Health Risk Assessment of Aerial Application of Malathion-Bait

Summary Report

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How to obtain copies of the Malathion Risk Assessment

Copies of the the complete *Health Risk Assessment of Aerial Application of Malathion-Bait* and a summary report are being widely distributed to public libraries in Los Angeles, Orange, San Bernardino, and Riverside counties, as well as to selected state depository libraries. They may also be obtained as follows:

Copies of the summary report are available free by writing or calling (Single copy requests only, please):

California Department of Health Services
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The *Health Risk Assessment of Aerial Application of Malathion-Bait* may be ordered from Copies Unlimited, 5904 Sunset Blvd, Los Angeles, CA 90028, (213) 462-5532 or 462-5688. The price is $15.00 plus tax and postage for a loose-leaf, three hole punch copy. Call for information on other options (bindings, bulk discounts, etc.).

Preface

Several times in the last decade, California has been faced with difficult choices as a result of the introduction of exotic agricultural pests into the State. Attempts by the California Department of Food and Agriculture (CDFA) to eradicate one of these pests, the Mediterranean fruit fly (Medfly), twice have led to programs involving multiple aerial applications of malathion-bait over large urban areas, first in 1980-1981 and again in 1989-1990.

In 1980-1981, the California Department of Health Services (CDHS) first addressed the safety of aerial application of malathion-bait during the large Medfly infestation in the Santa Clara Valley. At that time, CDHS made a number of recommendations to reduce the potential for public exposure to the malathion-bait and to improve the safety of CDFA's Medfly eradication program.

During the 1989-1990 Medfly eradication effort in the Los Angeles Basin, many questions were raised about the safety of the project, and CDHS was again asked to address the public health concerns involved in the eradication effort in general, and the aerial application of malathion-bait in particular. This summary is based on CDHS's comprehensive review of the safety of malathion as applied in aerial bait for the eradication of the Medfly.

To ensure a fully open scientific review of the potential health effects of malathion and to encourage public participation, I established the Malathion Public Health Effects Advisory Committee (MPHEAC) to advise us on this important issue and to provide independent peer review of the report. The MPHEAC is broadly representative of the medical, public health, and scientific community in California. Members of the general public were also present at MPHEAC meetings and many participated in discussions. The MPHEAC and I both heard citizens testify about their anger over their homes and families being sprayed involuntarily and their worry about potential adverse health effects. In many ways, the anger, anxiety, and distrust expressed by many people are an important public health concern over the aerial application of pesticides. The MPHEAC identified a clear need for better "risk communication" between government officials and the communities affected by pest eradication programs. In section three of this report, recommendations to improve communications about pest eradication programs and their potential health risks are noted. However, more needs to be done in this regard, as the report recommends.

All of the major health issues surrounding the aerial application of malathion-bait were presented at public meetings of the MPHEAC and openly discussed before achieving scientific consensus. This document reflects their public discussions and review of the health issues. The Committee members deserve the thanks of all Californians for their public service and dedication to this critical examination and lengthy review process.

Our conclusions, based on this thorough review, are presented in this report. In brief, malathion appears to be a relatively safe pesticide, particularly in the small amounts used in aerial malathion-bait. Indeed, for the majority of citizens in an aerial application area, we are confident that there is no significant risk to health. Notwithstanding this, though, for certain individuals with higher than normal contact with the malathion-bait or with unusual suscep-

About this summary

This document summarizes the main findings of the California Department of Health Services' health risk assessment on malathion-bait, which was prepared in response to the 1989-90 Medfly eradication program in southern California. So that readers may gain a wider overview of the health investigations concerning the malathion-bait spraying, this summary also describes the results of other studies that have been done concurrently by county health departments. Finally, work that remains to be done is summarized, as is some practical information for the public.

There are three main sections, as follows:

Section one describes the risk assessment and its findings and recommendations.

Section two discusses the additional studies, undertaken or proposed, to more completely assess the health risks of the aerial application of malathion.

Section three contains information that will be useful to the public in the event of another insect eradication campaign involving aerial spraying of pesticides. It also explains how we may help to prevent future infestations.

Contents

About this summary . . . 1
Section one: The risk assessment on aerial malathion-bait . . . 2
The need for a new risk assessment . . . 2
Risk assessment conclusions . . . 3
What is the CDHS risk assessment? What does it cover? . . . 4
Step 1: Determining toxicity . . . 4
Step 2: Measuring exposure and estimating dose . . . 5
Endpoints and test species selected for developing Reference Exposure Levels (RELs) . . . 5
Acetylcholinesterase (AChE) depression . . . 6
Step 3: Establishing Reference Exposure Levels . . . 7
What are the health findings of the risk assessment? . . . 7
Step 4: Skin irritation and AChE depression are the potential adverse effects . . . 7
Sensitive populations . . . 10
Eye effects . . . 11
Illness and malathion spraying . . . 12
Cancer . . . 13
Reproductive and developmental effects . . . 14
Epidemiological studies . . . 15
Immunotoxicity . . . 15
Genetic toxicity . . . 16
Overall conclusions and recommendations . . . 16
The role of the Malathion Public Health Effects Advisory Committee . . . 17
Section two: Other studies and remaining work . . . 18
What further studies are being done on malathion? . . . 18
Acute illness report studies . . . 18
Total Reports of Symptoms—Los Angeles County, December 1989-June 1990 . . . 19
Clinical study on allergic reactions . . . 21
Urinary metabolites measurement . . . 21
CDHS study on pesticide workers . . . 22
Alternatives to aerial malathion-bait spraying . . . 22
Section three: What public can do, and should know . . . 23
Steps people can take to reduce potential exposures . . . 23
Need to prevent reinfestation: How the public can help . . . 24
Risk communication recommendations . . . 25
Task force . . . 25
Risk communication advisory committee . . . 25

Section one: The risk assessment on aerial malathion-bait

The need for a new risk assessment

Pesticides have been applied by aircraft over urban areas of California since 1977 to control insect pest infestations. The 1989-90 Mediterranean fruit fly (Medfly) eradication program in southern California has been the latest of these episodes. Medflies were discovered in July and August 1989 in the Elysian Park and Silverlake areas in Los Angeles, and eradication was attempted with one aerial application of malathion mixed with a corn syrup bait and a release of 40 million sterile Medflies. In December 1989, however, the Medfly continued to spread to other areas of southern California, and the California Department of Food and Agriculture (CDFA) announced plans to counter the spread with up to 8 to 12 nighttime aerial applications of malathion-bait. The pesticide would be applied at a rate of 2.8 fluid ounces of malathion mixed with 9.6 fluid ounces of corn syrup bait per acre.

By the time the Medfly was declared successfully eradicated on November 9, 1990, the aerial spraying had expanded to include 21 treatment locations encompassing 536 square miles in Los Angeles, Orange, San Bernardino, and Riverside counties. Approximately 1.6 million people resided within the treatment areas, with some treatment areas receiving as many as 11 aerial malathion-bait applications.

When plans for the repeated spraying were announced, environmental groups, school boards, local governments, and citizens demanded that local health departments provide information on the health effects of malathion. The Los Angeles and Orange county health departments in turn requested information from the California Department of Health Services (CDHS). The information that CDHS had at that time is as follows:

CDHS assessed the health risks of malathion in 1980 when malathion-bait was aerially applied to combat a Medfly infestation in Santa Clara County. From this investigation, CDHS concluded that the malathion-bait did not pose any significant health hazard to the public, although anxiety was recognized as a likely outcome of the aerial spraying.

One reason why aerial application of malathion was not thought to pose a significant health hazard was that malathion is one of the least toxic organophosphorus insecticides. Malathion has been used for many years in combating mosquitos and other insect pests, with few reports of illness among workers exposed to it. The lack of effect among workers made it unlikely that effects would occur in residents in the spray areas experiencing levels far lower. Malathion has been used on the skin as a prescription medicine for killing head lice in adults and children.

An issue of major public concern during 1981-82 was the potential for malathion to cause cancer. Scientific evidence did not demonstrate that malathion was a carcinogen, that is, a substance that causes cancer. CDHS, however, calculated what the cancer risk would be if it were a carcinogen. The calculation built in a number of worst-case assumptions, including the scenario of an unclothed baby playing on a lawn that was recently sprayed with malathion-bait. Even under these worst-case scenarios, the estimated additional risk of developing cancer in a lifetime did not exceed one-in-a-million, a risk that is considered negligible.

CDHS also conducted several studies during the Medfly eradication campaign in Santa Clara County to determine if there were increases in the prevalence of any acute illnesses or adverse symptoms. Two of these studies found no changes in ambulance and emergency room use immediately following the spraying. Physicians are also required to report pesticide-related illnesses, but no cases were identified. CDHS also surveyed residents within and outside the spray area before and after the first malathion-bait application. This survey found no significant increase in 28 symptoms that were asked about, but it did find a significant drop in some symptoms, especially those that were considered "anxiety-related," which included "feeling blue," "difficulty in sleeping," and "tense and anxious."

CDHS had been advising and providing public health oversight to CDFA on pesticides including malathion since 1980, and had seen no new findings reported in the scientific literature that would significantly change the conclusions of the 1980 risk assessment. Two additional epidemiologic studies of possible human reproductive effects were completed

in 1986 and 1987. These studies, which are summarized later on, analyzed hospital records to determine if there was an increase in birth defects or miscarriages during or after the 1981-82 Medfly eradication program. Neither study had findings that would suggest reproductive effects relating to the low-level exposure to malathion.

In 1985, the National Toxicology Program (NTP) re-reviewed the animal data and pathology slides and concluded that malathion is not a carcinogen and that evidence for malaoxon, a coproduct and metabolite, was equivocal; that is, it could not be determined with the available evidence. The U.S. Environmental Protection Agency (EPA) and the International Agency for Research on Cancer shared these views.

Based on all this information, CDHS anticipated no significant public health risks from the Medfly eradication program in Los Angeles. CDHS was more concerned that a failure to control the Medfly would result in greater use of more toxic pesticides in agriculture and home gardening, with increased risks to agricultural workers and urban gardeners.

After more fertile Medflies were discovered in Los Angeles County in January 1990, however, concerns about and public opposition to the aerial

Risk assessment conclusions

- After conducting a thorough review of the scientific literature and assessing all potential effects, CDHS would not expect any significant health effects for the average person in the general population from the malathion-bait as applied during the Medfly eradication program in southern California.

- According to available evidence, it does not appear that either malathion or malaoxon causes cancer, birth defects, or reproductive damage or that they would cause serious eye damage, even at much higher dosages.

- There are certain groups within the general population, such as children, the aged, the homeless, and individuals with certain preexisting disease or taking certain medications, who may potentially be more sensitive to malathion's toxicity. CDHS believes that they should be alerted so that they can reduce unnecessary exposure.

- CDHS staff projected that under certain high exposure scenarios, such as playing outdoors for four hours wearing only shorts, there is some encroachment on margins of safety for skin irritation and a 20% depression in the level of acetylcholinesterase, a chemical involved in nerve signal transmission. This level of depression is not expected to produce clinically detectable symptoms.

