

US EPA ARCHIVE DOCUMENT

HED SECTION 18 ANALYSIS SUMMARY

JUN 14 1991

JUN 14 1991

TO: Rebecca Cool, PM 41
Registration Support and Emergency Response Branch
Registration Division (H7505C)

ACTION: 530 Section 18-QUR/PUB/HLTH OC F/F

Chemicals: malathion and diazinon

Requesting Agency: USDA (APHIS)

Crop(s): host crops in USDA quarantine areas (see Attachment for map of identified areas)

Maximum residue level: 8.0 ppm malathion in fruit and vegetables; tolerance levels of diazinon in nuts and fruit

HED Project Nos.: 1-0634, 1-0634A Caswell Nos.: 535, 342
1-0635, 1-0635A
1-0636, 1-0636A

ID No.: 91DA0002

Date in: 2/14/91
Due date: 3/14/91
Completion date: 6/10/91

CBRS Reviewer: F. Toghrol
OREB Reviewer: C. Lunchick
TB-1 Reviewer: W. Greer
Chemical Manager: F. Chow

HED Concurrence: R. Engler (SACB)

E. Zager (CBRS)

C. Trichilo (OREB)

K. Baetcke (TB-1)

[Handwritten signatures and dates]
Karl Baetcke 6/12/91

MalathionAnalysis for U.S. population (48 states)

Current TMRC based on existing tolerances:	0.099939 mg/kg/day
New TMRC (which includes new and pending tolerances):	0.099939 mg/kg/day (500% RfD)
Current ARC based on anticipated residue and crop treatment data	0.024216 mg/kg/day (121% RfD)

Comments

1. No residue data were submitted, and no specific commodities were listed in the petition. For the purpose of this Section 18 petition only, CBRS considers that residues of malathion in or on host crops will not exceed 8.0 ppm, which is the tolerance established for most fruit and vegetables. CBRS expects that residues of malathion are not likely to be found in livestock commodities as a result of this use.¹
2. The EPA RfD is 0.02 mg/kg/day. The incremental risk from consumption of treated crops is expected to be negligible. However, the most current DRES analysis shows that dietary exposure is already over 100% of the RfD: Based on TMRC data, the exposure is approximately 500% of the RfD, and based on ARC data, the exposure is approximately 120% of the RfD.
3. The non-dietary risk to the general population cannot be adequately assessed because of data gaps in toxicology and in bystander exposure.
 - Malathion has been classified in Group D with respect to carcinogenicity. Studies in the rat and mouse are required for the reregistration of malathion.
 - HED has concerns for potential damage to the eye from exposure to organophosphates, including malathion. Data to address ocular effects are being required for the reregistration of malathion.
 - OREB expects the exposure to individuals from the use of malathion to be low (and the incremental exposure to be small). However, the proposed aerial application of malathion would greatly increase the number of individuals exposed.²
4. The California Department of Health Services (CDHS) has concluded that the evaluation of the use of malathion over a

large human population (as in urban areas) would require a more extensive data base than that which is currently available, given the need to suitably evaluate the exposure and to assure the protection of the general population. Additionally, CDHS recommended that aerial application of malathion in urban areas be reconsidered in light of the results of its health risk assessment.^{3,4}

Diazinon

Analysis for U.S. population (48 states)

Current TMRC based on existing tolerances:	0.007474 mg/kg/day
New TMRC (which includes new and pending tolerances):	0.007549 mg/kg/day (8387% RfD)
Current ARC based on anticipated residue from treatment of 10% of the crops: ⁵	0.000763 mg/kg/day (848% RfD)

