents 67% of the pesticide illness symptoms, but this is reported as 75% in the RCD (page 10). OEHHA suggests clarifying why these numbers are different between the EAD and RCD.

OEHHA suggests creating a footnote to characterize the "Non-occupational" category in Table 3 (page 6) to include who was covered or considered in this category. It is not clear whether this category represents residents close to fields where propargite was applied, bystanders, or others.

Acute Toxicity and Pharmacokinetics

Acute Toxicity and Dermal Sensitization

Propargite has low acute toxicity via the oral and dermal routes of exposure (Category III). However, it is considered to be severely irritating to both the skin and eyes, and to be a dermal sensitizer (Category I) according to the EAD. OEHHA suggests adding citations for these endpoints. In the Re-registration Eligibility Decision (RED) document (US EPA 2008), the U.S. Environmental Protection Agency (U.S. EPA) cited evidence of sensitization (Kiplinger 1993). In the RCD, Kiplinger 1993 was cited for acute toxicity but sensitization was not mentioned. As stated in OEHHA RCD memo, the status of propargite as a dermal sensitizer is unclear. OEHHA supports DPR's decision to include an additional uncertainty factor of 3 for dermal irritation to protect against dermal sensitization in addition to the recommended factor of 10 for increased sensitivity of humans relative to guinea pigs to skin irritation from propargite.

Also, although of limited quality due to the small number of subjects, one more recent study in humans (Verma et al. 2007), shows some evidence of sensitization to propargite. DPR concluded (page 8) that because of the severe irritation properties of propargite, it is difficult to obtain evidence of sensitization. The EAD states, "Nonetheless, it has been DPR's practice that skin sensitization studies are not required if a chemical causes skin corrosion or irritation with Category I severity. This is because with such severe irritation properties, it is extremely difficult to obtain experimental evidence for the dermal sensitization potential of a chemical in its concentrate form."

OEHHA suggests citing the studies on sensitization for a more complete picture of the toxicity of propargite, as mentioned in the RCD, including the nectarine harvesters' study which suggests that humans may be significantly more sensitive to propargite-induced dermal irritation than rabbits.

Dermal and Inhalation Absorption

DPR determined that the dermal absorption rate for propargite is 17%. The EAD states "...a C14-based dose of 0.05, 0.5, or 5.0 mg/kg was applied to approximately 10 cm^2 [square centimeters] of the rat's shaved skin. For the dermal absorption in rats exposed to 0.05 mg/kg for 24 hours, the upper end of the range was calculated by the WHS reviewer as 17%. DPR recommended using this upper-end value in the human exposure assessment in part because he considered this test dose to be relatively more comparable to actual worker exposure to propargite." The sentence is referring to a previous exposure assessment conducted by Worker Health and Safety (WHS). It would improve the document to show how the 17% absorption rate was calculated. U.S. EPA uses a default of 14% based on two studies in rats. The later WHS review (Thongsinthusak 1990) cited in the EAD calculated an upper end value of 19% for dermal absorption rate, and the percent absorption rates were given as a range of results (10-19%) (page 8). It would be clearer if the EAD provided enough information and explanation to justify the choice of a 17% absorption rate. In addition, DPR's RCD states the following on page 16, "In the first set of studies, the dermal absorption for the various formulations (Comite, Omite 6E and Omite 30W) after the 24-hour exposure ranged from 3 to 17% after correction for recovery (Chadwick, 1989a-c; Andre et al.,1989)." The RCD also says, "In the second set of experiments, the corrected dermal absorption of the various formulations (Omite technical, Omite 30W, Omite 6E and Comite) ranged from 6 to 20% (Andre et al., 1990a-c; Mizens et al., 1990)." OEHHA suggests that DPR clarify why the range of values are different between the RCD and EAD.

OEHHA concurs with the use of a health-protective default value of 100% for inhalation absorption, since no data are available to define inhalation absorption rate.

Environmental concentrations

Ambient and onsite air concentrations

Ambient air levels were monitored by ARB for propargite after ground spraying in 1996; however, there were inherent analytical problems with the study. ARB performed another air monitoring study in the summer of 1999 (ARB, 2000) that did not have the same analytical problems. No quality assurance data were provided for the ambient and

onsite air monitoring in this section of the report. The limit of quantification was provided, but the specifics regarding rates of recovery or lab spikes were not mentioned in this section. A summary of the air monitoring data was provided in a later section (pages 43-45). OEHHA suggests describing the entire study here and referring to this chapter when using the data later for calculating exposure.