- CDHS would recommend taking simple precautions to avoid excessive exposures to the bait material, such as washing the skin after contact with contaminated surfaces, hosing down toddlers' play equipment, and washing backyard fruit and vegetables before consuming them. *It was assumed that these precautions were not taken when estimating the theoretical risks from potential exposures to the malathion-bait. Taking such precautions would have reduced exposures and the related health risks.*

- While individual actions can reduce health risks associated with malathion-bait applications, CDHS believes that there is a need for the development of additional information on specific biological endpoints, especially if aerial application in urban areas continues to be used as a treatment for Medfly eradication. Therefore, CDHS recommends more studies in a number of areas.

- CDHS recognizes the public's concerns about the aerial application of pesticides and the demand for development and use of pest control methods that are less intrusive and alarming. In the light of the results of the health risk assessment, CDHS recommends that aerial application in urban areas be reconsidered and that CDFA develop, and when possible, utilize available nonpesticide or selective pesticide alternatives to aerial application of malathion.

malathion-bait applications increased. CDHS Director Dr. Kenneth W. Kizer requested that CDHS staff undertake a new risk assessment on malathion. There were several reasons for this action. First, risk assessment methods had undergone major transformations since 1980, and it was important to incorporate these changes. Thus, a more detailed exposure assessment was needed, with sophisticated measures of environmental levels of malathion. Second, it was important to comprehensively review the scientific literature published subsequent to 1980. Third, the public health implications of the application of new risk assessment methods and better data on exposure and toxicology needed to be assessed. Fourth, it was important to identify and recommend where further studies were needed to reduce uncertainty.

Dr. Kizer also called for the convening of an advisory committee. The Malathion Public Health Effects Advisory Committee (MPHEAC) was convened in February 1990. It was composed of 25 members from southern California who were chosen for their medical and scientific expertise, their experience as public health officials, or their involvement in environmental organizations. The committee met frequently to review and advise CDHS in its efforts to prepare the risk assessment.

Dr. Kizer gave MPHEAC the following tasks:

- review the 1980 CDHS malathion risk assessment and the new risk assessment being prepared along with the supporting scientific literature
- provide a forum to address scientific and public health concerns about the use of malathion-bait
- review the public health issues and potential health effects of currently recognized alternative modes of Medfly eradication and compare these to the risks of aerial spraying of malathion-bait
- review the public health issues and potential health effects of not eradicating the Medfly
- review CDFA's risk communication efforts and make recommendations on what and how risk information about malathion-bait aerial spraying should be communicated to the public.

The risk assessment was completed in February 1991, and this section summarizes its main findings and describes the process of its development.

What is the CDHS risk assessment? What does it cover?

The malathion risk assessment is a summary and analysis of the health effects of malathion and its coproducts, impurities, and degradation products arising from the manufacture, storage, and environmental exposure of the commercial grade pesticide. The risk assessment addresses the question *"What is the risk posed to public health by the aerial application of malathion-bait in the form and amounts used in the Medfly eradication project?"* Answering this question must consider the amount of the pesticide applied, how much of it people would come in contact with, and how much they would likely absorb internally. With this information, actual or estimated exposures could be compared to risk levels developed to protect public health.

The risk assessment is better understood by following the steps by which it is derived. In simplified terms, these steps are as follows:

Step 1: Determining toxicity

The first step is to obtain all available information on malathion's toxic effects as well as the dose levels at which they were produced. All the studies that have been performed on malathion and its coproducts and impurities were examined. These studies included (1) experiments with animals and humans, (2) studies on agricultural workers and others who have had either repeated and/or high-level exposures to malathion, (3) studies on the chemistry of malathion and how it breaks down or degrades in the environment after it is applied, and (4) modeling studies on how malathion is distributed and excreted after it enters the body. Approximately 2300 citations on malathion and its coproducts and impurities were located in the published and unpublished scientific literature, the extensive databases maintained by CDFA and other on-line sources such as the National Library of Medicine,

and among citations submitted by the public. Roughly 500 were included in the document. More than 30 CDHS staff were involved in this effort.

Malathion has been used since the 1950s and is frequently studied. By today's standards, however, many of the toxicology studies that were done on malathion in the 1950s and 1960s are not adequate for complete public health risk assessment, and CDHS toxicologists had to use judgment in interpreting the available information. Few studies have been done on malathion's coproducts, and little is known about their health effects.

From these studies, adverse health effects or *toxicological endpoints* are identified. Also, the amount of chemical which would cause noncancer effects, *the threshold dose*, is estimated. At this stage of the process, approximately eight different types of endpoints were identified. (See table.) Some possible endpoints, such as cancer or birth defects, are not on this list because they were not found to be caused by malathion, as discussed later. Some endpoints that were included, such as behavioral effects seen only in rats, and small changes in clinical chemistry (altered counts in blood platelets, liver enzyme levels, etc.), are biological changes that can be measured, but are not necessarily adverse effects.

Of the possible endpoints in the table, later analysis showed that only two, skin irritation (and related potential allergic-type reactions) and depression of acetylcholinesterase (AChE—an enzyme involved in the transmission of nerve signals), might occur from exposure to the malathion-bait as used in the Medfly eradication. (See box on page 6)

Endpoints and test species selected for developing Reference Exposure Levels (RELs)

	Endpoint	test species
Neurological	AChE inhibition	human
	behavioral effect	rat
Skin effects	irritation, rash	human
Reproduction	testicular atrophy	rat
Development	decreased newborn weight	rat
	fetal resorptions	rabbit
Genetic toxicity	chromosome aberrations	mouse
Other effects	clinical chemistry	dog
	gastric ulcers	rat

Step 2: Measuring exposure and estimating dose

Besides toxicity, two other factors essential in determining risk are exposure and dose. Exposure refers to the amount of malathion that a person would contact in the environment through breathing it in the air (inhalation), getting it on the skin (dermal contact), or eating it, for example, on homegrown vegetables or transferring it to the mouth from dirt on the hands, as young children often do (ingestion).

Effective dose is the actual amount that is taken up on the skin or absorbed internally and is available to the organs, tissues, and cells in the body. The amount of chemical that is absorbed varies considerably according to the route or pathway of exposure: with malathion and malaoxon, it was predicted that skin contact would give the largest internalized dose, followed by ingestion, with inhalation contributing far less.

There are several reasons for this. For one, there are many ways to contact malathion, such as playing sports on lawns, doing garden work, or climbing on outdoor play equipment, and more outdoor activity would mean more contact. Inhalation, however, contributes little to the effective dose because the malathion-bait was applied in droplets that reached the ground within 15 to 30 minutes. These droplets were generally too large to be inhaled into the lungs. The malathion-bait was not intended to kill Medflies by direct contact; instead the Medflies would be killed when they ate the bait containing the pesticide. (Spraying was conducted at nighttime to reduce public exposure to the malathion-bait in air.)

To determine exposure, extensive measurements were taken of the amount of malathion and its breakdown products in air and deposited on the ground in and around the spray areas. Samples were also taken of swimming pool water. Drinking water sources were not contaminated by malathion. The ground deposition measurements

were done using special cardboard cards, which allowed examination by microscope to determine how much of the malathion-bait reached the ground. Actual concentrations in soil and on foliage or fruit had to be modeled, however.

Malathion has a half-life of three to seven days in the environment. In other words, half the malathion breaks down chemically within this period, and half of what is remaining breaks down in the next three- to seven-day period, and so on. Some of it becomes malaoxon, which is more toxic than malathion, but this breaks down even more quickly than malathion. Commercial-grade malathion is typically about 95% malathion and 5% coproducts and impurities like malaoxon. CDFA did extensive sampling of the pesticide throughout the program to make sure it met quality requirements and was properly mixed with bait.

Once the environmental levels were determined, *exposure scenarios* were then developed to estimate

Acetylcholinesterase (AChE) depression

The possibility of AChE depression of more than 20 percent was found to be the most sensitive effect of toxicological concern from exposure to malathion-bait in the Medfly eradication program. AChE is an enzyme needed for proper functioning of the nervous system. Its specific role is to neutralize acetylcholine immediately after the acetylcholine transmits a nerve signal across the nerve synapses. This prepares for the next signal to follow.

A crude analogy of how AChE works is the old telegraph system. In this system, messages were sent by tapping the key in certain sequences representing different letters. If the telegraph switch were to stick in the "on" position, a steady signal would go over the line but no information would be transmitted.

A 20 percent depression of AChE is unlikely to cause clinical symptoms but is a marker of exposure to malathion.

The symptoms that occur with severe poisoning resulting from a large exposure to a cholinesterase-inhibiting pesticide such as malathion include sweating, urination, loss of bowel control, salivation, tearing of the eyes, muscular twitching, and pinpoint pupils. Symptoms of mild poisoning include lack of appetite, nausea, vomiting, abdominal pain and cramps, diarrhea, and constricted pupils. (Because some of these symptoms closely resemble those that occur with other illnesses it is difficult to distinguish pesticide poisoning unless an exposure to a pesticide is known.) In these cases, if supportive care is given, the patients recover and permanent effects are not evident.

Clinically detectable symptoms, that is, symptoms that are directly observable, generally do not occur until there is at least a 50 percent depression of AChE. The point at which symptoms appear depends on two factors: the amount of AChE depression and the rapidity with which depression occurs. A very fast drop in AChE resulting from a large exposure could cause symptoms at less than 50 percent, but when exposure takes place in small amounts over a long time, symptoms may not be noticeable until AChE reaches a level that is 70 percent below an individual's normal baseline level.

Humans and other mammals have a liver enzyme that detoxifies malathion. Insects and fish lack this enzyme, which is why malathion is highly effective against insect pests but far less toxic to humans. (This is also why people were advised to cover their fish ponds during malathion spraying.) Exposure to a large single dose, or repeated exposures to smaller doses, however, may overcome the body's ability to completely detoxify or eliminate the active chemical in malathion rapidly enough to prevent adverse effects from occurring. This explains why the scenarios that assumed multiple exposures to malathion due to repeated sprayings resulted in a higher probability that a 20 percent depression of AChE would occur.

A 20 percent depression of AChE is not of clinical concern for healthy individuals; however, it reflects a decrease in the body's capability to respond to continuing challenges with these agents. CDHS takes the position that any biological effect from exposure to a toxic substance is undesirable, and efforts should be taken to avoid such unnecessary exposure.

how much malathion and malaoxon people would be exposed to through the different pathways under a wide range of activities and situations. These included playing outdoors in contact with malathion-contaminated surfaces such as lawns or playground equipment, consumption of unwashed and uncooked backyard-grown vegetables, working outdoors all day, and even running a marathon. Special considerations were given to unusual exposures, such as for children with pica (a tendency to eat substances not suitable for food, such as dirt) or homeless persons.

Although extensive measurements were made of environmental levels, many assumptions had to be made in estimating how much of the malathion or malaoxon that is environmentally available in the air, on vegetables, and on contact surfaces would be taken up by the body internally or on the skin. Whenever such uncertainties arose, CDHS scientists chose numerical values that would assume the more serious event could happen. This would build in an extra margin of safety for protecting public health. These health-conservative assumptions would tend to overestimate actual exposure.