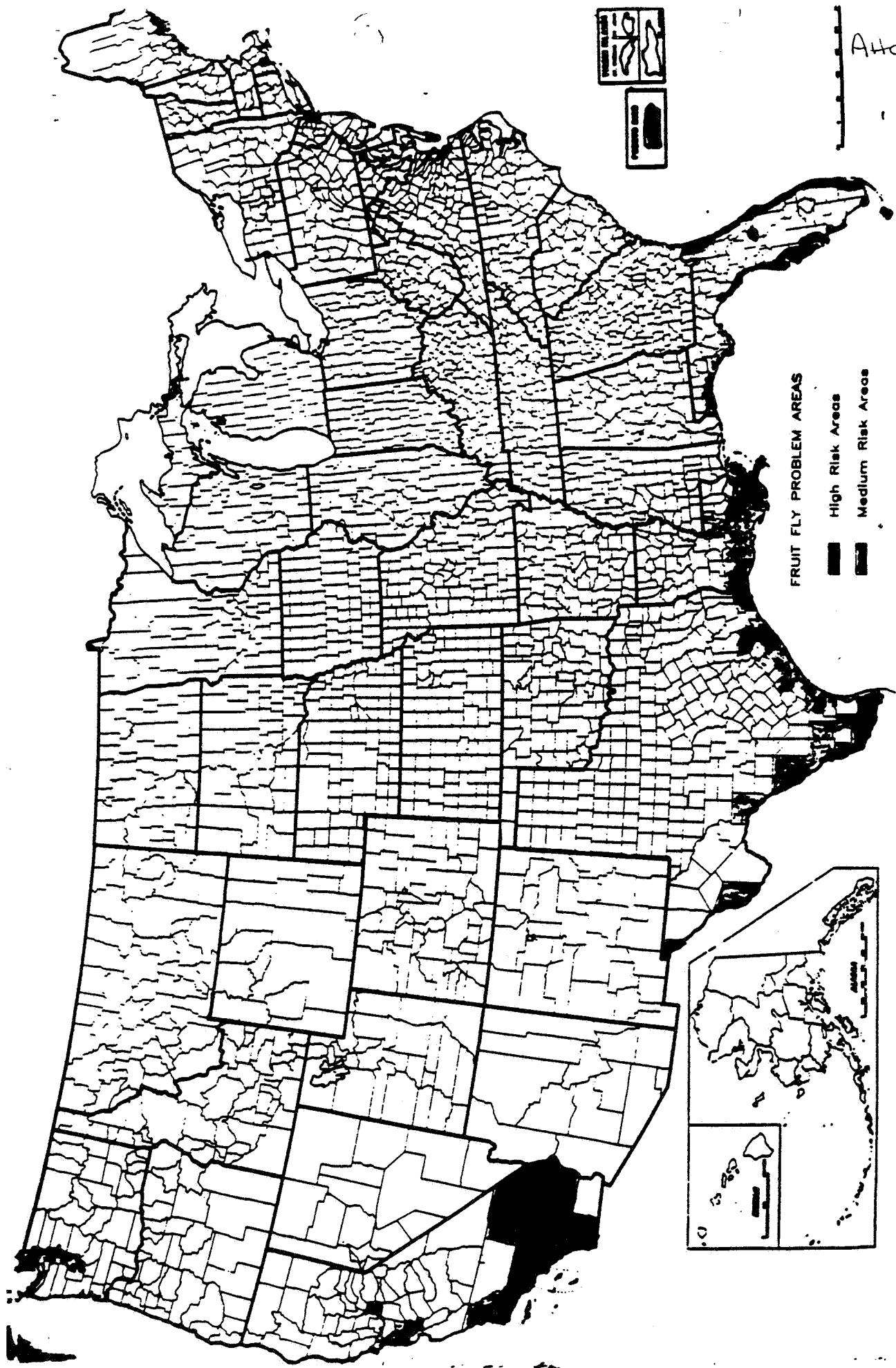
Comments

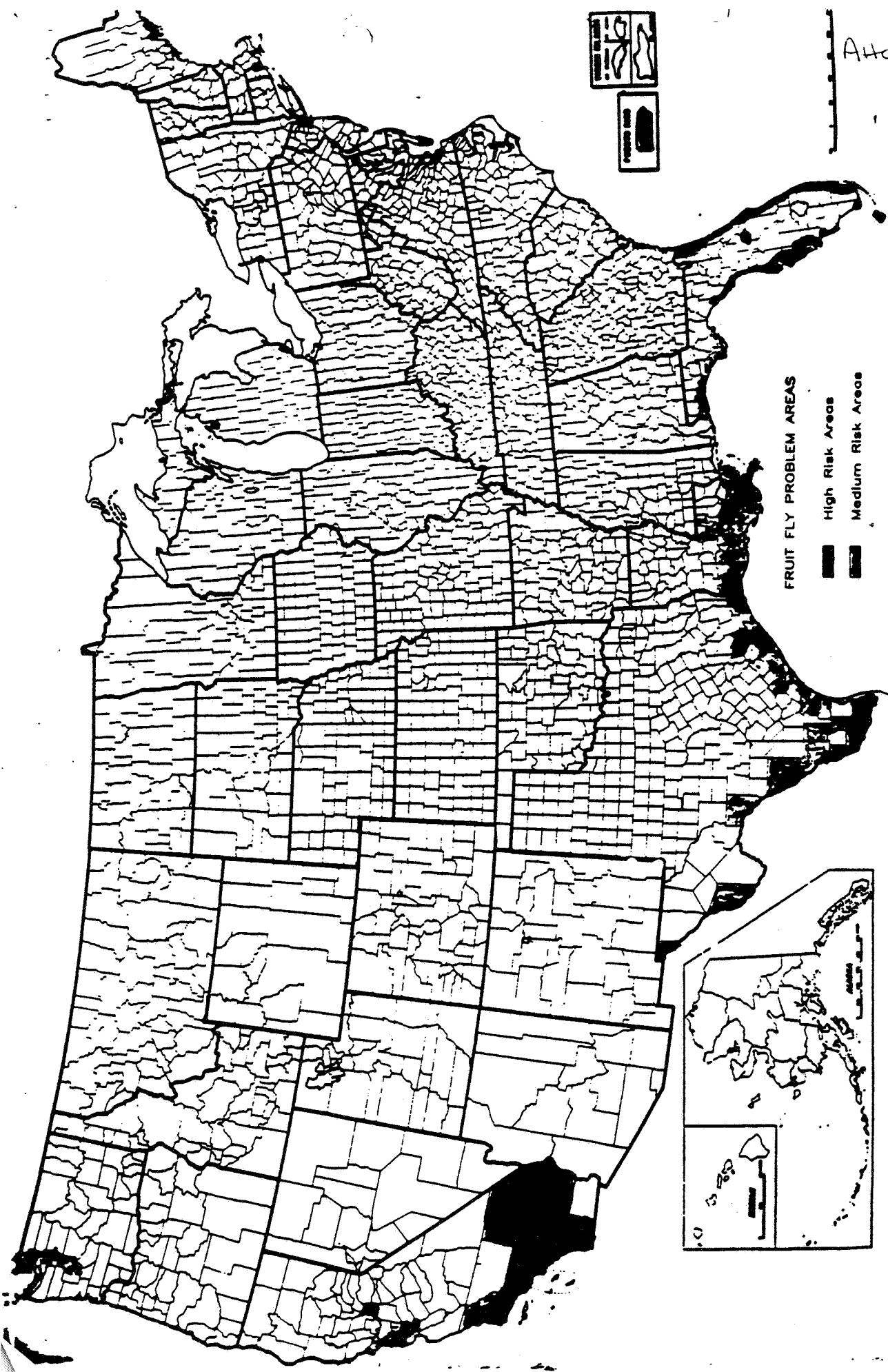
1. No residue data were submitted, and no specific commodities were listed in the petition. For the purpose of this Section 18 petition only, CBRS considers that residues of diazinon will not exceed the tolerances established for nuts and fruit. CBRS expects that secondary residues of diazinon are not likely to be found in livestock commodities as a result of this use.¹
2. The OPP RfD is 0.00009 mg/kg/day. The incremental risk from consumption of treated crops is expected to be negligible. However, the most current DRES analysis shows that dietary exposure is already over 100% of the RfD: Based on TMRC data, the exposure is approximately 8000% of the RfD, and based on ARC data,⁵ the exposure is approximately 800% of the RfD.
3. The incremental non-dietary risk to the general population is expected to be negligible. OREB expects the exposure to individuals from the use of diazinon to be low because the application of diazinon is by soil drenching techniques.²
4. The toxicology data base is adequate to support only minor new uses.⁶ The proposed use is not expected to significantly increase the dietary or non-dietary exposure of the general population.

ATTACHMENTS:

- A. Map of USDA quarantine areas
- B. DRES analysis results for malathion (9 April 1991) and diazinon (21 September 1989)
- C. CBRS memo (15 March 1991)
- D. OREB memo (28 February 1991)
- E. TB-1 memos (6 May 1991 and 12 June 1991)

1. F. Toghrol (15 March 1991). 91-DA-02. Section 18 Specific Quarantine Exemption for the Use of Diazinon and Malathion to Eradicate Mediterranean Fruit Fly in Florida. (No MRID #, DEB #7655). Memorandum to R. Cool/S. Stanton, PM 41 and TB/HED.
2. C. Lunchick (28 February 1991). Qualitative assessment of the incremental exposure to humans resulting from the proposed uses of malathion and diazinon under the APHIS Section 18 for fruit fly eradication (HED Project Nos. 1-0635 and 1-06355A). Memorandum to S. Stanton, PM 41.
3. W. Greear (6 June 1991). 91-DA-0002 -- Section 18 quarantine exemption for the use of malathion to eradicate exotic fruit flies "primarily" in Florida. Memorandum to F. Chow.
4. P. Fenner-Crisp (24 April 1991). Review of the health risk assessment of aerial application of malathion-bait submitted by California Department of Health Services. Memorandum to A. Lindsay.
5. Crop treatment data was not available. The DRES analysis was based on the assumption that 10% of all crops were treated with diazinon.
6. W. Greear (12 June 1991). 91-DA-0002 -- Section 18 quarantine exemption for the use of diazinon to eradicate exotic fruit flies "primarily" in Florida. Memorandum to F. Chow.





CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Malathion Caswell #535 CAS No. 121-75-5 A.I. CODE: 057701 CFR No. 180.111	Human ChE Study MOEL= 0.2300 mg/kg 0.00 ppm LEL= 0.3400 mg/kg 0.00 ppm ONCO: Class D (HED NOTE).	Decreased ChE activity. No evidence of oncogenicity in rats, mouse study equivocal.	PADI UF -->10 OPP Rfd= 0.020000 EPA Rfd= 0.020000	Chronic feeding- dog Reproduction- rat Developmental tox- rat Developmental tox- rabbit	HED complete 08/29/86. HED reassess 03/06/87. EPA verified 03/18/87. WHO last reviewed 1986. On IRIS.	

POPULATION SUBGROUP	TOTAL THRC (MG/KG BODY WEIGHT/DAY)		NEW THRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT THRC*	NEW THRC**			ARC	%RFD
U.S. POPULATION - 48 STATES	0.099939	0.099939	499.693590	0.000000	0.024216	121.07896
U.S. POPULATION - SPRING SEASON	0.096943	0.096943	484.715890	0.000000	0.023980	119.90088
U.S. POPULATION - SUMMER SEASON	0.100728	0.100728	503.640215	0.000000	0.024313	121.56351
U.S. POPULATION - FALL SEASON	0.100668	0.100668	503.341430	0.000000	0.024223	121.11663
U.S. POPULATION - WINTER SEASON	0.100411	0.100411	502.052500	0.000000	0.024094	120.46755
NORTHEAST REGION	0.106758	0.106758	533.792385	0.000000	0.025018	125.08849
NORTH CENTRAL REGION	0.099001	0.099001	495.004630	0.000000	0.024329	121.64577
SOUTHERN REGION	0.091933	0.091933	459.663725	0.000000	0.023089	115.44658
WESTERN REGION	0.104591	0.104591	522.956545	0.000000	0.024569	122.84724
HISPANICS	0.115940	0.115940	579.698390	0.000000	0.026948	134.74178
NON-HISPANIC WHITES	0.098960	0.098960	494.799880	0.000000	0.023984	119.92179
NON-HISPANIC BLACKS	0.094905	0.094905	474.525365	0.000000	0.023571	117.85286
NON-HISPANIC OTHERS	0.115359	0.115359	576.795165	0.000000	0.027195	135.97268
NURSING INFANTS (< 1 YEAR OLD)	0.139474	0.139474	697.371820	0.000000	0.017960	89.79827
NON-NURSING INFANTS (< 1 YEAR OLD)	0.262863	0.262863	1314.317310	0.000000	0.038455	192.27304
FEMALES (13+ YEARS, PREGNANT)	0.074800	0.074800	373.999955	0.000000	0.017283	86.41316
FEMALES 13+ YEARS, NURSING	0.083441	0.083441	417.202605	0.000000	0.018827	94.13492
CHILDREN (1-6 YEARS OLD)	0.222584	0.222584	1112.920045	0.000000	0.049740	248.70121
CHILDREN (7-12 YEARS OLD)	0.145287	0.145287	726.433185	0.000000	0.035075	175.37628
MALES (13-19 YEARS OLD)	0.093911	0.093911	469.555440	0.000000	0.025050	125.24784
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.081845	0.081845	409.223310	0.000000	0.020532	102.65956
MALES (20 YEARS AND OLDER)	0.074530	0.074530	372.651095	0.000000	0.020313	101.56389
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.073172	0.073172	365.860700	0.000000	0.017574	87.87244

