A public hearing will be held at the Ramada Inn, 10 Thomas Circle NW, Washington DC.

Materials relevant to this proposal have been placed in Air and Radiation Docket A–95–02 by EPA. The docket is located at the above address in room M–1500 Waterside Mall (ground floor) and may be inspected from 8 a.m. to 4 p.m., Monday through Friday, including all non-government holidays.

FOR FURTHER INFORMATION CONTACT: Kathryn Sargeant, Emission Control Strategies Branch, Emission Planning and Strategies Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105. (313) 668–4441.

SUPPLEMENTARY INFORMATION: The terms and substance of the rule changes proposed in this document, and a description of the subjects and issues involved, are included in the document announcing the interim final rule published in the Final Rules Section of this **Federal Register**. This proposal is identical in substance to the interim final rule, except that the proposal would not limit the application of the proposed rule changes to a six-month period.

Dated: January 31, 1995.

Carol M. Browner,

Administrator.

[FR Doc. 95–3002 Filed 2–7–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[PP 5F4427/P606; FRL–4936–6]

RIN 2070–AC18

Pesticide Tolerance for Chlorpyrifos

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a time-limited tolerance for residues of the insecticide chlorpyrifos [*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate] in or on the raw agricultural commodities oats and barley when blended together in a mixture containing 97% oats and 3% barley. The proposal to establish maximum permissible levels for residues of the insecticide was requested in a petition submitted by General Mills.

DATES: Comments, identified by the document control number, [PP 5F4427/P606], must be received on or before March 10, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Jr., Product Manager (PM) 19, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6386.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of November 21, 1994 (59 FR 60013), which announced that General Mills had submitted pesticide petition (PP) 5F4427 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, amend 40 CFR 180.342 by establishing a tolerance for residues of the insecticide chlorpyrifos in or on the raw agricultural commodity oats at 15 ppm, provided that such tolerance applies only to oats that were treated post-harvest with chlorpyrifos on or before June 15, 1994; that such tolerance applies only to oats to be used as animal feed or as a constituent of animal feed; that, notwithstanding any other provision of law or regulation, this tolerance does not authorize the presence of residues of chlorpyrifos in any human food item made from such treated oats, other than residues resulting from the use of the oats for animal feed purposes; and that such tolerance expires on December 31, 1996.

Chlorpyrifos is registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for application to many growing crops; associated tolerance regulations have been established under the FFDCA. It is not, however, registered for use on oats or for treatment of stored grain. A pest control operator under contract to General Mills improperly treated stored oats and fraudulently claimed to have used a different pesticide, chlorpyrifos-methyl, that is registered for use on stored grains such as oats. The illegal residues were discovered by a routine FDA inspection. Processed food products manufactured from improperly treated oats were determined by the Agency not to be a human health hazard and those that had entered commerce were not recalled. Processed products that had not yet entered commerce were retained by General Mills and subsequently destroyed. Approximately 18 million bushels of stored unmilled oats treated with chlorpyrifos are at present controlled by General Mills or its customers. Although the Agency has determined that the use of the stored oats for the production of food does not constitute a human health hazard, no approval has been sought by General Mills to use the treated oats for human food purposes.

Chlorpyrifos is registered for use on other crops that are used for livestock or poultry feed purposes. General Mills has submitted data to demonstrate that the use of treated oats for livestock or poultry feed will not yield residues in meat, milk, or eggs that exceed existing tolerances for chlorpyrifos in these commodities. To ensure that the oats will be unacceptable for human food production, General Mills has stated that they will be blended to include not less than 3% barley and 97% oats. Accordingly, the definition of the raw agricultural commodity in the petition has been amended to ''oats and barley when blended together in a mixture containing 97% oats and 3% barley.''

There were no comments or requests for a referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. Toxicological data considered in support of the proposed tolerance include:

1. A 2-year dog feeding study with a no-observed-effect-level (NOEL) for systemic effects of 1.0 milligram (mg)/kilogram (kg)/day and lowest-effect-level (LEL) (increased liver weight) of 3.0 mg/kg/day. The NOELs for cholinesterase (ChE) inhibition were as follows: 0.01 mg/kg/day for plasma, 0.1 mg/kg/day for red blood cells, and 1.0 mg/kg/day for brain cells. Levels tested were 0, 0.01, 0.03, 0.1, 1.0, and 3 mg/kg/day.

2. A voluntary human study with chronic ChE NOEL of 0.03 mg/kg/day (based on 20 days of exposure at this level).

3. A 2-year mouse chronic toxicity/carcinogenicity study with a NOEL of 15 ppm for systemic effects (equivalent to 2.25 mg/kg/day) and no carcinogenic effects observed under the conditions of the study at all levels tested (0, 0.5, 5, and 15 ppm, equivalent to 0.075, 0.75, and 2.25 mg/kg/day).