Step 3: Establishing Reference Exposure Levels

The third step in determining risk or hazard involved creating some benchmarks against which the effective doses could be compared. These benchmark doses are called *Reference Exposure Levels (RELs)*. An REL is the highest dose at which no effect is observed divided by some *uncertainty factor* (sometimes called a *safety factor*) to compensate for variations among humans and the uncertainty in extrapolating from animals to humans. They were developed for each of the toxicologic endpoints that might cause either adverse effects or biological changes in humans. Their purpose is to show a level at which no effects, whether adverse or otherwise, should occur. If these benchmark doses were exceeded, it would mean that the public had some probability or risk of experiencing an effect, but not necessarily that the effect would occur. The greater the degree the reference levels are exceeded, the higher the probability of an effect.

RELs are generally based on a determination of the maximum doses in experimental studies that would *not* produce an effect (i.e., the no-observed-effect level). Therefore, health protection is achieved if the estimated or actual human effective dose of malathion is below the relevant REL. A key concept in toxicology is that for endpoints other than cancer there is a threshold level below which no effect will occur. This is due to the body's ability to detoxify the chemical compound by converting it to something nontoxic by metabolizing it or eliminating it by excretion.

Unfortunately, it is not always exactly clear what these threshold levels are because most experimental studies have been done on animals instead of humans and because some studies may lack a no-observed-effect level. To compensate for these areas of doubt, *uncertainty factors* (usually 10-fold) are applied. Their effect is to build a margin of safety into the RELs. Typically RELs include one or two uncertainty factors: one to account for possible variations in human sensitivity, which would protect the most sensitive individuals, and one for applying a dose from an animal experiment to humans if an animal experiment is used. The two uncertainty factors would give an added safety margin of 100 times the estimated no-effect level (i.e., 10x10=100).

Earlier we stated that if the RELs were exceeded, it would mean that some persons had some probability of experiencing an effect. But it is also true that effective doses greater than the RELs are not necessarily hazardous even for the endpoints involving adverse health effects because of the safety margins that RELs incorporate. If an REL is exceeded by a small amount, the risk of a health effect from that exposure is still quite low.

What are the health findings of the risk assessment?

Step 4: Skin irritation and AChE depression are the potential adverse effects

The fourth or final step in the risk assessment process was to determine the potential hazards or risks by comparing the effective doses under different scenarios with the RELs. *CDHS scientists found that for the great majority of endpoints the estimated doses were well below the RELs, and the public was unlikely to experience any adverse health effects.* Under some scenarios, however, the doses exceeded the RELs for two endpoints: AChE depression, and skin irritation in the form of rashes, itching, or burning.

Skin irritation was found to be a possible outcome from direct contact with malathion-bait. AChE depression of more than 20 percent was found to be theoretically possible in high exposure scenarios involving multiple exposures due to repeated sprayings.

In the case of skin irritation, for the scenario that assumes an adult who leads a relatively sedentary lifestyle and spends only about 30 minutes outdoors, fully clothed, the effective dose is below the REL. In the scenario of a very active toddler, the estimated mean dose is 16 times the REL. The "very active toddler" scenario assumes that a toddler would be wearing only shorts and playing outdoors for eight hours a day.

For AChE depression, the highest risk would come from the cumulative effect of repeated exposures from multiple sprayings. The "sedentary adult" scenario produces an estimated exposure two-tenths of the REL. The "very active adult" scenario produces an estimated exposure seven times the REL. This scenario assumes that the adult is an outdoor worker who is exposed to malathion in outdoor air, has extensive contact with contaminated surfaces, and eats unwashed home-grown fruits and vegetables. The "very active toddler" scenario produces an estimated mean exposure about 18 times the REL. This scenario, like that for the "very active adult," also assumes high combined exposures through the inhalation, skin, and ingestion routes.

This comparison of the estimated effective doses under different exposure scenarios with the RELs gives a *hazard index* (i.e., ratio of dose to REL) in which a value of one or less means that the REL is not exceeded and there is an ample margin of safety provided through uncertainty factors built into the RELs. Hazard index values above one indicate that the safety margin is being encroached on or exceeded depending on the margin of safety contained in the REL. *Because the margin of safety incorporated into the REL for both skin irritation and AChE depression is 100, there is still a margin of safety remaining even in the highest exposure scenarios.* The highest hazard index level calculated was 40 for AChE depression for the "very active toddler" when an upper confidence limit (UCL) value of 98 percent was applied. Statistically, this means that one would expect no more than two percent of the population to have a greater exposure.

Because malaoxon constitutes less than 1% of the commercial malathion product and there is less of it in the environment, the hazard index levels for malaoxon are less than for malathion, although it is more toxic. The "very active toddler" scenario for malaoxon has a mean hazard index for AChE depression of only 1.

It must be emphasized that the risk of these outcomes is theoretical and is based on health-conservative assumptions that were made throughout the risk assessment process. As just one example, it was assumed that backyard-grown vegetables would be unwashed and uncooked when consumed although studies indicate that washing and cooking may remove 44 to 80 percent of the malathion (Washing alone may remove 28 to 67 percent of malathion). Although the calculated risks expressed in the hazard index numbers could theoretically be achieved, it is improbable that all the assumptions built into the calculations would be met by any individual. Moreover, the existence of the safety margins for these endpoints makes it more unlikely that adverse health effects will actually occur.

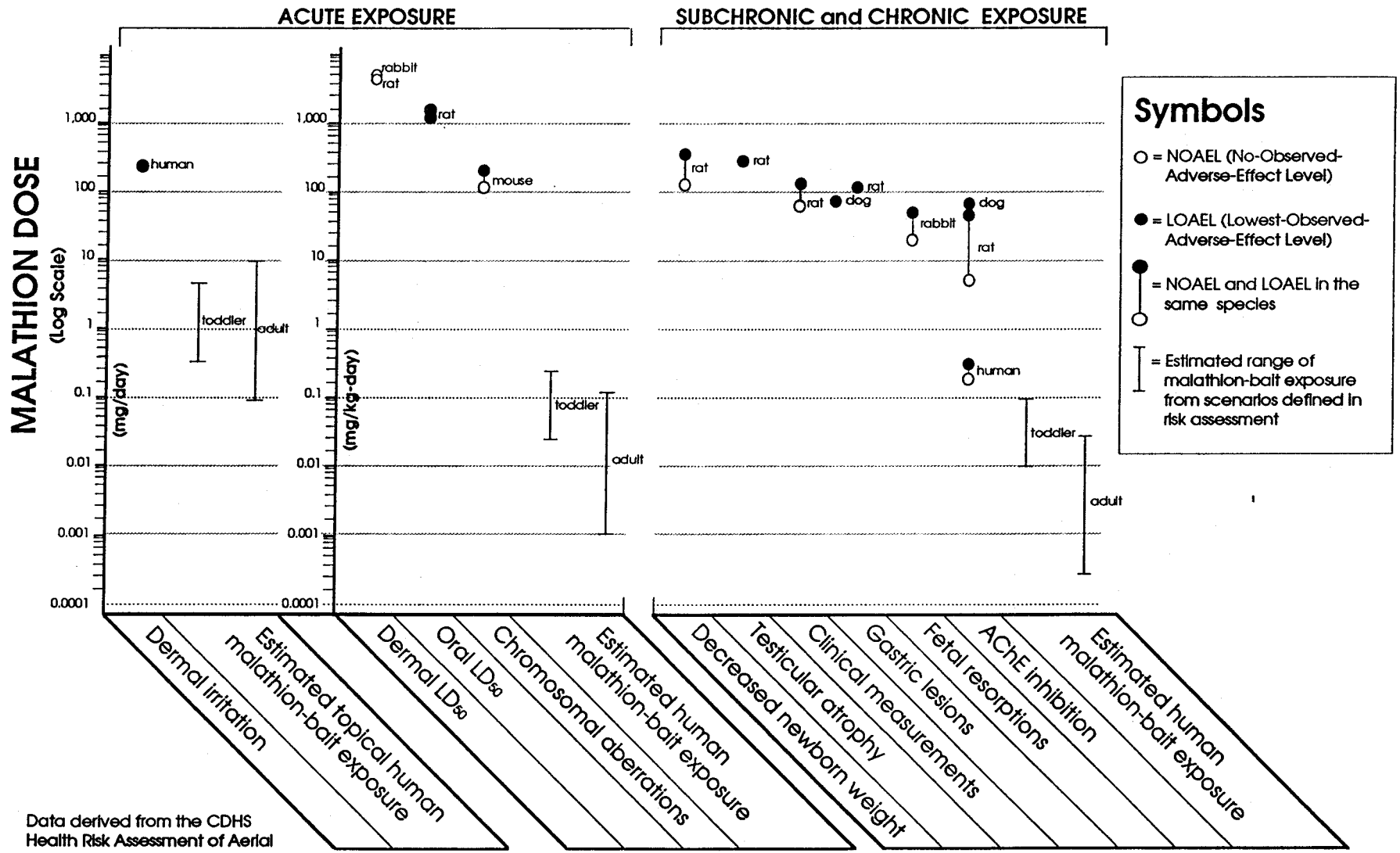
Nevertheless, the fact that the RELs were exceeded in some of the theoretical scenarios indicates the prudence of taking general precautions to reduce exposure. Such precautions would include washing the skin following contact with malathion-bait, covering sandboxes and other such play areas or hosing down toddlers' play surfaces when feasible during malathion-bait spraying, remaining indoors during nighttime aerial applications of malathion-bait, and washing backyard-grown vegetables before consuming them. These precautions were not figured into the exposure scenarios used in the analysis, and it would be expected that the estimates of theoretical hazards would be greatly reduced if these precautions were incorporated into the risk assessment.

The figure on page 9 graphically compares estimated malathion doses from aerial bait application with experimental doses that caused toxicity selected from studies reviewed for the risk assessment. This comparison demonstrates that the estimated ranges of doses for the average adult and child in the general population from environmental exposure to malathion-bait are below the doses that produced toxic effects under experimental conditions.

Several points should be made to explain the figure. Doses used in experimental studies are typically expressed on a per weight basis and can be compared directly with the estimated malathion exposures. However, for topical effects such as dermal irritation, exposures are expressed as a total dose received.

The toxicological endpoints were selected from a large array of studies that were included in the full

COMPARISON OF EXPERIMENTAL DOSES WITH ESTIMATED HUMAN DOSES FOR MALATHION-BAIT EXPOSURE



Data derived from the CDHS Health Risk Assessment of Aerial Application of Malathion-bait Feburary 1991

TOXICOLOGICAL ENDPOINT

risk assessment review to describe malathion toxicity, but the data shown here are not all-inclusive. LD_{50} doses refer to the levels that produce death in half the animals dosed, a common measure of lethality in toxicity studies. The LD_{50} for orally administered malathion is included for rats, but dermal LD_{50}s are not known and only a no-observed-adverse-effect level can be given here (The actual LD_{50}s would be higher). Also, acute exposures are usually defined as lasting about one day or less.

