

paragraph (d)(1) and add the language “§ 1.905–4T(c)” in its place.

■ 3. Remove the language “§ 1.905–4T(b)(3)(ii)(A)” from paragraph (d)(2) and add the language “§ 1.905–4T(c)(2)” in its place.

■ 4. Remove the language “paragraph (b)(3)(iii)” from paragraph (d)(3) and add the language “§ 1.905–4T(c)(3)” in its place.

■ 5. Remove the language “§ 1.905–4T(b)(3)(iii) in lieu of the exchange rate for the date of the accrual” from paragraph (d)(4) and add the language “§ 1.905–4T(c)(3)” in its place.

■ 6. Revise the heading and first sentence of paragraph (f).

■ 7. Add a new paragraph (g).

The revision and addition read as follows:

**§ 1.905–5T Foreign tax redeterminations and currency translation rules for foreign tax redeterminations occurring in taxable years beginning prior to January 1, 1987 (temporary).**

\* \* \* \* \*

(f) *Special effective/applicability date.* See § 1.905–4T(f) for the applicability date of notification requirements relating to foreign tax redeterminations that affect foreign taxes deemed paid under section 902 or section 960 with respect to pre-1987 accumulated profits accumulated in taxable years of a foreign corporation beginning on or after January 1, 1987. \* \* \*

(g) *Expiration date.* The applicability of this section expires on or before November 5, 2010.

**PART 301—PROCEDURE AND ADMINISTRATION**

■ **Par. 5.** The authority citation for part 301 continues to read as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*

■ **Par. 6.** Section 301.6689–1T is amended as follows:

■ 1. Add a new sentence at the end of paragraph (a).

■ 2. Revise paragraph (e).

The addition and revision read as follows:

**§ 301.6689–1T Failure to file notice of redetermination of foreign tax (temporary).**

(a) \* \* \* Subchapter B of chapter 63 of the Internal Revenue Code (relating to deficiency proceedings) shall not apply with respect to the assessment of the amount of the penalty.

\* \* \* \* \*

(e) *Effective/applicability date—(1) In general.* This section applies to foreign tax redeterminations (as defined in § 1.905–3T(c) of this chapter) occurring in taxable years of United States taxpayers beginning on or after

November 7, 2007, and in the three immediately preceding taxable years. For corresponding rules applicable to foreign tax redeterminations occurring in earlier taxable years of United States taxpayers, see 26 CFR 301.6689–1T (as contained in 26 CFR part 301, revised as of April 1, 2007).

(2) *Expiration date.* The applicability of this section expires on or before November 5, 2010.

**Kevin M. Brown,**  
*Deputy Commissioner for Services and Enforcement.*

Approved: August 9, 2007.

**Karen A. Sowell,**  
*Deputy Assistant Secretary of the Treasury (Tax Policy).*

[FR Doc. E7–21766 Filed 11–6–07; 8:45 am]

BILLING CODE 4830–01–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 52 and 97**

[EPA–R03–OAR–2007–0448; FRL–8493–2]

**Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Withdrawal of Direct Final Rule**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Withdrawal of Direct final rule.

**SUMMARY:** Due to an adverse comment, EPA is withdrawing the direct final rule to approve a SIP revision submitted by West Virginia pertaining to its abbreviated SIP for the Clean Air Interstate Rule (CAIR) Nitrogen Oxides (NO<sub>x</sub>) Annual and NO<sub>x</sub> Ozone Season trading programs. In the direct final rule published on September 13, 2007 (72 FR 52289), we stated that if we received adverse comment by October 15, 2007, the rule would be withdrawn and not take effect. EPA subsequently received an adverse comment. EPA will address the comment received in a subsequent final action based upon the proposed action also published on September 13, 2007 (72 FR 52325). EPA will not institute a second comment period on this action.

**DATES:** *Effective Date:* The Direct final rule is withdrawn as of November 7, 2007.

**FOR FURTHER INFORMATION CONTACT:** Marilyn Powers, (215) 814–2308, or by e-mail at [powers.marilyn@epa.gov](mailto:powers.marilyn@epa.gov).

**List of Subjects**

*40 CFR Part 52*

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone, Particulate Matter, Reporting and recordkeeping requirements, Sulfur oxides.

*40 CFR Part 97*

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements.

Dated: October 29, 2007.

**Donald S. Welsh,**  
*Regional Administrator, Region III.*

■ Accordingly, the addition of entries for 45 CSR 39 and 40 to the table in paragraph (c) and the addition of an entry for Article 3, Chapter 64 of the Code of West Virginia to the table in paragraph (e) of § 52.2520 are withdrawn as of November 7, 2007.