4. A voluntary human study with acute ChE NOEL of 0.10 mg/kg/day (based on daily single-dose exposures of 0, 0.014, 0.03, or 0.10 mg/kg/day) determined at 1, 3, 6, and 9 days of treatment.

5. A 2-year rat feeding/carcinogenicity study with ChE NOEL of 0.1 and LEL of 1.0 mg/kg/day (based on decreased plasma and brain ChE activity), and a systemic NOEL of 1.0 mg/kg/day and LEL of 10 mg/kg/day (based on decreased erythrocyte and hemoglobin values and increased platelet count during the first year). There were no observed carcinogenic effects at the levels tested (0.05, 0.1, 1.0, and 10 mg/kg/day) under the conditions of the study. Chlorpyrifos is classified as a Group E chemical (no evidence of carcinogenicity).

6. A three-generation reproduction study in rats with no reproductive effects observed at the dietary levels tested (0, 0.1, 0.3, and 1.0 mg/kg/day).

7. Two rat developmental toxicity studies: one negative for developmental toxicity at all dose levels (levels tested were 0.1, 3.0, and 15.0 mg/kg/day); and one with maternal NOEL of 15 mg/kg/day and developmental NOEL of 2.5 mg/kg/day (levels tested, by gavage, were 0, 0.5, 2.5, and 15 mg/kg/day).

8. A mouse developmental toxicity study with a teratogenic NOEL greater than 25 mg/kg/day (highest dose tested) and a developmental fetotoxic NOEL of 10 mg/kg/day and LEL of 25 mg/kg/day (decreased fetal length and increased skeletal variants).

9. A developmental toxicity study in rabbits with maternal and developmental NOELs of 81 mg/kg/day, and maternal and developmental LELs of 140 mg/kg/day (based on maternal decreased food consumption on gestation day 15 to 19, and body weight loss during the dosing period followed by a compensatory weight gain; and based on a slight reduction in fetal weights and crown-rump lengths, and fetal increased incidence of unossified fifth sternebrae and/or xiphisternum). Levels tested were 0, 1, 9, 81, and 140 mg/kg/day.

10. An acute delayed neurotoxicity study in the hen that was negative at 50 and 100 mg/kg/day.

11. Several mutagenicity studies which were all negative. These include an Ames assay, two Chinese hamster ovary cell mutation assays, a micronucleus assay for chromosomal aberration, an in vitro chromosomal aberration assay with and without enzymatic activation, and an unscheduled DNA synthesis assay.

12. A general metabolism study in rats shows that the major metabolite of chlorpyrifos is 3,5,6-trichloro-2-pyridinol (TCP). The studies listed below were conducted to demonstrate that TCP is less toxic than chlorpyrifos and is not a ChE inhibitor.

a. A 90-day rat feeding study with a systemic NOEL of 30 mg/kg/day. Levels tested were 0, 10, 30, and 100 mg/kg/day.

b. A rat developmental toxicity study with no developmental toxicity observed at the dosages tested (0, 50, 100, and 150 mg/kg/day).

c. Mutagenicity studies (including an Ames assay and an unscheduled DNA synthesis assay) were negative for mutagenic effects.

Based on the above studies, the Agency has concluded that the TCP metabolite is not of toxicological concern.

For the assessment of chronic dietary risk, the reference dose (RfD) based on the human voluntary ChE study (ChE NOEL of 0.03 mg/kg/day) and using a 10-fold uncertainty factor is calculated to be 0.003 mg/kg of body weight/day. Tolerances for food uses appear in 40 CFR 180.342 and 40 CFR 185.1000. The Dietary Risk Exposure Section (DRES) used, when justified and appropriate, anticipated residues rather than published tolerance values, and data regarding percent crop treated (when less than 100%). The anticipated residue contribution (ARC) from published uses of chlorpyrifos is 0.000860 mg/kg of body weight/day for the overall U.S. population. This represents 28.7% of the RfD. None of the DRES subgroups has an exposure that exceeds the RfD. The population subgroup most highly exposed is nonnursing infants, less than 1 year old, with an ARC from published uses of 0.002147 mg/kg of body weight/day, 71.6% of the RfD. The next most highly exposed population subgroup is children, 1 to 6 years old, with an ARC from published uses of 0.001914 mg/kg of body weight/day, 63.8% of the RfD. The proposed tolerance on oats does not raise the ARC as a percentage of the RfD because the oats are not to be used for human food and any secondary residues occurring in milk, eggs, or meat of livestock and poultry will fall within existing tolerances for these commodities. The ARC was calculated assuming tolerance level residues of chlorpyrifos on these commodities.

