



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

OCT 16 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 - USDA Quarantine Exemptions for Use of
Malathion and Diazinon to Eradicate Exotic Fruit Fly
Species in Florida --ACTION MEMORANDUM---

FROM: Anne E. Lindsay, Director
Registration Division

A handwritten signature in cursive script, appearing to read "Anne E. Lindsay", is written over the typed name and title.

TO: Douglas D. Campt, Director
Office of Pesticide Programs

I. APPLICANT REQUEST:

APPLICANT: United States Department of Agriculture
(USDA), Animal and Plant Health Inspection
Service (APHIS)

CHEMICALS: Malathion
Diazinon

PRODUCTS: Malathion: Any federally registered product
containing 91 to 95 percent a.i.; or any
federally registered 25 percent a.i. wettable
powder formulation

Diazinon: Any federally registered
emulsifiable product containing 47.5 percent
a.i.; or federally registered granular
formulation containing 14.3 percent a.i.

SITES: Quarantined areas within the state of Florida
where active infestations of exotic fruit
flies have been identified

PESTS: Exotic (nonindigenous, quarantined),
subtropical members of the fruit fly family,
Tephritidae, including, but not limited to:

PESTS (con't.) Mediterranean fruit fly (Ceratitis capitata)
Melon fruit fly (Dacus cucurbitae)
Oriental fruit fly (Bactrocera dorsalis)
West Indian fruit fly (Anastrepha obliqua)
Mexican fruit fly (Anastrepha ludens)
Caribbean fruit fly (Anastrepha suspensa)

USE PATTERN: Malathion: Malathion will be applied by air or ground equipment in quarantined areas where active infestations of exotic fruit flies have been identified. Bait spray applications using 2.4 ounces of a.i. mixed with 9.6 ounces of protein hydrolyzate per acre will be made at 5 to 21 day intervals until eradication is achieved. Dilution with water will be allowed for ground applications to host crops only.

Diazinon: Diazinon soil treatments will be made to soil around host nursery stock within the quarantine area and to other host trees within the quarantine area when fruit fly larvae are found infesting the fruit. In the latter case, when larvae are detected, ground applications of diazinon will be made to the soil within the drip line of host trees on the infested property and adjacent properties. Applications of diazinon will be made at the rate of 1.8 ounces of a.i. per 1,000 square feet of soil surface. Soil drench applications will be made in sufficient water to wet the top inch of soil. Diazinon will be "watered in" following granular applications.

NO. OF APPL: Malathion: The number of applications required to eradicate an infestation varies; however, the preferred control procedure is two applications of malathion bait-spray, followed with sterile insect technique (SIT) to complete the eradication process.

Diazinon: A single ground application

TREATMENT
AREA:

The minimum malathion treatment area is approximately 9 square miles surrounding a fruit fly "find". Treatment areas may enlarge as new flies are found. A diazinon treatment area is the soil under host trees on infested and adjacent properties and host

plant nursery soils. An estimate of the area which will require treatment is not possible.

POUNDAGE: Approximately 865 pounds of malathion will be required per application to treat each 9-square mile treatment area. Estimates cannot be made for diazinon, since treatment area will vary significantly.

USE SEASON: Three years from the date of issuance

EMERGENCY/ECONOMICS: The Mediterranean fruit fly (Medfly) is one of the world's most notorious agricultural pests due to the female fly's destructive habit of ovipositing eggs directly into developing fruit. The hatching maggots tunnel through the fruit, causing it to rot and drop from the tree. Larvae of Medfly have been reported infesting more than 260 different varieties of fruits and vegetables worldwide. However, Medfly is not known to exist anywhere in the continental United States.

USDA estimates that, if the Medfly were to become established in this country, losses of between \$821 and \$831 million could be expected annually. Potentially, economic losses to agricultural production and trade from establishment of fruit fly pests could run into the billions of dollars. Numerous governmental and international organizations conduct fruit-fly related programs and activities. USDA has cooperated with state departments of agriculture in programs to eradicate Medfly infestations which have occurred intermittently on the U.S. mainland since 1929. Those programs, representing federal and state expenditures of nearly \$322 million over this time period, have prevented the Medfly from becoming established in the continental United States.

According to the Applicant, the United States maintains the finest fruit fly exclusion, detection, regulation and eradication system in the world, maintaining a perfect record of early detection and rapid eradication of all isolated introductions of Medfly. USDA's fruit fly program, including the role of malathion and diazinon in eradication efforts, is briefly summarized below:

The quarantine program begins at potential ports of entry where efforts are directed at preventing fruit flies from entering the country (exclusion) through various education and inspection programs. In addition, USDA\APHIS maintains an impenetrable network of Medfly traps at densities of up to 30 traps per square mile throughout high risk areas (particularly urban areas with favorable climates and adequate hosts that are major hubs of international travel and trade) to detect fruit flies which penetrate the exclusion barrier. If a Medfly is detected, trapping is increased in the area to a minimum of 105

traps in the square mile surrounding the detection, and 55 and 30 traps per square mile in the 1st and 2nd one mile buffers surrounding the detection site. These traps and additional traps within the 100 square mile area surrounding the detection site are checked and serviced on a daily or weekly schedule to ensure identification of a new infestation in its earliest stages of development and limit the scope of subsequent eradication efforts.

If additional Medflies are detected near the initial detection site, it could indicate the existence of an active infestation. Generally, if six or more flies are detected within one Medfly life cycle, an active infestation is assumed to exist and a full scale quarantine and eradication program is triggered. If two to five Medflies are detected, a risk assessment is conducted by a Medfly Technical Committee which considers such elements as time of year, trapping array, distribution of detections, and other factors. The Medfly Technical Committee recommends an appropriate course of action based on their review of these factors.