[FR Doc. E7–21863 Filed 11–6–07; 8:45 am]

BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2006–0524; FRL–8153–7]

**Oxytetracycline; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of oxytetracycline in or on apples. Interregional Research Project #4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective November 7, 2007. Objections and requests for hearings must be received on or before January 7, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0524. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All

documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:**

Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to

certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0524 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before January 7, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0524, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to

4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

**II. Petition for Tolerance**

In the **Federal Register** of October 11, 2006 (71 FR 59783) (FRL-8097-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E4855) by Interregional Research Project #4 (IR-4), 500 College Rd., East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.337 be amended by establishing a tolerance for residues of the fungicide oxytetracycline, in or on apple at 0.35 parts per million (ppm). That notice referenced a summary of the petition prepared by Nufarm Americas Inc., the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit IV.C.

Oxytetracycline has two major agricultural uses. It is used to treat plant and animal disease and at subtherapeutic doses in animals to promote growth. Clinically, oxytetracycline is a second-line of defense against a host of infections. The pesticidal use of oxytetracycline on plants is small compared to the animal and human usage; it has been estimated as <0.5% of all antibiotic uses.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” These provisions

were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of oxytetracycline on apple at 0.35 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by oxytetracycline as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as document 0027 (pages 20 thru 24) in Docket ID EPA-HQ-OPP-2005-0492.

For oxytetracycline a definitive target organ has not been identified. The most common effect in intermediate- or long-term oral exposures was a decrease in body weight and/or body weight gain. Clinical signs noted were increased incidence of respiratory signs and rough hair coat and decreased maternal survival and percent of treated dams found pregnant. In a chronic toxicity study in dogs, a yellow discoloration of the thyroid was observed in all dosed animals at necropsy. No other changes in clinical signs, mortality, body weight, food consumption, macroscopy, or histopathology were reported in dogs.

In prenatal developmental toxicity studies, maternal toxicity was evident in rats as a dose-related increase in mortality. A dose-related decrease in fetal body weight was observed in rats. No maternal or developmental toxicity was observed in mice treated up to 2,100 milligrams/kilograms/day (mg/kg/day). No treatment-related external, visceral, or skeletal abnormalities were found in either species. In a study citation that was reported by a Joint

FAO/WHO committee, oxytetracycline did not adversely affect reproductive parameters in rats over two generations. There is no evidence of increased sensitivity in pups versus adults based on rat and mice developmental studies and the rat multi-generation reproduction study. In prenatal developmental studies in both rats and mice treated with oxytetracycline, there was no toxicity identified in the pups at any dose tested. In the 2-generation study, there was no toxicity identified in pups at the highest dose tested. The degree of concern is low for prenatal and/or postnatal toxicity resulting from exposure to oxytetracycline. No evidence of neurotoxicity was observed in any study.

The microbiological effects of oxytetracycline were examined by studies examining the induction of drug-resistant organisms in dogs. In a 6-week study in dogs, which received oxytetracycline, there was no increase in the level of resistant fecal coliforms at 2 ppm in the diet (equivalent to 0.05 mg/kg/day). Dogs receiving 10 ppm (equivalent to 0.25 ppm) displayed an increase in a multiple antibiotic-resistant population of enteric lactose-fermenting organisms.

The mechanisms of action of antimicrobials, such as oxytetracycline, are based on affecting the pathogenic organism and not the host. The database for oxytetracycline demonstrates that it is indeed of low toxicological concern as most adverse effects seen following oral oxytetracycline treatment in animals are observed at very high dosages (e.g. near or above 1,000 mg/kg/day in animals). In humans, there are demonstrated toxicological concerns associated with the use of oxytetracycline, although the risk of adverse effects are low.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute

and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for oxytetracycline used for human risk assessment can be found at [www.regulations.gov](http://www.regulations.gov) in document 0027 (pages 27 thru 29) in Docket ID EPA-HQ-OPP-2005-0492.