The graphic display does not tell the quality of the studies, and it is important to be aware of the limitations of the studies, as discussed in the full risk assessment report, before making judgments. Also, because of the millionfold spread in doses represented in this figure, a log scale was used to compress the information for graphical representation. The inexperienced reader should be aware that each major division on the left vertical axis of the figure is ten times higher or lower than the adjoining one. Finally, it should be pointed out that although the graph indicates margins of safety between the experimental and estimated exposure doses, uncertainty factors were not applied to the experimental doses as was done to develop RELs.

Special cases

Some special cases of exposure were also estimated that would exceed what the population would typically receive. For example, the dose was estimated for a child who stays outdoors during the malathion-bait application and is exposed directly to the bait droplets. For this exposure alone, the estimated acute dermal dose exceeds the dermal REL by up to 18 times. Homeless persons who spend the majority of their time outdoors may receive significantly higher dermal and ingested doses than the general population. For some people like the homeless, the precautions listed above would be difficult to follow.

Sensitive populations

Some groups within the general population may be potentially more susceptible to the effects of toxic exposure, such as to malathion-bait spraying. These groups include children, persons taking certain medications, persons with preexisting diseases, and persons who are heavily exposed to other insecticides.

Two other groups also need to be mentioned: individuals with a predisposition to allergy and individuals who are reportedly sensitive to multiple environmental chemicals. For persons with allergy, the evidence for allergic reactions to malathion-bait is lacking, and recent skin patch tests for allergic reactions to malathion have so far been inconclusive.

Regarding "environmental illness," the risk assessment states: "None of the studies that have been published and cited in the reviews [considered in the risk assessment] specifically includes the relationship between malathion exposure and syndromes of environmental illness. The published articles regarding the alteration of immune parameters before and after various treatment methods also do not provide adequate evidence to conclude that immune dysfunction results from occupational and environmental exposure either to malathion or other chemicals in general, or that immune dysfunction due to environmental exposure can be correlated with clinical disease."

Children

Of the groups mentioned above, CDHS reviewed hazards to children for several reasons. For one, children are already *theoretically* at risk because of their higher exposure to cholinesterase-inhibiting pesticides because they eat proportionately more fruits and vegetables than adults per unit of body weight, and their daily food consumption relative to body weight is also higher. The estimates of dietary risk are theoretical because they are based on the many allowable levels of pesticides in food; *actual* pesticide residues on food may be less than one percent of these levels, according to U.S. Food and Drug Administration market basket studies. (Whether children are at risk from pesticide residues in food is a controversial issue. The National Research Council of the National Academy of Sciences is currently studying this matter and is expected to issue a report later this year.)

Children also may have higher exposure to anticholinesterase compounds due to normal exploratory and hand-to-mouth activity, greater length of time spent outdoors, and higher consumption of backyard vegetables and soil.

Children with certain metabolic diseases might have increased or decreased sensitivity to these compounds.

While we have no documented evidence with low-level exposures, in theory malathion at much higher levels may also intensify common childhood conditions. In the respiratory tract, for example, bronchial muscle contraction and bronchial secretions may in-

crease, which might affect children with asthma at lower levels than other children. Evidence for such changes in the Santa Clara population in 1981 or in the Los Angeles population in 1990 could not be found.

Children living in poverty are thought to be potentially more susceptible to any toxic insult because of compromised health status. Surveys have indicated that children in this category are more likely to have more severe asthma, more illness, lead poisoning, and iron-deficiency anemia.

Increased sensitivity due to medication or preexisting diseases

Persons being medicated with certain drugs may have a greater sensitivity to cholinesterase inhibitors. These drugs may include:

1) AChE inhibitors
2) Anticonvulsant drugs
3) Drugs for heart disease
4) Drugs that alter blood flow in the liver

Individuals with Parkinson's disease taking anticholinergic agents may have heightened sensitivity to AChE depression. Skin abrasions are likely to increase the uptake of any toxicant.

Exposure to other insecticides

Exposure to other pesticides may increase sensitivity, especially those that inhibit the carboxylesterase enzymes responsible for the detoxification of malathion. Isomalathion, which occurs as a low-level impurity in malathion, inhibits this enzyme and is toxic as a result. Hundreds of the samples of malathion used on the project were analyzed for isomalathion. None was detected at a sensitivity of 0.2%.

Conclusion on sensitive populations

A number of groups, as discussed above, have been identified as potentially having greater sensitivity to malathion. These are concerns that are operative primarily in the workplace setting where exposure to toxicants such as pesticides including malathion are far higher than those resulting from malathion aerial bait application. Nevertheless, in recognition of human variability, including sensitive populations, the RELs for malathion includes at least one 10-fold uncertainty factor.

Eye effects

One special concern that emerged early in the aerial application program was the allegation that malathion spraying would cause eye damage, including loss of vision. This claim was based on a few reports from a single group of investigators in Japan in the early 1970s. MPHEAC was immediately asked to give its full attention to this issue and spent several months examining the evidence in detail. The principal author in Japan was contacted, and these reports were thoroughly investigated by CDHS staff and members of MPHEAC.

MPHEAC unanimously adopted a consensus statement that said "that eye damage and vision impairment in Japan were part of a large epidemic of pesticide poisoning in children resulting from indiscriminate use of agricultural pesticides. These findings may signal the need for better research, but they do not apply to the malathion bait application program for Medfly."

MPHEAC cited several points as a basis for its findings, as follows:

> "Pesticides having as much as 100 times greater acute and chronic toxicity than malathion were used in Japan. Several of the pesticides used in Japan were banned in California because of their extreme toxicity and their ability to directly damage nerves.
>
> "Pesticide applications in Japan involved quantities many times greater than those used in the Medfly program. Farmers regularly sprayed their fields with potent organophosphates, and, in addition, the Japanese government routinely conducted aerial pesticide applications to the same fields.
>
> "The Japanese pesticide applications were intended to kill pests on contact by drenching the crops. The fine mist spray could remain suspended in air for a long time, increasing the chance of inhalation. The bait mixture used for Medfly settles out of the air quickly, reducing the potential for public exposure, and only kills insects when they eat it.
>
> "The intermingling of small fields and houses in Japan brought about public exposure to full-strength agricultural pesticide spraying in the air and through drinking water contamination with pesticides. Drinking water contamination is not associated with the Medfly program.
>
> "Japanese children reported to have suffered eye damage and visual impairment were also reported to have suffered long-term cholinesterase depression (a condition of impaired nerve conduction) resulting from lengthy exposure to several very potent organophosphate pesticides.
>
> "Fundamental design flaws in the Japanese studies make it difficult to conclude that a causal ef-

fect of organophosphate pesticide exposure on eye disease has been convincingly demonstrated.

"Animal toxicology studies of the ocular effects of organophosphate pesticides conducted by Japanese investigators do not meet modern laboratory standards and are difficult to interpret. In its review of the scientific literature, the Committee found no evidence that malathion has ever been tested for chronic ocular toxicity in animals. While there is some evidence that chronic, high level exposure to other organophosphates can cause ocular toxicity, the Committee finds no scientific evidence that any organophosphate pesticide has ever been shown to cause chronic ocular toxicity at doses below those which cause systemic poisoning as evidenced by depression of cholinesterase levels. The Committee concurs with EPA on the need for modern toxicology studies in animals to better understand the potential of malathion and other organophosphate pesticides to damage the ocular system.

"Despite widespread, intensive use of organophosphate pesticides throughout the United States for several decades, only a small number of workers who handle or come in close contact with organophosphate pesticides have been reported to have developed chronic ocular toxicity. All of these cases were associated with overt poisoning (systemic toxicity). None of these human cases was associated with documented malathion use. Due to the rarity of ocular effects among heavily exposed agricultural workers, the Committee believes it is extremely unlikely that the small amounts of malathion in the aerial bait mixture pose a risk of chronic ocular toxicity."

At MPHEAC meetings two local eye specialists raised the concern about the possibility of malathion-bait exacerbating the effect of organophosphate medications used to treat glaucoma and myasthenia gravis in certain patients. Many of these drugs are far more potent than malathion and rely on large pharmacological doses to achieve the desired medical effects, often to the point of causing systemic cholinesterase inhibition in the patients taking them. The relatively small potential exposure to malathion-bait would be unlikely to materially affect their clinical status, in that the dose of malathion would be insignificant in comparison to the large amount of organophosphate administered in the medications. Such patients face a far greater risk from overmedication than from malathion.

After a long and careful review of the potential eye effects of malathion, MPHEAC concluded: "A review of the scientific literature shows that viable questions exist regarding malathion's ability to produce external eye irritation, a reversible condition. Acute exposure to high levels of organophosphate pesticides, including malathion, can cause temporary visual disturbances, but are not anticipated to result from the Medfly eradication program. There is no convincing evidence of lasting visual impairment from chronic exposure to malathion, particularly at the low levels likely to be encountered from the malathion bait application."

Since MPHEAC made its findings, DHS has discovered and had translated from Japanese a more recent scientific article from Japan which casts doubt on the accuracy of the diagnoses of eye disease in the original reports. A Japanese eye specialist, not involved with the earlier reports, examined a number of patients that had previously been diagnosed by the original investigators as suffering from organophosphate-induced eye disease. He found that all of them had been misdiagnosed and that they had relatively common eye problems, many of which had been inappropriately treated and were easily correctable with proper therapy. He was openly skeptical of the original claims of widespread organophosphate-induced eye disease. Reports such as this emphasize the need for caution in interpreting the original reports, particularly since the original reports have not been corroborated by other groups of investigators in Japan or anywhere else in the world. CDHS is confident that the conclusions of MPHEAC that malathion-bait poses no threat of chronic eye disease are scientifically valid.

Illness and malathion spraying

The risk assessment was based mainly on studies involving humans or animals exposed to large doses of malathion. Estimating effects at the much lower doses experienced by the population in the spray areas requires extrapolating over a wide dose range. Some persons reported acute illness or symptoms such as skin rash or headache or nausea they believed were associated with the pesticide.

Cases of people experiencing these effects were often the subject of news reports. The Los Angeles Department of Health Services, whose phone number was made widely available for those with health questions or symptoms, logged in over 1,800 cases of self-reported illness. Citizens who felt they had been made sick by the malathion-bait appeared at the advisory committee meetings and described their experiences.

Is it likely that malathion caused these health problems? Epidemiological studies of illness in ex-

posed populations are being conducted. Clinical evaluations are in progress or have been proposed to directly test and measure clinical signs and symptoms such as skin reactions to patches containing malathion, or respiratory effects when people are given measured doses of malathion in test chambers. Some individuals may show an allergic response to the corn-syrup protein bait rather than to the malathion itself. Preliminary results from these studies are discussed in section two of this summary.

Cancer

One of the most difficult issues encountered in the risk assessment was the issue of malathion and/or malaoxon's ability to induce cancer. This subject received extensive deliberation from CDHS staff and the advisory committee.

