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Office of Environmental Health Hazard Assessment

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MEMORANDUM

TO: Charles M. Andrews, Chief
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DATE: May 5, 2006

SUBJECT: COMMENTS ON THE DEPARTMENT OF PESTICIDE REGULATION'S (DPR) PROPOSED MITIGATION STRATEGY FOR METHYISOTHIOCYANATE (MITC)

Thank you for your request and the opportunity to participate in the MITC Interagency Work Group meetings to discuss public health issues related to development of the methyl isothiocyanate (MITC) mitigation strategies. We look forward to continuing the interagency dialog on this important and difficult issue. We note that you requested each of the participating agencies to provide you with comments on DPR's risk management decision regarding the development of use restrictions on metam-sodium and other MITC generating pesticides and on the mitigation strategies being considered by your department. We appreciate this opportunity as well. This management decision was announced in a memorandum to "Interested Parties" entitled *RISK MANAGEMENT DIRECTIVE*, dated December 2, 2002. We note that the listing of MITC as a Toxic Air Contaminant (TAC) on August 23, 2002 compels the development of these use restrictions.

Pursuant to Food and Agricultural Code, section 14023, OEHHA provides consultation to DPR regarding the need for and appropriate degree of control measures for pesticides listed as toxic air contaminants. Further, under Food and Agricultural Code, section 13129, OEHHA has the authority to provide advice, consultation, and recommendations to DPR concerning the risks to human health associated with exposure to pesticide active ingredients. It is under these provisions that we offer our comments on this important matter.

The proposed mitigation strategies are described in this directive and in "Attachment A: Methyl Isothicyanate Mitigation Development," a handout distributed at the MITC Interagency Workgroup meeting held on March 22, 2006, to address acute, off-site exposures to residents and bystanders only. We understand that the strategies to mitigate seasonal, ambient, and occupational exposures will be addressed at a later date. There are two components to the strategies, first is the identification of an acute target level for MITC, and the second is the proposed regulatory measures/use restrictions to minimize offsite movement of MITC to levels less than the target value. We offer the following comments on these two components:

Appropriate Target Values for Acute Exposure

The no-observed-adverse-effect-level (NOAEL) of 220 ppb based on eye irritation in human volunteers at the highest dose (800 ppb) in the critical study is proposed as the target level. The stated rationale for selecting this value is that the endpoint is not very severe and that since this is a NOAEL, exposures between this level and the REL (22 ppb) "would not be expected to pose a health threat."

OEHHA disagrees with this conclusion and raises a number of objections to the use of this level as the target level:

Use of the NOAEL as the target value does not consider human variability; therefore, an unknown proportion of the population may be at risk at this level of exposure. Further, since this study had such a small sample size (four subjects), confidence in the NOAEL is relatively low. Use of this NOAEL is in essence, mitigation to a margin of exposure (MOE) of 1, which is not an acceptable level for public health protection. A MOE of at least 10 is generally accepted as health protective when based on a NOAEL from a human study.

We note that California Code of Regulations, Title 3, section 6890, states that "a pesticide shall be determined to be a Toxic Air Contaminant (TAC) if its concentrations in ambient air are greater than ... 10-fold below the air concentration which has been determined by the director to be adequately protective of human health." OEHHA assumes and agrees that the REL of 22 ppb developed in DPR's risk characterization document for MITC is such an air concentration.

Therefore, at the mitigated MOE of 1 (220 ppb), MITC should still be considered a TAC, thus, the mitigation would be unsuccessful in both the "spirit" and "letter" of the regulation. The NOAEL of 220 ppb for eye irritation effect is possibly too high, since the volunteers were exposed "eyes only." In an actual exposure situation, in addition to the eyes, the nose and mouth would be simultaneously exposed, which may effectively lower the NOAEL for this endpoint. A lower NOAEL would place an even greater proportion of the human population at risk. We also note that other irritation endpoints were not evaluated in this study since exposure was limited to the eyes only. Eye irritation is not an inconsequential endpoint when experienced over a period of time that would be typical during and after an MITC application. Significant concentrations of airborne MITC may be found near application sites for several days following an application. Since the proposed target value is a 24-hour time-weighted-*average* of 220 ppb, individuals may be exposed to very high, short-term levels that could result in substantial adverse health effects. It is well known that many any irritants can trigger asthmatic reactions in individuals previously sensitized by different sensitizers. The proposed mitigation target level of 220 ppb does not specifically respond to the fumigant's potential to induce asthma reactions. We note that according to the Department of Health Services (DHS, 2005), the lifetime asthma prevalence rates are relatively high in counties where MITC pesticides are typically used. For example, the lifetime asthma prevalence rate for all ages in Fresno County is 15.1 percent (about 126,000 people). In Kern County, the rate is 16.8 percent, (about 117,000 people). These two examples underscore our concerns about the high potential for MITC to effect asthmatic individuals residing near application areas. Isocyanates are also well-documented sensitizers (Wheeler et al., 1998), which complicates the efforts to establish public health protective objectives.

To accommodate these concerns, we recommend the adoption of a target value of 22 ppb, which is the reference exposure level (REL) for MITC, and would yield a margin of exposure (MOE) of 10, a margin that would more effectively protect public health.

Regulatory Control Measures for Acute Exposure

A number of possible control measures, including water caps, notifications, field size limitations, buffer zones, and weather requirements have been proposed to mitigate offsite MITC movement. Information regarding the anticipated effectiveness of these measures was not provided to the workgroup, so it is quite difficult to evaluate which possible controls would be the most appropriate. Once additional information regarding the effectiveness of these possible measures is made available, OEHHA may provide comments regarding their application and implication in mitigating MITC exposure. We strongly suggest that, in addition to modeling predictions, field validation studies be included in the proposal in support of any proposed strategies.

OEHHA has concerns that any control strategies that are implemented may have the unintended consequence of promoting the use of other fumigants that have not yet undergone regulatory processing. We are particularly concerned about promoting the use of chloropicrin. Without concurrent use restrictions on other fumigants, these materials may be applied right up to the property line, posing a potential health threat to bystanders and residents. Accordingly, we recommend that restrictions on the use of other fumigants be addressed in the overall mitigation strategy that is ultimately adopted.

Lastly, we recommend that DPR should explore the establishment of a community notification plan to be used by local agencies and/or applicators and a 1-800 number for complaints of eye irritation and other adverse effects resulting from the use of MITC-producing pesticides. Complaints registered via the 1-800 number should be monitored by DPR in order to proceed with additional public health protective actions, if necessary.

OEHHA appreciates the opportunity to collaborate with DPR and other agency representatives in protecting the public from potentially hazardous exposure to pesticides. Should you have any questions regarding our comments, please contact either of us.

cc: Val F. Siebal
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Reference:

Wheeler S, Rosenstock L, Barnhart S (1999). A case series of 71 patients referred to a hospital-based occupational and environmental medicine clinic for asthma. *West J Med*; 168:98-104.

Department of Health Services, Environmental Health Investigations Branch. California Breathing Program. October 2005. (http://www.californiabreathing.org/asthma_data/)