When a full scale quarantine and eradication program is warranted, intra- and interstate quarantines are immediately implemented which prohibit the movement of all potentially infested host material from at least an 81 square mile area around the detections. The 81 square mile regulated area is not an arbitrarily chosen figure; rather, it is based on an evaluation of the biology and behavior of the pest, which indicates that it would take at least three generations of strongly directed migration, not random movement, for an infestation to support mated females extending their oviposition range beyond three miles from the epicenter of the introduction.

During the eradication portion of the program, the preferred control procedure calls for two applications of malathion bait-spray followed with sterile insect technique (SIT) to complete the eradication process. The two applications of malathion bait-spray are needed to eliminate the pregnant females and reduce the wild fly population so that adequate overflooding ratios of 100 sterile flies to 1 wild fly can be attained. Diazinon is applied only to soil around host nursery stock within the quarantine area or within the drip line of host trees found to be infested with Medfly larvae and host trees on adjacent properties.

No prophylactic applications of either malathion or diazinon are made prior to initiation of a full eradication program. Aerial applications of malathion are used only after USDA has determined that a reproducing population of Medfly exists. Eradication procedures continue until sufficient time has elapsed since the last wild fly detection for completion of two Medfly life cycles. Life cycle projections are based on Tassen's day degree model for Medfly and can be as short as 28 days during

Miami, Florida summers or as long as 3 months during San Jose, California winters.

REG. ALT.: There are no registered pesticides or alternative practices available for the eradication of nonindigenous, subtropical fruit flies. Alternative treatment methods recommended to APHIS by others in the past have included biological control, exclusive use of SIT, boric acid, genetic manipulation, and host elimination. Although many organisms show promise as biocontrol agents, much more research and development are needed before biological control technology of subtropical fruit flies can be exploited. SIT is effective against low-level Medfly populations where high overflooding ratios of at least 100:1 can be achieved; however, infestations are often so heavy that such release ratios cannot be achieved. Also, sterile flies are currently not available for non-indigenous subtropical fruit flies other than the Medfly and the Mexican fruit fly. Boric acid has not been considered for use due to a lack of appropriate product labeling, toxicity to nontarget organisms, and unproven efficacy in the field against Medfly. Genetic manipulation involves the use of genetically altered insects to mate with wild Medflies to render the wild populations less vigorous, less prolific, or genetically sterile. Except for development of sterile flies, this approach has not proven efficacious in the field. Host elimination involves destruction of wild hosts of these subtropical fruit flies. The technique is not usually considered because of the difficulty in employing it in diverse terrain, its costs, and its potential adverse environmental effects as a result of the removal and disposal of plant material.

USDA uses male annihilation spot treatments in lieu of malathion bait sprays to eradicate infestations of the Oriental fruit fly and other Dacus spp. which occur in urban and residential areas. This program is carried out under a quarantine exemption granted to USDA which authorizes spot applications of methyl eugenol/naled lure baits to tree trunks, telephone poles and other inanimate objects and causes considerably less community and environmental concern than the malathion area treatments. USDA is investigating development of a male annihilation technique for other fruit fly species, particularly Medfly; however, while the technique shows promise, more research and development are needed before it can be used in place of malathion bait sprays.

II. BACKGROUND:

Malathion and diazinon have been used in USDA/state cooperative fruit fly quarantine programs for several decades. Quarantine exemptions for use of both chemicals have been issued to USDA/APHIS since the mid-1970s to control fruit flies in Florida. USDA also cooperates with the state of California in

its Medfly quarantine program. Historically, however, California has had the lead role in implementing its Medfly program. EPA has issued quarantine exemptions to the California Department of Food and Agriculture (CDFA) for use of malathion to eradicate fruit flies since the early 1980s. CDFA's current exemption expires December 8, 1992. Amendments to CDFA's quarantine exemption have been under review at EPA since November of 1989. Although the amendments are largely technical in nature, concerns about the aerial spraying of malathion over urban populations were raised during review of the amendments which have significantly delayed final action on the CDFA amendment requests.

On June 17, 1987, a 3-year quarantine exemption was granted to USDA/APHIS for use of malathion and diazinon to eradicate fruit flies in Florida. This exemption expired June 17, 1990. On May 30, 1990, at the height of public controversy over California's malathion program, USDA requested renewal of the malathion/diazinon quarantine exemption for an additional 3-year period. EPA renewed the quarantine exemption for an additional one-month period only to allow USDA to complete eradication of a Medfly infestation identified in Dade county, Florida, in April, 1990. EPA notified USDA that prior to making a final decision whether to renew the exemption for an additional 3-year period, EPA would conduct a thorough review and risk-benefit analysis of the request. At the same time, we asked USDA to provide additional information to facilitate EPA's risk-benefit analysis of the quarantine exemption request. In October, 1990, USDA submitted a new application for a 3-year quarantine exemption which included the additional information requested by EPA. Review of the request is now complete.

It should be pointed out that in May, 1991, a single male Medfly was trapped in Florida. Although there have been no additional detections since then that would trigger an eradication effort, USDA is increasingly concerned about the potential for an outbreak to occur and extremely anxious for EPA to make a decision on the quarantine exemption request. They continue to express their willingness to cooperate with EPA to mitigate risks from the proposed program (see EPA EVALUATION section of this memorandum for a discussion of these risks) or provide better data to evaluate the potential risks.

