



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

AUG 31 1980

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 - Quarantine Exemption for the Use of
Malathion to Control Fruit Flies in California
-- ACTION MEMORANDUM --

FROM: Anne E. Lindsay, Director
Registration Division

A handwritten signature in cursive script, appearing to read "Anne E. Lindsay".

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

I. APPLICANT REQUEST:

APPLICANT: California Department of Food and Agriculture

CHEMICAL: Malathion

PRODUCT:

1. Clean Crop Malathion ULV Conc.
EPA Reg. No. 34704-18
2. Prokil Malathion 25-WP
EPA Reg. No. 10163-61
3. Malathion 25 Spray
EPA Reg. No. 279-739
4. Cythion Insecticide 'The Premium
Grade Malathion'
EPA Reg. No. 241-208
5. Malathion ULV Concentrate Insecticide
EPA Reg. No. 241-110

SITE: Allspice, Bananas, Chapote, Chayote,
Cherimoya, Custard Apple, Eugenia Fruits
(edible), Kiwi, Litchi, Longan Fruit, Loquats,
Mulberry, Olives, Opuntia (cactus fruit),
Persimmons, Pineapple, Guava, Sapodilla,
Sapote, Star Apple, Tomatillos, Tree Tomatoes,
and Pummelos

PESTS: Exotic (non-established, quarantined) Fruit Fly members of the Family, Tephritidae, including:

Mediterranean Fruit Fly (Ceratitis capitata),
Oriental Fruit Fly (Dacus dorsalis)
Mexican Fruit Fly (Anastrepha ludens)
Caribbean Fruit Fly (Anastrepha suspensa)
Melon Fly (Dacus cucurbitae)
Peach Fruit Fly (Dacus zonatus)
Guava Fruit Fly (Dacus correctus)
Queensland Fruit Fly (Dacus tryoni)

RATE: A maximum of 2.8 oz. active ingredient malathion mixed with a maximum of 9.6 fl. oz. per acre of Staley's Protein Bait, Nu-Lure or other similar bait material cleared for use on food crops

NO. OF APPL: Multiple ground or aerial applications at a minimum of 7-day intervals with a 3-day PHI

USE-SEASON December 9, 1989 to December 8, 1992

EMERGENCY/ALTERNATIVES: Fruit fly species of the family Tephritidae are quarantined pests in California that periodically enter the state from infested areas. These fruit flies would pose a serious threat to California's fruit and vegetable industry if they should become established in the state.

Members of the fruit fly family are among the worst pests of cultivated fruits 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. In warmer climates, these flies are capable of producing up to 12 generations per year. Since the larvae are somewhat protected inside the fruit and because many of the subtropical fruits break down when exposed to methyl bromide, eradication efforts are directed against the adult flies.

A quarantine treatment is needed to allow movement of fruit outside the quarantined area. The treatment must be efficacious in eradicating the pest, phytotoxically acceptable, and satisfactory to both the grower and the buyer. Several alternative treatments exist, but they do not satisfy all the requirements for a quarantine treatment. Cold storage is not acceptable, because most tropical fruits will not tolerate the cold temperatures and exposure periods necessary for quarantine efficacy. Fumigation results in phytotoxicity to many

subtropical fruits and is only marginally efficacious. In addition, tolerances for residues resulting from fumigation with methyl bromide, aluminum phosphide, and hydrogen cyanide have not been established for these minor crops. Host stripping is not a viable alternative for commercially grown specialty fruits, since destruction of the fruit would be economically devastating to the grower and unacceptable to the State in terms of liability.

USDA currently has an emergency exemption for California to eradicate the Oriental fruit fly using the male annihilation technique, a method which attracts the male fly to bait stations and uses dibrom to kill the fly. This treatment is good for eradicating small populations of the genus Dacus, but is not an acceptable commodity treatment. This technique does not control female flies and will not prevent egg laying. Also, tolerances for dibrom have not been established for these minor crops.

ECONOMICS: An estimated 33,500 acres of olives, valued at over \$50 million, and 4,500 acres of kiwi fruit, valued at approximately \$17 million, are currently grown in California. Small commercial acreages of the other crops exist scattered throughout the state. Growers of these crops in quarantine areas will experience major crop losses if a treatment is not available, to allow movement of the fruit outside the quarantine area.

II. BACKGROUND:

The California Department of Food and Agriculture requested and was granted a quarantine exemption for the use of malathion to control fruit flies on the subject commodities in December of 1986. This exemption expires on December 8, 1989.

California currently has 24C registrations (CA-820062, CA-820063) for the use of malathion to control the Mediterranean fruit fly on various commodities (apricots, apples, avocados, cherries, filberts, nectarines, peaches, pears, pecans, plums, prunes, quinces, eggplant, peppers, blackberries, dewberries, loganberries, raspberries, strawberries, grapefruit, lemons, limes, oranges, tangerines, tangelos, kumquats, grapes, and tomatoes). These 24Cs are used to carry out the quarantine program on the above commodities to allow shipment of the fruit outside the quarantine area. California is seeking this quarantine exemption to allow treatment of additional crops that are being grown in the quarantine area.

