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PETS 03-5

Office of Environmental Health Hazard Assessment

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MEMORANDUM

TO: Charles M. Andrews, Chief
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P.O. Box 4015
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FROM: Anna M. Fan, Ph.D., Chief MAD for AMF
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DATE: June 30, 2003

SUBJECT: COMMENTS AND RECOMMENDATIONS ON THE PROPOSED METHYL BROMIDE FIELD FUMIGATION REGULATIONS

The Office of Environmental Health Hazard Assessment (OEHHA) received your electronic mail correspondence sent on June 11, 2003, which included your memorandum concerning the development of proposed methyl bromide field fumigation regulations by the Department of Pesticide Regulation (DPR), a copy of the draft Notice, Initial Statement of Reasons (ISOR), Proposed Regulation Text, and documents supporting these proposed changes. According to your memorandum "(DPR) proposes to notice regulations to repeal and adopt sections 6450, 6450.1, 6450.2, 6450.3, 6784, and two definitions in section 6000. The purpose of this proposed action is to implement appropriate mitigation measures to protect the public and workers from acute (short-term) and subchronic (intermediate) methyl bromide exposure hazards."

As you are aware the Food and Agricultural Code (FAC), section 12980, states that the Legislature finds and declares that the development of regulations relating to pesticides and worker safety should be the joint and mutual responsibility of DPR and OEHHA. Additionally, FAC, section 12981, states that OEHHA shall participate in the development of any regulations adopted pursuant to this article and such regulations that relate to health effects shall be based upon the recommendations of the OEHHA. Pursuant to these statutes and DPR's need to meet the *Carillo* case settlement agreement, OEHHA has appreciated

DPR's invitation to participate in the development of regulations pertaining to methyl bromide field fumigation and its request for a review and recommendations from OEHHA on the proposed regulatory changes to repeal and adopt sections 6450, 6450.1, 6450.2, 6450.3, 6784, and two definitions in section 6000 of the California Code Regulations.

Since February 2003, OEHHA has been working with DPR to develop regulations that address subchronic exposure to methyl bromide during field fumigation. During this period, permanent regulations for acute exposure to methyl bromide during field fumigation were not proposed or discussed. OEHHA has previously concurred with DPR on the adoption of *emergency* regulations for methyl bromide field fumigation, which were last approved by the Office of Administrative Law to be effective from May 21, 2003 through September 18, 2003. Since the proposed regulations are now under consideration to become permanent, OEHHA believes it is appropriate to review the regulations concerning acute exposure to methyl bromide and the basis for them. The following comments on the proposed methyl bromide regulations, address both the acute and subchronic exposures issues.

ACUTE EXPOSURE REGULATIONS

Target Air Concentration

The target air concentration of 210 ppb calculated in the risk characterization document (RCD) for methyl bromide (DPR, 2002) is used for buffer zone calculations for methyl bromide soil fumigation. It is based on a no-observed-adverse-effect-level (NOAEL) of 40 ppm from a developmental toxicity study in rabbits. An adult human equivalent NOAEL of 21 ppm was estimated in the RCD based on a default adult respiration rate and conversion from a 6-hour exposure to a 24-hour exposure period. The target air concentration of 210 ppb was then calculated by dividing the human equivalency NOAEL by the conventional uncertainty factor of 100 applied for inter- and intra-species variation. OEHHA has previously commented on and discussed with DPR its concerns regarding the assumptions and methods used in deriving this target air concentration, and the adequacy of this value in protecting children and infants from methyl bromide exposure. In brief, OEHHA is concerned that the target air concentration of 210 ppb adopted by DPR might not be sufficiently protective of the most vulnerable populations (children, infants and developing fetus). We have also shared our concerns regarding the use of the rabbit developmental toxicity study as the basis for a 24-hour exposure standard because of the nature of the study design. It is difficult and may not be appropriate to apply time corrections to developmental toxicity endpoints because the critical time frame for exposure is usually unknown. The Scientific Review Panel (SRP) for Toxic Air Contaminants also expressed reservations for time extrapolation of developmental toxicity studies at its February 10, 1999 meeting.