In 1990, APHIS was asked to cooperate in separate eradication programs for Medfly in both California and Florida. Because of the urgent need to implement eradication efforts, there was insufficient time to prepare comprehensive environmental analyses as required under the National Environmental Policy Act (NEPA). Therefore, APHIS sought emergency authorization from the President's Council on Environmental Quality (CEQ) to proceed with eradication efforts while preparing environmental analyses for the programs. The

emergency authorization, granted by CEQ in accordance with 40 CFR 1506.11, allowed APHIS to cooperate with state departments of agriculture in the 1990 Medfly eradication programs. APHIS and its cooperators, however, acknowledge that such emergency actions are recurrent, have common features, may be considered broad in scope, and can be reasonably planned for in advance. Therefore, APHIS decided to develop a comprehensive environmental impact statement (EIS) for the Medfly Cooperative Eradication Program. A Notice of Intent to prepare the EIS was published in the **Federal Register** on June 22, 1990. The EIS will analyze potential environmental effects of emergency actions taken to eradicate periodic infestations of the Medfly from the U.S. mainland. APHIS and its cooperators hope to develop a comprehensive, high-quality analysis which will provide the program decision makers and the public with complete and accurate information about the potential environmental effects of the program. APHIS expects to complete the draft EIS by June or July, 1992 and the final EIS by September or October, 1992.

Reregistration/Special Review Considerations

A) Malathion:

Malathion is a List A chemical for which a Registration Standard was issued in February, 1988. The Standard did not identify any concerns requiring immediate regulatory action; however, it identified the need for additional data to fully evaluate the risks from use of malathion, including several additional chronic toxicity studies. According to SRRD, a substantial amount of data has already been submitted in response to the Registration Standard. The majority of the outstanding studies are due at the Agency during 1992; however, certain long-term studies are not due until September, 1994. The status of the malathion database by discipline is discussed below:

Environmental Fate and Effects: Several ecological effects studies have been submitted in response to the Standard. An aquatic study (mollusc shell deposition) which had to be redone is due at the Agency this fall. A bobwhite quail reproduction study must also be repeated. This study will be due in 1993. In addition, the Agency is requiring additional ecological effects studies that were not required in the 1988 Standard: a duck reproduction study which was inadvertently omitted from the 1988 Standard, a fish full life cycle study which is required as a result of Tier 1 test results, and an aquatic mesocosm study for malathion. Several environmental fate studies are under review in EFED and several additional studies are still outstanding. The last one is due at the Agency by the summer of 1992.

Health Effects: A substantial amount of toxicology data have already been submitted to the Agency and reviewed. A 21-day dermal study is currently under review in HED. The Agency has

required new chronic/carcinogenicity studies, however, which are not due until 1994. In addition, SRRD is preparing to issue a DCI for malathion which will include ocular toxicity testing, a 90-day inhalation study, acute and sub-chronic neurotoxicity studies, an occupational exposure study, and a combined chronic/carcinogenicity study in the rat, which was recommended in the Standard but not previously required.

Residue Chemistry: The Standard required residue chemistry data to support nearly all of the registered food/feed crop uses of malathion. Most of these data are due at the Agency by December, 1992.

In the March 18, 1991 **Federal Register** EPA published a notice of intent to delete certain malathion uses and solicited public comment on the proposed label amendments, following withdrawal of reregistration support by the Malathion Reregistration Task Force (MRTF), comprised of the two registrants of technical malathion, American Cyanamid and Cheminova Agro A/S. The comment period, which was originally to have ended June 17, 1991, was extended first through September, 1991, and recently through October 31, 1991, at the request of the Chemical Producers and Distributors Association (CPDA).

Approximately 80 to 90 uses are affected by this action. The MRTF has withdrawn reregistration support for these uses because it does not intend to provide the required residue data (for certain food and feed crops, tobacco, and stored commodities); the 90-day inhalation study (for indoor uses, stored commodity treatments, domestic animals, animal premises, and food-handling establishments); and domestic animal safety testing (for poultry uses). All malathion end-use registrants have been notified and given the opportunity to commit to generate data in support of the reregistration of these uses. It is not yet known how many of the uses proposed for deletion will be supported by registrants, by CPDA or by other interested parties, such as commodity organizations or IR-4.

The Agency decided at the time of the Registration Standard not to place malathion in Special Review. Due to the limited amount of available data, the Agency was not able to make a determination as to whether any of the Special Review criteria had been met or exceeded. At the April 18, 1991, meeting of OPP division directors held to discuss malathion issues, this position was reaffirmed. The consensus of those present was that there is insufficient basis to consider malathion for Special Review now and that it will be 3 or 4 years before there is sufficient information to make a determination.

B) Diazinon:

Diazinon is a List A chemical for which a Registration Standard was completed in December, 1988. The Standard identified numerous data gaps in the areas of residue chemistry, toxicology, environmental fate, and ecological effects. According to SRRD, the Registrant, Ciba-Geigy, continues to submit the studies required by the Standard in a timely manner.

In January, 1986, the Agency initiated a Special Review of diazinon's uses on golf courses and sod farms due to the risk of acute toxicity to avian species. This concern was based on available laboratory data on acute and dietary avian toxicity, exposure data, field studies, and reported bird kill incidents associated with these two sites of diazinon application. After assessing these risks and comparing them to the benefits afforded by diazinon on these sites, the Agency concluded on September 24, 1986, that the risks exceeded the benefits and canceled the registrations for these two use patterns. This Special Review decision was the subject of two completed unsuccessful legal appeals and a third appeal which was withdrawn. The golf course and sod farm uses remain canceled.