The DRES detailed acute analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-1978 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of chlorpyrifos in the commodity (oats). Since the toxicological endpoint to which exposure is being compared in this analysis is neurotoxicity, four human population subgroups (infants, less than 1 year old; children, 1 to 12 years old; females, 13 years old and older; males, 13 years old and older), as well as the overall population, are of interest.

The Margin of Exposure (MOE) is a measure of how close the high-end exposure comes to the NOEL and is calculated as the ratio of the NOEL to the exposure. (NOEL/exposure = MOE.) For neurotoxicity, the Agency is generally not concerned unless the MOE is below 10 when the NOEL is based on human data. For the overall population the calculated MOE at high end (top-most eaters—defined as the top 0.5% of the population in terms of consumption) as a result of all commodities, other than oats, treated with chlorpyrifos is less than 10. In the overall population 6% of consumers have an MOE less than 10.

The DRES analysis to estimate the potential increased risk of neurotoxicity resulting from residues of chlorpyrifos in meat, poultry, eggs, and milk obtained from animals fed treated oats indicates that the MOE is greater than 10 for the overall U.S. population and for each of the 4 population subgroups. The calculated MOE at high end (top-most eaters—in this case defined as the top 0.5% of the population/subpopulation in terms of consumption) for the overall population is 33; for infants, less than 1 year old it is 20; for children, 1 to 12 years old it is 25; for females, 13 years old and older it is 83; and for males, 13 years old and older it is 71.

The Margin of Exposure estimates are considered conservative because a major assumption is that the high-end eater consumed only meat, poultry, eggs, and/or milk from animals fed only oats containing chlorpyrifos residues. The increase in calculated estimates of acute

risk from chlorpyrifos residues as a result of the proposed temporary tolerance would be negligible.

The petition for a tolerance has resulted from a misuse of chlorpyrifos, and the Agency does not generally grant a tolerance to cover misuse. The following points, however, were considered. The petitioner was not directly responsible for the misuse. Although human food produced from the treated chlorpyrifos was not determined by the Agency to be a human health hazard, the petitioner has not sought approval for use of the treated oats as human food and destroyed all human food made from the treated oats that had not entered commerce. The tolerance is time limited. Finally, if this tolerance is not approved, 18 million bushels of oats, or approximately 15% of the privately held U.S. stocks, will have to be destroyed despite EPA's conclusion that use of the oats as an animal feed protects the public health.

To ensure that the oats are used as an animal feed, EPA has amended the commodity definition from ''the raw agricultural commodity oats'' to ''the raw agricultural commodities oats and barley when blended together in a mixture containing 97% oats and 3% barley.'' Blending barley with oats will make the oats unsuitable for milling to produce human food. The petitioner has agreed to blend barley into the treated oats prior to sale or distribution.

The nature of the residue in plants and animals is adequately understood. Adequate methodology is available for enforcement purposes and for analysis of chlorpyrifos in oat grain. The FDA Pestrack data base (PAM Vol. I, January, 1994) indicates that complete recovery has been obtained for chlorpyrifos under FDA multiresidue methods 302 and 303, and partial recovery has been obtained with method 304.

The pesticide is considered useful for the purpose for which the tolerance is sought.

There are currently no actions pending against continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 5F4427/P606]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-54, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 1, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.342, by adding new paragraph (f), to read as follows:

§ 180.342 Chlorpyrifos; tolerances for residues.

* * * * *

(f) A tolerance of 15 ppm is established for residues of the pesticide chlorpyrifos [*O,O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate] in or on the raw agricultural commodities oats and barley when blended together as a mixture containing 97% oats and 3% barley.

(1) Such tolerance applies only to oats that were treated post-harvest with chlorpyrifos on or before June 15, 1994.

(2) Such tolerance applies only to oats to be used as animal feed or as a constituent of animal feed.

(3) Notwithstanding any other provision of law or regulation, this tolerance does not authorize the presence of residues of chlorpyrifos in any human food item made from such treated oats, other than residues resulting from the use of the oats for animal feed purposes.

(4) Such tolerance expires on December 31, 1996.

[FR Doc. 95–3206 Filed 2–3–95; 5:06 pm]

BILLING CODE 6560–50–F

40 CFR Parts 185 and 186

[FAP 3H5673, 4H5695, 4H5696/P591; FRL–4915–1]

RIN 2070–AC18

Food and Feed Additive Regulations for d-Limonene, Dihydro-5-Pentyl-2(3H)-Furanone, and Dihydro-5-Heptyl-2(3H)-Furanone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish food/feed additive regulations for residues of the insecticides d-limonene, dihydro-5-pentyl-2(3H)-furanone, and dihydro-5-heptyl-2(3H)-furanone when used as active ingredients in insect-repellent tablecloths and in insect-