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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: California Department of Health Services' Malathion Exposure Studies From Medfly Sprays.

TO: Susan Stanton
Registration Support Branch
Registration Division (H7505C)

FROM: Mark I. Dow, Ph.D. Acting Section Head
Special Review and Registration Section II
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Health Effects Division (H7509C)

THRU: Charles L. Trichilo, Ph.D., Chief
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Please find below, the OREB review of:
HED Project # 1-2267
ID # 91DA0002
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Review Time 6 days

I. INTRODUCTION

Per your request, Dr. Ruth Allen and I have reviewed three studies conducted by the California Department of Health Services (DHS) regarding various health effects as they might be related to the California malathion bait spray for the medfly eradication program. The "studies" are actually epidemiological surveillance activity reports and although very carefully planned and conducted, do not provide the kinds of exposure monitoring data that Curt Lunchick and I described during our meeting of 12 JUN 91.

The three documents are: (1) "Summary of Public Health Surveillance Activities Carried Out by the Toxics Epidemiology Program, Los Angeles County Depart of Health Services"; (2) "Peak Flow Rates in Asthmatics--Effects of Malathion Aerial Applications and Daily Pollutant Levels"; (3) Acute Illness Reports Following Aerial Malathion-Bait Applications Los Angeles County, December 1989 to June 1990".

Document (1), "Summary of Public Health...", contains two smaller documents which are part of the Summary. The most meaningful for our purposes is titled "Evaluation of Malathion Urinary Metabolites in Individuals Potentially Exposed to Aerial Applications of Malathion Bait in the Medfly Eradication Campaign."

Based on detectable urinary metabolites, the highest doses, "using fairly conservative parameters", were 2.0 mg in a two year old (approximately 0.2 mg/kg) and 9.6 mg for an adult or about 0.13 mg/kg. According to the authors, "These estimates are likely to be high, perhaps by a factor of 2 to 5." Indeed, if DHS' underlying assumptions, pharmacokinetic excretion model, and dose calculations are correct, plausible worst case exposures for an individual outdoors during spraying or who subsequently has extensive skin contact with sprayed surfaces is not likely to exceed a few milligrams.

The second subtitle of the "Summary" is "Malathion Evaluation Clinic Summary." It and the documents numbered (2) and (3) noted earlier, are epidemiological surveillance activity reports. The intent, via survey, was to try to discern any statistically significant increase in a number of physiologically detrimental conditions that could have resulted from exposure to medfly sprays. Some of the conditions monitored were: changes in asthmatics' peak respiratory flow rates, allergic dermal and ophthalmic responses, and a number of acute symptoms such as headache, nausea, sore throat, nasal congestion, cough, and others.

Our concerted opinion is that, although the surveys were well designed and conducted, they did not yield data of a definitive nature. This is due to a number of factors but primarily due to a relatively small population sampled and to a multitude of confounding factors (e.g., normally occurring air pollutants etc.) that make defining a cause and effect relationship with malathion spray, very difficult.

Questions regarding details of the epidemiological aspects may be directed to Dr. Allen. As noted earlier, OREB assumes that the toxicological and pharmacokinetic assumptions are in accord with what is currently used in the Agency. Continued epidemiological surveillance activities are a prudent public health measure, however exposure assessments for malathion require careful attention since the potential for confounding is great where the disease endpoints of concern (e.g., headache, nausea, and eye irritation) have high prevalence. The mode and route of exposure for children may require particular care and attention to additional preventive measures. The current studies

did not provide the type of exposure data discussed in June 1991. Therefore, OREB suggests that other biomonitoring studies, following the guidelines delineated in Subdivision U, be conducted to assess bystander exposure. This suggestion is already incorporated in the OREB recommendations to obtain bystander exposure data in the malathion DCI.

cc: CHEMICAL FILE
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