At the time of the 1988 Registration Standard, the Agency deferred a decision on whether to place diazinon back into Special Review for its potential hazard to non-target species resulting from its use on agricultural crops, turf, and other grassy sites (including athletic fields, recreational parks, and home lawns). The Standard indicated that the available laboratory data, field toxicity studies, residue and exposure studies, and bird kill incidents would be closely examined and that, upon completion of the examination, a decision would be made. A final decision has not been made at this time; however, according to SRRD, Regulatory Options briefings for diazinon, although not yet scheduled, are expected to take place in the near future.

Progress toward registration

Progress toward registration is not a requirement under the regulations governing quarantine exemptions. However, USDA has indicated on numerous occasions that they intend to seek section 3 registration for the use of malathion in fruit fly quarantine programs. USDA is actively involved in the Malathion Reregistration Task Force and is in contact with the Registrants regarding a cooperative effort to secure section 3 registration for this use.

III. EPA EVALUATION:

BEAD Review

BEAD has previously concluded that exotic, subtropical fruit fly species such as Medfly are notorious destroyers of fruit and

that eradication would be the only responsible course of action when their presence is detected. According to BEAD, malathion is the most logical and practical choice for use in aerial fruit fly spray programs like the one proposed for Florida for several reasons:

1. Malathion is registered on a vast range of sites, including agricultural crops, livestock, ornamentals, household sites, and other non-food sites.
2. Malathion has relatively low toxicity, compared to other insecticides, and is effective against fruit flies at low doses.
3. Malathion is relatively inexpensive and available in quantities that are required to conduct the quarantine program. BEAD felt that other alternatives, such as pyrethrins, would probably not be available in adequate quantities and that the cost would be prohibitive.

Residue Chemistry Review

Chemistry Branch II (CB-II) reviewed this request for use of malathion and diazinon in USDA's fruit fly eradication program and, TOX considerations permitting, has no objections to the proposed quarantine exemption. Residues of malathion are not expected to exceed 8.0 ppm in or on treated commodities as a result of this use, and residues of diazinon are not expected to exceed the established tolerances in or on nut and fruit crops as a result of this use. Secondary residues of malathion and diazinon in livestock commodities are not expected to result. Adequate analytical methods are available for enforcement purposes in PAM II for both malathion and diazinon, and analytical reference standards for both chemicals are available from the Pesticides and Industrial Chemicals Repository at RTP, N.C.

Toxicological Review

HED's Toxicology Branch I (TB-I) and Science Analysis and Coordination Branch (SACB) reviewed this request and reached the following conclusions regarding the use of malathion and diazinon in USDA's proposed fruit fly quarantine program.

A) Malathion:

In February, 1991, the California Department of Health Services (CDHS) published a health risk assessment for the use of malathion in Medfly eradication programs in Southern California. In general, HED agrees with CDHS's overall conclusion that "although the existing database may be adequate to support the continued registration of malathion for use in agriculture to

control pests, the data do not necessarily provide information pertinent to the evaluation of the use of this pesticide in urban areas with large populations to control pest infestations". Other conclusions reached by CDHS in its risk assessment and cited by TB-I in its review of USDA's quarantine exemption request include the following:

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

"Given the findings of this risk assessment, DHS recommends that the use of aerial malathion-bait applications in urban areas for agricultural pest eradication be reconsidered... Although the theoretical adverse health risks from exposure to aerially applied malathion-bait in the general population may be reduced by following some simple precautions, potential exposures in more sensitive subpopulations may not be avoided as easily... DHS also recommends that CDFA develop, and when possible, utilize available non-pesticide or selective pesticide (e.g., natural attractants) alternatives to aerial application of pesticides."

HED pointed out that this risk assessment does not preclude aerial applications of malathion-bait when all other measures prove inadequate. However, TB-I believes the toxicological database for malathion is sufficient to support only minor new uses that will not significantly increase the dietary and non-dietary exposure of the population to malathion. Significant toxicological data gaps for malathion exist in the areas of chronic toxicity and carcinogenicity. In addition, TB-I is concerned about the potential ocular toxicity of all organophosphates, including malathion.

Carcinogenicity:

The HED Peer Review Committee met on February 7, 1990, and agreed to classify malathion as a Group D carcinogen (not classifiable as to human carcinogenicity) due to inadequate carcinogenicity data. The Committee reaffirmed the stipulations in the malathion Registration Standard which require the Registrant to perform an additional mouse carcinogenicity study with malathion and an additional rat carcinogenicity study with maloxon, both of which are due by February, 1994. The Committee also determined that the recommendation in the Standard to perform a carcinogenicity study in combination with the required chronic rat study using malathion be made into a requirement.

Ocular Toxicity:

HED's RfD/Peer Review Committee convened on February 21, 1991, to discuss the possible association between ocular effects and organophosphate pesticides. The Committee concluded that the combined toxicological data from epidemiology studies and from bioassays demonstrate the potential for organophosphates to produce a wide range of ophthalmological effects and support the need to establish ocular testing as a registration requirement for this class of chemicals for the purpose of hazard characterization and risk assessment. The DCI being prepared by SRRD for malathion will require ocular testing in the dog.

The potential for malathion to produce ocular effects is of special concern in light of an incident which occurred in California during the 1990 Medfly eradication effort. A 15-year old boy was declared legally blind after being outside watching helicopters spraying malathion on March 28, 1990. The boy, Juan Macias, was treated initially by a school nurse and by several physicians, none of whom could diagnose his condition, before being referred to Dr. Sadun, an ophthalmologist in California. Dr. Sadun diagnosed the disease as Saku disease and attributed it to exposure to aerially applied malathion during the Medfly spray program. The case report of Dr. Sadun was subsequently submitted to Dr. Sheldon Wagner, an OPP consultant in this field, who concluded that the boy's condition could be Saku disease resulting from malathion exposure. HED concluded in its review of this incident that the opinions of Drs. Sadun and Wagner do not establish a cause and effect relationship between malathion spraying and the blinding incident in California and that, due to the nature of the incident, it may be impossible to determine the extent, if any, to which malathion was responsible for these effects.