*Current THRC does not include new or pending tolerances.
**New THRC includes new, pending, and published tolerances.

Table 2

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			IPADI SF -->100	Chronic feeding- rat		
Diazinon	90d feeding- rat	Inhibition of plasma ChE.	0.0090 mg/kg	0.00090	Chronic feeding- rat	HED complete 09/19/86.
Caswell #342	NOEL=	No evidence of oncogeni-	0.10 ppm	0.000000	Chronic feeding- dog	EPA deferred 11/25/86.
CAS No. 333-41-5	LEL=	city in rats or mice.	0.0250 mg/kg	0.000000	Reproduction- rat	Pending RAC approval of
A.I. CODE: 057801			0.50 ppm			RAF CHE report
CFR No. 180.153	ONCO: Negative- 2 species					WHO last reviewed 1978.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		DIFFERENCE AS PERCENT OF RFD		EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**	AS PERCENT OF RFD	AS PERCENT OF RFD	ARC	8RFD
U.S. POPULATION - 48 STATES	0.007474	0.007549	8387.263333	83.301111	0.000763	847.76556
U.S. POPULATION - SPRING SEASON	0.007314	0.007377	8197.078889	70.150000	0.000745	828.18444
U.S. POPULATION - SUMMER SEASON	0.007671	0.007778	8641.958889	118.384444	0.000785	872.76222
U.S. POPULATION - FALL SEASON	0.007430	0.007496	8328.996667	73.300000	0.000757	841.65333
U.S. POPULATION - WINTER SEASON	0.007389	0.007435	8261.301111	51.567778	0.000751	834.90000
NORTHEAST REGION	0.008069	0.008142	9046.843333	81.741111	0.000822	913.64667
NORTH CENTRAL REGION	0.007442	0.007517	8352.416667	83.776667	0.000760	844.71333
SOUTHERN REGION	0.006690	0.006743	7492.455556	59.075556	0.000682	757.54556
WESTERN REGION	0.007951	0.008040	8933.373333	99.131111	0.000811	900.90556
HISPANICS	0.008444	0.008507	9452.466667	70.166667	0.000859	954.93222
NON-HISPANIC WHITES	0.007456	0.007530	8366.918889	82.605556	0.000760	844.98778
NON-HISPANIC BLACKS	0.006845	0.006894	7660.460000	54.701111	0.000699	776.18000
NON-HISPANIC OTHERS	0.008366	0.008435	9372.102222	76.563333	0.000853	948.01556
NURSING INFANTS (< 1 YEAR OLD)	0.009432	0.009454	10504.188889	24.505556	0.000953	1059.33667
NON-NURSING INFANTS (< 1 YEAR OLD)	0.017551	0.017583	19536.708889	35.524444	0.001773	1970.33222
FEMALES (13+ YEARS, PREGNANT)	0.005710	0.005749	6387.761111	43.476667	0.000581	645.04556
FEMALES 13+ YEARS, NURSING	0.006395	0.006477	7196.751111	90.774444	0.000653	725.43444
CHILDREN (1-6 YEARS OLD)	0.016723	0.016918	18797.557778	216.564444	0.001707	1896.51222
CHILDREN (7-12 YEARS OLD)	0.010916	0.011047	12274.822222	145.536667	0.001115	1238.62444
MALES (13-19 YEARS OLD)	0.006948	0.007004	7782.358889	62.296667	0.000708	787.04889
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.006190	0.006245	6939.163333	61.928889	0.000630	700.51889
MALES (20 YEARS AND OLDER)	0.005461	0.005503	6114.887778	47.661111	0.000558	620.43111
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.005578	0.005627	6252.117778	54.171111	0.000568	631.03333

*Current TMRC does not include new or pending tolerances.
 **New TMRC includes new, pending, and published tolerances.



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

Attachment C

MAR 15 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: 91-DA-02. Section 18 Specific Quarantine Exemption for the Use of Diazinon and Malathion to eradicate Mediterranean Fruit Fly in Florida. (No MRID #, DEB # 7655).

From: Freshteh Toghrol Ph.D., Chemist *F. Toghrol*
Special Review Section II
Chemistry Branch II Reregistration Support
Health Effects Division (H7509C)

THRU: Francis B. Suhre, Section Head *Francis B. Suhre*
Special Review Section II
Chemistry Branch II Reregistration Support
Health Effects Division (H7509C)

To: R. Cool/S. Stanton, PM Team 41
Emergency Response Section
Registration Support Branch
Registration Division (H7505C)

and
Toxicology Branch
Health Effects Division (H7509C)

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) in cooperation with the State of Florida requests a Section 18 specific quarantine exemption for the use of diazinon (soil drenches) and malathion (bait spray) in urban and/or host crop areas to eradicate fruit flies.

Malathion is a non-systemic insecticide and acaricide of low mammalian toxicity. Diazinon is a non-systemic insecticide.

Similar Section 18 Quarantine Exemptions for the use of malathion to eradicate fruit fly on numerous raw agricultural

commodities were reviewed by CBRS in 1987 (87-CA-02, M. Metzger, memo dated 10/30/86), and 1990 (89-CA-26, S. Hummel, memo dated 1/3/90).

Several Section 18 and a Section 24(C) have been issued for the use of diazinon as a soil treatment beneath fruits, and nut trees, grapes, vegetables, and caneberry plantings (80-DA-10, 80-DA-11, R. J. Hummel, 7/17/81, CA-830056, R. Loranger, 10/15/83, 89-CA-28, F. Toghrol, memo dated 9/6/89).

Tolerances

Tolerances are established (40 CFR 180.111) for residues of malathion (O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate) in or on numerous (120 rac) commodities ranging from 0.1 ppm to 135 ppm. Most tolerances on fruit and vegetables are set at 8.0 ppm.

Tolerances are established (CFR 40 180.153) for diazinon (O,O)-diethyl O-[6-methyl-2(1-methylethyl)4-pyrimidinyl] phosphorothioate) in or on numerous (100 rac) commodities ranging from 0.1 to 60 ppm. Most established tolerances for nuts and fruits are set at 0.5 and 0.75 ppm respectively.

Registration Standard:

The Residue Chemistry Chapter of the Malathion Registration Standard was issued 4/7/87. The Guidance Documents for Diazinon Registration Standard was completed on 2/88.

The Residue Chemistry Chapter of the Diazinon Registration Standard was issued on 8/8/86, the Guidance Documents for the Reregistration of Pesticide Products Containing Diazinon as the Active Ingredient was issued on December 1988.

Proposed Use

This Section 18 quarantine exemption calls for multiple application of malathion bait at the rate of 2.4 oz malathion/A, which is mixed with 9.6 fl. oz. of protein bait hydrolase. Application are repeated at 5 to 21 days intervals. Ground equipment will be used to spray the bait to host crops. An estimated 865 lbs of malathion may be used in 9 square-miles of host crops in Florida

This Section 18 quarantine exemption calls for application of diazinon at the rate of 1.8 oz ai /1,000 ft² (4.79 lbs ai/A/application) of soil surface beneath host trees where flies are found. Diazinon may be applied in sufficient water to wet the top inch of soil or watered in following a granular application. Applied as needed.