CDHS does not classify either malathion or malaoxon as a carcinogen because of a lack of good evidence of carcinogenicity, and thus did not determine cancer potency or estimate cancer risk in the health risk assessment. This decision was arrived at after a long and careful review of the data, reevaluations of the malathion and malaoxon cancer bioassays (studies involving the administration of doses to laboratory test animals), and consultation with several scientists from the U.S. Environmental Protection Agency (EPA), the National Toxicology Program (NTP), and other organizations that participated in conducting these studies or in interpreting the results.

From its review of the available data, CDHS concluded that the evidence that malathion produced a carcinogenic effect in the animals tested was inadequate. CDHS concluded, however, that there was equivocal or uncertain evidence of a carcinogenic effect of malaoxon in male and female rats arising from the increased incidences of thyroid C-cell adenomas and carcinomas (thyroid tumors) among dosed animals compared to controls (animals not dosed with malaoxon). These views are shared by EPA, NTP, the National Cancer Institute, and the International Agency for Research on Cancer.

After CDHS staff presented its review of the cancer data in March 1990, MPHEAC formed a nine-member subcommittee to conduct its own review of the cancer bioassay data and reach a consensus opinion on carcinogenicity. During its eight months of deliberation, the subcommittee consulted with staff at CDHS, NTP, and EPA. The subcommittee not only tried to settle the question of carcinogenicity, but also considered what the risks would be if malathion were carcinogenic. In November, the subcommittee issued a statement, which was adopted by the full MPHEAC, concluding that *"the evidence that malathion is even weakly carcinogenic is suspect and that, even if it were weakly carcinogenic, the risk to the public would be negligible."*

In the statement, the subcommittee explained its conclusion as follows:

> The strongest evidence [of carcinogenicity] relates to the induction of certain tumors of the thyroid gland in rats by malaoxon. In a 2-year feeding study, three dose groups of 50 male and 50 female rats were given malaoxon in the diet, one group at 500 ppm (low dose), a second group at 1000 ppm (high dose), and a third group given none at all (control). At the end of the experiment, the rats were killed and autopsied. A statistically significant dose-related trend in C-cell thyroid tumors was found in both male and female rats. In another study, malaoxon showed no carcinogenic effect in mice, and malathion itself showed no carcinogenic effect on the thyroid gland in experiments with either rats or mice.
>
> Weak associations were also seen for certain other cancer sites, but none showed any consistent patterns across sexes, species, or the two chemicals tested.
>
> Alternative mechanisms have been considered for the thyroid tumors. One possible mechanism is a direct genotoxic action which is consistent with data for both malathion and malaoxon showing effects on chromosomes. A second mechanism is an indirect action of chronic irritation induced by the extremely high dose used in the experiment, a mechanism that would not likely be operating at the doses that the public is exposed to from the aerial application of malathion-bait used in the Medfly Eradication Program.
>
> The daily doses used in the animal experiments were more than a million times higher than the estimated lifetime daily doses for the current aerial application. Various methods have been used to estimate the cancer risk which this community exposure might pose if malathion were in fact carcinogenic, and all indicate that the resulting theoretical excess lifetime cancer risk would be less than one in a million. This is a widely used criterion for negligible risk in cancer risk assessment.
>
> The Committee noted the long and widespread use of malathion by farm workers, manufacturers, home gardeners, as well as applicators involved in community aerial application programs, with no evidence of a carcinogenic effect having been reported to date. However, all of the available epidemiological studies have major limitations, and it is unlikely that any epidemiological studies of

malathion exposure would be able to detect anything other than large increases in risk.

The Cancer Subcommittee was unable to reach a consensus on how malathion should be classified under the guidelines used by the EPA and other regulatory agencies—whether as category C ("possible human carcinogen") or category D ("unable to classify"). The reason for this lack of consensus was primarily difficulties in the interpretation of the data and questions about the adequacy of the studies themselves. Similarly, the Peer Review Committee of EPA's Pesticides and Toxic Substances agreed that malathion is not classifiable as to human carcinogenicity because of inadequacy of the available studies to make a definitive determination. This decision represented the conclusion of a majority of the EPA committee; the vote was not unanimous. One member of the [MPHEAC] Cancer Subcommittee felt that the uncertainties described above were so large that one could not conclude with certainty that the risk to the population was negligible. Nevertheless, all members felt that the risk was likely to be quite small.

The equivocal nature of the pathology data is of public concern considering the widespread use of malathion. In response, the EPA has recently called for a new series of animal carcinogenesis experiments using modern protocols. However, in our opinion, the current state-of-the-art of rodent bioassays has limitations in the detection of compounds that may be weak human carcinogens. For malathion and malaoxon, the Committee believes that there is a need for studies, in addition to the standard cancer bioassay, which would permit a better understanding of the suggestive endocrine pathology observed in the NCI chronic rat studies.

CDHS is concerned about the lack of resolution on the carcinogenicity of malathion and malaoxon and concurred with MPHEAC that there is a need for studies to resolve this question and to examine the suggestive endocrine pathology observed in the NCI tests. EPA has already notified the manufacturers of malathion that they are required to perform three new cancer bioassays on malathion and malaoxon in rats and mice. The details as to how these studies will be conducted are being negotiated with the principal manufacturer, American Cyanamid. Results of the two-year feeding studies are anticipated in approximately four years partly because of the time required to analyze the histopathology slides and perform statistical calculations. The former activity involves examining thin slices of tissue under microscopes to detect small tumors or changes indicative of cancer.

Reproductive and developmental effects

Reproductive effects

After reviewing the experimental studies, CDHS concluded that there was no evidence that malathion affects the female reproductive system. Effects on the male reproductive system have been reported, however. Several studies in male rats have demonstrated testicular atrophy following long-term exposures at high dose levels. The effect of this on reproductive success is unknown. An REL was developed for male reproductive toxicity, which was not exceeded under the exposure scenarios developed.

Developmental effects

Based on studies conducted in the 1980s and in 1990, CDHS concluded that at high dose levels there is limited evidence for developmental toxicity, which covers a wide range of outcomes including birth defects. These studies may be summarized as follows:

- A 1990 study in rats showed postnatal development (e.g., decreased pup weights) at maternal doses of 394 and 595 milligrams per kilogram of body weight per day (mg/kg-day) and but not at 132 mg/kg-day.

- A 1984 study in rabbits demonstrated reduced maternal weight gain and greater increases of fetal resportions (With rodents, at an early stage of development, a dead fetus may be absorbed back into the dam rather being aborted) at the two higher doses (50 and 100 mg/kg-day) but not at the low dose of 25 mg/kg-day. There was a statistically significant increase in maternal mortality at all doses.

- Two teratology studies were conducted on rats in 1984 and 1990. The former study showed an increased incidence in the appearance of hemorrhagic spots on the backs of pups from dams administered the highest dose (50 mg/kg-day), but this effect is not considered an adverse health effect and is of little consequence to the pups. The latter study showed a small and transient decrease in weight gain in dams receiving the highest dose of 800 mg/kg, but no birth defects were noted in offspring.

Malathion in these studies was usually administered by gavage (inserted directly into the stomach through a tube) over a period of days or weeks. These doses are much higher than what even the highly exposed individuals might receive in the Medfly eradication program.

Epidemiological studies

Two epidemiological studies were conducted on reproductive outcomes associated with the 1981-1982 Medfly campaign in Santa Clara County. The first study, by CDHS scientists, reviewed hospital discharge summaries for congenital anomaly codes. Six "statistically significant" effects were seen in incidence rates: four increases and two decreases. Eight "statistically significant" increases in incidences of defects would have been expected based on chance alone because 150 different types of birth defects are possible. The four anomalies showing significant increases in incidences were anomalies of the ear, bowed legs, deformity of the foot, and club foot; none of the anomalies showed excess incidences, however, in comparison to *both* 1981 and 1982 unexposed groups. For each of the anomalies, the rate of occurrence is lower in the 1981 exposed group than in the 1982 *un*exposed group, suggesting a general elevation in 1982 not limited to the exposed group.

The authors concluded that overall no important association was found between low dosage aerial application of malathion and the occurrence of congenital anomalies and low birthweight among liveborn infants. Moreover, no consistent pattern was found among the anomalies that would suggest a biologically plausible association with the low-dose malathion exposure.

The study had limited sensitivity to detect an effect because the hospital records gave information only up to time of discharge. Because half of all birth defects are detectable only about one year after birth, some would have been missed by the study. Case ascertainment, however, should be similar in both exposed and control areas, so it is not clear how much this affected the power of the study.

A second study was conducted with CDHS funding by the Kaiser Research Foundation and Dr. Duncan Thomas of University of Southern California (Dr. Thomas is also a MPHEAC member). This study was designed to overcome some of the limitations of the other study by obtaining detailed information on exposure and potential confounding factors on individuals (e.g., maternal age, health status, etc.), although on a smaller sample. The study also used medical information on women registered at the Kaiser Permanente facilities, and reviewed spontaneous abortions (miscarriages) as well as congenital anomalies and intrauterine growth retardation. This study found inconsistent and non-statistically-significant associations between spontaneous abortions and stillbirths for certain exposure variables. Of ten types of anomalies, some were increased and others decreased. Although some small positive trends were seen, because of their inconsistency they were not thought to represent an association with exposure to malathion. Intrauterine growth retardation was also considered not associated with malathion exposure.

Immunotoxicity

Disease resistance and allergic reactions

Chemicals may interfere with the immune system and may decrease resistance to diseases such as infections or tumor growth. Animal experiments with malathion have shown enhancing and depressing effects in immune functions depending on factors such as the level or repeat administration of the dose. These studies have examined certain factors in immune function, such as serum factors and cellular components, but have not evaluated the end result of these changes, which is the effect on the ability of the host animal to resist disease. This is usually measured by challenge with an infectious agent or transplantable tumors after the animal has been treated with a chemical. For malathion these experiments have not been done.

The main concern is the finding in some experiments of depressions of immune function at high levels of exposure to malathion. There is a reserve capacity, however, so that even though immune function is depressed, there is no decrease in host resistance to disease until a certain point is reached. Some sensitive groups, such as the malnourished, may have a limited reserve capacity for resisting disease and thus may have an increased risk of disease if exposed to malathion. Without studies showing where the point of reserve capacity for disease resistance is exceeded, CDHS could not develop an REL for this endpoint and estimate risk. CDHS recommends that further research be done in this area.

A concern has been raised with regard to the potential for an allergic response (i.e, immediate reaction) or delayed-type hypersensitivity following ex-

posure to the malathion-bait. There is no data in the scientific literature indicating that malathion causes allergic response in animals or humans, and data on delayed-type hypersensitivity are suggestive but not conclusive. As reported later in this summary, clinical studies are being conducted by the Los Angeles Department of Health Services on some volunteers who reported allergic responses to the malathion-bait.

Genetic toxicity

In 1980 when CDHS did the first risk assessment, it was not thought that malathion caused genetic damage. Since 1980, however, several published studies have shown that malathion has the ability to damage genes. This is one of the major new findings examined in the new risk assessment. The human health implications of these findings, however, are not clear.