No appropriate acute dietary endpoint attributable to a single exposure was identified for females age 13-49 or for the general population. A chronic dietary endpoint (cPAD) was identified for all populations based on the microbiological study in dogs with a NOAEL of 0.05 mg/kg/day based on a shift from a predominantly drug-susceptible population of enteric lactose-fermenting organisms to a multiple antibiotic-resistant population at 0.25 mg/kg/day (LOAEL) in mature beagle dogs. This chronic endpoint is considered conservative and protective for the entire toxicological database and was selected based on the qualitative classification of overall risk of resistance being medium. Other studies in the toxicological database demonstrated NOAELs near or above 1,000 mg/kg/day with the exception of a cited 2-generation reproductive study which had a NOAEL of 18 mg/kg/day. Based on the data available, the UF for the dog study is 10X for intraspecies variations and 10X for interspecies extrapolation. The cPAD was selected using an animal resistance endpoint in mature beagle dogs. The risk assessment team acknowledges that this study is not a precise description of antibiotic resistance in animals or humans. It is, however, a good indicator of the selective pressure of antibiotic usage and recognizes the potential for resistance in future infections.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to oxytetracycline, EPA considered exposure under the petitioned-for tolerances as well as all existing oxytetracycline tolerances in (40 CFR 180.337). EPA assessed dietary exposures from oxytetracycline in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for oxytetracycline; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues and percent crop treated (PCT) information for all commodities.

Anticipated residue levels for apples, peaches (nectarines), and pears, percent crop treated information, default processing factors, and Food Safety and Inspection Service (FSIS) monitoring data from 2002, 2003, and 2004 to estimate residue levels in livestock commodities were used. Tolerances are currently established under 40 CFR 180.337 for residues of oxytetracycline *per se* in/on peach and pears at 0.35 ppm. As indicated in 40 CFR 180.1(h), tolerances for peaches also cover nectarines. Therefore, nectarines were included in the analysis using the peach residue data. For apples, an anticipated residue level of 0.033 ppm was used, based on the mean residue level measured in the field trial studies reflecting a total oxytetracycline application rate of 1.53 lb ai/A. For peach, nectarine, and pears, an anticipated residue level of 0.20 ppm was used, based on average residue levels from the available field trial data.

Based on the registered uses of oxytetracycline on pears, peaches, and nectarines, and the proposed use on apples, no quantifiable residues in meat, milk, poultry, and eggs (MMPE) are expected. However, the Food and Drug Administration (FDA) has established tolerances in MMPE commodities for the sum of the residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline as listed in 21 CFR 556.500.

Accordingly, the analysis includes estimates of possible oxytetracycline residues in livestock commodities making use of monitoring data from the FSIS collected in 2002, 2003, and 2004. These data were taken from the FSIS National Residue Program Data publications (Red Books).

The relevant FSIS data sampled kidney tissue from a variety of livestock (cattle, swine, poultry, goats, etc), analyzing for oxytetracycline residues. As tetracycline residues partition preferentially into fat and kidney, measured oxytetracycline residues in kidney were used as worst-case level for all other livestock tissues. In 2004 and 2002, no oxytetracycline residues were detected in 4,270 and 6,942 samples, respectively. In 2003, three kidney samples had finite oxytetracycline residue levels out of 5,260 samples. To compute an estimated residue level for use in Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID), an average residue level was calculated using  $\frac{1}{2}$  level of detection (LOD) for nondetects (0.005 ppm) together with the three detected levels of 2.5, 5.0, and 5.0 ppm. This provided an estimated residue level of oxytetracycline in livestock commodities of 0.0058 ppm. This value was used for all livestock commodities in the DEEM-FCID analyses.

iii. *Cancer* There was no evidence of carcinogenicity for male or female mice fed oxytetracycline hydrochloride for two years. Results from carcinogenicity studies in rats were less clear cut (equivocal); however, based on the weight of the evidence, the EPA has classified oxytetracycline as a “Group D” carcinogen (“Not Classifiable as to Human Carcinogenicity”). Therefore, a cancer risk assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) of FFDCA require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

a. The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

b. The exposure estimate does not underestimate exposure for any significant subpopulation group.

c. Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 5% peaches, 5% nectarines, and 25% pears. The Agency used projected percent crop treated (PPCT) information for apples assuming 10% of apples are treated.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

Generally, estimated PCT at the national level for a given crop/year may be equated to the average of all corresponding state PCTs weighted by their state acres grown. Such estimates take account of usage (or lack of usage) in all states for which the crop is grown and for which data are available. However, for a new use with previous usage occurring only under Section 18s, estimated PCT calculated over all growing states may understate what PCT would be upon Section 3 registration

because that calculation may include states with no usage because they were not granted Section 18s. (However, this may not hold if all states where the product is efficacious were granted Section 18 emergency exemptions.)

Therefore, to provide conservative PPCT estimates based on historical usage under Section 18s, only states with Section 18s are included in the PCT computations for each year. That is, for each year, estimated PCT for states with Section 18s is computed as the weighted average of state PCTs taken over only states with Section 18s. This extrapolates Section 18 usage to the national level. The computation utilizes data from the U.S. Department of Agriculture National Agricultural Statistics Service (USDA/NASS) because such data are readily available and are not proprietary. For risk assessment, the average over years of the weighted average state PCTs is appropriate to use as the PPCT estimate for use in chronic dietary risk assessment, and maximum over years is appropriate for use in acute dietary risk assessment. This approach is conservative because use is likely to be higher in states which requested emergency exemptions as compared to states which did not have such a severe need that they relied on the emergency exemption route.