Dislodgeable foliar residues (page 10)

If no monitoring data were available, DPR used chemical-specific dislodgeable foliar residues (DFR) values. But if no DFR data were available on specific crops, as in most cases, data from other crops were used which introduced uncertainties as acknowledged by DPR. Data were selected on the basis of job functions for reentry field exposure. The characterization and derivation of these values are in Appendix II. OEHHA concurs with this approach in the absence of crop-specific DFR data.

Turf and Other Surface Residues (page 11)

Because propargite uses are not registered for residential, recreational, or other non-agricultural settings, surface residues were not expected to be available. OEHHA suggests taking into account surface residues as a result of mixing, storage, or cleaning areas where workers could be exposed.

Other Environmental Concentrations

Concentration in soils and surface water residues are presented here but were not included in the scope of this EAD assessment. The EAD states (page 11, paragraph 6, line 4), "Furthermore, it is not expected that any significant amount of oral intake or dermal uptake of soil residues would occur near a worksite, as this is not a place where children would frequent much." OEHHA disagrees with this statement because children may indeed play in the soil or water bodies near worksites and could represent a significant bystander exposure. Children of farmworkers and children residing close to treated fields (at the agricultural-urban interface) are potentially at risk. The Pesticide Illness Report (PIR) data showed 18 cases of pesticide illness due to drift. In addition, the U.S. EPA RED (US EPA 2001) states: "In water or in moist conditions, propargite degrades rapidly under alkaline conditions and is rated as "moderately persistent" to "persistent" under neutral and acid conditions. Soil and aquatic photolysis and aerobic and anaerobic metabolism occur at moderate rates. Because of its high affinity for soil and sediment, propargite has the potential to move off the site of application during rainfall, irrigation, erosion, runoff on soil particles and by drift. Given the moderate to slow degradation rates for metabolism and photolysis, and the high Koc values, propargite will probably be adsorbed to sediments and organic material if transported to surface waters." Finally, DPR's document, "Environmental Fate of Propargite" (Xu

2001) states, "Propargite is a possible contaminant for surface water; 32 detections among 330 samples were reported in California during a period from 1993 to 1998." Thus, OEHHA recommends that DPR, at a minimum, look at dermal exposure for children playing in soil as part of the bystander exposure scenario.

Exposure Assessment

The introduction of this section should also be incorporated into the abstract and introduction indicating the scope of this assessment. This would clarify which scenarios are being covered, including the nine worker categories as well as the three subsections (handler exposure, field recovery exposure, and inhalation exposure of bystanders and residents).

Handler Exposure from Agricultural Use

The EAD identifies 9 occupational exposure scenarios defined by activity, pesticide formulation and application method. Appropriate personal protective equipment is assumed per label specifications for each scenario. Tables 4-6 describe data and assumptions used for estimation of propargite dosage for applicators from Mixer/Loaders, Mixer/Loader Applicators and Human Flaggers. OEHHA suggests giving a sample calculation of the use of the equation for ADD in the text or footnote of the table (pages 13, 14 or 20).

The 90% reduction with gloves does not account for other dermal exposures or other PPE. In addition, this reduction in exposure assumes that PPE is used and used correctly. OEHHA suggests that DPR provide additional justification for a 90% reduction in hand exposure by gloves. It was also not clear what protective assumptions were used for the other parts of the body from personal protective equipment.

Daily Acreage and Application Rates

OEHHA agrees with the use of 600 acres as the maximum daily acreage for aerial sprays (page 12, paragraph 3, line 4) and 100 acres for groundboom sprays. OEHHA suggests clarifying if whether the same pilot would use two different application rates when applying propargite to two fields on the same day (page 12, paragraph 3-5). In the "Exposure Appraisal" section (page 51, paragraph 4), DPR gives a good explanation regarding the maximum acreages (100 acres/day) for groundboom application. OEHHA suggests providing this justification in the Daily Acreage and Application Rates section on page 12.