Residue Data

Malathion

The proposed Section 18 calls for application of malathion bait at 2.4 oz ai/A. Application are to be repeated at 5 to 21 day intervals as needed.

No residue data for malathion were submitted with this Section 18 request. No specific commodities are listed in this request. However, for the purpose of this Section 18 only, we consider that the residues of malathion in or on host crops will not exceed 8.0 ppm, which is the established tolerance for malathion in most fruits and vegetable. A similar conclusion was reached in connection with 89-CA-26, a Section 18 request for the use of malathion bait at 2.8 oz ai/A in CA (S. Hummel, memo dated 1/30/90).

Diazinon

The proposed Section 18 calls for application of diazinon at 1.8 oz of ai/1000 ft² (equivalent to 4.79 lbs ai/A/application) of soil surface beneath host trees.

No residue data for this proposed use (multiple and high concentration applications on soil) were submitted.

Most of the available diazinon residue data reflect foliar applications, e.g.: 1-8 treatments, at 0.5-1 lb ai/100 gal water/A, on nuts and fruits (with PHI of 10-21 day), 1-2 treatments at 1.0 lb ai/A on berries, and several treatments at 0.6 lb ai/A on grapes.

Residue data reflecting the application of diazinon 14G to the soil beneath fruit trees were previously reviewed in connection with 84-CA-36. These data reflect three applications (10 day interval) of diazinon at 5.6 lbs ai/A in late summer and 3 additional applications (10 day interval) the following spring. Granules were applied with ground equipment, then thoroughly watered. These data indicate that residues of diazinon is ND to 0.01 ppm, at PHIs ranging from 28 and 78 days (see 84-CA-36, M. L. Loftus, memo dated 10/3/84).

Based on these data RCB concluded that the residues of diazinon in or on nuts and fruits will not exceed the established

tolerances (see 84-CA-36, M. L. Loftus memo, dated 10/3/84).

Meat, Milk, Poultry, and Eggs:

Secondary residues of malathion are not likely to be found in livestock commodities as a result of this proposed use.

Secondary residues of diazinon are not likely to be found in livestock commodities as a result of this proposed use.

Conclusion for malathion

- 1a. For the purpose of this Section 18 only, we consider the residue of concern is malathion per se.
- 1b. For the purpose of this Section 18 only, we consider the residue of concern is diazinon per se.
2. Analytical methods for (malathion and diazinon) enforcement purposes are available in PAM II.
3. Analytical standards for malathion and diazinon are available from the Pesticide and Industrial Chemical Repository, RTP, NC.
- 4a. Residues of malathion are not expected to exceed 8.0 ppm in the host crops as a result of this proposed use.
- 4b. Residues of diazinon are not expected to exceed the established tolerances in or on nut and fruit crops as a result of this proposed use.
5. We do not expect secondary residues of malathion and diazinon to be found in livestock commodities as a result of this proposed use.

Recommendations:

TOX consideration permitting, we have no objection to the quarantine exemption use described in 91-DA-02. An agreement should be made with FDA, regarding the legal states of the commodities in commerce.

cc: Malathion S.F., R.F., Section 18, Circ., Malathion Reg. Std.,
Diazinon S.F., R.F., Section 18, Diazinon Reg. Std., Circ., DRES
(J. Kariya), F. Toghrol, PMSD/ISB.
RDI: F. B. Suhre Section Head (3/1/91): E. Zager: Acting Chief
(3/13/91):
H7509C:CBIIRS:F.Toghrol:F.T.:RM:802:CM#2:3/14/91: (703) 557-7887.



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

Attachment D

FEB 28 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: QUALITATIVE ASSESSMENT OF THE INCREMENTAL EXPOSURE TO HUMANS RESULTING FROM THE PROPOSED USES OF MALATHION AND DIAZINON UNDER THE APHIS SECTION 18 FOR FRUIT FLY ERADICATION (HED PROJECT NO.s 1-0635 and 1-0635A)

TO: Susan Stanton, PM #1
Registration Support Branch
Registration Division (H7505C)

FROM: Curt Lunchick, Acting Section Head *Curt Lunchick*
Special Review and Registration Section
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

THRU: Charles L. Trichilo, Ph.D, Chief *Charles L. Trichilo*
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

The Occupational and Residential Exposure Branch has reviewed the USDA APHIS request for a FIFRA Section 18 permitting the use of malathion and diazinon to eradicate exotic fruit flies (October 3, 1990). Malathion will be applied by air or ground equipment within the quarantined areas. Diazinon will be applied on the ground within the drip line of host trees or to soil around host nursery stock in the quarantined areas. Malathion would be applied with a protein hydrolyzate bait at 0.15 lbs ai per acre. Diazinon would be applied at 1.6 ounces ai per 1000 square feet.

Both insecticides are common insecticides used by homeowners or professionally applied indoors. The products are readily available over the counter in hardware stores, lawn and garden shops, drug stores, and grocery stores. A review of poisoning incidences for both products indicate that agricultural use does not produce large numbers of poisonings. Most poisonings occur among homeowners misusing the materials or doing other incredibly stupid things. OREB has sufficient information to quantify exposure to malathion for mixer/loaders and pilots. As you noted in the bean sheet, CREB is currently working with APHIS and Dr. Nigg to develop a protocol to monitor human exposure to individuals in the spray areas. Because these materials are often used by homeowners, the increased exposure from the proposed Section 18 is expected to

be minimal. The application rates are lower than most agricultural and residential rates. In addition, the diazinon application is a ground directed soil drenching, a technique that minimizes exposure. Although incremental exposure from the use of malathion by air is expected to be small, one must understand that the aerial application over residential areas will increase the overall numbers of individuals exposed to malathion.

In conclusion, OREB believes the exposure resulting from the proposed uses of malathion and diazinon will be low. The increase to individuals already exposed from personal use of these products will likely be minimal. The aerial application of malathion would greatly increase the number of individuals exposed to malathion, although at low exposure levels.

cc: K. Baetke
Malathion file
Diazinon file
Correspondence file
Curt Lunchick



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: 91-DA-0002 - Section 18 Quarantine Exemption for
the Use of Malathion to Eradicate Exotic Fruit
Flies "Primarily" in Florida

TOX Chem. No.: 535
Project No.: 1-0634
Record No.: S384597

FROM: William B. Greear, M.P.H. *William B. Greear 4/18/91*
Review Section II
Toxicology Branch I
Health Effects Division (H7509C)

TO: Flora Chow
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THRU: Marion P. Copley, D.V.M., Section Head
Review Section II
Toxicology Branch I
Health Effects Division (H7509C)

*Marion P. Copley
4/28/91*

and

Karl P. Baetcke, Ph.D., Chief
Toxicology Branch I
Health Effects Division (H7509C)

*Karl P. Baetcke
5/6/91*

I. CONCLUSIONS

Toxicology Branch I (TB-I) believes that the
toxicological data base on malathion is adequate to support
only minor new uses that will not significantly increase the
dietary and nondietary exposure of the population to
malathion. Although the incremental risk cannot be

quantified for this quarantine exemption, the Occupational and Residential Exposure Branch (OREB) has indicated that "The aerial application of malathion would greatly increase the number of individuals exposed to malathion, although at low exposure levels" (see memorandum of C. Lurchick dated February 28, 1991; HED Project Nos. 1-0635 and 1-0635A). It is not possible to determine the extent of the exposed area due to the vagueness of the areas to be sprayed. The California Department of Health Services (DHS) has published a risk assessment for the use of malathion in medfly eradication.¹ Though only recently received in HED, and requiring thorough review, the document probably would stand as the most thorough risk assessment (embracing toxicology data and exposure analyses) performed to date. Essential conclusions reached in this risk assessment might best be conveyed by direct quote from the report.

