MEMORANDUM

SUBJECT: "Exposure Estimation" in: California Department of Health Services' "Health Risk Assessment of Aerial Application of Malathion-Bait"

TO: Penelope Fenner-Crisp, Ph.D., Director Health Effects Division (H7509C)

FROM: Mark I. Dow, Ph.D. Special Review and Registration Section Occupational and Residential Exposure Branch Health Effects Division (H7509C)

THRU: Curt Lunchick, Section Head Special Review and Registration Section Occupational and Residential Exposure Branch Health Effects Division (H7509C)

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I have reviewed "Exposure Estimation" pp 7-1 through 7-68 of the document "Health Risk Assessment of Aerial Application of Malathion-Bait" (prepared by S.A. Book, R.J. Jackson, A.M. Fan, and M.J. Bartolomeis for the California Department of Health Services, Feb. 1991). The purpose of the review was to determine the extent of, or the existence of, any human monitoring data resulting from the aerial application of malathion-bait. There are no human monitoring data in the document relative to post-application exposure. The DHS and CDFA collected additional monitoring data during the summer of 1990, however, those data were not available for incorporation in the current risk assessment. Further, the data were not characterized as to whether they were human monitoring data or otherwise.

The monitoring that was performed utilized one square foot pieces of laboratory bench top paper ("Kimbie cards") that were affixed to cardboard and in turn fastened to bricks one foot above the ground. The process measures Mass Deposition which is the "primary method used by CDFA to evaluate the application program." The exposure assessment "uses CDFA mass deposition data collected in February 1990...." The CDFA monitored air at
18 indoor and 19 outdoor sites. Specifications for the air monitors were not presented. "It should be noted that it is uncertain what fraction of inspirable particles were collected" since the "air samplers used by CDFA were not calibrated for particle size collection efficiency...."

Estimates of total acute and subchronic exposure were derived from estimates of inhalation and several routes of oral and dermal exposure. The estimates were based on 11 applications because that was the greatest number of applications in any one area. Quite a number of assumptions were utilized regarding such things as compound half life, rate of decay, plant concentrations, water concentrations, air concentrations, amounts of vegetation and soil and water ingested, and various physical activities that might result in dermal exposure. "Inhalation dose estimates are based on atmospheric concentrations measured both indoors and outdoors. Ingestion and dermal dose estimates are based on malathion and malaoxon mass deposition data on the ground and other upward facing outdoor surfaces."

OREB agrees with several statements in the document with regards to the applicability of the information presented. "The level of uncertainty in estimating exposure doses is probably large, but not quantifiable." "Several assumptions used in the dose estimate calculations are sources of uncertainty. The environmental monitoring was not designed to be 'representative' nor was it designed to look at specific issues addressed by these calculations." "Models, not sampling results, were used to calculate exposures...."

In conclusion, these remarks are in no way to be construed as disparaging. The difficulties involved with deriving exposure estimates based on less than perfect data are not new or unique. However, if this information had been submitted in support of an application for registration, it would not be acceptable. OREB cannot utilize the information in any way to derive more significant estimates of exposure that might result from the aerial application of malathion bait. Obviously, changes in underlying assumptions could alter calculated results. However, since the assumptions used are already quite conservative, any alterations would only tend to reduce the estimated or perceived risk.

As a point of interest, I refer you to the apparent dichotomy of thought contained in the fifth paragraph of the Preface and the concluding paragraph of the Executive Summary. Dr. K.W. Kizer notes that there is concern for theoretically susceptible groups but states that the current evidence indicates that there have been very, very few malathion associated illnesses or reactions. He further indicates that if the Medfly eradication program posed any significant health risks, he would recommend that it be halted immediately. The Executive Summary is much more conservative and suggests that the entire aerial Medfly program be reconsidered in urban areas.
I'll be happy to answer any questions you may have on this matter.

cc:  K. Baetcke
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