Predominant factors that bear on whether the estimated PPCTs for oxytetracycline on apples could be exceeded may include the history and scope of the relevant Section 18s, the presence or lack of alternatives and other factors. All relevant information currently available for predominant factors has been considered for oxytetracycline on apples.

The Agency believes that the three conditions listed in Unit III.D.iv. have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to

residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which oxytetracycline may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for oxytetracycline in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of oxytetracycline. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of oxytetracycline for chronic exposures are estimated to be 4.6 parts per billion (ppb) for surface water and 0.33 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The estimates were calculated based on the maximum use pattern for oxytetracycline assuming 9 separate applications of oxytetracycline calcium to peaches and/or nectarines at a rate of 0.642 lb ai/A with a 7-day retreatment interval. For chronic dietary risk assessment, the annual average concentration of 4.6 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Oxytetracycline is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to oxytetracycline and any other substances and oxytetracycline does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that oxytetracycline has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* No quantitative or qualitative evidence suggests increased susceptibility of rat or mouse fetuses from *in utero* exposure to oxytetracycline in the developmental toxicity studies. Effects on offspring body weight were seen in the presence of systemic effects in the dam. The data requirement for the 2-generation reproduction study has been waived but a study available in literature demonstrates no quantitative or qualitative evidence of increased susceptibility in rats.

3. *Conclusion.* Historically, all the toxicological data requirements for oxytetracycline have been waived. The prenatal developmental and carcinogenicity studies in rats and mice were the only acceptable studies submitted to the EPA. However, given the extensive literature and study reports available on oxytetracycline, the risk assessment takes a weight-of-the-evidence approach, considering the

available data from a variety of sources, including studies submitted and reviewed by the EPA, the National Toxicology Program, the World Health Organization (WHO), the FDA, and open literature studies. The information available on the effects of oxytetracycline in laboratory animals is sufficient to evaluate the toxicity of oxytetracycline and related compounds. Based on the information available from these sources, the database is complete and there are no datagaps. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. The decision is based on the following findings:

- i. The toxicity database is complete.
- ii There is a low degree of concern and no residual uncertainties with regard to pre- and/or postnatal toxicity.
- iii. A developmental neurotoxicity study is not required because there was no evidence of neurotoxicity in the current toxicity database.
- iv. The dietary food exposure assessment utilizes mean residue levels and percent crop treated information for all relevant commodities, and monitoring data to estimate possible livestock residue levels. By using these refined assessments, chronic exposures are not likely to be underestimated. The dietary drinking water assessment (Tier 1 estimates) yields values generated by modeling methods which are designed to provide conservative, health protective, high-end estimates of water concentrations.

v. In the previous risk assessments for oxytetracycline the 1993 Reregistration Eligibility Decision ([http://www.epa.gov/pesticides/reregistration/status\\_page\\_o.htm](http://www.epa.gov/pesticides/reregistration/status_page_o.htm)) the reference dose was established at 0.005 mg/kg/body weight per day based on a NOAEL of 0.05 mg/kg body weight per day from the microbiological study in dogs. However, only a UF of 10 to account for intraspecies variability was used since it was determined that the dog gut is similar to that of humans. For this current assessment, EPA has used an UF of 100 to account for intraspecies and interspecies variability. Though the reduction of the FQPA safety factor from 10x to 1x does not explicitly address the bacterial resistance issue, the chronic dietary endpoint (cPAD) is based on this effect. Therefore, the current risk assessment is sufficiently conservative and protective of infants and children.

#### *E. Aggregate Risks and Determination of Safety*

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD

and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* There were no toxic effects attributable to a single dose. An endpoint of concern was not identified to quantitate an acute-dietary risk to the U.S. general population or to the subpopulation females 13-50 years old. Therefore, oxytetracycline is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to oxytetracycline from food and water will utilize 32% of the chronic population adjusted dose (cPAD) for the U.S. population, 97% of the cPAD for all infants less than 1 year old, the subpopulation at greatest exposure, and 92% of the cPAD for children 1-2 years old. There are no residential uses for oxytetracycline that result in chronic residential exposure to oxytetracycline.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Oxytetracycline is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.D.iii., EPA has classified oxytetracycline as a "Group D" carcinogen ("Not Classifiable as to Human Carcinogenicity"). Therefore, a cancer risk assessment was not conducted.