The Malathion Public Health Effects Advisory Committee, established by the Director of the California Department of Health Services to review the Department's assessment of health risks from using malathion to eradicate the Medfly in Southern California, also reviewed the ocular incident. The Committee issued a consensus statement on the ocular toxicity of malathion on June 7, 1990, which concluded that, while acute and chronic exposure to malathion can lead to visual impairment, such impairment is unlikely to result from the exposures encountered in the Medfly eradication program.

B) Diazinon:

According to TB-I, the toxicology data base for diazinon is adequate to support only minor new uses. Although it is not possible to quantify the incremental risk from the proposed use, SACB concluded that the proposed use is not expected to

significantly increase the dietary or non-dietary exposure of the general population to diazinon.

USDA submitted historical data showing that during 1990, only 7.5 gallons of diazinon were used in fruit fly eradication programs in Florida. Prior to 1990 only 2.03 gallons were applied (1987). Therefore, SACB's assumption that the proposed use should not result in a significant increase in exposure appears to be valid.

Dietary Exposure Review

The EPA and OPP reference dose (RfD) committees have established an RfD for malathion of 0.02 mg/kg body wt/day, based on the NOEL of 0.23 mg/kg/day from a human cholinesterase study. The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from existing malathion tolerances utilizes approximately 500 percent of the RfD. When adjusted for percent of registered crops actually treated with malathion, exposure is estimated to utilize approximately 120 percent of the RfD for the overall U.S. population. According to SACB, the incremental dietary exposure to malathion from consumption of crops treated under this exemption is expected to be negligible.

HED has established an RfD for diazinon of 0.00009 mg/kg body wt/day, based on the NOEL of 0.009 from a 90-day rat feeding study with an uncertainty factor of 100. The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from existing diazinon tolerances utilizes approximately 8,000 percent of the RfD. When adjusted for percent of registered crops actually treated with diazinon, exposure is estimated to utilize approximately 800 percent of the RfD for the overall U.S. population. Crop residue data to develop anticipated residues for diazinon are not yet available. Again, SACB concluded that the incremental dietary exposure to diazinon from consumption of crops treated under this exemption is expected to be negligible.

Non-Dietary Exposure Review

The Occupational and Residential Exposure Branch (OREB) reviewed this quarantine exemption request and concluded that the exposure resulting from the proposed uses of malathion and diazinon in USDA's fruit fly quarantine program will be low. Both insecticides are readily available over the counter in hardware stores, lawn and garden shops, drug stores, and grocery stores; and both are commonly used by homeowners or professionally applied indoors. The incremental increase in exposure of individuals who are already being exposed through personal use of malathion or diazinon products is expected to be minimal.

OREB also concluded that aerial application of malathion would greatly increase the number of individuals exposed to malathion but that the increase cannot be quantified, since the number of individuals exposed will vary with the location and size of the infestation. In addition, adequate data to estimate exposure to malathion from its aerial application over residential areas are not available; however, OREB expects the incremental increase in exposure from aerial applications of malathion to be small.

Ecological Effects Review

The Ecological Effects Branch (EEB) reviewed this request and reached the following conclusions regarding the use of malathion and diazinon in USDA's proposed fruit fly quarantine program.

A) Malathion:

EEB concluded in its review of this request that the use of malathion in the proposed fruit fly eradication program in Florida does not pose a hazard to terrestrial vertebrates. However, it may result in risk to honeybee populations and aquatic organisms.

The acute LD₅₀ for the honeybee is 0.27 ug/bee. Spray deposition studies conducted by the California State Water Resources board have shown that the California spray program, which is very similar to the program proposed for Florida, results in deposition levels significantly greater than the LD₅₀. EEB recommends that the following label statement be required on supplemental §18 labeling to mitigate risk to honeybees:

"This product is highly toxic to bees exposed to direct treatment of blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

Malathion is highly toxic to both warmwater and coldwater fish and very highly toxic to aquatic invertebrates. Residue levels observed in both Florida and California monitoring programs exceed the special review trigger for fish and aquatic invertebrates.

EEB notes that malathion is registered for use on more than 100 sites as well as for control of adult mosquitoes and flies in aerial programs similar to the proposed use. Although the proposed rate of application is lower than registered rates for adult mosquito control and much lower than registered rates for use on numerous crops and noncrop sites, Medfly eradication programs in California and encephalitis aerial spray programs in Massachusetts using slightly higher rates have resulted in

numerous fish kills. Therefore, the potential also exists for adverse effects on aquatic organisms to occur in Florida from the proposed use of malathion in USDA's quarantine program. EEB recommends that, in the event this exemption is granted, the following statement be required on supplemental §18 labeling to help mitigate risk to aquatic organisms:

"This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in areas near the application site. Do not contaminate water when disposing of equipment washwaters."

EEB also concluded that four endangered species might be threatened by the proposed use of malathion in areas where malathion is likely to be applied under this exemption: the Okaloosa Darter (Okaloosa and Walton counties), the Schaus Swallowtail Butterfly (Dade and Monroe counties), the Stock Island Snail (Florida Keys), and the Apple Snail, which is the sole food source of the Everglades Kite (several counties in south Florida). During past eradication cycles in Florida, USDA has contacted USFWS about the presence and protection of endangered, threatened, and proposed species within or near the treatment area. USFWS Special Agent Terry English confirmed that there were no endangered species or critical habitats in the 1990 treatment area. EEB recommends that if an expanded treatment area becomes necessary, USDA/APHIS should again contact USFWS regarding the presence and protection of endangered species.