After reviewing the available data and considering the evidence for the variability in human responses to methyl bromide, we recommend that the acute 1-hour reference exposure level (REL) of 1,000 ppb developed by OEHHA (1999), which was approved by the SRP, be used to derive a 24-hour REL for calculating buffer zones for soil fumigation with methyl bromide. Using Haber's Law, converting the 1-hour REL of 1,000 ppb to a 24-hour REL yields a value of 90 ppb. The procedures used in calculating the acute REL for methyl bromide were accepted by the SRP during public comment periods and were discussed and considered during public meetings of the SRP. It should be noted that acute RELs of 23 (24-hour), 77 (24-hour) and 60 ppb (6-hour) for children can also be calculated based on available experimental toxicity studies on file at DPR. We want to emphasize that in developing its REL, OEHHA did not apply additional uncertainty factors to protect children or to account for the data gap for developmental neurotoxicity.

We further recommend that DPR calculate buffer zones based on the acute (24-hour) REL of 90 ppb. Once the results of these calculations are available, DPR and OEHHA should compare and discuss the different buffer zones calculated based on the target air concentration of 210 ppb adopted by DPR and the 90 ppb REL recommended by OEHHA. Revised regulations may be drafted accordingly.

Chloropicrin as an active ingredient

As the regulations currently read, it appears as if the intent is to regulate chloropicrin as an active ingredient, in addition to methyl bromide. However, in our discussions with DPR we understand that DPR is not proposing chloropicrin regulations at this time. Therefore, to avoid any misinterpretation of the regulations, we recommend that the first sentence of section 6450 of the proposed regulations be revised to read "The provisions of this section and sections 6450.1, 6450.2, 6450.3, and 6784(b) pertain to field soil fumigation use requirements using methyl bromide, singly or in combination with chloropicrin or any other pesticide ~~or~~ <u>used as a</u> warning agent." Alternatively, DPR could present mitigation measures for acute exposure to methyl bromide and chloropicrin mixtures to be considered as a basis to regulate formulations where chloropicrin is present at levels higher than needed for the purposes of a warning agent.

In the ISOR, starting on page 7, "6450. Chloropicrin and Methyl Bromide-Field Fumigation," we recommend adding the following language at the beginning of this section: "<u>These regulations pertain to field soil fumigation use requirements using methyl bromide. Methyl bromide may be used singly or in combination with chloropicrin or other pesticides. These regulations only consider the health effects of methyl bromide and are not necessarily protective for chloropicrin or any other pesticide used with methyl bromide</u>."

Although not specifically related to the text of the regulation or the ISOR, we have previously requested from DPR a timeline in which technical support documents would be

completed to support new regulations for use of chloropicrin as an active ingredient in soil fumigation. In addition to the timeline, we have also requested information on the feasibility of promulgating emergency regulations to be effective until the necessary technical documents are completed to support permanent regulations for acute exposure to chloropicrin. If DPR does not have an acute target level for chloropicrin, we recommend the use of the acute 1-hour REL of 4.4 ppb for chloropicrin developed by OEHHA and approved by the SRP (OEHHA, 1999).

SUBCHRONIC EXPOSURE REGULATIONS

Concerning the regulations pertaining to subchronic exposure to methyl bromide field fumigation, OEHHA's position on the target air concentrations remains the same as stated in its previous memoranda of June 13, 2003, May 28, 2003, and March 11, 2003 as well as at the March 12 and April 9, 2003 meetings of the Methyl Bromide Interagency Work Group. OEHHA reiterates its position that the basis for the subchronic methyl bromide exposure regulations should be the REL of 1 ppb for the general public (including children) and 2 ppb for adult workers, which is consistent with DPR's peer review by the National Academy of Sciences (NAS). These RELs are lower than the respective target air concentrations of 9 and 16 ppb that DPR has proposed to adopt as the basis for the subchronic regulations. Therefore, OEHHA does not concur with the mitigation methods proposed in sections 6450(h) and 6784(4)(A)(B) and possibly (C) as written since these were based on the higher target air concentrations of 9 and 16 ppb rather than the lower RELs of 1 and 2 ppb recommended by OEHHA.

