US EPA ARCHIVE DOCUMENT

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Amendment to the Section 18 Quarantine Exemption for the use of malathion in California (89-CA-26) -- incremental risk assessment

FROM: Penelope Fenner-Crisp, Ph.D., Director
Health Effects Division (H7509C)

TO: Anne E. Lindsay, Director
Registration Division (H7505C)

At the request of the Registration Division, the Health Effects Division has conducted an incremental risk assessment based on exposure to malathion under the amendment (dated April 17, 1990) to the Section 18 Quarantine Exemption, 89-CA-26, issued to the state of California. The amendment provides for the expansion of the Crop/Site/Commodity section of the Quarantine Exemption to include all crops in the treatment areas.

The Health Effects Division has no data for a quantitative risk assessment. (The Peer Review Committee placed malathion in Group D, i.e., not classifiable as to human carcinogenicity.) However, the Health Effects Division has established a reference dose (RfD) based upon some chronic data. The reference dose is used here to calculate the incremental risk associated with the treatment of additional crops in the treatment areas. These crops were not included in the Section 24(c) Quarantine Program (SLN Registration Number CA830012), as amended on November 21, 1989, or included in the Section 18 Quarantine Exemption.

Basically, there are two considerations, and they relate to exposure: (1) the incremental risk associated with dietary exposure to additional crops, and (2) the incremental risk to the general population in the spray area following application of malathion.

An analysis of the dietary contribution (DRES analysis) was performed based on 8 ppm malathion residues on those additional crops. The incremental risk is estimated to be < 1%. This estimate does not take into account the crops for which food consumption data are unavailable. However, it is unlikely that the inclusion of such crops would increase the incremental risk beyond 1%.

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An analysis of non-dietary exposure shows that, under the amendment, there would not be an increase in the number of acres treated or the amount of malathion applied.

CONCLUSION

- Based on the information available to date, the Quarantine Exemption, as amended, is expected to result in negligible incremental dietary risk.
- Based on the information available to date, the Quarantine Exemption, as amended, is expected to result in negligible incremental human non-dietary risk.

It is clear that in determining the incremental risk posed by the amendment, the health concerns did not factor into the considerations, but remain a constant. Therefore, so as not to lose perspective in the enthusiasm to eradicate the medfly in California, the Health Effects Division is reiterating some of the health concerns for malathion:

(1) The carcinogenic potential has not been adequately determined. According to the Registration Standard, the studies are scheduled to be completed in 1992, but American Cyanamid has been granted an extension.
(2) Nerve damage to the eyes from exposure to organophosphates including malathion has been reported in Japan. There has been no confirmatory testing to address this issue.
(3) The dietary exposure from use of treated commodities is estimated to be greater than 500% of the Provisional ADI (PADI), based on the assumption of exposure at the tolerance level.
(4) The non-dietary risk to the general population cannot be determined because of data gaps in the toxicological profile and in the non-dietary exposure.

Data to resolve these issues are being requested through the Special Review and Reregistration Division.

Attachments:
NDEB memo
DRES memo
Tox-I memo

cc: SRRD
K. Baetcke
W. Burnam
R. Engler
J. Kariya
L. Rossi (H7508C)
R. Schmitt

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

AUG 8 1990

OFFICE OF
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MEMORANDUM

SUBJECT: California Malathion Section 18 Amendment - Incremental Occupational and Residential Exposure and Risk (HED #~~Intra~~ 00073)

FROM: Michael P. Firestone, Ph.D., Supervisory Chemist
Non-Dietary Exposure Branch/HED (H7509C)

THRU: Charles L. Trichilo, Ph.D., Chief
Non-Dietary Exposure Branch/HED (H7509C)

TO: Reto Engler, Chief
Science Analysis and Coordination Branch/HED (H7509C)

X Deferral to SACB and/or TOX-I

The purpose of this memorandum is to evaluate the incremental human non-dietary exposure and risk resulting from the current (April 17, 1990) amendment to the 1989-issued Section 18 quarantine exemption covering the control of fruit fly members of the family Tephritidae in California.

It appears that the purpose of the April 17, 1990 amendment prepared by the California Department of Food and Agriculture (CDFA) was to broaden the "Crop/Site/Commodity" section of the Section 18 quarantine exemption to include the wording "Commercial and residential plantings of food and feed crops such as but not limited to ..." CDFA claims that this language is "comparable to the standard wording used on other Section 18 quarantine exemptions."

According to CDFA, this amendment was prepared to include "any additional crops or plantings which may be encountered ... because the quarantine area is constantly changing with the discovery of new medfly infestations." As such, it appears that the current amendment has been submitted to cover food contamination concerns associated with the Federal Food, Drug and Cosmetic Act (FFDCA) and is not specifically designed to increase the number of acres treated or the amount of malathion applied in conjunction with the 1989 Section 18 quarantine program.

Thus, NDEB concludes based on the information available to date that the subject April 17, 1990 amendment will result in negligible incremental human non-dietary exposure or risk.

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It should be noted that NDEB does not currently have data available to assess residential post-application (including bystander) exposure as a result of the California Section 18 program or similar ones in other States. In order to support the development of a quantitative risk assessment, exposure data reflecting air and ground surface residue monitoring following repeated treatments and residue dissipation with time would be required. The exposure data currently being generated by CDFA may partially fulfill this need.