For the Mixer/Loader (M/L) category, DPR assumed a U.S. EPA value (200 acres/day) to be reasonable (page 16, paragraph 5 to page 17, paragraph 1). As for the Mixer/Loader (M.L.)/Applicator category, DPR used 5 acres/day (high pressure) and 1 acre/day (backpack and low pressure), which are values similar to U.S. EPA's when conversions were made to gallons/day. DPR noted that the defaults by U.S. EPA for M.L/applicators and those used in this document were considered comparable. OEHHA recommends providing the U.S. EPA actual default values in the document for comparison to those used by DPR.

Data on Exposure Rates

OEHHA agrees with the use of Pesticide Handler Exposure Data (PHED) surrogate subsets to estimate inhalation and dermal exposure rates. The EAD adequately describes the pros and cons of using the PHED information, including the significant data gaps and need for validation. OEHHA concurs with the use of the 90% upper confidence limit(UCL) on the 95th percentile when using surrogate PHED data for short-term exposures in the absence of specific information on a type of application (as described on pages 17 and 18). Furthermore, OEHHA agrees with the use of the 95th percentile for longer term exposures when using the PHED data. These are health protective approaches in the absence of specific data.

C-F Applicators, Mixers/Loaders, Human Flaggers, Mixer/Loader Applicators

DPR defined 6 subgroups depending on equipment and formulation, separating between users of emulsifiable concentrate (EC) and water soluble bags (WSB) products. OEHHA agrees that it is appropriate to separate workers into subgroups based on the job they do, the associated activities and potential for exposure. It is not clear to us, other than reduction in hand exposure due to gloves, whether exposure was adjusted by other types of clothing.

Reentry Exposure Following Agricultural Use

The EAD states that only dermal exposure following re-entry was considered because inhalation was assumed negligible since propargite has very low vapor pressure (page 31, paragraph 3) and the restricted reentry intervals (REIs) were long enough for airborne residues to settle. On page 31, the EAD states: "Propargite is a compound having a very low vapor pressure (4.5×10^{-8} mm Hg, as listed in Subsection II.1). The inhalation component thus was not included in this reentry exposure assessment as it was considered negligible compared to the dermal component. This is especially the case when the REI (or preharvest interval (PHI), if applicable) is long enough to settle the airborne residues from application, which typically is not more than a few hours for a nonvolatile compound." DPR should clarify whether they have considered and

estimated exposure due to re-entrainment of particle-bound propargite. This is not mentioned in the EAD. This may be a small fraction of total exposure, but nevertheless it should be addressed in the EAD.

In addition, DPR provides detailed explanations on the limitations and uncertainties of the dermal transfer rates (TR) and DFR in the "Exposure Appraisal" section of the EAD, (pages 51-52). Appendix II provides a nice analysis of the available studies on DFR in a number of crops. DPR also used adequate surrogate data when necessary. OEHHA agrees with the transfer rates (TR) chosen by DPR for each category and considers their approaches to be adequately health protective.

Exposure Frequency:

OEHHA suggests incorporating the most current PUR data (2004-2008) (page 4) into the exposure assessment. The EAD states that, "These use patterns (Appendix IV) were investigated by examining percent of use based on pounds per month for the most recent five years for which the PUR were available at the time of the exposure assessment." (page 20, paragraph 4, lines 3-5). OEHHA is unclear based on this sentence if the 2000-2004 data were used here or the 2004-2008 data. The EAD continues to state, "For the purpose of this exposure assessment, data from the highest use county over the five-year period from 2000 through 2004 were used as surrogates." (page 20, paragraph 4, lines 5-7). If the 2004-2008 data are available now, OEHHA suggests that DPR add a discussion of how the data are different and when and why each data were used.

Exposure from Non-Agricultural Settings

Exposure of Bystanders to Onsite Air

As mentioned in the General Comments section of this memo, OEHHA suggests using the breathing rates from the latest OEHHA risk assessment guidelines (OEHHA 2012).

The bystander exposure of non-users (residential or bystander) is limited to "infants" for 1-hour and 24-hour ADDs (page 45, line 6, Table 23). Other potential scenarios are possible for swimmers, take-home and other indoor exposure, and dermal contact from drift. OEHHA suggests considering other scenarios including children in the context of an aggregate exposure. OEHHA also suggests specifying in the report in more places how "infant" is defined (e.g. age or age range considered).