Registration Standard/Special Review

A Registration Standard for malathion was issued in February of 1988. Based on review and evaluation of all available data for malathion, the Agency has taken the following regulatory positions:

1. Malathion is not being placed in Special Review at this time.
2. The Agency will not approve tolerances for significant new uses until the Agency has received data sufficient to evaluate dietary exposure to malathion.
3. The Agency is concerned about potential hazard to aquatic organisms, but is not taking regulatory action at this time for fish and wildlife concerns.
4. The Agency is not restricting the use of malathion products at this time.
5. Certain uses may jeopardize endangered species. The Agency is seeking Office of Endangered Species evaluation of the potential hazard and developing a program to reduce or eliminate exposure to these species.
6. Malathion products must bear revised and updated fish and wildlife toxicity warnings.
7. The Agency is deferring decisions concerning malathion's potential for contaminating groundwater until information on its environmental characteristics and fate have been submitted and reviewed.
8. The Agency is not requiring reentry intervals for agricultural uses of malathion beyond the minimum reentry interval (sprays have dried, dusts have settled and vapors have dispersed).

III. EPA EVALUATION:

BEAD Review

BEAD concluded in its previous review of California's application for this quarantine exemption that the fruit fly species listed in the request are notorious destroyers of fruit and that eradication would be the only responsible action when their presence is detected. BEAD considered malathion to be the most practical choice for a program such as the one being proposed to eradicate fruit flies within quarantine areas.

Residue Chemistry Review

Dietary Exposure Branch previously reviewed this request and concluded that residues of malathion are not likely to exceed 8 ppm in or on the subject commodities as a result of the proposed use. Secondary residues in meat, milk, poultry, and eggs are not expected as a result of the proposed uses. Analytical methods are available in PAM II, and analytical reference standards are available from the Pesticides and Industrial Chemicals Repository in RTP, N.C.

Toxicological Review

Toxicology Branch previously reviewed the proposed use and concluded that, since residues on the subject commodities would not exceed the established tolerances on a host of widely consumed commodities (including apples, berries, grapes, melons, oranges, peaches, potatoes, tomatoes, and wheat), the toxicology database for malathion would support the proposed use.

In the Registration Standard, the Agency is requiring several additional toxicology studies, including chronic toxicity and oncogenicity studies. These studies are not due to be completed until 1992. Because of these toxicology data gaps and the fact that additional residue data are needed to support most of the existing tolerances, the Agency was unable to perform a tolerance reassessment at the time the Registration Standard was completed.

The Provisional ADI (PADI) for malathion is 0.02 mg/kg/day, based on the NOEL of 0.23 mg/kg/day from a human cholinesterase study with an uncertainty factor of 10. The TMRC from existing tolerances utilizes 509% of the PADI. The TAS food database contains consumption estimates for most, but not all, of the commodities to be treated under the quarantine exemption. Use on these commodities would increase the percent of the PADI utilized from 509% to 518.5%, which represents an increase of 1.8% in total dietary exposure.

Nearly all of the increased dietary exposure is from the single commodity, bananas. Since most of the bananas consumed in the U.S. are produced outside of California (in Hawaii or South America), actual exposure to malathion from treatment of bananas in California would be considerably lower than the estimate based on total banana consumption. The same would be true for many of the other subtropical fruits to be treated under the quarantine exemption. Therefore, it is unlikely that the proposed use would significantly increase total dietary exposure to malathion.

Ecological Effects Review

EEB's previous review of California's request concluded that the proposed quarantine exemption may pose a hazard to aquatic invertebrates and possible chronic hazard to nontarget aquatic and terrestrial organisms. EEB recommended precautionary labeling to mitigate the potential hazard. In addition, the Registration Standard for malathion, issued in February of 1988, requires revised environmental hazards labeling for all manufacturing and end use products containing malathion. All malathion products sold after March 31, 1990 must bear labels which comply with these requirements. These same label restrictions and precautions have been incorporated into the telegram authorizing this quarantine exemption:

"This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. Do not apply directly to water or wetlands (i.e., swamps, bogs, marshes, and potholes). Drift and runoff may be hazardous to aquatic organisms in areas near the application site. Do not contaminate water when disposing of equipment washwaters.

This product is highly toxic to bees exposed to direct treatment on 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."

The U.S. Fish and Wildlife Endangered Species Office in Sacramento was contacted concerning the proposed quarantine exemption. USFWS's concerns have not changed since its previous review of this use in April of 1987. USFWS concluded that malathion applications in ten California counties (Butte, Colusa, Glenn, Kern, Merced, Sacramento, Solano, San Joaquin, Tehama, and Yolo) may adversely affect three federally-listed endangered and threatened species: the valley elderberry longhorn beetle (Desmocerus californicus), the Kern primrose sphinx moth (Euproserpinus euterpe), and the delta green ground beetle (Elaphrus viridis). USFWS has provided the California Department of Food and Agriculture with habitat maps for these three species. Applications of malathion to these habitats or any areas where the drift of malathion spray may reach these habitats will be prohibited.