5. *Pharmaceutical aggregate risk.* Section 408 of the FFDCA requires EPA to consider potential sources of exposure to a pesticide and related substances in addition to the dietary sources expected to result from a pesticide use subject to the tolerance. In order to determine whether to maintain a pesticide tolerance, EPA must "determine that there is a reasonable certainty of no harm." Under FFDCA section 505, the Food and Drug Administration reviews human drugs for safety and effectiveness and may approve a drug notwithstanding the possibility that some users may experience adverse side effects. EPA

does not believe that, for purposes of the section 408 dietary risk assessment, it is compelled to treat a pharmaceutical user the same as a non-user, or to assume that combined exposures to pesticide and pharmaceutical residues that lead to a physiological effect in the user constitutes "harm" under the meaning of section 408 of the FFDCA.

Rather, EPA believes the appropriate way to consider the pharmaceutical use of oxytetracycline in its risk assessment is to examine the impact that the additional nonoccupational pesticide exposures would have to a pharmaceutical user exposed to a related (or, in some cases, the same) compound. Where the additional pesticide exposure has no more than a minimal impact on the pharmaceutical user, EPA could make a reasonable certainty of no harm finding for the pesticide tolerances of that compound under section 408 of the FFDCA. If the potential impact on the pharmaceutical user as a result of co-exposure from pesticide use is more than minimal, then EPA would not be able to conclude that dietary residues were safe, and would need to discuss with FDA appropriate measures to reduce exposure from one or both sources. EPA provided its findings with respect to oxytetracycline to FDA in a letter dated May 24, 2006, which is available in the public docket (EPA-HQ-OPP-2005-0492).

The pesticidal exposure estimates described in the May 24, 2006 letter reflect the dietary dose from pesticidal uses of oxytetracycline that a user treated with a pharmaceutical oxytetracycline product would receive in a reasonable worst-case scenario. EPA's pesticide exposure assessment has taken into consideration the appropriate population, exposure route, and exposure duration for comparison with exposure to the pharmaceutical use of oxytetracycline.

EPA estimates that the pharmaceutical oxytetracycline exposure a user is expected to receive from a typical therapeutic dose (25 mg/kg/day for children) is 50,000 to 200,000 times greater than the estimated dietary exposure from the pesticidal sources of oxytetracycline (0.000121 mg/kg/day to 0.000473 mg/kg/day). Therefore, because the pesticide exposure has no more than a minimal impact on the total dose to a pharmaceutical user, EPA believes that there is a reasonable certainty that the potential dietary pesticide exposure will result in no harm to a user being treated therapeutically with oxytetracycline. FDA is aware of EPA's conclusions regarding pesticide exposure in users

receiving treatment with a pharmaceutical oxytetracycline drug product and FDA's June 7, 2006 response to EPA is available the public docket (EPA-HQ-OPP-2005-0492).

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to oxytetracycline residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

HWI Method MR-OPAP-MA with modifications is used to measure and evaluate oxytetracycline residues. The method is adapted from Pfizer Method STP No. 012.14 entitled Microbiological Agar Diffusion Assay for Oxytetracycline in Fruit Extract and Hazelton Method OTCF entitled Oxytetracycline in Feeds which is published in Official Methods of Analysis of the AOAC, 15th Edition as Method 968.50. The method is similar to Final Action Microbiological Methods I and II in the AOAC Official Methods of Analysis (1984; 42.293-42.298).

Although there is an enforcement method for oxytetracycline, it could be improved. The available method is nonspecific and the data generated by the method indicate that recoveries are generally low and markedly variable. As a condition of registration, EPA has required that the registrant develop an improved enforcement method based on HPLC, similar to AOAC methods 995.09 and 995.04, which use HPLC to determine tetracycline levels in animal tissues and milk, respectively.

*B. International Residue Limits*

There are currently no Codex maximum residue levels (MRLs) for oxytetracycline.

*C. Response to Comments*

Several comments were received from a private citizen objecting to IR-4 Rutgers University increasing the use of this pesticide and establishment of tolerances. The Agency has received these same comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), 69 FR 63096-63098 (October 29, 2004) for the Agency's response to these objections.

**V. Conclusion**

Therefore, the tolerance is established for residues of oxytetracycline in or on apple at 0.35 ppm

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded

Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: October 29, 2007.

**Donald R. Stubbs,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—AMENDED**

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

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.337 is amended by alphabetically adding the following commodity to the table to read as follows:

**§ 180.337 Oxytetracycline; tolerance for residues.**

\* \* \*

Commodity	Parts per million
Apple .....	0.35
* * * * *	*

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