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Dated: July 24, 1978.

DOUGLAS D. CAMPT,
Acting Director,
Registration Division.

Statutory Authority: Section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)).

It is proposed that part 180, Subpart c, § 180.298 be revised in its entirety by editorially revising the section into an alphabetized columnar listing and by alphabetically inserting the tolerance of 0.5 ppm on safflower seed, as follows:

§ 180.298 Methidathion; tolerances for residues.

Tolerances are established for residues of the insecticide methidathion (*O,O*-dimethyl phosphorodithioate, *S*-ester with 4-(mercaptomethyl)-2-methoxy-Δ^2-1,3,4-thiadiazolin-5-one) in or on the following raw agricultural commodities:

Commodity:	Parts per million
Alfalfa	6
Alfalfa, hay	6
Clover	6
Clover, hay	6
Cottonseed	.2
Grapefruit	2
Grass	6
Grass, hay	6
Lemons	2
Oranges	2
Peaches	.05
Pecans	.05
Potatoes	.2
Safflower seed	.5
Sorghum, fodder	2
Sorghum, forage	2
Sorghum, grain	.2
Sunflower seeds	.5
Walnuts	.05

[FR Doc. 78-21015 Filed 7-28-78; 8:45 am]

[6560.01]

[40 CFR Part 180]

[PP 7E1881/P81; FRL 934-4]

PROPOSED TOLERANCE FOR THE PESTICIDE CHEMICAL MALATHION

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes that the insecticide malathion be used on wild rice. The proposal was submitted by the Interregional Research Project No. 4. This amendment to the regulations would establish a maximum permissible level for residues of malathion on wild rice.

DATE: Comments must be received by August 30, 1978.

ADDRESS: Comments, Register Section, Technical Division (WH-569), Office of Pesticide Programs, EPA, Room 401, East Tower, 401 M Street SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

Mrs. Patricia Critchlow, Registration Division (WH-567), Office of Pesticide Programs, EPA, 202-755-2516.

SUPPLEMENTARY INFORMATION: Dr. C.C. Compton, Coordinator, Interregional Research Project No. 4 (IR-4), New Jersey State Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, N.J. 08903, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of Minnesota has submitted a pesticide petition (PP 7E1881) to the EPA. This petition request that the Administrator propose that 40 CFR 180.111 be amended by the establishment of a tolerance for residues of the insecticide malathion (*O,O*-dimethyl dithiophosphate of diethyl mercaptosuccinate) in or on the raw agricultural commodity wild rice at 8 parts per million (ppm).

The data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerance included two 2-year rat feeding studies, one with a no-observable-effect level (NOEL) of 100 ppm; the other showing cholinesterase-inhibition at 100 ppm but no systemic effects at 1,000 ppm; a one-generation rat reproduction study in which reproductive effects were observed at 4,000 ppm, the only level tested; a negative neurotoxicity study; a negative single dose (900 milligrams (mg)/kilogram (kg) of body weight (bw)) intraperitoneal teratology study in rats; rat and mouse oral lethal dose (LD_{50}) tests; two negative mutagenicity tests using microbial assay systems; and a 47-day human feeding study with an NOEL at 0.2 mg/kg bw/day. Based on this last study and using a safety factor of 10, the acceptable daily intake (ADI) is 0.02 mg/kg bw/day. The maximum permissible intake for a 60-kg man is 1.2 mg/day.

Tolerances have previously been established for residues of malathion on a variety of raw agricultural commodities at levels ranging from 135 ppm to 0.1 ppm. Food additive tolerances have also been established for malathion residues on raisins at 12 ppm and in safflower oil at 0.6 ppm. Feed additive tolerances have been established for malathion residues in dehydrated citrus pulp at 50 ppm and in nonmedicated cattle feed concentrate blocks at 10 ppm.

On a theoretical basis, the total maximal residue contribution (TMRC) of these tolerances exceeds the ADI; however, total diet surveys show that over a 4-year period the actual exposure to malathion was not more than 0.00013 mg/kg bw/day, which is less than 1 percent of the ADI. The increment of human exposure due to the tolerance on wild rice would be negligible, and thus, the increment in risk, if any, is acceptable. The metabolism of malathion is adequately understood, and an adequate analytical method (gas chromatography using a flame photometric detector) is available for enforcement purposes. The following studies are currently lacking: oncogenicity studies in two mammalian species using currently acceptable protocols, a multigeneration reproduction study, and a teratology (oral) study. However, it has been determined that the proposed tolerance can be established because: (1) Tolerances currently exist for malathion on a majority of food and feed items in the United States and (2) the use of malathion on wild rice would not significantly increase human exposure to malathion residues. There is no reasonable expectation of residues in eggs, meat, milk, or poultry as delineated in 40 CFR 180.6(a)(3).

The pesticide is considered useful for the purpose for which a tolerance is sought, and it is concluded that the tolerance of 8 ppm established by amending 40 CFR 180.111 will protect the public health. It is proposed, therefore, that the tolerance be established as set forth below.

Any person who has registered, or submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act which contains any of the ingredients listed herein may request, within 30 days after publication of this proposal in the FEDERAL REGISTER, that this rulemaking proposal be referred to an advisory committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. The comments must bear a notation indicating both the subject and the petition/document control number, "PP7E1881/P81." All written comments filed in response to this notice of proposed rulemaking will be available for public inspection in the Office of the Federal Register Section from 8:30 a.m. to 4 p.m. Monday through Friday.