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

"Based on these results, DHS believes that a subpopulation of potentially sensitive individuals such as children, the aged, individuals with certain preexisting diseases, 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. (p. 1-6)

"Given the findings of this risk assessment, DHS recommends that the use of aerial malathion-bait applications in urban areas for agricultural pest eradication be reconsidered. This recommendation excludes the use of malathion in human infectious disease vector control in which the risks of contracting a debilitating or fatal disease are far greater than the potential risks for adverse health effects associated with malathion exposure. Although the theoretical adverse health risks from exposure to aerially applied malathion-bait in the general population may be reduced by following some simple precautions, potential exposures in more sensitive subpopulations may not be avoided as easily. DHS recognizes the public concerns related to the aerial application of pesticides such as malathion, and the public demand for the development and use of pest control methods that are less intrusive and alarming. Therefore, DHS also recommends that CDFA develop, and when possible, utilize

¹Health Risk Assessment of Aerial Application of Malathion-Bait. Department of Health Services, State of California, 1991.

available non-pesticide or selective pesticide (e.g., natural attractants) alternatives to aerial application of pesticides." (p. 8-46)

This risk assessment does not preclude aerial applications of malathion-bait when all other measures prove inadequate. TB-I would reiterate that the California risk assessment at this moment stands in need of review within HED.

II. REQUESTED ACTION

The Registration Division (RD) has provided the following specific instruction to TB-I to use in review of this submission:

"Please review USDA's section 18 application for quarantine exemptions to use malathion and diazinon in its Fruit Fly eradication program, primarily in Florida. This use of malathion is very similar to the use of malathion in California's Med Fly Program. Your review should address the incremental risks associated with the registered uses of malathion, as agreed in the December 12, 1990 meeting with RD, HED, and EFED."

This section 18 quarantine exemption application has been submitted by Peter L. Joseph of the Animal Plant Health Inspection Service (APHIS) of the USDA under a letter to Anne Lindsay (RD) dated October 3, 1990. The request is for permission to use malathion and diazinon to eradicate exotic fruit flies. APHIS was requested by RD, in their meeting of June 15 and July 3, 1990, to identify the areas of potential outbreak. A map indicating the areas of potential outbreaks of exotic fruit flies was enclosed (see Attachment 1). The application site was specified to be in quarantine areas where nonindigenous, subtropical fruit flies have been identified. The map identified several States such as Texas, California, Louisiana, etc., and included Puerto Rico. The section 18 quarantine exemption appears to be a generic request that encompasses several regions of the country, in addition to the State of Florida.

Background Information

APHIS indicates that exotic fruit flies, which includes the Medfly, pose a serious threat to the fruit and vegetable agriculture of the United States. If infestations are established, national and international restrictions on the movement of host fruits and vegetables would result. Production of dooryard host fruits and vegetables would require more extensive use of pesticides in order to grow consumable produce. APHIS states that "Commercial fruit and vegetable production may not be possible if controls are not available." It has been estimated that if the Medfly becomes established in the United States, losses would be expected to

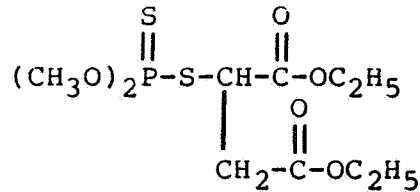
range from approximately \$821 to \$831 million annually. The eradication program proposed is comprehensive entailing the use of malathion (91 to 95% ai and a 25% wettable powder) as well as diazinon (47.5% ai emulsifiable concentrate). Malathion will be applied by air or ground equipment within quarantined areas. Malathion will be applied as a bait spray in urban areas and to host crops at a rate of 2.4 oz ai mixed with 9.6 oz of protein hydrolyzate per acre. Applications will be made at 5- to 21-day intervals. The treatment area will be approximately 9 square miles around each fly find, but may increase in size as new fly finds are identified. It is estimated that 865 lb ai of malathion will be applied per treatment to an approximate 9 square mile treatment area. Ground bait sprays will be applied until the flies are eradicated or the host crop is harvested. APHIS is unable to estimate the total amount of ai of malathion that will be required because of such variables as treatment area size, number of fly finds, temperature, number of treatments, etc. Special precautionary measures will be taken such as: no applications will be made when weather forecasts indicate a greater than 50 percent chance of rain and there is not enough time between the application and the anticipated rain for the spray to dry; no applications will be made when wind speed exceeds 10 mph; hours of operation will be restricted to minimize potential human exposure to the spray; sensitive areas will be marked and avoided and alternate treatment methods will be considered; and applications will not be over bodies of water. All applications will be made by or under the direct supervision of certified pesticide applicators of the Florida Department of Agriculture and Consumer Services and/or APHIS (USDA).

APHIS indicates that no alternative practices are available for the eradication of nonindigenous subtropical fruit flies. Alternative methods of treatment that have been recommended include biological control, sterile insect technique (SIT), boric acid, genetic manipulation, and host elimination. More research and development (in targeting efficacy, rearing and potential impacts) is needed before biological control technology of subtropical fruit flies is feasible. SIT is effective against low-level Medfly populations in which ratios of 100:1 sterile to wild male Medflies can be achieved. In addition, sterile flies are only available for Mexican fruit flies and the Medfly are not available for other nonindigenous subtropical fruit flies. Boric acid has not been considered for use because of the lack of product labeling, toxicity to nontarget organisms, and unproven efficacy in the field against the Medfly. The use of genetically altered insects to mate with wild Medflies to produce less vigorous progeny has not been considered due to its unproven efficacy in the field as well. Host elimination has not been considered because of the difficulty involved in employing it in diverse terrain, its costs, and its potential adverse environmental impact.

III. PRODUCT INFORMATION

Malathion; No. 535
Updated: April 1991

Malathion is an organophosphate insecticide and miticide for which the primary mechanism of action is cholinesterase inhibition. The chemical name for malathion is (S-[1,2-bis(ethoxycarbonyl)-ethyl] 0,0-dimethylphosphorodithioate. Its chemical structure is as follows:



Malathion has a molecular weight of 330.36 and the empirical formula is C₁₀H₁₉O₆PS₂. The CAS Registry Number is 121-75-5 and the Shaughnessy Number is 057701. The physical and chemical properties are described in the Registration Standard for Malathion (EPA, 1988). Malathion has been registered since 1956 for use against diverse insect pests on field crops, vegetables, fruits, ornamentals (and their premises), and stored grain. It is also used in mosquito control and Medfly eradication programs. Trade names include Calmathion, Celethion, Cythion, Chemathion, Malaspray, and Zithol. Annual usage was estimated to be 15 to 20 million pounds in 1988.

Tolerances have been established under 40 CFR 180.111.

IV. REQUIREMENTS FOR TERRESTRIAL FOOD-USE (40 CFR 158.340)

Malathion; No. 535
Updated: April 1991

<u>Malathion Technical</u>	<u>Required</u>	<u>Satisfied</u>
81-1 Acute Oral Toxicity	Y	Y
81-2 Acute Dermal Toxicity	Y	Y
81-3 Acute Inhalation Toxicity	Y	Y
81-4 Primary Eye Irritation	Y	Y
81-5 Primary Dermal Irritation	Y	Y
81-6 Dermal Sensitization	Y	Y
81-7 Acute Delayed Neurotoxicity (Hen)	Y	Y
82-1 Subchronic Oral (Rodent)	N	-
82-1 Subchronic Oral (Nonrodent)	N	-
82-2 21-Day Dermal	Y	N
82-3 90-Day Dermal	N	-
82-4 90-Day Inhalation	Y	N
82-5 90-Day Neurotoxicity (Hen)	N	-
82-5 90-Day Neurotoxicity (Mammal)	R	-
83-1a Chronic Toxicity (Rodent)	Y	N ¹
83-1b Chronic Toxicity (Nonrodent)	Y	Y
83-2a Carcinogenicity (Rat)	Y	N ¹
83-2b Carcinogenicity (Mouse)	Y	N
83-3a Developmental Toxicity (Rat)	Y	N ²
83-3b Developmental Toxicity (Rabbit)	Y	Y
83-4 Reproduction	Y	N ²
83-5 Chronic/Carcinogenicity	-	-
84-2 Mutagenicity - Gene Mutation	Y	Y
84-2 Mutagenicity - Structural Chromosomal Aberration	Y	Y
84-2 Mutagenicity - Other Genotoxic Effect	Y	Y
85-1 General Metabolism	Y	Y
85-2 Dermal Penetration	N	-
86-1 Domestic Animal Safety	N	-

Y = Yes; N = No; R = Reserved.

