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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: California Health Risk Assessment of Aerial
Application of Malathion-Bait

FROM: Brian Dementi, Ph.D., D.A.B.T. *Brian Dementi 4/19/91*
Review Section III, Toxicology Branch I
Health Effects Division (H7509C)

TO: Flora Chow, Chemical Manager
Reregistration Section
Science Analysis & Coordination Branch
Health Effects Division (H7509C)

THRU: Henry Spencer, Ph.D. *HSP 4/23/91*
Acting Section Head
Review Section III, Toxicology Branch I
Health Effects Division (H7509C) *RS 4/23/91*

The California Department of Health Services (DHS) has completed and published (February, 1991) a risk assessment for the aerial application of malathion-bait in the control/eradication of the mediterranean fruit fly. The assessment estimated doses of malathion and malaoxon that individuals residing in the spray zone would receive as a consequence of a variety of some 25 exposure scenarios. These doses were compared to a parameter termed the Reference Exposure Level (REL) calculated for several toxicity end points to determine if doses received by individuals posed a threat to human health. The REL is defined in the risk assessment as a NOAEL (NOEL) or LOAEL (LOEL) for a given toxicity end point adjusted (divided) by factors of 10 (in most cases) until the major sources of uncertainty (e.g. inter- and intra-species variations, the use of a LOAEL rather than a NOAEL, experimental design, etc.) in the data base have been considered. An REL is a level of exposure at which no adverse human health effects would be anticipated. Hence, according to the California document, health protection is achieved if the estimated or actual human dose of malathion is below the relevant REL. (p. 8-5)

The following conclusions expressed in this risk assessment are cited here uncritically, contingent upon a thorough review of the document within HED.

The risk assessment concluded that under certain exposure scenarios, dose estimates for malathion were greater than relevant RELS

by more than 10-fold in the cases of dermal irritation and acetylcholinesterase inhibition of 20% or more. The particular exposure scenarios in question included individuals eating unwashed vegetables grown in the backyard and individuals spending a minimum of four hours per day outdoors wearing only shorts during or following malathion-bait applications. (p. 8-45)

The study employed by DHS for acetylcholinesterase inhibition was the human (male) study by Moeller and Rider (1962). The same study serves as the basis for EPA'S RfD. As derived from this study, the REL for acute exposure is the same as EPA'S RfD, namely 0.02 mg/kg (p. 8-21). It is upon this figure that the >10-fold exceedance of the REL has been identified in the risk assessment based upon certain circumstances of exposure. It should be noted that the California risk assessment advises that the REL is based upon a dose which actually resulted in 10% acetylcholinesterase inhibition, but is considered a NOAEL in the sense that 10% inhibition is not viewed as producing clinical symptoms, hence, this is a NOAEL rather than a true NOEL (p. 8-11)

The DHS referenced study cited in calculating the REL for dermal irritation was that of Hayes, et. al. (1960), a study which employed human (male) volunteers. This study, while not present on the HED one-liners, was used by the Food and Drug Administration in licensing a 0.5% malathion topical lotion to treat head lice. (pp. 8-9, 10)

Other toxicity end point RELs which were equalled or exceeded (by factors estimated to be less than 10-fold, or of unknown magnitude) under particular circumstances of exposure include those for genetic toxicity (p. 8-25), behavioral effects (indicated in the risk assessment as not well documented in animals or humans) (p. 8-27), developmental effects (p. 8-28), malaoxon acetylcholinesterase inhibition of 20% or more (p. 8-31) and malaoxon dermal effects. (p. 8-33)

In performing the risk assessment, the Malathion Public Health Effects Advisory Committee (MPHEAC), a group of experts appointed by DHS to evaluate certain toxicity parameters, considered the data bases for carcinogenicity and ocular toxicity and concluded in essence that the findings were not sufficiently definitive to determine that either effect should be used as a toxicity end point in assessing risk based upon the exposure data. As to the question of carcinogenicity, the risk assessment document advises that MPHEAC was unable to reach a consensus on whether to classify malathion as a "C" or "D" carcinogen according to EPA'S Cancer Risk Assessment Guidelines, but felt that risks likely would be small. The committee endorsed an additional cancer bioassay as is being required by EPA, plus special studies to resolve questions of endocrine pathology. (pp. 8-3, 4). For purposes of comparison, the EPA carcinogenicity peer review of April 1990 placed malathion in category "D" and required new chronic/oncogenicity studies for malathion and malaoxon in the rat and oncogenicity testing in the mouse. Special study requirements to assess endocrine pathology have not been entertained by HED.

On the question of ocular effects, DHS concluded that evidence is insufficient to classify malathion as causing irreversible or severe eye damage as reported for certain residents of Japan following exposure to "numerous and high levels of organophosphate insecticides." "It is not appropriate, therefore, to derive an REL for ocular effects." (p. 8-11) DHS does however support further testing. An HED Peer Review of organophosphate induced eye effects concluded that combined epidemiologic studies and toxicologic data indicate the potential for organophosphates to produce a wide range of ophthalmologic effects. As a result of the peer review, all organophosphates, including malathion, will undergo required testing for ocular effects.

Tox Branch advises, based upon the organophosphate/ocular effects review, that malathion was one of the principal organophosphate pesticides reportedly used in Japan when the ocular effects were identified and published in the Japanese literature. As described in that literature certainly one mode of application of malathion was via helicopter. To the extent that organophosphate ocular toxicity actually occurred in Japan as identified in that literature, it is not possible to conclude that the effects were limited to any particular organophosphate among those principally in use.

Tox Branch is concerned over a physician reported case of legal blindness in a teenager following malathion-bait spraying last year in the Los Angeles California area.

Important quotations after the nature of conclusions appearing in the California risk assessment document might be cited as follows:

"Although the existing database may be adequate to support the continued registration of malathion for use in agriculture to control pests, the data do not necessarily provide information pertinent to the evaluation of the use of this pesticide in urban areas with large populations to control pest infestations." (p. 8-45)

"Based on these results, DHS believes that a subpopulation of potentially sensitive individuals such as children, the aged, individuals with certain pre-existing diseases, and the homeless who receive upper-bound exposures (and in some cases average exposures) to malathion may be at risk of exhibiting some adverse health effects from aerial malathion-bait application." (p. 1-6)

"Given the findings of this risk assessment, DHS recommends that the use of aerial malathion-bait applications in urban areas for agricultural pest eradication be reconsidered. This recommendation excludes the use of malathion in human infectious disease vector control in which the risks of contracting a debilitating or fatal disease are far greater than the potential risks for adverse health effects associated with malathion exposure. Although the theoretical adverse health risks from exposure to aerially applied malathion-bait in the general population may be reduced by following some simple precautions, potential exposures in more sensitive subpopulations may not be avoided

as easily. DHS recognizes the public concerns related to the aerial application of pesticides such as malathion, and the public demand for the development and use of pest control methods that are less intrusive and alarming. Therefore, DHS also recommends that CDFA develop, and when possible, utilize available non-pesticide or selective pesticide (e.g., natural attractants) alternatives to aerial application of pesticides." (p. 8-46)