It is not known whether malathion causes genetic damage in humans. The question has not been adequately addressed. In a few epidemiological reports, pesticide applicators exposed to commercial malathion and other pesticides have exhibited higher levels of chromosomal damage than have persons without such exposures. This damage, however, may not have been caused by malathion but by exposures to other mutagenic or gene-damaging factors (for example, other pesticides, cigarette smoking and alcohol consumption). Consequently, these studies are considered inadequate to determine whether malathion was the specific agent that caused the genetic damage.

In animals or in cell cultures of human or animal cells, commercial malathion has been shown to cause damage to chromosomes. Chromosomes are very long molecules of DNA complexed with protein, containing genetic information arranged in a linear structure. In cytogenetic studies, this damage is measured by counting chromosome abnormalities (a group of conditions associated with abnormalities in the number or structure of chromosomes that can be produced by insertion, deletion, or rearrangement of chromosomal segments) or micronuclei in bone marrow. In contrast to these effects on chromosomes, malathion does not appear to cause the less visible gene mutations (point mutations or deletions) in standard tests for these effects. If malathion does interact with the genetic material, it appears to do so via mechanisms that produce effects at the level of the chromosome rather than at the level of the gene.

The chromosomal effects in animals and cell cultures indicate that malathion has the potential to cause genetic damage in humans. Whether any effects are detectable in humans depends very much upon dose levels. The dose levels that caused chromosomal damage in animals were much higher (about 10,000-fold) than the levels experienced by residents exposed to aerial malathion-bait application. At these low dose levels, standard epidemiologic or cytogenetic methods are unlikely to be sensitive enough to directly measure genetic damage even if very large (e.g., 500) study populations are used.

If malathion, its contaminants, or breakdown products were capable of causing genetic damage in humans, what would the health significance be? Chromosome abnormalities, or mutations, are not clinical effects. They are surrogate measures of other effects in the body. The consequences of mutation may include cancer, birth defects, atherosclerosis, cataracts, or aging. Alternately, they may have no effect, or a beneficial effect, as in evolution. Many mutations occur naturally, and are not necessarily associated with deleterious outcomes. Increased numbers of mutation are not likely to produce in an individual a beneficial effect.

CDHS concludes that it is not possible at present to estimate risks of cancer or risks of adverse reproductive outcomes or other health effects based on levels of measured genetic damage. Consequently, an REL was not developed for genetic toxicity.

Overall conclusions and recommendations

After a thorough review of the literature and documentation on the toxicology of malathion and its related products, CDHS does not expect any significant health effects in the average person in the general population from the malathion-bait as applied during the Medfly eradication program in southern California.

CDHS concludes that there is insufficient evidence to classify malathion or malaoxon as either carcinogens, teratogens, or reproductive toxicants, or to believe that they would cause irreversible eye damage. CDHS does conclude that there is evidence that malathion has the potential to cause genetic damage in humans, but it is unlikely to be a significant hazard in humans at the dose levels experienced by the population in the spray areas. The potential doses of malathion exposure estimated in

the risk assessment are generally below the RELs that CDHS developed to protect public health.

For two toxicological endpoints, skin irritation and acetylcholinesterase depression, the RELs were exceeded under certain exposure scenarios. These scenarios include eating unwashed and uncooked vegetables grown in the backyard and spending a minimum of four hours a day wearing only shorts during, or closely following, a malathion application. In deriving RELs for human exposure, a 10-fold uncertainty factor was applied to account for variability within the general population. The dose estimates in some scenarios exceeded the REL by 10 times; there is little or no margin of safety for individuals who would receive malathion doses estimated under these scenarios. Based on these results, CDHS believes that some individuals in the population, such as children, the aged, those on certain medications, the homeless, and individuals with certain preexisting diseases, who receive average or well above average exposures to malathion are at a greater theoretical risk of exhibiting some health effects (i.e., skin irritation or rash, or 20 percent acetylcholinesterase inhibition) from aerial malathion-bait application than the average adult in the general population.

Certain simple precautions can greatly reduce exposures. These precautions include washing the skin after contact with contaminated surfaces, hosing down toddlers' play equipment, and washing backyard fruit and vegetables before consuming them.

CDHS recognizes that considerable data are already available for the assessment of health risks of malathion, and that these data may be adequate to support its continued registration (licensing) for use in agriculture to control insect pests. However, CDHS also recognizes that data that are developed for a pesticide to evaluate its use in applications in agricultural settings are not necessarily the same data that would be required for public health reasons to assure that the periodic application of the same pesticide over a large human population would be without significant risk. Therefore, the risk assessment document contains numerous recommendations for further research, particularly in the areas of cancer, reproductive and developmental toxicity, metabolism and pharmacokinetics (the study of how a chemical enters and leaves the body), and immunotoxicity. Human exposure estimates could also be improved by an expanded environmental monitoring database and newer, more sensitive biological monitoring methods.

Because of the concerns set forth in this document, specifically the small margins of safety for certain groups in the population, and the need to develop additional information suitable for evaluating exposures of urban populations to malathion, CDHS recommends that the aerial application of malathion-bait in urban areas to eradicate agricultural pests be reconsidered. Although the theoretical health risks from exposure to aerially applied malathion-bait in the general population may be reduced by following some simple precautions, potential exposures in some subpopulations may not be avoided as easily. DHS recognizes the public concerns related to the urban aerial application of pesticides such as malathion to control economic pests, and urges the development and use of more selective pest control methods that are less potentially toxic, intrusive, and alarming. (Studies to this effect are in the proposal stage, as discussed below.)

The role of the Malathion Public Health Effects Advisory Committee

To help ensure that risk assessment would be scientifically accurate and comprehensive, the CDHS director established the Malathion Public Health Effects Advisory Committee. This committee represented a broad range of scientific and medical expertise in such relevant areas as toxicology and environmental health as well as a variety of views regarding the use of malathion.

The committee has been highly involved in reviewing a number of issues, as well as on commenting on the risk assessment in various drafts. As already indicated, MPHEAC issued statements on eye damage and carcinogenicity. The committee will continue to be involved with CDHS in exploring the health effects of alternative ways of eradicating the Medfly as well as the risks of not eradicating it, which was not covered in the scope of this risk assessment. MPHEAC has discussed the possibility of producing a separate report documenting its work (This might be a compilation of the minutes of the meetings) and recommending the specific studies it believes necessary for a complete investigation of the health effects of malathion and its coproducts.

MPHEAC meetings have been open to the public and have served as an important public forum. Interested citizens have regularly attended the meetings

and been able to ask questions and offer comments. Physicians from the southern California area have brought their concerns to the meetings, for example, about eye effects, and had their views addressed. Some of these discussions appeared on television nightly news reports and in newspapers. At one early meeting a large group of concerned citizens appeared before the committee and testified about health effects they were experiencing, which they attributed to the malathion-bait spraying. Members of this group appealed for a halting of further spraying until all health studies could be completed. In spite of the emotionally charged testimony, the committee decided on the basis of the considerable existing scientific information about malathion, a cessation to the spraying was not warranted.

Section two: Other studies and remaining work

As already noted, the risk assessment recommends that additional studies be conducted to further investigate the health effects of exposure to malathion. Some studies, including an analysis of acute illness cases reported by callers during the 1989-90 eradication program, have already been undertaken by CDHS and county health departments in California. This section of the summary provides information on these studies, as well as on some related issues not addressed in the risk assessment.

What further studies are being done on malathion?

Acute illness report studies

Los Angeles County

The Toxics Epidemiology Program (TEP) of the Los Angeles Department of Health Services, under the direction of Dr. Paul Papanek, has been involved with the surveillance of acute medical problems in the community that might be associated with the aerial applications of malathion in the 1987, 1988, and 1989 Medfly eradication campaigns in Los Angeles County. TEP staff have provided telephone consultation to any callers with medical questions regarding the campaigns. Staff have also collected information about any cases of illness arising shortly after any aerial application, as reported by an affected individual or by a health care provider.

The TEP phone number was publicized widely to assist these efforts. It was placed on spray notification fliers. It was listed on information sent to physicians and emergency rooms in spray areas (TEP did two informational mailings to more than 20,000 health care providers in the spray areas in 1989 and 1990). The Medfly Hotline operated by CDFA also referred callers with medical questions to TEP.

In spite of these publicity efforts, some persons complained that people did not know where to call or had difficulty reporting illnesses. One citizens group asserted that many callers were either not able to get through to the county health department or were ignored when they complained of health symptoms. This group publicly claimed to have logged more than 10,000 reports of illness although it repeatedly refused to make its records available for verification or study, even if the names of cases were removed to preserve anonymity. Dr. Papanek, who is an MPHEAC member, reported that his staff put in many hours of overtime to be available to record illness reports from callers.

Despite hundreds of frightened or angry calls typically received before each aerial application of malathion-bait, before October 1989 TEP staff received no calls or case reports from any health care provider relating a case of illness to the aerial applications. Until that time, the number of reports of illness reported by callers with plausible exposure to malathion-bait was typically four to six reports per aerial application with no evident pattern of common symptoms. Between December 1989 and June 1990, however, TEP received approximately 10,000 calls. Most of these were requests for information or calls from citizens expressing anger or frustration at the continuation of the eradication program. Out of these calls, 1,874 reports of illness were received. A final report on the analysis of these illness reports is expected soon, but the preliminary results reported by TEP in September 1990 are considered quite accurate and will be summarized here.

Exposures for each person reporting an illness were ranked into three categories: plausible, borderline, and remote. A plausible exposure was defined as direct exposure out-of-doors within two hours of the actual aerial application, or direct skin contact subsequently with a sprayed object or sprayed surface. A borderline exposure was defined as living or spending a significant amount of time in a spray area or within one quarter mile of a spray area, but without the immediate circumstances of exposure required for a "plausible" categorization. A remote exposure was defined as any exposure not included in the plausible or borderline category.

Of the 1,874 illness reports, 1,431 were for adults and 417 for children. Among adults, reports regarding women outnumber reports regarding men approximately 3:1 while among children, reports regarding boys outnumber reports regarding girls by approximately 25 percent. Thirty-eight of the illness reports were from physicians. Of the physicians who made illness reports to TEP, 18 confirmed association of illness with malathion application, 14 were unsure of such an association, and 6 did not confirm an association.

Total Reports of Symptoms—Los Angeles County, December 1989-June 1990

Headache	30%	585
Nausea	25%	471
Sore Throat	21%	397
Nasal congestion	21%	392
Cough	18%	342
Eye Irritation	17%	313
Diarrhea	12%	222
Skin Rash	11%	213
Asthma	10%	190
Dizziness	10%	187
Malaise	10%	179
Shortness of Breath	8%	153
Chest Tightness	8%	152
Sneezing	5%	84
Sputum	3%	57
Hives	3%	47
Nose Bleed	2%	45
Muscle Weakness	2%	43
Angioedema	2%	39
Confusion	2%	16
Total Number of Reports		1874

The table below, taken from the TEP report, lists the 20 symptoms reported in order of decreasing frequency of report. This table includes adults and children in all exposure categories, including unknown, and all symptom onset categories. The percentages of symptoms do not total 100% because illness reports included multiple symptoms.