Finally, EEB pointed out that the proposed residue monitoring program is inadequate to assess potential impact to nontarget species.

B) Diazinon:

EEB concluded that the proposed use of diazinon can be expected to kill birds, even with a limited treatment area; the larger the treatment area, the greater the number of birds likely to be killed. Mortality of aquatic organisms due to diazinon under the proposed use may be less likely than for birds. However, aquatic mortality is also possible in coastal and lake regions of Florida.

The proposed use of diazinon may result in significant adverse effects on endangered or threatened species, particularly birds. Numerous endangered/threatened species are present in various Florida counties. EEB concluded, as they did in their malathion review, that prior to making applications of diazinon in counties of concern under this exemption, if granted,

USDA/APHIS must contact the USFWS to ensure protection of Florida's endangered species.

Again, EEB concluded that the Environmental Monitoring Plan submitted by APHIS, proposing water and soil sampling, is inadequate to assess hazard from the use of diazinon. EEB feels that it would be far more relevant to measure residues of diazinon on avian dietary items, count numbers of granules on the soil surface, and search for dead birds.

As noted above under "Special Review Considerations" for diazinon, the golf course and sod farm uses of diazinon were canceled due to unacceptable avian risk. APHIS has been informed that use of diazinon on these sites would not be allowed under this quarantine exemption. This restriction will be incorporated into the authorizing mailgram, if the exemption is granted.

IV. SUMMARY OF AGENCY CONCERNS/APHIS RESPONSE:

The Agency is primarily concerned about the aerial application of malathion over residential and urban areas with large human populations. To a lesser degree, EPA is concerned about the risk to non-target aquatic organisms from the proposed use of malathion. Although the use of diazinon also poses risks to non-target organisms, particularly birds, the amount of diazinon which has historically been applied in Florida to control quarantined fruit flies and which is likely to be applied under the proposed exemption is insignificant, compared to the amount applied as a result of the registered agricultural and homeowner uses of diazinon. During the most recent eradication effort in 1990, only 7.5 gallons of diazinon were applied. Prior to that, only 2 gallons of diazinon were applied in Florida during the 1987 eradication program.

The Agency is concerned that the database for malathion is inadequate to assess the risks from aerial bait-spray applications over densely populated areas. Significant toxicology data gaps exist in the areas of chronic toxicity, carcinogenicity, ocular toxicity, and neurotoxicity. Data to adequately assess exposure of the population to malathion as a result of this use are also unavailable. The data which are needed to fully evaluate the human health risks from this use are being required through the reregistration process; however, much of these data are not due at the Agency until 1992, and certain critical toxicology studies (chronic/carcinogenicity) are not due until 1994.

Nevertheless, the Agency recognizes the importance of USDA's fruit fly quarantine program and the need to act quickly on USDA's quarantine exemption request. Although no fruit flies have been trapped since the single male Medfly was trapped in May, an infestation could occur at any time that would require

prompt action on the part of USDA. With this in mind, EPA met with USDA/APHIS on June 12, 1991, to discuss our concerns and ways to better define and mitigate potential risks from the proposed quarantine program. At the meeting, APHIS clarified certain aspects of the proposed program, agreed to certain risk mitigation procedures, and made a commitment to generate certain data which will allow EPA to better define the risks from this program. The major concerns discussed at the meeting are summarized below, together with USDA/APHIS's response:

1. The Agency expressed its concern that the proposed program, as outlined in USDA's October 3, 1990, request was somewhat vague and open-ended as to the size of the potential treatment area and the number of aerial applications of malathion which might be made in a given area. Although the application focused mainly on Florida, USDA's request was not restricted to Florida, and maps included in the application seemed to indicate that coastal areas from Florida westward to Texas might potentially be sprayed. In addition, the application gave little indication of the total number of aerial applications which might be made in a given area to eradicate an infestation. EPA representatives recalled the situation which developed in California in 1990, where some residential and urban areas were sprayed as many as 13 times.

APHIS Response: APHIS responded that Florida is the area of immediate concern and, on June 14, 1991, submitted a letter modifying the request to indicate that the exemption would be "for use in the State of Florida (only)".

APHIS explained that the situation in California in 1990 which resulted in multiple malathion applications in some areas was unique and is not expected to recur. The preferred eradication procedure calls for only two applications of malathion, followed by the release of sterile male flies to complete the eradication program. The malathion sprays are necessary to eliminate pregnant females and reduce the wild fly population so that adequate overflooding ratios of 100:1 (sterile flies to wild flies) can be attained. The use of Sterile Fly Technique (SIT) is contingent upon the availability of sufficient numbers of quality sterile Medflies to attain and maintain this overflooding ratio. During 1990, contamination of sterile fly feed at rearing facilities led to death of many of the sterile flies and a shortage of sterile flies for use in California's eradication program. USDA has taken steps to ensure that this problem does not recur. The APHIS sterile fly rearing facility in Waimanalo, Hawaii, is now fully operational and can produce 500 million sterile flies per week. APHIS also has backup facilities in Mexico and Guatemala that can provide additional flies if needed.

Consequently, APHIS does not anticipate that there will be any shortage of high-quality sterile flies.

2. EPA expressed the concern that people living in areas where spray blocks intersect could receive a double "dose" of malathion.

