



Department of Pesticide Regulation



Mary-Ann Warmerdam
Director

MEMORANDUM

Arnold Schwarzenegger
Governor

TO: Paul H. Gosselin
Chief Deputy Director

FROM: Mary-Ann Warmerdam
Director
(916) 445-4000

DATE: September 18, 2006

SUBJECT: DIRECTOR'S PROPOSED DECISION CONCERNING SULFURYL FLUORIDE
AS A TOXIC AIR CONTAMINANT

Attached is a public notice of the proposed decision concerning my response to the Scientific Review Panel's (SRP's) findings on sulfuryl fluoride 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 Regulations¹ that mandate this determination.

Thanks to you, our staff, and all the members of the SRP for the excellent work.

Attachment

cc: Robert Sawyer, Chair (w/Attachment)
Air Resources Board

Joan E. Denton, Ph.D., Director (w/Attachment)
Office of Environmental Health Hazard Assessment

Jim Behrmann, Scientific Review Panel, Air Resources Board Liaison (w/Attachment)

Scientific Review Panel (w/Attachment)

¹The SRP's findings were transmitted on September 8, 2006. The Food and Agricultural Code and California Code of Regulations mandate that the DPR Director must respond within ten working days.





Post Until
October 27, 2006

NOTICE OF PROPOSED DECISION CONCERNING THE DIRECTOR'S DECLARATION OF SULFURYL FLUORIDE AS A TOXIC AIR CONTAMINANT

Section 14023 of the Food and Agricultural Code 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 SRP's assessment of the report entitled "Final Draft Sulfuryl Fluoride (Vikane) Risk Characterization Document" and the criteria given in Title 3, California Code of Regulations (3 CCR) section 6890(b), DPR's Director proposes to declare sulfuryl fluoride as a TAC.

Background

With the enactment of California's TAC 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 SRP. Based on the results of this comprehensive evaluation, DPR's Director determines whether the candidate is a TAC. If DPR's 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. For more information describing how DPR prioritizes pesticides for evaluation and risk assessment see the document entitled "Process for Human Health Risk Assessment Prioritization and Initiation" on DPR's Web site at <http://www.cdpr.ca.gov/docs/risk/raprocess.pdf>.



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.

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 DPR’s 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 DPR’s Director to be a negligible risk.”

The reference concentration is the estimate of daily human exposure that is not likely to result in health concerns. It is calculated from the no observed effect levels from toxicity studies in experimental animals and applicable uncertainty factors. The reference concentrations for sulfuranyl fluoride included an uncertainty factor of 1000 to account for the extrapolation of data from laboratory animal study, variation in response between individuals, and the lack of a developmental neurotoxicity study. The no observed effect levels for acute, 1-2 weeks, subchronic (13-weeks), and chronic exposures were 300, 100, 30, and 5 parts per million (ppm), respectively. The reference concentrations (and exposure durations) for infants, the highest exposed group in the general population, are 0.12 ppm (acute), 0.023 ppm (1-2 weeks), 0.007 ppm (subchronic), and 0.002 ppm (chronic). As described above, air concentrations exceeding one-tenth (10 percent) of the reference concentrations meet the criteria for listing as a TAC. Therefore, sulfuranyl fluoride air concentrations exceeding 0.012 ppm (acute), 0.0023 ppm (1-2 weeks), 0.0007 ppm (subchronic), and 0.0002 ppm (chronic) would meet the criteria for listing as a TAC.

Human exposures were estimated using the monitoring data for structural fumigation during application and aeration phases, and the label limit of 5 ppm for nonfood commodity fumigation. Infant bystander acute exposures (air level as 24-hour time weighed average) ranged from 0.31 to 5 ppm. These were 255 percent to 4,167 percent of the acute reference concentration of 0.12 ppm, meeting the criteria for identifying sulfuranyl fluoride as a TAC.

SRP agrees with the science presented in the risk characterization document and recommends that DPR's Director identify sulfuryl fluoride as a TAC.

Actions

DPR proposes to adopt a regulation designating sulfuryl fluoride as a TAC. DPR proposes to add sulfuryl fluoride to the list of pesticides in 3 CCR section 6860(a).

DPR will conduct a public hearing concerning the proposed regulation.



APPROVED BY: _____
Mary-Ann Warmerdam, Director

Date: September 18, 2006