Average Air Concentrations for Bystanders

DPR mentioned that there was a lack of onsite data for long-term exposure. They note that use of ambient data would underestimate exposure for a bystander and that use of a 24-hour air concentration measured near an application site would overestimate long-term exposure. Therefore, DPR opted for an extrapolation/projection from the short-term monitoring data provided by the Air Resources Board (ARB). This approximation method relied on many assumptions described on page 46 and in Appendix II of the EAD. Two log-regression models were performed, with and without the 90 minute application period. Re-application issues (intervals, number/year and adjacent fields) were discussed on pages 46-47. OEHHA agrees that it is difficult to estimate a long-term bystander exposure given that monitoring data are lacking to evaluate inhalation exposure with certainty. A key concern is that the onsite monitoring results for the extrapolation indicated only a 50% field recovery. However, from the EAD description, it is the only available data to use. Further, DPR utilized the highest measured concentration from the onsite monitoring in the first 90 minutes post-application to estimate the bystander exposure. As noted in the text, this is a conservative assumption (although we disagree that it is impossible as indicated in the text on the bottom of page 47). Notwithstanding the choice of the highest measurement to base the ADD estimate, it should be emphasized that the lack of data results in much uncertainty and this uncertainty can lead to either an underestimate or an overestimate of exposure. Notably, the EAD indicates that DPR was unsure whether ARB had adjusted the reported concentrations for the field recovery. The EAD goes on to state, "Regardless, no effort was made in this subsection to resolve this adjustment issue at this time, considering that the background amount in each of the three background triplicates was reportedly greater than the spike used for field recovery test. More specifically, for any field spike recovery determination to be valid, the spike level used should be at least several times *greater* than the background (ambient) level. Otherwise, the inherent variability or error of measurements on the much higher background level could easily mask, overshadow, or otherwise obscure the actual recovery of the much lower level of spike added to the background." This explanation itself is unclear. Further, if we understand correctly, then the concentrations reported from the ARB monitoring effort during the application were potentially underestimated by 50%. OEHHA suggests that DPR discuss this problem with ARB staff who wrote the monitoring report.

The paragraphs in the EAD on pages 47 and 48 appear to overemphasize the "impossibility" of having an exposure as high as the one used to calculate the ADD for bystanders. The discussion regarding the impracticality of bystander exposure (pages 47-48) was confusing. OEHHA suggests revisiting the discussion, editing for clarity and succinctness, and shifting the emphasis more to the uncertainty inherent in a lack of data and less to how the ADD is likely to be an overestimate.

Exposure of Local Residents to Ambient Air

DPR considered the exposure of local residents living nearby treated fields to ambient airborne propargite. Bystanders were expected to have higher exposure than residents and were therefore used as a worst case scenario. OEHHA concurs with the inclusion of local residents in the EAD and the use of bystander data.

Aggregate exposure

No aggregate scenario was evaluated for bystander and residential because only inhalation was considered. This could underestimate total exposure. OEHHA suggests that DPR consider other exposure scenarios such as dermal contact of bystanders following application, and the possibility of take-home exposure and swimmer exposure in contaminated surface water.

EDITORIAL COMMENTS

Formulations and Label Uses: Page 3, line 17. "The five special local need (SLN) registrations still in effect as of this date have been extended certain uses or application methods for cotton...." (underline emphasis added). Please clarify by adding the date here.

Label Precautions: Page 4, line 9. OEHHA suggests that the potential for worker exposure when cleaning the equipment be further discussed in the EAD. It is currently mentioned in the sentence on page 4, line 9: "For handling the EC products, workers are additionally required to wear coveralls over normal work clothes, chemical-resistant gloves, chemical resistant headgear (for head exposure), and when mixing, loading, or cleaning, also a chemical-resistant apron" (underline emphasis added). DPR also alludes to potential exposure during cleaning of equipment on page 16, paragraph 4, line 14: "What matters here is the physical limitation involved for each mixer/loader in a day's work which includes cleaning the equipment" (underline emphasis added).

Usage in California: Page 4, section 5, line 7-8. "Review of the sales (mill assessment) data thus would not reveal any unreported crops/sites for this AI." OEHHA suggests changing "would" to "did" if this was indeed the case. This sentence is unclear.

Reported Illnesses in California: Page 6, Table 3. Under "Attributed to propargite alone", the subheading, "Occupational[d]" indicates footnote (d), which does not appear in the legend.