¹A chronic feeding/carcinogenicity study in rats with malaoxon is required in addition to a study on malathion.

²Study is currently under review.

Malathion; No. 535
Updated: April 1991

V. TOXICOLOGY PROFILE

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81-1	<p>Acute oral LD50 Species: rat American Cyanamid Co. ACC#1: Subst.</p> <p>Date: 1968</p> <p>DOC#s: 000389 <i>Tox cat. III</i></p>	<p>LD50 (M) = 1,375 mg/kg. LD50 (F) = 1,000 mg/kg.</p>
81-2	<p>Acute Dermal LD50 Species: rabbit American Cyanamid Co. ACC#1: 265986 <i>Tox cat. III</i></p> <p>Date: 2/25/80 CORE - MINIMUM DOC#s: 006419</p>	<p>LD50 > 2464 mg/kg (M&F).</p>
81-3	<p>Acute inhalation LC50 Species: rat Cosmopolitan Safety Eval. ACC#1: Subst. <i>Tox. Cat. IV</i></p> <p>Date: 1953</p> <p>DOC#s: 000389 000316</p>	<p>LC50 > 60 mg/L/8 hrs. (M&F).</p>
81-4	<p>Primary eye irritation Species: rabbit American Cyanamid Co. Study#: A77-4 ACC#1: <i>Tox. Cat. III</i></p> <p>Date: 1/26/77 CORE - MINIMUM DOC#s: 000317</p>	<p>Conjunctivitis in all animals at 4 hrs, cleared by 72 hrs. No corneal opacity - Dose tested: 0.1 ml test material.</p>
81-5	<p>Primary dermal irritation Species: rabbit American Cyanamid Co. ACC#1: 265986 <i>Tox. Cat. IV</i></p> <p>Date: 2/25/80 CORE - MINIMUM DOC#s: 006419</p>	<p>POIS = 0.79</p>
81-6	<p>Dermal sensitization Species: human Cosmopolitan Safety Eval. ACC#1:</p> <p>Date: 1964</p> <p>DOC#s: 000389</p>	<p>10% solution Malathion produced strong skin sensitization. Sensitized persons would react to a solution of 0.9% Malathion and water.</p>

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81-7	<p>Acute oral delayed neurotox. Species: hen Bio-Life Ass. Study#: BLAL87DN109 MRID: 409393-01</p> <p>Date: 4/1/88 CORE - SUPPLEMENTARY DOC#s: 007524</p> <p>CORR - GUIDELINE Acc#s: 009026</p>	<p>LD50 = 775 mg/kg ai AC6,601 did not elicit delayed neurotoxicity in the hen at the dose of 1007.5 mg/kg ai (1.3 X the LD50 dose) for the first 21-day phase and 852.5 mg/kg ai (1.1 X the LD50 dose) during the second 21-day phase the study, while protected by 30 mg/kg atropine sulfate. Positive control (T0TP) did elicit the response at 500 mg/kg. AC6,601 treated animals displayed a weight loss and food consumption initially in the two 21-day of testing.</p>
83-1(b)	<p>Feeding-1 year Species: dog Tegeris Labs Study#: 85010 MRID: 401885-01</p> <p>Date: 4/30/87 CORE - SUPPLEMENTARY DOC#s: 006349</p>	<p>Levels tested: 0, 62.5, 125 and 250 mg/kg/day in beagles. ChE NOEL < 62.5 mg/kg/day (plasma & RBC activity inhibited about 25%) 62.5 mg - elevated liver and kidney wts. Dose related elevated combined thyroid/parathyroid wt. Elevated platelet count; reduced creatinine in both sexes; reduced BUN in M; reduced SGPT. 125 mg- Elevated liver & kidney wts. Dose related combined thyroid/parathyroid wt.; elev. platelet count; reduced RBC count in female; red. creatinine in both sexes; red. BUN in M & F; red. SGPT. 250 mg- Elevated liver & kidney wts. Elevated combined thyroid/parathyroid wt. & platelet count; reduced RBC count & hematocrit (M & F). reduced creatinine in both sexes; red. BUN in M & F; red. SGPT; decr albumin; decr calcium (F).</p>
83-1(a)	<p><i>refer to 83-5</i></p>	
83-2(b)	<p>Oncogenic-80 week Species: mice National Cancer Inst. Study#: 24 ACC#1: 242903</p> <p>Date: 1978 CORE - MINIMUM DOC#s: 000314</p>	<p>Oncogenic NOEL > 16,000 ppm (MOT). (questionable liver findings - not significant with Bonferroni criteria. However dose related trend (p = 0.019) & incr of tumors at high dose. (P = 0.031), a level EPA normally considers significant). Doses: 8000 or 16000 ppm.</p>
83-3(a)	<p>Developmental Toxicity Study Species: rat IBT MRID#: 401093-01</p> <p>Date: 11/14/77 CORE - SUPPLEMENTARY DOC#s: 006349</p>	<p>Levels tested: 0, 50, 100, 200 and 300 mg/kg/d in Wistar str by gavage on gestation days 6 thru 15. Maternal NOEL > 300 mg/kg/day. Developmental NOEL > 300 mg/kg/day. A/D ratio = 300/300 = 1.0</p>
83-3(b)	<p>Developmental Toxicity Study Species: rabbit Food and Drug Research Lab Study#: 8171 ACC#1: 260123</p> <p>Date: 10/15/84 CORE - MINIMUM DOC#s: 007376</p>	<p>Developmental NOEL = 25 mg/kg & LEL = 50 mg/kg (increased resorption). Maternal NOEL = 25 mg/kg & LEL = 50 mg/kg (reduced body weight gain during the period of gestation). Levels tested: 0, 25, 50 & 100 mg/kg/day in NZW strain. At 100 mg/kg/d - same effects as 50 mg/kg/d.</p>
83-4	<p>Reproduction Species: rat Food and Drug Research Lab Study#: Kalow & Marton ACC#1:</p> <p>Date: 1965 Doc#s: 000314</p>	<p>Reproductive NOEL < 240 mg/kg/day (Only dose tested - reduced number of live pups and reduced pup body weight)</p>

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CITATIONS

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83- 5	<p>Feeding/oncogenic-2 year Species: rat Food and Drug Research Lab Study#: 5436 ACC#: 248179</p> <p>Date: 5/13/80 CORE - GUIDELINE DOC#: 002504</p>	<p>Levels tested 0, 100, 5000 ppm. Systemic NOEL = 100 ppm Systemic LEL = 1000 ppm (decrease in body weight, decreased brain ChE) Oncogenic NOEL > 5000 ppm (HOT). Sprague-Dawley rats</p>
84-2(a)	<p>Mutagenic-Ames Species: salmonella American Cyanamid Co. Study#: 114 MRID: 409393-02</p> <p>Date: 3/9/87 CORE - ACCEPTABLE DOC#: 008032</p>	<p>Negative for reverse mutation in five salmonella strains and E. coli WP-2 exposed with/without activation to doses up to 5000 ug/plate.</p>
84-2(b)	<p>Mut- Chrom aberr. in vivo Species: rat bone marrow SITEK Res. Labs, Rockville MD. Study#: 0125-1531 MRID: 414512-01</p> <p>Date: 1/10/90 CORE - ACCEPTABLE DOC#: 007965</p>	<p>Negative for chromosomal aberrations in bone marrow cells of rats treated orally up to toxic doses (2000 mg/kg).</p>
84-4	<p>Mutagenic-unscheduled DNA synt Species: rat hepatocyte SITEK Res. Labs, Rockville MD. Study#: 0125-5100 MRID: 41389301</p> <p>Date: 12/22/89 CORE - ACCEPTABLE DOC#: 007864</p>	<p>Negative for inducing unscheduled DNA synthesis (UDS) in primary rat hepatocyte cultures (HPC), exposed up to toxic levels, 0.12-0.16 ul/ml (equivalent to 150-200 ug/ml).</p>
85-1	<p>Metabolism Species: rat Midwest Research Inst. Study#: 9354-8 MRID: 413677-01</p> <p>Date: 12/20/89 CORE - GUIDELINE DOC#: 007791</p>	<p>C14-labeled malathion was dosed orally at 40 & 800 mg/kg and 40 mg/kg/d. 90+ percent of the dose was excreted in 72 hrs with 80-90% excreted in the urine. Females excreted slightly more in the urine than males. Between 4 and 6% of the dose was converted to the active inhibitor malaaxon.</p>
OTHER <i>Study used for RFD</i>	<p>Feeding-8 week Species: human American Cyanamid Co. ACC#: 000389 000316</p> <p>Date: 1962</p>	<p>ChE NOEL = 0.27 mg/kg/day. ChE LEL = 0.40 mg/kg/day (blood cholinesterase depression).</p>