APHIS Response: APHIS shares this concern and has already taken steps to prevent overlapping treatments. APHIS and the cooperating State agency routinely use sensitized "spray cards" to monitor pesticide drift along the border of spray blocks, and results of past monitoring efforts indicate that overlapping spray swaths do not occur. Rather, a narrow untreated band usually occurs at the intersection of adjoining spray blocks. APHIS is also requiring aerial spray contractors to use PATH-COR equipment, which generates a permanent record of aircraft flight lines in relation to spray block boundaries and will allow APHIS to better monitor contractor performance.

- 3.. USDA's October, 1990, application did not address the issue of public notification and education. EPA feels that a strong and effective public notification and education program is essential to reducing the potential human health risks from aerial spraying of malathion.

APHIS Response: APHIS explained that they and the cooperating state agency make every effort to keep the public informed and actively involved in all fruit fly control programs. Public awareness is an integral part of USDA's eradication protocol, and APHIS will continue to work with the state of Florida to assure adequate public notification of all of its fruit fly quarantine activities. On June 14, 1991, APHIS submitted a copy of its draft public information and notification plan, which would be implemented in Florida in the event an eradication program is triggered (A copy is attached at the back of the exemption application in the front of this package). The plan employs a tiered approach to provide increasing levels of public involvement and information resources as the size of an infestation increases. The program relies heavily on the mass media for public notification and education.

In addition, the state of Florida operates a voluntary sensitive individuals registry. State law requires that any person who is registered through this program as a sensitive individual must be notified of any pesticide application in their area.

4. EEB representatives reiterated their concern that the use of malathion and diazinon may pose significant risks to avian (diazinon) and aquatic (malathion and diazinon) nontarget

organisms and that the proposed environmental monitoring program, as outlined in USDA's application, is inadequate to detect any adverse effects which may occur. EEB recommended that the monitoring program be revised to include monitoring for bird and fish kills. In addition, EEB recommended that where diazinon is applied, APHIS should also monitor residues on avian dietary items.

APHIS Response: APHIS agreed to review its Environmental Monitoring Plan and to incorporate EEB's recommendations. In APHIS's June 14, 1991, letter to EPA they committed to incorporate carcass searches and residue monitoring of avian dietary items in the monitoring plan.

EEB reviewed the proposed plan for carcass searches and residue monitoring and made the following suggestions: First, under the proposed plan, avian dietary items (including insects, seeds, grasses, forbs, and possible, aquatic invertebrates) would be analyzed for both malathion and diazinon residues. Since malathion is not expected to pose a risk to avian species, analysis for malathion residues is not necessary. In addition, monitoring of residues in aquatic invertebrates is also not necessary.

EEB concluded that, due to the nature of the proposed eradication program, a specific monitoring study protocol cannot be prepared in advance of the time when an eradication program is triggered. The location of the treatment area and the types of habitats which would be treated will not be known until an infestation occurs. Consequently, EEB recommends that, if this exemption is granted, USDA should be made aware of the need for adequate adverse effects monitoring and referred to EPA's general field study guidelines for guidance in conducting carcass searches and residue monitoring in situations where monitoring is warranted. EEB recognizes that they may not be able to adhere strictly to these guidelines. However, since there is potential for adverse effects to occur, USDA/APHIS should adhere as closely as they can in each situation.

5. Finally, EPA stressed the need for human exposure data to evaluate the human health risks from aerial malathion bait spray applications over residential and urban populations.

APHIS Response: APHIS has already been in contact with Dr. Herbert Nigg of the University of Florida regarding development of a human exposure study protocol to generate the necessary data. In the June 14, 1991, letter to EPA, APHIS reaffirmed its commitment to work with EPA and State cooperators in designing and conducting human exposure studies for this purpose. The actual study would be

conducted either in California or Florida, depending on where the first eradication program occurs. The data generated in the study would be used to support the emergency exemptions in both states.

During a spring, 1991 trip to California, Curt Lunchik, Head of the Reregistration and Special Review Section in OREB, learned that some human exposure data had already been collected by the California Department of Health Services (CDHS) in connection with the Medfly program in Southern California. These data, which USDA was able to obtain from CDHS, are currently under review in OREB. Although the final review is not complete, it appears that the data are not adequate to assess bystander exposure from the proposed use of malathion in Florida. USDA/APHIS has agreed that if they are not adequate, they will work with EPA and State cooperators to generate additional data which may be required.

Malathion is registered for use on a wide variety of sites, and exposure data are also needed to assess the health risks from these uses. Since the June meeting with APHIS, OREB has been working with the Reregistration Branch on an exposure DCI to obtain these data. OREB's initial cost estimates for the proposed requirements are quite high. As a result, OREB has been asked to reevaluate the exposure data requirements to determine if some uses could be clustered to eliminate the need for some of the studies. OREB has also been asked to identify those exposure studies which are most critically needed to evaluate the human health risks from the registered use of malathion. OREB indicated in the meeting with SRRD on October 7, 1991, that data to estimate exposure to malathion from "homeowner" uses and from uses involving broad-scale, aerial applications over urban areas (such as the public health uses for mosquito abatement and the aerial Medfly uses) should be given highest priority by the Agency.

It now appears that the issues of what exposure data will be required to support the public health and quarantine uses of malathion and who should be responsible for providing the data will be resolved through the reregistration process. USDA may or may not be directly involved in conducting the exposure studies. However, APHIS continues to express its willingness to cooperate with EPA in the development of exposure data to support this use, once EPA finalizes the exposure data requirements.

