ADDRESSES at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 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. 96-354, 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: January 23, 1996.

Stephen L. Johnson.

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is 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 § 180.434, paragraph (a) is amended in the table therein by adding and alphabetically inserting an entry for mushrooms, and paragraph (b) is amended in the table therein by adding and alphabetically inserting an entry for mint, to read as follows:

§ 180.434 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Mushrooms	0.1
* * * * *	

(b) * * *

Commodity	Parts per million
* * * * *	
Mint, tops (leaves and stems) ..	0.3
* * * * *	

* * * * *

[FR Doc. 96–1719 Filed 1–30–96; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 4E4288 and 4E4289/R2198; FRL–4995–1]

RIN 2070–AC18

Chlorpyrifos; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule revises tolerances for residues of the insecticide chlorpyrifos in or on the raw agricultural commodities peaches, pears, plums, and nectarines by establishing the current time-limited tolerances as permanent tolerances. The regulations to establish maximum permissible levels of residues of the insecticide were requested in petitions submitted by DowElanco and are needed to cover maximum expected residues in or on imported commodities.

EFFECTIVE DATE: This regulation became effective January 24, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [PP 4E4288 and 4E4289/R2198], may be submitted to: Hearing Clerk (A–110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted 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 copy of objections and hearing requests to Rm. 1132, CM 1B2, 1921 Jefferson Davis Highway, Arlington, VA. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to:

opp-docket@epamail.epa.gov

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 4E4288 and 4E4289/R2198]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Jr., Product Manager (PM) 19, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 207, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-6386; e-mail:edwards.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a proposed rule, published in the Federal Register of September 28, 1993 (58 FR 68621) which announced that DowElanco had submitted pesticide petitions (PP 4E4288 and PP 4E4289) to the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), to amend 40 CFR 180.342 by revising the tolerances for residues of the insecticide chlorpyrifos [*O*,*O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl)

phosphorothioate] in or on the raw agricultural commodity pears from 0.01 to 0.05 part per million (ppm) and peaches, nectarines, and plums from 0.01 ppm to 0.05 ppm. These revisions in the tolerances were needed because of differing use patterns of chlorpyrifos in other parts of the world as compared to the U.S.

The Agency reviewed preliminary residue data and concluded that residues should not exceed the proposed tolerances, but determined that additional residue data for imported pears, peaches (data for peaches suffices for nectarines), plums and prunes (the processed commodity of plums) were required.

Pending submission and review of the data, the Agency issued a final rule, published in the Federal Register of February 25, 1994 (59 FR 9095), which announced that the Agency had revised the tolerances for a 2-year period. The expiration date is January 28, 1996, at which time the tolerances would revert to the previous 0.01 ppm for the named commodities.

Additional residue data for pears, peaches, and plums were submitted. (It was determined that chlorpyrifos residues do not concentrate in the processing of plums to prunes, and no data were submitted or required.) The data were reviewed and were determined to be sufficient to justify removing the time limitation from the existing tolerances. The available data do not support a change in the U.S. use pattern for the crops listed above. If such a change is desired, additional residue data generated in the U.S. must be submitted.

The scientific data submitted in the petitions and other relevant material have been evaluated. The toxicological data considered in support of the 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 non-nursing 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, 1-6 years old, with an ARC from published uses of 0.001914 mg/kg of body weight/day, 63.8% of the RfD. It should be noted that these values include contributions from pears, nectarines, peaches, and plums with tolerances of 0.05 ppm; the tolerances are already in place as temporary tolerances. This rule converts existing, temporary tolerances to permanent tolerances and does not raise the ARC as a percentage of the RfD.

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 1977-78

Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of chlorpyrifos in the commodity. 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, 1-12 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 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. Using refined exposure estimates generated in the preparation of the Reregistration Eligibility Document (RED) for chlorpyrifos, MOEs are greater than 10 for all population subgroups evaluated except for children 1 through 6 years. Although the Agency has concerns when low MOEs are calculated, this tolerance action does not raise risk concerns. The MOEs are not affected by the rule because any incremental change in exposure resulting from the tolerances for pears, nectarines, peaches, and plums is negligible. Thus MOEs are not changed by the tolerances for these commodities, much less by the raising of the tolerance from 0.01 ppm to 0.05 ppm. It should also be noted that the Agency will reassess chlorpyrifos tolerances in general as part of the reregistration process. The RED is scheduled to be issued in 1996.

A record has been established for this rulemaking under docket number [PP 4E4288 and 4E4289/R2198] (including any objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines ''a significant regulatory action'' as an action that is likely to result in 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 referred to 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 the rights and obligations thereof; 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. 96-354, 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: January 24, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is 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 revising paragraph (e), to read as follows:

§ 180.342 Chlorpyrifos; tolerances for residues.

* * * * *

(e) Tolerances are established as follows for residues of the insecticide chlorpyrifos [*O*,*O*-diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate] in or on the following raw agricultural commodities:

Commodity	Parts per million
Nectarines	0.05
Peaches	0.05
Pears	0.05
Plums	0.05

* * * * *

[FR Doc. 96–1905 Filed 1–26–96; 2:55 pm]
BILLING CODE 6560–50–F