IV. RECOMMENDATION:

I recommend that a quarantine exemption be granted to the California Department of Food and Agriculture for use of malathion as quarantine treatment for fruit flies to allow shipment of treated commodities outside the quarantine area. This recommendation is based on the following:

1. If quarantined species of fruit flies become established in California, fruit and vegetable growers in the state would suffer significant economic losses. There are currently no registered pesticides for eradication of these pests.
2. The proposed use is not expected to result in residues in excess of 8 ppm in or on the subject commodities and should not significantly increase dietary exposure to malathion.
3. California has made identical quarantine applications of malathion to a number of major crops since 1982 under two 24Cs with no reported adverse effects to nontarget organisms or the environment. The proposed use on these additional minor crops should not significantly increase the risk of adverse effects.

Approve: E. J. [Signature] Day, C. [Signature]

Disapprove: _____

Date: 9/11/80

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EPA9945

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Attention: Regina Sarracino, Supervisor
Pesticide Registration Branch

The Environmental Protection Agency hereby grants a quarantine exemption pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to the California Department of Food and Agriculture for use of malathion on allspice, bananas, chapote, chayote, cherimoya, custard apple, eugenia fruits (edible), guava, kiwi, litchi, longan fruit, loquats, mulberry, olives, opuntia (cactus fruit), persimmons, pineapple, pummelos, sapodilla, sapote, star apple, tomatillos, and tree tomatoes as a quarantine treatment for exotic (non-established, quarantined) fruit fly members of the family Tephritidae, including, but not restricted to, the Mediterranean fruit fly (*Ceratitis capitata*), the Oriental fruit fly (*Dacus dorsalis*), the Mexican fruit fly (*Anastrepha ludens*), the Caribbean fruit fly (*Anastrepha suspensa*), the melon fly (*Dacus cucurbitae*), the peach fruit fly (*Dacus zonatus*), the guava fruit fly (*Dacus correctus*), and the Queensland fruit fly (*Dacus tryoni*). The quarantine exemption is subject to the following conditions and restrictions.

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1. The California Department of Food and Agriculture is responsible for ensuring that all provisions of this quarantine exemption are met. It is also responsible for providing information in accordance with 40 CFR 166.32. This information must be submitted to EPA Headquarters.

2. EPA-registered malathion products: Clean Crop Malathion ULV Conc., EPA Reg. No. 34704-18; Prokil Malathion 25-WP, EPA Reg. No. 10163-61; Malathion 25 Spray, EPA Reg. No. 279-739; Cythion Insecticide 'The Premium Grade Malathion', EPA Reg. No. 241-208; Malathion ULV Concentrate Insecticide, EPA Reg. No. 241-110 may be used. All applicable directions, restrictions, and precautions on the EPA-registered product label must be followed.

3. Formulations used under this exemption will consist of a maximum of 2.8 ounces active ingredient mixed with a maximum of 9.6 fluid ounces of Staley's Protein Bait, Nu-Lure or other similar bait material per acre. Baits will be used at a rate equivalent to a maximum of 9.6 fluid ounces of Staley's Protein Bait.

4. Applications under this exemption will be made at a minimum of 7-day intervals with ground or aerial application equipment. A 3-day PHI will be observed.

5. All applications will be made by or under the direct supervision of trained pesticide applicators of the California Department of Food and Agriculture, Division of Plant Industry, or other cooperating agencies.

6. Applications made in accordance with the above provisions are not expected to result in residues of Malathion in excess of 8 ppm in or on the subject commodities. Secondary residues in meat, milk, poultry, and eggs are not expected as a result of this use. The Agency has determined that these levels are adequate to protect the public health. Analytical methods are available in PAM II, and analytical reference standards are available from the Pesticides and Industrial Chemicals Repository in RTP, N.C. The Food and Drug Administration, DHHS, has been advised of this action.

Residue data will be taken upon treatment of a specified crop under this quarantine exemption. Any treated commodities with residues of malathion in excess of 8 ppm will be withheld from the channels of trade and EPA will be notified by phone. Residue data should be submitted to the Agency with the reports required in item 11.

7. Prior to initiation of this treatment program, notification should be made through the public media as to the time and area to be treated. Individual property owners in the treatment area should be contacted and advised of the treatment and appropriate precautions.

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8. This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. Do not apply directly to water or wetlands (i.e., swamps, bogs, marshes, and potholes). Drift and runoff may be hazardous to aquatic organisms in areas near the application site. Do not contaminate water when disposing of equipment washwaters.

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.

9. Malathion should not be applied to endangered and threatened species habitats as identified by the U.S. Fish and Wildlife Service in its letter dated April 1, 1987, to the California Dept. of Food and Agriculture, and application should not be made to any areas where the drift of malathion spray may reach these habitats.

10. The EPA shall be immediately informed of any adverse effects resulting from the use of malathion in connection with this exemption.

11. A final report summarizing the results of this program must be submitted by June 9, 1993. Interim reports must be submitted annually.

12. This quarantine exemption becomes effective December 9, 1989 and expires December 8, 1992.

13. Future correspondence regarding this exemption should refer to file symbol 89-CA-26.


Douglas D. Campt, Director
Office of Pesticide Programs

Date: 9/1/89