TEP stated that statistical analysis of the data "suggests that some individuals may have allergic or irritative symptoms following exposure to the malathion-bait. Such symptoms include eye irritation, and skin rash in adults, and possibly hives and certain types of upper respiratory irritation in children. By and large, reported symptoms tended to be mild and transient, although not invariably so. Overall, the statistical associations described here are quite tenuous."

TEP qualified the findings of their analysis with the following statement:

> Sorting out the question of illness causation is difficult because nonspecific symptoms are so very common in the population, affecting up to 5 or 10% of the population in any given week. Therefore it is difficult to determine if some of the illnesses reported in this study would have occurred regardless of the malathion-bait applications. There is a reporting bias inherent in this data that is in the direction of showing an effect of malathion-bait exposure. Those individuals who chose to report their symptoms often had already made a connection between the spraying and their symptoms. The individuals in this study do not represent all residents of spray areas, only those who believe they experienced symptoms because of the malathion-bait applications. This bias would increase the likelihood of finding an association between exposure to the malathion-bait applications and symptom occurrence. Also when multiple simultaneous comparisons are made, the probability of finding an association due to chance rather than a true association is increased.
>
> The presence of a correlation between some symptoms and exposure indicates that they occur together not necessarily that the exposure caused the symptoms. A correlation can be an indication for further studies to objectively measure cause and effect if the correlation demonstrated appears to have biological plausibility. The results of this study cannot be used to 'prove' that any single individual's illness was caused by malathion-bait applications. That can only be done by clinical evaluations to rule out the many other potential causes of the symptoms that have been reported by individuals in this study or to perform objective tests which demonstrate sensitivity to malathion or to the bait material.

Orange County

A health survey of residents in Orange County included questions about awareness of the malathion-bait sprayings and related health problems. The survey was part of an ongoing research program conducted at the University of California, Irvine, Public Policy Research Organization's Center for Orange County Research. Each year, two surveys are conducted, which question about 800 randomly selected adults by telephone. Two of the four principal investigators, Drs. Hoda Anton-Culver and Dwight Culver, are also MPHEAC members.

The survey, conducted in April 1990, found that awareness about the spraying was high (98%) as was residents' awareness about spraying in their community (81.5%). Also, 425 of 829 respondents (51%) said that the state should stop spraying malathion and use some other method to control the Medfly.

The percentage of reported health problems resulting from the malathion spraying was low, however. "Only 31 (3.8%) reported any health problems related to the malathion-bait application. Most of these problems were respiratory and cutaneous (skin-related). Only 12 of the 130 respondents (9.2%) who resided in spray areas complained of health problems. The other 19 individuals who complained of health problems lived in areas adjacent or remote from the spray zones."

The researchers have proposed to add another segment to the Orange County Health Surveys to "allow us to understand the relationship between the health symptom information and public perceptions, available information, advance notice, and other factors potentially affecting public response to malathion in Orange and Los Angeles counties." Among the issues to be investigated are (1) a comparison of reported health symptoms between exposure period and present (i.e., health status changes and recall accuracy), and (2) utilization of health care providers (information, services, etc.) in response to aerial malathion application. State funding for this study was not provided, but the researchers intend to pursue alternate funding.

Citizen epidemiological study

A Los Angeles County resident, Jean Hinsley, conducted five health surveys in relation to the malathion-bait spraying. She conducted her first survey between December 15 and 17, 1989, in her neighborhood of Norwalk and contacted 96 households. She then conducted three other community surveys between March and June 1990 in the Lakewood and Norwalk areas. Her fifth survey involved 60 families representing 157 individuals who were among those attending two Pony League baseball games on April 17 at a park in Norwalk when helicopters applying malathion-bait passed overhead.

Ms. Hinsley presented the results of her surveys at the September 13, 1990, MPHEAC meeting. These results have been analyzed by Dr. Papanek and his staff at TEP. In a December 5, 1990, draft report of their analysis, they commended Ms. Hinsley for the substantial effort she put into the surveys, but concluded:

> The data...do not provide strong evidence that rates of acute symptoms are increased in the population following aerial applications of malathion-bait. However, the data suggest that direct out-of-doors exposure to the sprayed droplets, during the actual time of aerial application, may cause eye, nose, and throat irritation, and headache. Any future epidemiologic studies would have to be very carefully designed. Such studies, however, could probably provide only limited information about the impact of malathion-bait exposure on rate of symptoms which are already common in the population.

The TEP staff found that "when the results of Ms. Hinsely's surveys are analyzed symptom by symptom, reported illness rates in exposed persons are not much different from, and often lower than, background rates of illness as described in other studies." They also noted certain technical problems in the way these surveys were conducted, including recall bias due to the long length of time (up to two months prior to the interview), that subjects had to recall symptoms and selection bias in which "people who already have symptoms and who are angry or otherwise concerned about the aerial sprayings may well be more likely to respond to the survey than those who do not share these characteristics."

Designing future epidemiological studies

In analyzing the citizen survey above, TEP recommended that "any future studies of acute symptom rates in the population following the aerial applications of malathion-bait must be done extremely carefully, in order to minimize recall bias, selection bias, interviewer bias, and ambiguities related to imprecise "case definitions" for specific symptoms. Studies not meeting these criteria will not add to our understanding of possible acute allergic reaction or

other 'sensitivity' to malathion-bait in the population."

TEP recommended against any future epidemiologic studies that depend on "passive symptom reporting" of common symptoms, as was done in the citizen and two county health studies above because "...the clearly demonstrated effects of reporting bias and recall bias in the matter of acute symptoms...[make the studies] all but impossible to interpret."

Some of the problems with conducting epidemiological studies on effects of malathion-bait spraying are explained by TEP, as follows:

> The CDHS studies from 1981-82 argue strongly that the malathion-bait applications do not cause a measurable increase in acute symptoms in the population at least in persons not directly exposed to the spray as in the case of the 'baseball game' episode studied by Ms. Hinsley. However, an increase in symptom rates lower than a few percent would not have been measurable in the CDHS studies. To increase our level of confidence that malathion-bait is not causing an increase in symptoms in the population at some more refined level of detection, a very much larger epidemiologic study would be required. For example, if one wished to determine that the rate of particular symptoms increased from, say, 1% to 2% in the population following exposure to malathion-bait, roughly 1,000 persons would have to be surveyed in both exposed and control groups. At some point, the level of 'noise' in the survey—that is, differences in symptoms rates due to uncontrollable confounding factors—would overwhelm any possibility of detecting a malathion effect.
>
> We believe that for the majority of common symptoms which might possibly be linked with malathion-bait exposures, we are probably already at this point. The studies of background rates of illness cited above argue that there is so much variability in symptom rates in the population that it may simply be impossible to detect very small changes in rates for common symptoms. Instead one could perhaps detect changes in symptoms rates for a small number of very specific and very well defined symptoms, using a rigorous case definition of illness, and controlling tightly for sources of bias.

TEP suggests that only allergic symptoms, irritative respiratory symptoms, and perhaps certain immunologic symptoms are possible candidates for further study. The design of future studies will depend in large part on what level of increase is seen as important from a public health viewpoint.

Clinical study on allergic reactions

In May 1989, TEP in Los Angeles proposed a study to clinically evaluate patients who claimed to be having allergic reactions to the malathion-bait. TEP was receiving up to 300 calls per month of illness. Most of these were self-reported, and were not confirmed by a physician or other health care provider. There was no specific health care facility designated to evaluate such complaints.

The study proposed providing examination of up to 100 individuals who phoned local health departments in the Medfly eradication treatment areas with complaints specifically relating to skin irritation or lower respiratory tract irritation. The clinical examinations were to be conducted at the Southern Occupational Health Center at the University of California at Irvine or at the Barlow Occupational Health Center in Los Angeles County.

Preliminary results of skin patch testing of 17 adults among 32 who have been evaluated for both skin and respiratory symptoms at clinics arranged by TEP have recently been made available, although too late to be included for evaluation in the CDHS risk assessment. The subjects wore a skin patch impregnated with the malathion-bait material for 48 to 72 hours. In four of these cases was there a slight reddening of the skin to the material when the patches were removed, the results were marginal and equivocal. This study is being expanded to include children.

The other part of the study involving persons who claimed to have respiratory irritation has not been funded yet. This study would test some of these individuals, as well as volunteers known to have asthma and others with no respiratory problems, in a chamber where measured amounts of material could be mixed in the air. Although this has not yet been carried out, some individuals with asthma who are known to the local health departments to have peak flow meters at home were asked to keep journals of the readings. The meters record lung function at a given moment. These journals showed that no apparent change in lung function occurred immediately after the sprayings.

Urinary metabolites measurement

Until the last few years, the amount of absorbed dose of malathion that would result from exposure to aerial spraying of malathion could only be estimated from environmental levels. It is now possible to measure metabolites of organophosphate pes-

ticides, including malathion, in the urine of exposed persons. TEP did a study to quantify exposure to malathion by measuring urinary metabolites, monocarboxylic (MCA) or dicarboxylic (DCA) acid, in some individuals who were or may have been exposed to malathion.

The study included 75 specimens from 67 individuals. Fifty-four were people who had called the Los Angeles or Orange county health departments to complain of some symptom or illness that they believed was related to aerial spraying of malathion-bait and who were willing to submit a urine sample and answer a questionnaire. Five were children who were recruited from a child care center located within a treatment area. Eight were agricultural workers who had contact with malathion in their work.

A TEP draft report, which was received by CDHS too late to be included in the risk assessment, indicates that urinary metabolites are detected in the urine of some exposed individuals who were outside during the aerial application or who had direct skin contact with the malathion-bait. The amounts detected were somewhat lower than what had been predicted by CDHS based on environmental monitoring information and consideration of the rates of dermal absorption, metabolism, and urinary excretion of the metabolites.

The TEP study found no association between the types of symptoms and metabolite levels. Several of the individuals who had detectable levels of DCA did not exhibit any illness while some individuals who described themselves as very ill did not have detectable amounts of DCA; however, allergic reactions could theoretically occur following a very low exposure. CDHS may include the final results of this study in future analyses of malathion's health hazards.

CDHS study on pesticide workers

To evaluate the genotoxicity of malathion and related compounds, CDHS is undertaking an epidemiologic study to determine the exposure levels, symptomatology, acetylcholinesterase levels, and genotoxic effects among an agricultural worker population with exposures to malathion. This will include identifying and recruiting suitable exposed and control populations; determining levels of internal and external exposure to malathion and/or related compounds using questionnaire data, standard industrial hygiene methods and analysis of malathion-specific urinary metabolites; separating and storing erythrocytes and lymphocytes from blood specimens of study subjects; determining the acetylcholinesterase levels in these preparations using standard procedures; determining the frequency of mutation in selected preparations using suitable genotoxicity assays; and determining the relationships between the various measures of exposure and (1) the levels of cholinesterase inhibition and (2) the mutation frequencies.

CDHS is also evaluating the genotoxicity of malathion and related compounds in normal human cells (lymphocytes) in culture using two *in vitro* assays: the HLA-A assay, and the micronucleus assay with recent anti-kinetichore antibody modification.

