



Department of Pesticide Regulation



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Governor

Winston H. Hickox
Secretary, California
Environmental
Protection Agency

Paul Helliher
Director

December 2, 2002

TO: Interested Parties

SUBJECT: RISK MANAGEMENT DIRECTIVE

This letter outlines the Department of Pesticide Regulation's (DPR's) risk management decision related to the development of use restrictions on metam-sodium and other methyl isothiocyanate (MITC)-generating pesticides.

Summary

We recently completed our assessment of the risks associated with potential exposure to residents and bystanders from ambient and off-site air concentrations of metam-sodium and MITC-generating pesticides. We determined that the use of metam-sodium and other MITC-generating pesticides results in unacceptable acute and seasonal exposures. Annual and lifetime exposures were not addressed in the document and will be considered in the future. DPR's regulatory goal is to ensure that the use of metam-sodium and other MITC-generating pesticides do not result in exposures that cause recognizable eye or respiratory irritation. We have initiated efforts to develop mitigation measures according to the procedures described in DPR's risk mitigation policy (January 2001).

Since the risk from acute (short-term) off-site exposures to residents and bystanders poses the most immediate concern, it will take priority over managing seasonal exposures. Once we implement the mitigation strategy for acute off-site exposures, we will initiate the process of developing mitigation measures for seasonal off-site and ambient exposures. Although our initial efforts will focus on managing acute exposures, we have begun discussions with registrants to address seasonal exposures to residents and bystanders. In communicating with the registrants, we described our concerns associated with seasonal off-site and ambient air concentrations resulting in unacceptable exposures and are seeking their mitigation proposals. We will consider evaluating the impacts of adopted mitigation measures for acute exposures before addressing seasonal exposures.

In regard to occupational exposures to metam-sodium and MITC, we will forgo activity on risk mitigation until completion of the comprehensive risk characterization document. Upon completion of these documents we will determine which occupational exposures require risk mitigation through another risk management directive.

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Developing the regulatory guidance for metam-sodium and other MITC-generating pesticides presents a unique situation since the regulatory concern (eye and respiratory irritation) is an effect recognized by exposed individuals. We recognize that the onset of reversible effects is a prelude to more severe systemic effects. The data we rely on come largely from human studies that provide us the opportunity to use very sensitive endpoints but may not fully account for the variation in the human population to these effects.

Methodology

In developing use restrictions, we will clearly define the limits of the important factors (e.g., weather conditions, amount/acre applied, acres treated, application method) that affect the magnitude and duration of off-site air concentrations. Sophisticated analytical modeling tools allow adjusting various input factors to estimate off-site air concentrations. We will utilize a standardized modeling approach; however, we will consider alternative modeling approaches. The final decision on the use restrictions will be based on the results of modeling, clarity of restrictions, minimizing high exposure of a short duration, and the potential impact to surrounding communities.

An important variable needed for the modeling effort is the choice of an exposure target value. The exposure target value is typically described as a concentration over a period of time. As a result of limited human studies and unanticipated human exposures (primarily in cases of accident or misuse), we have information suggesting doses at which MITC can be expected to cause reversible eye and respiratory irritation in humans. The exposure levels capable of causing irritation occur at levels lower than more severe adverse effects. The information provides an indication of exposures at which no adverse effects can be expected, and has guided our conclusion that adequate public health protection is achieved if mitigation measures prevent the onset of irritation.

For this modeling effort, we will allow an exposure target value for MITC of 220 parts per billion (ppb) averaged over an eight-hour period. This value was identified in the risk assessment as the no-observable effect level (NOEL). In using the NOEL as the exposure target value, we will establish restrictions for the highest acceptable exposures. The restrictions based on the NOEL will not provide the highest level of health protection, but will be adequate. As described, exposures between the NOEL and the reference exposure level (REL) value would not be expected to pose a health threat.

The maximum level of human health protection was described in DPR's Toxic Air Contaminant document. We identified an acute concentration level below which no adverse health effects are anticipated. This acute concentration is called an REL. For MITC, the acute REL was determined from a human study that limited MITC exposure only to the subjects' eyes. In that study, the NOEL (that is, the level where no statistically significant adverse effects were seen)

was 220 ppb for exposures up to eight hours. The lowest dose at which effects were seen (the lowest-observable effect level) was 800 ppb. Subjects exposed to 800 ppb for one-two hours were reported to have a statistically significant increase in eye blink rate, and the majority of subjects reported eye irritation. The effects seen at 800 ppb represent the onset of reversible, mild health effects, while acknowledging that the small number of subjects inherently limits this human study, and that the group may not adequately represent the most sensitive individuals. The REL (22 ppb) was determined by taking the NOEL plus 220 ppb and including a ten-fold factor to address intrahuman variability. Ensuring that exposures do not exceed the REL would provide the highest level of public health protection. However, levels above an REL do not necessarily indicate the potential of adverse health effects, but rather indicate a progression of increasing risk. Our approach in preparing use restrictions will be based on exposures not exceeding the NOEL value, recognizing that intrahuman variability may occur. Therefore, using the NOEL in the initial development of use restrictions would provide an appropriate baseline to protect public health.

Conclusion

We have initiated efforts to develop mitigation measures to address unacceptable acute offsite exposures. Our goal is to ensure the use of metam-sodium and other MITC-generating products does not result in noticeable eye or respiratory effects. To meet this goal, we will develop and provide restricted-material permit guidance to county agricultural commissioners, and may adopt or amend regulations. We will also consider changes to product labeling proposed by the registrants.

In developing the final set of use restrictions, we will consider other factors in addition to the modeling results. In regard to the modeling results, we will consider the uncertainties associated with the results. Minimizing the likelihood of short-term peak concentrations above 220 ppb will be factored into the use restrictions. We will also rely heavily on the professional judgment of staff, given the diversity of agricultural practices used for this pesticide and variability in weather conditions.

Finally, the clarity of the use restrictions will be critical in terms of fostering compliance. We have seen that failure to follow existing restrictions can have devastating effects on surrounding communities. Typically, restrictions are based on the presumption that the rules are followed. We will continue to follow this premise. However, given the unique set of circumstances, our regulatory restrictions must account for the impact to surrounding communities in the event of noncompliance, and we must strive to maximize the likelihood of compliance. The final decision on use restrictions will seek to protect communities adjacent to fumigated sites using a high level of confidence.

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If you have any questions, please contact Mr. Charles Andrews, Chief of DPR's Worker Health and Safety Branch, at (916) 445-4222.

Sincerely,

A handwritten signature in cursive script that reads "Paul H. Gosselin".

Paul H. Gosselin
Chief Deputy Director
(916) 445-4330

cc: Mr. Charles Andrews