VI. DATA GAPS

Malathion Technical

- 82-3 - 21-Day Dermal
- 82-4 - 90-Day Inhalation - Rat
- 83-1 - Chronic Feeding - Dog (with special emphasis on ocular toxicity)
- 83-2 - Carcinogenicity - Mouse
- 83-3 - Developmental Toxicity - Rat*
- 83-4 - Two-Generation Reproduction*
- 83-5 - Chronic Feeding/Carcinogenicity - Rat
- 83-5 - Chronic Feeding/Carcinogenicity - Rat (With Malaoxon)

*Studies have been received and are currently under review.

VII. ACTION TAKEN TO REMOVE DATA GAPS AND OBTAIN ADDITIONAL INFORMATION

The sponsor has been informed of the data gaps on the technical by means of the 1988 Registration Standard and TB-I's memoranda from Brian Dementi dated September 7, 1990 and February 15, 1991 concerning the Data Call-In Notice.

VIII. REFERENCE DOSE (RfD)

The Agency's RfD for malathion is 0.02 mg/kg/day. The verification date is March 18, 1987.

IX. PENDING REGULATORY ACTIONS

There are no pending regulatory actions against this pesticide at this time that TB-I is aware of.

X. TOXICOLOGICAL ISSUES

A. Carcinogenicity

The following excerpt was taken from the Peer Review of Malathion document dated April 12, 1990 and appropriately addresses the carcinogenicity concern:

"The Health Effects Division Peer Review Committee met on February 7, 1990 to discuss and evaluate the weight-of-the-evidence on Malathion with particular reference to its carcinogenic potential. The Committee agreed to classify malathion as a Group D Carcinogen; that is, malathion is not classifiable as to human carcinogenicity. This decision was based on the inadequacy of the available studies to make a definitive determination of the carcinogenicity of malathion.

The Committee reaffirmed the requirements of the Malathion Registration Standard that requires the Registrant to perform an additional mouse carcinogenicity study with malathion and an additional rat carcinogenicity study with malaoxon. The Committee also determined that the Registration Standard recommendation to perform a carcinogenicity study in combination with the required rat chronic study on malathion be made into a requirement that both be performed."

B. Ocular Toxicity

Very recently TB-I has decided to require that a 1-year chronic dog study be conducted in which special attention is given to its potential to elicit ocular effects. The assessment of ocular effects should include but not be limited to:

Retinal electrical activity
(electroretinography)
Ophthalmoscopic observations
Fundus observations/photographs
Clinical observations for cholinergic effects
Histopathology of the eye; light and electron
microscopy, including intra- and
extraocular muscle, optic nerve, and
retina.

[It is strongly recommended that the sponsor submit a detailed protocol of the chronic dog study for comment by TB-I prior to initiation of the study].

XI. OTHER

The Registration Standard on Malathion (1988) indicates under Section IV. Regulatory Positions and Rationales that toxicological data gaps exist for chronic toxicity, carcinogenicity, developmental toxicity, reproduction, mutagenicity, and metabolism studies. The lack of data precluded the Agency from conducting a full tolerance assessment. In addition, the TMRC occupies 507 percent of the PADI. For the reasons given above, significant new uses¹ would not be granted until the data gaps have been filled. To date, the sponsor has submitted mutagenicity and metabolism studies that have filled their respective data gaps. A two-generation reproduction study and a developmental toxicity study in rats are currently under

¹"Significant new use" is defined in 44 FR 27934, May 1, 1979. In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TMRC) of greater than 1%.

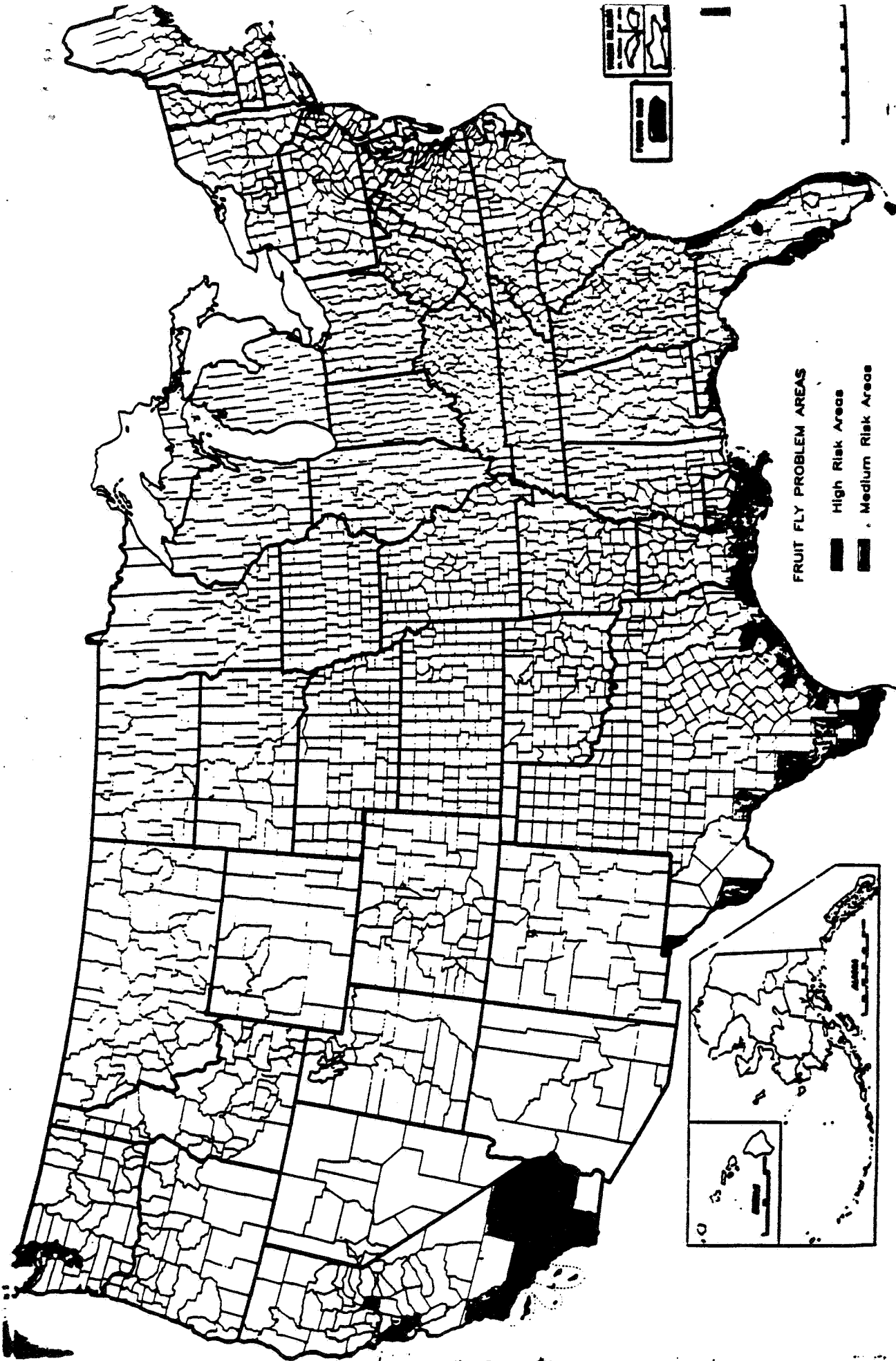
review. As a result of the Peer Review Committee's review of the carcinogenicity of malathion, several new requirements have arisen.