The compounds studied will include:

1) malathion mixture used to control the Medfly in the Los Angeles basin;

2) malathion mixture applied to date palms;

3) reagent grade malathion;

4) malaoxon (metabolite);

5) isomalathion (impurity);

6) *O,S,S*- and *O,O,S*-trimethyl phosphorodithioate and *O,O,S*-trimethyl phosphorothioate (impurities);

7) selected environmental transformation products.

Alternatives to aerial malathion-bait spraying

Dr. Isi Siddiqui, CDFA Assistant Director responsible for the Division of Plant Industry, reported to MPHEAC on November, 8, 1990, on other insecticide alternatives to malathion and the impact on California agriculture if the Medfly became established. He said that CDFA used a seven-point list of criteria for evaluating pesticides for the Medfly project, and only malathion met all the criteria. The criteria included effectiveness against Medflies, usability on a wide range of host plants, low environmental impact, low mammalian toxicity, "non-restricted" use, permitted use in urban areas, and not causing a surge of secondary pests.

If the Medfly becomes established, he estimated that 1.6 million pounds of methyl bromide would be used annually after harvest to fumigate fruits and vegetables exported overseas or sent out of state to satisfy quarantine requirements. This amount could

potentially be cut in half if cold storage treatment was used instead of fumigation. However, not all crops can be treated by cold storage. Little methyl bromide is now being used to fumigate for fruit flies. Moreover, farmers would probably apply malathion-bait six times routinely to their Medfly-susceptible crops before harvest. This would increase malathion use by 1.7 million pounds. Backyard usage of pesticides would be anticipated to increase by about 2.2 million pounds annually. It is difficult to compare the estimated increased usage of malathion in agriculture to present usage because malathion is not a restricted pesticide and its usage is not closely monitored. CDFA has records for 663,477 pounds of malathion used in California in 1988 other than home use.

Since December 1989, the capacity for rearing sterile Medflies has been increased by six-fold so that if another infestation were to occur, CDFA would have enough sterile flies to be able to limit aerial spraying to two applications.

CDFA has subsequently announced the awarding of $745,000 for funding four proposals by the United States Department of Agriculture and universities regarding Medfly and Mexican fruit fly research. The research is to develop better traps and lures and/or effective alternatives to aerial pesticide application for eradicating the two insects.

The main research emphasis will be on development of bait stations, as have been used successfully to eradicate the Oriental fruit fly. Bait stations consist of a pheromone sex lure that attracts the male fly. The lure also contains a small amount of pesticide (3 percent), which kills the fly on contact. The material is squirted onto telephone poles eight feet above ground level and is absorbed into the wood. The only people who might have any contact with the bait stations are utility workers who climb poles, and they have been informed that there is no health hazard to them. The problem with bait stations for the Medfly and Mexican fruit fly is that an effective sex lure has not been developed. CDFA anticipates that it may take several years of research to develop a successful alternative to aerial pesticide application.

CDHS is also reviewing the health effects of the alternatives to malathion including the health hazards of failure to eradicate exotic pests such as the Medfly.

Section three: What public can do, and should know

Steps people can take to reduce potential exposures

It is unknown at this time when alternatives will be found that will totally replace malathion-bait to eradicate the Medfly or the Mexican fruit fly if future infestations occur. There are, however, steps that people in spray areas can take to reduce potential exposures if malathion-bait is again applied.

These simple but prudent precautions include staying indoors when spraying is taking place, thoroughly washing after contacting malathion-bait contaminated surfaces, washing home-grown fruit and vegetables before consuming them, washing off lawn furniture, and bringing in line-dried laundry before scheduled sprayings. The amount of additional exposure that would occur from leaving windows open or air conditioners on during aerial applications of malathion-bait is insignificant, so no special efforts in this regard should be needed.

To minimize children's potential exposures to malathion-bait, one could wash or hose off swing sets, climbing structures, and similar play equipment when feasible. Toys, tricycles, and bikes could be brought inside and sand boxes and outdoor eating surfaces covered. Likewise, it would be prudent to water down a lawn following spraying before allowing a scantly clad child out to play on it. Both children and adults should wash up after coming in from work or play.

The amount of malathion-bait that children would be exposed to by playing outdoors is small, but extensive outdoor activity could reduce the margin of safety. The main reason for suggesting these measures is to prevent *unnecessary* exposure.

Other groups within the population who could be more sensitive or more exposed to malathion-bait are the aged, the homeless, individuals taking certain medications, and individuals having certain preexisting diseases. They also may wish to minimize their

potential exposures to malathion-bait by observing these simple but prudent precautions.

Need to prevent reinfestation: How the public can help

There has been considerable controversy over whether the Medfly has become established as an endemic pest in California. The consensus of an expert advisory panel to CDFA as well as CDFA itself is that the Medfly has not become established. CDFA declared the Medfly successfully eradicated on November 9, 1990, when no wild flies had been discovered in detection traps for a period of three months, which would cover three generations of the Medfly.

Although two instances of isolated wild fly finds have occurred since then, CDFA does not believe that this indicates reestablishment of Medfly infestation.

CDFA believes that the reason for the repeated infestations in California by the Medfly, Mexican fruit fly, and certain other insect pests, is their reintroduction by people carrying or shipping prohibited fruits and vegetables into California. In spite of agricultural inspection stations at major entry points and laws banning such shipments, this has been difficult to control. Fruits and vegetables exotic to California can have an important cultural and religious significance to ethnic groups in California. In some instances, individuals may encourage relatives in their homelands to ship them prohibited foods.

CDFA carried out three major inspection "blitzes" in 1990 to determine the amount of prohibited fruit entering California in the luggage of passengers at the Los Angeles (LAX) and San Francisco (SFO) international airports. The large volume of travelers limits inspectors' ability to check each piece of luggage on a day-to-day basis with current resources, so additional state employees joined the usual federal staff for the effort.

The inspections at LAX during May 14-20 involved 16,997 passengers on 153 flights coming from Mexico, and Central and South America. Inspectors made 677 interceptions of contraband produce totalling 1,928 pounds and containing 61 live fruit fly larvae, 20 of which were confirmed as Mexican fruit flies and several others as fruit flies of major importance. During the previous week, May 5-12, with the usual inspections, the interceptions included 434 significant agricultural plant pests.

Augmented inspections at SFO conducted during August 19-25 resulted in 1,159 interceptions of prohibited fruits and vegetables, weighing 2,546 pounds, in an inspection of the luggage of 10,341 travelers from 50 countries and Hawaii. Among the 110 separate pests found, 40 were of serious economic importance, including *Myiopardalis pardalina*, larvae of a rare melon fly that destroys up to 60% of watermelon crops and 85% to 90% of melons and muskmelons in the Middle East. Infestations of a another serious melon fly, *Dacus cucurbitae*, have occurred and been eradicated twice in Los Angeles County in 1956 and 1987. The inspections also intercepted Oriental fruit fly larvae from Taiwan. In 1989, 12 Oriental fruit fly infestations occurred in southern California.

Another sampling conducted during July 1990 at LAX included sampling of cargo to look for unmanifested or undeclared or prohibited produce and found 1.3% of the cargo met this criterion. Inspectors intercepted a number of pests including citrus canker in lemons from Kuwait.

The United States Department of Agriculture has pilot tested increased inspections using a beagle trained to sniff out prohibited items. The inspections of first-class parcels of produce mailed from Hawaii, where fruit flies are endemic, resulted in a total 477 illegal parcels between May 22 and October 31, 1990. This included 45 interceptions (1,562 individuals) of Mediterranean, Oriental, and melon fruit flies; 29 parcels were en route to California.

To prevent mailing of prohibited plants, fruits, vegetables, or other items capable of introducing pests, the 1989 Agricultural Quarantine Enforcement Act was passed to augment earlier quarantine laws. Senders of illegal produce are fined $250 to $1,000. USDA estimates that the introduction of exotic pests to the U.S. mainland during the past fifteen years has cost taxpayers more than $200 million.

The illegal importation of untreated fruits and vegetables is clearly a source for the introduction of insect pests into the United States. Greater public understanding of this problem, and observance of the law, is needed to prevent reintroduction of the Medfly and other harmful agricultural pests.

Risk communication recommendations

In any future eradication campaigns that may involve any risk to the public from pesticide spraying or other measures, risk communication is recognized as having an integral role. In discussing risk communication, CDHS staff stated, "It should be recognized at the outset that notification does not equal education, and that education alone is not necessarily synonymous with risk communication. For example, notification and education both can be just one way of giving information from an 'expert' to the public. However, the recent literature and research on risk communication defines it as a process that should include two-way communication and discussion and, in many cases, public participation with shared decision making. It is within the broader definition that the following...recommendations are made."

The following are some of the recommendations that were developed by CDHS staff coordinated by the health education consultant. The recommendations evolved from discussions at MPHEAC meetings, from the risk communication subcommittee members, and from research with activist groups, county, and city health department officials, CDFA and county agricultural commissioners.

Task force

A task force with representatives from CDHS, CDFA, county and local governments, and representative community groups should be convened to evaluate the risk communication and public notification component of the eradication effort. Specific recommendations for the future should be developed. The product from this process would be a plan for a proactive organized risk communication campaign taking into account all of the appropriate infrastructures and community groups. Some issues and questions that should be addressed are:

Inclusion of day care centers, veterinarians, school boards, local and state educational offices and city councils in communication and notification system mandated by AB 3886 (Food and Agriculture Code Section 5771, Article 4.5) and AB 3989 (Section 5029) (this is in addition to private physicians, medical societies, and county health departments);

Involvement of elected officials and other community leaders from affected communities in decisions regarding eradication and prevention programs;

Inclusion of pest control and entomology information with health effects information;

Assessment of the best way to communicate the message (including focus groups to pretest various messages);

Evaluation of current written materials and development of written materials in appropriate languages (in addition to Spanish);

Advancement of recommendations for precautionary measures for the general population and the potentially more sensitive subpopulations to be taken prior to, during, and immediately following any future aerial applications of pesticides.

Risk communication advisory committee

If, in the future, it is necessary to convene another committee like MPHEAC, the following issues should be considered:

Develop two committees for the separate functions of providing a public forum discussion of public policy, and the function of a scientific (health effects) review panel; the 1989-1990 MPHEAC tried to accomplish both these functions which require different areas of expertise and different approaches;

Develop a proactive media relationship (regular press conferences, focus sessions, specific media liaison) to release statements and reports on committee activities;

Appoint citizen representatives from affected communities and/or have specific liaison from committee to communities;

Include at least one communication or education expert on the committee, develop a risk communication subcommittee along with other subcommittees, and view risk communication as an integral part of ongoing effort of all committees;

Hold some public meetings to respond to questions and concerns, and any public meetings should have both medical and agricultural experts present to answer questions.

Finally, the risk communication recommends, "There should be more research into alternatives to aerial spraying. Even if malathion is shown to, and is believed, to have no serious health effects, many citizens still are in disagreement with the idea of aerial spraying, and no amount of risk communication will override serious public opposition."