Acute Toxicity and Pharmacokinetics. Acute Toxicity and Dermal Sensitization: Page 7, paragraph 4, line 3. The EAD states, "...the AI is now listed in California as a chemical

known to cause reproductive toxicity". DPR should add cancer to this sentence and a reference to this statement to identify the cited list. OEHHA suggests adding Proposition 65 or Safe Drinking Water and Toxic Enforcement Act to the sentence and the specific reproductive effect that is the basis for the listing. Note that the sentences in both the abstract and introduction correctly state that propargite is listed under Proposition 65 as both a developmental and reproductive toxicant and a carcinogen. The Proposition 65 list can be found here:
http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html

Exposure Assessment: Pages 13-15, Tables 4-6. OEHHA suggests defining what the maximum label rate is in footnote (c).

The EAD document needs editing for clarity. There are a number of paragraphs with run-on sentences or excessive verbiage, and inappropriate use of words. The following describes a few such examples.

Exposure Assessment: Handler Exposure from Agricultural Use. OEHHA notes several sentences on page 16 that, if modified, will improve the readability of the text.

- Paragraph 1, line 2. The first sentence would benefit by the removal of the term, "at this time." The sentence reads, "Another reason why the WHS default is used in this case with propargite is that, to a great extent, the PUR data for the 10 most recent available years <u>at this time</u> (1999-2008) also supported the use...." Underline emphasis added in the previous quote.
- Paragraph 1, line 7. OEHHA suggests changing the word "yearly" to "highest annual" in the context of the following sentence, "...with an average of 479 for the 10 yearly highest (635, 640, 519,450,..."
- Paragraph 2, line 6. OEHHA suggests removing the italics from the phrase, "on the same day" which reads, "...them to use two different use numbers for two fields that they treat *on the same day*, it is unlikely for...."
- Paragraph 3, lines 4-6. The sentence reads, "Further justification was given in the Exposure Appraisal section for using 100 acres as the maximum daily default for groundboom applications (except for ground mixer/loaders)." OEHHA suggests changing "was given in" to "is presented in the Exposure Appraisal section" since that section is later in the document.
- Paragraph 4, line 4. OEHHA suggests changing the underlined portion of the following sentence to read "it can take up to twice the time". "This presumption, while consistent with U.S. EPA's practice, was actually based more upon the observation that <u>it takes as much as twice the time</u> and effort for an applicator to

maneuver an airblast spray rig than to drive a groundboom tractor in a field." Underline emphasis added in the previous quote.

- Paragraph 4, lines 12-15. OEHHA suggests separating the content of this sentence into several sentences to improve readability and clarity. The sentence currently reads, "What matters here is the physical limitation involved for each mixer/loader in a day's work which includes cleaning the equipment, while taking into account the potential that more efficient equipment is employed to provide hence more spray solutions for certain ground application methods."

Irrigators/Other Cultivators Engaging in Low-Contact Activity: Page 39, paragraph 1, line 5.

- The EAD states, "In fact, for some crops including strawberries and field-gown roses, scouting can be accomplished by visual inspection with little dermal contact with the treated foliage." OEHHA suggests changing the typo "field-gown roses" to "field-grown roses."

Use of Pharmacokinetics and Toxicity Data: Page 54, paragraph 1, line 2.

- The EAD states, "As pointed out in Ross *et al.* (2000), a review of several compounds tested indicated that the rat overestimated human dermal absorption by two- to ten-fold. In addition, dosage is expressed as a single static value both in worker exposure and animal toxicology studies. The rates of dermal absorption and acquisition are often seen or expected to be lower than the rates of oral absorption and acquisition in animals used for toxicology testing. In short, the dose via the nonbolus dermal route is likely to be less potent than the same amount administered orally. This factor was discussed in Dong and Haskell (2000) and in Ross *et al.* (2000)." First, the term "acquisition" does not have any meaning in toxicokinetics. Second, the implication that dermal absorption across rodent skin is always greater than across human skin, based on a review of "a number of compounds" is not justified, and cannot be made across the board for all chemicals or even propargite, as it is here. Third, it is not clear what the relevance is of comparing dermal and oral absorption in this paragraph. This section is confusing. It needs to be rewritten or just deleted as it does not add anything to the EAD.

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