To meet the RELs supported by OEHHA, a revision to the township cap and work hour restrictions in the proposed regulations may be necessary. Accordingly, OEHHA recommends that DPR reexamine the basis for its proposed target concentrations for the methyl bromide field fumigation regulations.

With regard to the derivation of the 1 ppb value for subchronic exposures, the 2002 RCD for methyl bromide inhalation did not indicate that an additional uncertainty factor to protect children was applied in its calculation (DPR, 2002). We want to emphasize, therefore, that the REL of 1 ppb that OEHHA recommends to be used as the basis for the subchronic regulations for children does not include an additional uncertainty factor for the protection of infants, children, and the developing fetus. Rather, OEHHA has stated previously that although the target level of 1 ppb methyl bromide in air was not specifically developed to protect the most vulnerable population, "we support the use of 1 ppb as the target air concentration for subchronic exposures due to the overall poor quality of the data, the uncertainty in the protection of infants and children, and the uncertainty in the evaluation of MeBr/chloropicrin formulations." If an additional factor(s) were applied in the derivation of the residential REL to account for any or all of these uncertainties, then the REL would be lower than 1 ppb.

INITIAL STATEMENT OF REASONS

In reference to the chronology presented in the ISOR beginning on page 3, OEHHA is concerned that the summary included on page 6 with regard to the RCD addendum is missing some important factual information. First, although not officially requested, we reviewed the addendum and the supporting (new) toxicity study (Schaefer 2002) and provided written comments to DPR on March 11, 2003. Secondly, the summary should reflect that OEHHA recommends different levels for use in formulating mitigation measures, which are 1 ppb (for the general public, including children) and 2 ppb for adult workers. These are the same values DPR calculated and presented in the final RCD for methyl bromide (2002). Third, the summary should reflect that the peer review of the methyl bromide RCD conducted by the NAS supports the use of 1 and 2 ppb, respectively.

We request that the ISOR be amended to reflect these important historical facts regarding the peer review of the RCD addendum, and OEHHA's health-based recommendation to use lower RELs for the subchronic exposure mitigation plans and regulations to protect public health.

CLARIFICATION OF EARLIER COMMENTS

In addition to the main concerns expressed above, we would like to take this opportunity to clarify two specific comments we made in our June 13, 2003 memorandum. That memorandum contained four comments that addressed some specifics in the memorandum of May 22, 2003 from DPR concerning mitigation measures for seasonal exposures of agricultural workers to methyl bromide during soil fumigations.

Comment number one reads:

"Page 3 of the memorandum from Drs. Thonginthusak and Frank dated May 22, 2003, contained a discussion of two options of mitigation measures that was confusing in how they were presented. It would be clearer if "Option 1" is called "the mitigation measure" (instead of an option) and "Option 2" is called an "exception to 'the mitigation measure,' only if the stated requirements can be met". This was discussed with Dr. Frank, who also recognized that a clarification of the "Options" was needed."

The intent is now more clearly stated in section 6784(b)(4)((B)(1) and (2) of the proposed regulations.

Comment number four reads:

"If the OEHHA proposed reference exposure level for adults of 2 ppb were used by DPR as the target air concentration, it is not clear if the respirator cartridge that has been proposed for use would adequately protect the workers from overexposure since it may not have been certified for this level of protection."

After further consideration of this comment, the issue of concern is more accurately addressed in OEHHA's comment number three of the same memorandum and therefore, we are withdrawing comment number four.

Thank you for the opportunity to participate in the development of the proposed methyl bromide field fumigation regulations. If you have further questions, please call me, Dr. Michael DiBartolomeis, or Dr. William Ngai at (510) 622-3170.

Attachment

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