The Peer Review Committee specified the requirements for the following data (see memorandum of Kerry L. Dearfield dated April 12, 1990):

- 83-2 - Carcinogenicity - Mouse
- 83-5 - Chronic Feeding Carcinogenicity - Rat
(With Malaoxon)
- 83-5 - Chronic Feeding/Carcinogenicity - Rat

It has also recently been brought to TB-I's attention that nerve damage to the eyes from exposure to organo-phosphate pesticides, including malathion, has been reported in Japan. There has been no confirmatory testing on malathion to address this issue. However, TB-I has requested that the sponsor conduct a chronic feeding study in dogs with special emphasis on potential ocular toxicity.

TB-I believes that the toxicological data base on malathion is adequate to support only minor new uses that will not significantly increase the dietary and nondietary exposure of the population to malathion.



FRUIT FLY PROBLEM AREAS

- High Risk Areas
- Medium Risk Areas



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: 91-DA-0002 - Section 18 Quarantine Exemption for
the Use of Diazinon to Eradicate Exotic Fruit Flies
"Primarily" in Florida

TOX Chem. No.: 342
Project No.: 1-0634A
Submission No.: S384596

FROM: William B. Greear, M.P.H. *William B. Greear 6/10/91*
Review Section II
Toxicology Branch I
Health Effects Division (H7509C)

TO: Flora Chow
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THRU: Marion P. Copley, D.V.M., Section Head *Marion P. Copley 6/2/91*
Review Section II
Toxicology Branch I
Health Effects Division (H7509C)

and

Karl P. Baetcke, Ph.D., Chief *Karl P. Baetcke 6/12/91*
Toxicology Branch I
Health Effects Division (H7509C)

I. CONCLUSIONS

Toxicology Branch I (TB-I) believes that the toxicological data base on diazinon is adequate to support only minor new uses that will not significantly increase the dietary and nondietary exposure of the population to diazinon. The incremental risk cannot be quantified because it is not possible to estimate the amount of active ingredient that will be required.

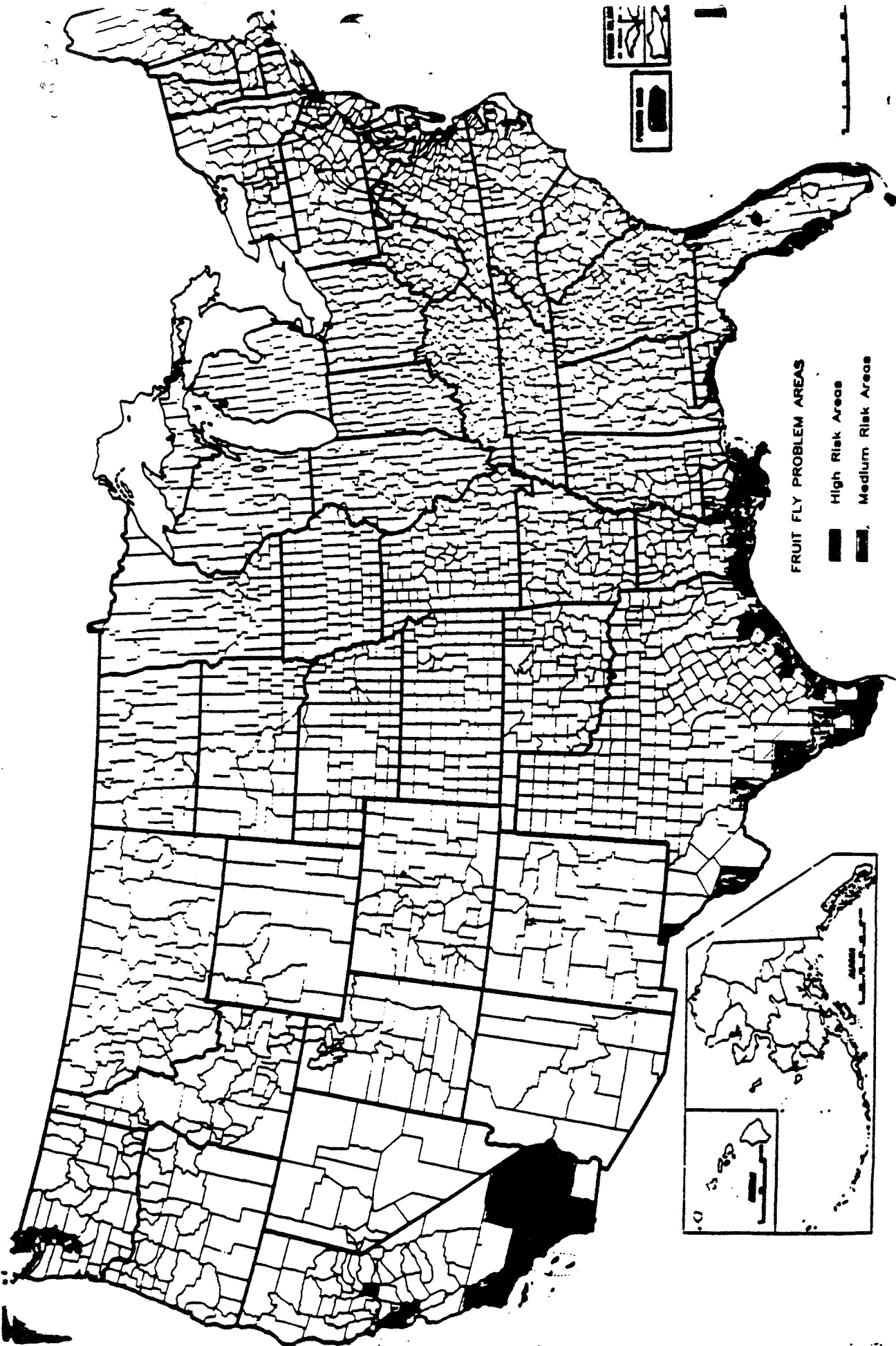
II. REQUESTED ACTION

This section 18 quarantine exemption application has been submitted by Peter L. Joseph of the Animal Plant Health Inspection Service (APHIS) of the USDA under a letter to Anne Lindsay (RD) dated October 3, 1990. The request is for permission to use malathion and diazinon to eradicate exotic fruit flies. A map indicating the areas of potential outbreaks of exotic fruit flies was enclosed (see Attachment 1). The application site was specified to be in quarantine areas where nonindigenous, subtropical fruit flies have been identified.

Background Information

APHIS indicates that exotic fruit flies, which includes the Medfly, pose a serious threat to the fruit and vegetable agriculture of the United States. If infestations are established, national and international restrictions on the movement of host fruits and vegetables would result. Production of dooryard host fruits and vegetables would require more extensive use of pesticides in order to grow consumable produce. It has been estimated that if the Medfly becomes established in the United States, losses would be expected to range from approximately \$821 to \$831 million annually. The eradication program proposed is comprehensive entailing the use of malathion (91 to 95% ai and a 25% wettable powder) as well as diazinon (47.5% ai emulsifiable concentrate). Diazinon will be applied at a rate of 1.8 oz ai/1000 sq ft of soil surface within the dripline of host trees where flies are found and to the soil around nursery stock. The diazinon may be applied in a water mix sufficient to wet the top inch of soil or watered in following a granular application. The treatment area is the soil under host trees on infested and surrounding adjacent properties. Diazinon will be applied on an as-needed basis under host trees in the area where nonindigenous fruit flies are caught and identified, and to nursery soils around host nursery stock within the quarantined area. Therefore, APHIS is unable to estimate the total amount of active ingredient of diazinon that will be required. All applications will be made by or under the direct supervision of certified applicators of the Florida Department of Agriculture and Consumer Services and/or APHIS (USDA).

[APHIS indicates that no alternative practices are available for the eradication of nonindigenous subtropical fruit flies.]



FRUIT FLY PROBLEM AREAS

- High Risk Areas
- Medium Risk Areas