



Paul Helliker
Director

Department of Pesticide Regulation



Gray Davis
Governor

Winston H. Hickox
Secretary, California
Environmental
Protection Agency

MEMORANDUM

TO: Paul H. Gosselin
Chief Deputy Director

FROM: Paul E. Helliker *Paul Helliker*
Director
(916) 445-4000

DATE: August 21, 2002

SUBJECT: DIRECTOR'S PROPOSED DECISION CONCERNING METHYL
ISOTHIOCYANATE AS A TOXIC AIR CONTAMINANT

Attached is a public notice of the proposed decision concerning my response to the Scientific Review Panel's findings on methyl isothiocyanate as a toxic air contaminant. My response has been made in accordance with all authorities and requirements stipulated in the Food and Agricultural Code and California Code of Regulations that mandate this determination. The Scientific Review Panel's findings were transmitted to me on August 14, 2002. Therefore, my response has been made within the 10-day statutory deadline.

I thank you, staff, and all the members of the Scientific Review Panel for the excellent work.

Attachment

cc: Alan Lloyd, ARB, Chair (w/Attachment)
Joan Denton, OEHHA, Director (w/Attachment)
Scientific Review Panel (w/Attachment)
Tobi Jones, Assistant Director (w/Attachment)
Douglas Y. Okumura, Assistant Director (w/Attachment)
Chuck Andrews, Chief (w/Attachment)
Barry Cortez, Chief (w/Attachment)
David Duncan, Chief (w/Attachment)
Gary Patterson, Chief (w/Attachment)
Scott T. Paulsen, Chief (w/Attachment)
John Sanders, Ph.D., Chief (w/Attachment)





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Post Until
September 27, 2002

NOTICE OF PROPOSED DECISION CONCERNING THE DIRECTOR'S DECLARATION OF METHYL ISOTHIOCYANATE (MITC) AND OTHER PESTICIDES THAT GENERATE MITC AS TOXIC AIR CONTAMINANTS

Section 14023 of the Food and Agricultural Code (FAC) requires the Director of the Department of Pesticide Regulation (DPR) to determine if a pesticide is a toxic air contaminant (TAC) after receiving the findings of the Scientific Review Panel (SRP), a panel of experts representing a range of scientific disciplines. Based on the findings of the SRP's assessment of the report entitled, "Evaluation of Methyl Isothiocyanate as a Toxic Air Contaminant," and the criteria given in Title 3, California Code of Regulations (CCR) section 6890(b), the Director proposes to declare Methyl Isothiocyanate (MITC) and other pesticides that generate MITC as TACs.

Background

With the enactment of California's Toxic Air Contaminant Act (Assembly Bill 1807, Tanner, Chapter 1047, Statutes of 1983; amended by Tanner, Chapter 1380, Statutes of 1984), the Legislature created the statutory framework for the evaluation and control of chemicals as TACs. The statute defines TACs as air pollutants that may cause or contribute to increases in serious illness or death, or that may pose a present or potential hazard to human health. DPR is responsible for the evaluation of pesticides as TACs.

In general, the law focuses on the evaluation and control of pesticides in ambient community air. In implementing the law, DPR must: (1) conduct a review of the physical properties, environmental fate, and human health effects of the candidate pesticide; (2) determine the levels of human exposure in the environment; and (3) estimate the potential human health risk from those exposures. The law requires DPR to list in regulation those pesticides that meet the criteria to be TACs.

For each pesticide, the law requires the preparation of a report that includes: the environmental fate and use of the pesticide, an assessment of exposure of the public to air concentrations of the pesticide, and a health assessment. The report is reviewed by the Office of Environmental Health Hazard Assessment and the Air Resources Board, and is made available for public review. Based on the results of these reviews, the draft report is revised as appropriate. The draft undergoes a rigorous peer review for scientific soundness by the SRP. Based on the results of this comprehensive evaluation, the DPR Director determines whether the candidate is a TAC. If the Director determines the pesticide meets the criteria to be a TAC, DPR declares the pesticide a TAC in regulation, and adds it to the TAC list.

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Once a candidate pesticide has been declared a TAC, it enters phase two of the program--the mitigation, or control, phase. In the mitigation phase, DPR investigates the need for, and appropriate degree of, control for the TAC. If reductions in exposure are needed, DPR must develop control measures to reduce emissions to levels that adequately protect public health.

Department Conclusions

Title 3, CCR section 6890 states, "A pesticide shall be identified as a toxic air contaminant if its concentrations in ambient air are greater than the following levels (for the purposes of this section, a threshold is defined as the dose of a chemical below which no adverse effect occurs):

(a) For pesticides which have thresholds for adverse health effects, this level shall be ten-fold below the air concentration which has been determined by the Director to be adequately protective of human health.

(b) For pesticides which do not have thresholds for adverse health effects, this level shall be equivalent to the air concentration which would result in a ten-fold lower risk than that which has been determined by the Director to be a negligible risk."

DPR expresses risk as the margin of exposure (MOE), the ratio of the no observable effect level (NOEL) to the air concentration. DPR considers an MOE of ten adequate to protect humans if the NOEL is derived from human data. This takes into account the possibility of ten-fold variations in susceptibility within the human population. DPR considers an MOE of 100 adequate to protect humans when the NOEL is determined in animals. This accounts for an additional ten-fold uncertainty between laboratory animals and humans, and assumes that humans are more sensitive than animals. Therefore, according to the criteria established in regulations, pesticides with an MOE less than 100 or 1,000 if the NOEL is derived from human or animal data, respectively, should be identified as TACs.

Using the critical acute NOEL of 220 parts per billion (ppb) established in a human eye irritation study, and the short-term ambient exposure levels, MITC acute ambient MOEs ranged between 15 and 2200, and meet the criteria (MOE <100) for identifying a TAC. Under the short-term application site exposure scenarios, the MOEs for 1-, 8-, and 24-hour exposures were <1 to 5, <1 to 7, and <1 to 17, respectively, also meeting the criteria for identifying a TAC.

Using the critical estimated subchronic NOEL of 100 ppb established in the four-week rat inhalation study and the ambient exposure levels mean seasonal ambient MOEs ranged between 28 and 166,667, meeting the criteria (MOE <1000) for identifying a TAC. Under seasonal application site exposure scenarios, the MOEs ranged between 1 - 50, also meeting the criteria for identifying a TAC.

The SRP agrees with the science presented in the report and recommends that the Director identify MITC and all pesticidal sources of MITC as TACs. The SRP also recommends listing other metam sodium breakdown products, such as hydrogen sulfide, as TACs, if not already designated.

The law (FAC section 14021) and regulations (Title 3, CCR section 6890) defines TACs as pesticides. Breakdown products are not defined as pesticides in the law or regulations, so DPR lacks legal authority to list hydrogen sulfide and other metam sodium breakdown products as TACs. However, DPR can control exposure to the breakdown products by regulating the parent compound.

Department Actions

DPR proposes to adopt a regulation designating MITC and other pesticides that generate MITC as TACs. DPR proposes to add MITC and other pesticides that generate MITC to the list of pesticides in Title 3, CCR section 6860(a).

Although metam sodium is not specifically listed as a TAC, it is one of the pesticides that generate MITC. DPR will regulate it as a precursor to MITC, and the potential effects from the other metam sodium breakdown products will be considered in managing the risks.

DPR will conduct a public hearing concerning the proposed regulation.

APPROVED BY: Paul Helliker Date: 8/23/02
Paul Helliker, Director