NDEB defers to SACB and/or TOX-I as to the need for a quantitative risk assessment and the endpoint(s) of possible regulatory concern such as cholinesterase depression, eye effects, carcinogenicity, etc. The endpoint(s) of concern could affect the nature of the exposure data required.

cc: Larry Dorsey/SACB
Karl Baetcke/TOX-I
Curt Lunchick/NDEB
Circulation
Correspondence File
Malathion File
Becky Cool/RD (H7505C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
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MEMORANDUM

SUBJECT: Malathion Dietary Incremental Risk Assessment

FROM: Rita Briggs, Ph.D. 2.3.
Dietary Risk Evaluation System (DRES) Staff
HED/SACB (H7509C)

THROUGH: James P. Kariya
Acting Section Head, DRES
Health Effects Division (H7509C)

TO: Albin Kocialski/Flora Chow
SACB/HED

Anne Lindsay, Director of Registration Division has requested HED (memo to Penny Fenner-Crisp, 8/2/90) to provide a dietary exposure analysis for residues of malathion on food crops which are grown in the malathion treatment areas of California and are not covered either by published tolerances or tolerances proposed for crops under the current Section 18 Quarantine Exemption #89-CA-26. Since you are responsible for coordinating HED's exposure/risk assessments on malathion, I am sending the completed analyses to you for transferral to RD. Note that I have run two analyses: (1) to determine the incremental exposure from crops under the Section 18 only; and (2) to determine the incremental exposure from additional crops exposed to malathion which is the estimate that RD has requested. The following paragraphs summarize the information used in the DRES analyses.

DATA:

Toxicology Endpoint: The routine chronic DRES analysis used a reference dose (PADI) of 0.02 mg/kg body weight/day, based upon a NOEL of 0.23 mg/kg body weight/day for cholinesterase (ChE) inhibition and an uncertainty factor of 10 from a human ChE study. This value has been approved by HED (03/06/87) and Agency (03/18/87) reference dose committees.

Residue Information: Food uses evaluated were published tolerances from 40 CFR 180.111, the proposed tolerance of 8 ppm for crops specified in Section 18 Quarantine Exemption #89-CA-26 and a tolerance of 8 ppm for additional crops being treated under the quarantine exemption.

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It should be noted that not all of the crops reported to be treated with malathion have been incorporated into the present analyses simply because there are no consumption estimates in the DRES database for some of these commodities. The commodities that were excluded are listed in the overall summary section.

Table 1 summarizes the residue information used in the analysis for the Section 18 (entered as 'New') and the residue information used to evaluate exposure to the additional crops (entered as 'Pending').

EXPOSURE ANALYSIS:

The DRES chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. TMRC summaries based on the Section 18 request only and the additional crops only are shown in Tables 3 and 4, respectively. In addition, the following tables summarize the contribution from published and new tolerances to the TMRC exposure estimates for the overall U.S. population, non-nursing infants, and children aged 1-6.

TMRC EXPOSURE SUMMARY
(for Section 18, 89-CA-26)

	Overall U.S. Population	Non-Nurs. Infants	Children 1 - 6
Published Tolerances:	0.099958[a] 499.8[b]	0.262864 1314.3	0.222585 1112.9
Proposed Uses:	0.001876 9.4	0.008671 43.4	0.005900 29.5
TOTAL:	0.101834 509	0.271534 1358	0.228484 1142

a Exposure estimate in mg/kg/day
b Estimated exposure expressed as percent of the ADI.

TMRC EXPOSURE ESTIMATE
(for Additional Crops under
Quarantine Exemption)

	Overall U.S., Population	Non-Nurs. Infants	Children 1 - 6
Published Tolerances:	0.099958[a] 499.8[b]	0.262864 1314.3	0.222585 1112.9
Proposed Uses:	0.000042 0.2	0 0	0.000042 0.2
TOTAL:	0.100000 500	0.262864 1314	0.222626 1113

a Exposure estimate in mg/kg/day
b Estimated exposure expressed as percent of the ADI

Also attached as Table 4 is the Commodity Contribution which shows the amount of exposure which each crop contributes to the total exposure. This information shows that bananas are the major contributor for the U.S. population. Bananas also contribute the bulk of the exposure for non-nursing infants and children aged 1-6 (tables not attached).

OVERALL SUMMARY:

1. Two DRES analyses were conducted to include: (1) crops which have existing tolerances (40 CRF 180.111) and crops to be treated with malathion under Section 18 Quarantine Exemption #89-CA-26, and (2) crops with existing tolerances and additional crops grown within the malathion treatment areas and not covered under the quarantine exemption.

2. Food consumption estimates were not available for all crops listed. The commodities which were not included in the analyses are :

Chapote
Chayote
Custard apple
Eugenia Fruits
Fava Beans
Opuntia
Pummelos
Sapodilla
Sapote
Satsuma
Star apple
Tomatillos

3. The TMRC from published tolerances for the overall U.S. population utilizes approximately 500% of the PADI. The increase in exposure from the use of malathion on crops to be treated under the Section 18 represents approximately 9.4% of the reference dose while the incremental exposure estimate from use on additional crops under the quarantine exemption represents only 0.2% of the PADI.

4. For the population subgroups, non-nursing infants and children aged 1-6 years, the exposure from published tolerances alone are very high (see above tables) when compared to the PADI; the incremental increases from the Section 18 uses and additional crop uses are small in comparison.