V. RECOMMENDATION:

I recommend that the United States Department of Agriculture, Animal and Plant Health Inspection Service, be granted quarantine exemptions for use of malathion and diazinon to eradicate exotic (nonindigenous, quarantined), subtropical members of the fruit fly family, Tephritidae, in quarantined areas within the state of Florida where active infestations of exotic fruit flies have been identified. This recommendation is based on the following:

1. Under 40 CFR §§ 166.3 and 166.25, I find that an emergency condition exists because: no effective pesticides are available under the Act that have labeled uses registered for control under the conditions of the emergency; no economically or environmentally feasible alternative practices provide adequate control of the pest, and the situation involves the introduction of a pest new to or not heretofore known to be widely distributed within the United States. Also, the situation will cause significant economic loss due to an outbreak or expected outbreak of a pest.

Exotic, subtropical fruit fly species such as the Mediterranean fruit fly are notorious destroyers of fruit, which could cause economic losses of nearly \$1 billion per year to the U.S. agricultural industry, if they were to become established in this country. In addition, establishment of subtropical fruit flies could result in a significant increase in pesticide usage to prevent damage from these pests. Eradication would appear to be the only responsible course of action when an exotic fruit fly infestation is detected.

2. Malathion and diazinon will only be used as a last resort in USDA/APHIS's fruit fly quarantine program to eradicate reproducing infestations which occur despite the rigorous exclusion and detection measures employed by APHIS to prevent such infestations from occurring. When eradication is triggered, malathion will only be used to eliminate pregnant females and reduce the wild fly population to the level where adequate sterile fly overflooding ratios of 100:1 (sterile flies to wild flies) can be attained to complete the eradication program. In most cases, the maximum number of applications required will be two. Diazinon will only be applied to soil under host trees on properties where fruit fly larvae are found infesting fruit and to soil under host trees on adjacent properties.
3. Furthermore, under 40 CFR § 166.25, I find that the use of the pesticide under the exemption will not cause unreasonable adverse effects on the environment. The toxicological databases for malathion and diazinon are

adequate to support only minor new uses that will not significantly increase the dietary and non-dietary exposure of the population. HED has determined that the proposed use of diazinon in fruit fly eradication programs in Florida will result in a negligible increase in both dietary and non-dietary exposure of the population. HED has also determined that the use of malathion in these programs will result in an insignificant increase in dietary exposure.

Aerial application of malathion over residential and urban areas would greatly increase the number of individuals exposed to malathion, but it is not possible to quantify the increase, since the number of individuals exposed will vary with the location and size of the infestation. In addition, adequate data to estimate bystander exposure to malathion from its aerial application over residential areas are not available. Nevertheless, the incremental increase in exposure from aerial applications of malathion is expected to be small.

Malathion is registered for use on a wide range of sites and is readily available over the counter in hardware stores, lawn and garden shops, drug stores, and grocery stores; and is commonly used by homeowners or professionally applied indoors. In addition, malathion is widely used in public health mosquito control programs which also involve aerial application over large populated areas. From 1985 to 1988, approximately 600,000 lbs. of malathion a.i. per year were applied in Florida mosquito control programs. By comparison, 4,040 and 14,956 lbs. of malathion a.i. were applied in USDA Medfly eradication programs in Florida in 1987 and 1990, respectively, the two most recent fruit fly eradication programs there.

Despite the fact that the incremental increase in exposure to malathion from the proposed use is expected to be small, the Agency has determined that human exposure data are needed to evaluate the human health risks from aerial malathion bait spray applications over residential and urban populations. The issue of what exposure data will be required to support this type of use of malathion, including the public health mosquito abatement uses and the Medfly quarantine uses, will be resolved through the reregistration process. The issue of who should be responsible for generating the required data will also be resolved through reregistration. USDA may or may not be directly involved in conducting the exposure studies. However, APHIS continues to express its willingness to cooperate with EPA in the development of exposure data to support this use, once EPA finalizes the exposure data requirements.

4. The proposed use of malathion and diazinon may pose risks to avian (diazinon) and aquatic (malathion and diazinon) non-target organisms. The use of malathion may also pose a risk to honey bees.

Although the use of diazinon may result in adverse effects on non-target organisms, particularly birds, the amount of diazinon which has historically been applied in Florida to control quarantined fruit flies (2.0 gallons in 1987 and 7.5 gallons in 1990) and which is likely to be applied under the proposed exemption is insignificant, compared to the amount applied as a result of the registered agricultural and homeowner uses of diazinon. Therefore, the incremental increase in risk is expected to be negligible. USDA/APHIS has agreed to limit total diazinon usage under this exemption to 10 gallons per year or less. This restriction will ensure that the incremental increase in risk remains negligible. Should USDA/APHIS wish to increase the amount of diazinon which may be applied under the exemption, they must request an amendment to the exemption.

The proposed use of malathion may result in hazard to honeybee populations and aquatic organisms. To mitigate risk to non-target organisms, label statements recommended by EEB prohibiting applications when bees are visiting the area and prohibiting applications over water will be imposed.

EEB concluded that the environmental monitoring plan submitted with USDA's application is inadequate to assess hazard to non-target organisms from the use of diazinon and malathion and recommended that the monitoring plan be revised to include monitoring for bird and fish kills and, where diazinon is applied, monitoring of residues on avian dietary items. USDA/APHIS has agreed to incorporate EEB's recommendations into its monitoring plan.

Several endangered or threatened species are present in Florida which may be jeopardized as a result of the use of malathion and diazinon in the proposed program. To mitigate risk to endangered species, prior to making applications of either malathion or diazinon under these exemptions, USDA will be required to contact the USFWS regarding the presence and protection of endangered species.

Approve: _____

Disapprove: _____

Date: OCT 26 1991