STATUTORY AUTHORITY: Section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)).

Dated: July 24, 1978.

DOUGLAS D. CAMPT,
Acting Director
Registration Division.

It is proposed that part 180, subpart C, § 180.111 be amended by alphabetically inserting the tolerance of 8 ppm on wild rice in the table to read as follows:

Section 180.111 Malathion; tolerances for residues.

* * * * *

Commodity:	Parts per million
* * * * *	
Rice, wild	8
* * * * *	

[FR Doc. 78-21016 Filed 7-28-78; 8:45 am]

[4110-84]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

[42 CFR Part 23]

NATIONAL HEALTH SERVICE CORPS

Subpart A—Assignment of National Health Service Corps Personnel

AGENCY: Public Health Service, HEW.

ACTION: Notice of proposed rulemaking.

SUMMARY: These proposed regulations prescribe the requirements for the assignment of National Health Service Corps personnel under Section 333 of the Public Health Service Act (42 U.S.C. 254f) to public or nonprofit private entities to provide health services in or to a health manpower shortage area designated under Section 332 of the Public Health Service Act.

DATE: Comments must be received August 30, 1978.

ADDRESSES: Written comments, preferably in triplicate, should be addressed to the Director, Division of Policy Development, Bureau of Community Health Services, Health Services Administration, room 6-17, 5600 Fishers Lane, Rockville, Md. 20857. All comments received will be available for public inspection and copying at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT:

Fitzhugh S. M. Mullan, M.D., Director, National Health Service Corps, Bureau of Community Health Services, Room 6-05, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4434.

SUPPLEMENTARY INFORMATION: On October 12, 1976, a new section 333 was added to the Public Health Service Act (42 U.S.C. 254f) by Pub. L. 94-484, the Health Professions Educational Assistance Act of 1976. This section allows the Secretary to assign, pursuant to regulations, members of the National Health Service Corps to public and nonprofit entities to provide health services in or to a health manpower shortage area.

Based upon the enactment of this new section 333, the Assistant Secretary for Health, Department of Health, Education, and Welfare, proposes to revoke the existing part 23, subpart A, and add a new Subpart A entitled "Assignment of National Health Service Corps Personnel."

A notice of intent to issue regulations for this program was published in the FEDERAL REGISTER on May 20, 1977 (42 FR 25992). Interested persons were invited to comment on the issues raised and several comments were received.

The regulations establish the conditions applicable to the assignment of National Health Service Corps personnel to a public or nonprofit private entity to provide health services in or to a health manpower shortage area. In the interest of streamlining regulations and reducing regulatory burden, minute program particulars have not been set forth in the regulations. For this reason, most of the comments received on the notice of intent were not pertinent to the development of these regulations, but will be considered by the Department in developing program policies.

Following is a brief summary of the major features of the proposed regulations:

(1) In approving applications for assignment, section 23.5(b) provides that if two eligible entities, one located in the health shortage area and one not located in the area but having a demonstrated interest in it, submit applications for assignment of National Health Service Corps personnel to provide health services to the area, special consideration will be given to the entity located in such health manpower shortage area. This special consideration was adopted in response to the several public comments received suggesting that such a consideration would promote greater community involvement between the approved entity and the individuals receiving health services.

(2) Section 333(c) of the Public Health Service Act requires that the Secretary take into consideration four factors in assigning National Health Service Corps personnel to entities with approved applications. The four factors are (i) Need of the health manpower shortage area, (ii) Use of physician assistants, nurse practitioners, or expanded function dental auxiliaries, (iii) Willingness of the individuals within the health manpower shortage area to assist and cooperate with the National Health Service Corps and (iv) Comments of professional societies serving the health manpower shortage area. In implementing this statutory requirement, the regulations provide that the Secretary will utilize a weighted-value system in which weights will be assigned to the four statutory factors, with the greatest weight being assigned to the first factor listed above and weights being assigned to the remaining factors in descending order. Based on this approach, approved applications will be assigned to priority categories. Personnel assignments will then be made to entities in accordance with these priority categories to the extent possible consistent with the statutory mandate that in assigning personnel to provide health services to a health manpower shortage area, the Secretary shall seek to assign to an area personnel with those characteristics which will increase the probability of their remaining to serve the area upon completion of the assignment period.

(3) The proposed regulations require that individuals receiving services from assigned National Health Service Corps personnel be charged on a fee-for-service or other basis at a rate to be approved by the Secretary. Fees are to be based upon the cost of delivering services and on fees charged for similar services by similarly situated practitioners and facilities. The proposed regulations further provide that no individual will be denied health services based upon his inability to pay for such services. With respect to this inability to pay, § 23.9 of the proposed regulations states that those individuals with annual incomes at or below the "CSA Income Poverty Guidelines" (45 CFR 1060.2) may receive services at a reduced charge. Individuals who have annual incomes above the "CSA Income Poverty Guidelines" but which do not exceed 200 percent of such CSA levels will also receive health services at reduced charge. Charges will be made, however, for services to individuals to the extent that payment will be made by a third party which is authorized or under legal obligation to pay such charges.

(4) The statute requires in section 334(a)(3) that the National Health Service Corps site repay the Federal Government for the costs involved in providing assigned National Health Services Corps personnel. The statute also provides that repayment may, under certain specific circumstances,