Dated: December 2, 2016.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(255)(i)(G)(*2*) and (c)(474)(i)(D) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(255) * * *

(i) * * *

(G) * * *

(*2*) Previously approved on December 7, 2000, in paragraph (c)(255)(i)(G)(*1*) of this section and now deleted without replacement Rule 26.10.

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(474) * * *

(i) * * *

(D) Ventura County Air Pollution Control District.

(*1*) Rule 26.13, ''New Source Review—Prevention of Significant Deterioration (PSD),'' revised on November 10, 2015.

* * * * *

■ 3. Section 52.270 is amended by adding paragraph (b)(17) to read as follows:

§ 52.270 Significant deterioration of air quality.

* * * * *

(b) * * *

(17) The PSD program for the Ventura County Air Pollution Control District (VCAPCD), as incorporated by reference in § 52.220(c)(474)(i)(D)(*1*), is approved under part C, subpart 1, of the Clean Air Act. For PSD permits previously issued by EPA pursuant to § 52.21 to sources located in the VCAPCD, this approval includes the authority for the VCAPCD to conduct general administration of these existing permits, authority to process and issue any and all subsequent permit actions relating to such permits, and authority to enforce such permits.

[FR Doc. 2017–04680 Filed 3–9–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0539; FRL–9959–19]

Oxytetracycline; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of oxytetracycline in or on fruit, citrus, group 10–10. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide in citrus production. This regulation establishes a maximum permissible level for residues of oxytetracycline in or on the commodities in this crop group. The time-limited tolerance expires on December 31, 2019.

DATES: This regulation is effective March 10, 2017. Objections and requests for hearings must be received on or before May 9, 2017, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0539, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, 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–2016–0539 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 9, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0539, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you considered to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l*)*(6) of 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for combined residues of oxytetracycline, including its metabolites and degradates, expressed as only oxytetracycline, (4S,4aR,5S,5aR,6S,12aS)-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide, in or on fruit, citrus, group 10–10, at 0.4 parts per million (ppm). The time-limited tolerance expires on December 31, 2019.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18-related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received a petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Oxytetracycline on Citrus and FFDCA Tolerances

The Florida Department of Agriculture and Consumer Services (FDACS) asserted that an emergency situation existed in accordance with the criteria for approval of an emergency exemption and requested the use of two oxytetracycline products on citrus to suppress *Candidatus Liberibacter asiaticus* (*C*Las) bacterium that causes Huanglongbing (HLB) also known as citrus greening. One product contains oxytetracycline calcium, and the other contains oxytetracycline hydrochloride. HLB was recently introduced to the US, is vectored by the invasive insect, the Asian citrus psyllid, and is the most serious disease of citrus worldwide. This disease has rapidly spread throughout Florida's citrus production area, causing severe losses with an overall decrease in production of more than 60% primarily due to HLB. Significant losses have occurred, many producers have gone out of business, and FDACS asserts that the long-term economic viability of the citrus industry in Florida is threatened by this disease. The bacteria reside in the phloem (the circulatory system of the tree), disrupting circulation of water and nutrients, which ultimately leads to death of the infected tree. Currently there is no cure. FDACS has submitted data that indicates that some treatments, including nutritional supplementation and use of pesticides like oxytetracycline, may help improve the health of infected trees. After reviewing the submission, EPA determined that an emergency situation exists for Florida, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of oxytetracycline on citrus in Florida for management of the *C*Las bacterium that causes HLB (citrus greening) disease.

Oxytetracycline is part of the tetracycline class, and is a broad-spectrum antibiotic produced from the actinomycete *Streptomyces rimosus.* Two salts of oxytetracycline, oxytetracycline hydrochloride and oxytetracycline calcium, are the forms of oxytetracycline registered as pesticides for use against bacteria, fungi and mycoplasma-like organisms (there are no active registrations for oxytetracycline *per se*). The toxicity of all three forms of oxytetracycline is similar and they are considered equivalent for the purposes of assessing toxicity and establishing tolerances. Hereafter this document will use 'oxytetracycline' to refer to all three of these materials. As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by dietary exposure through residues of oxytetracycline in or on citrus fruit. All commodities in the crop group 10–10, citrus fruit were included in the dietary exposure estimates used. In assessing potential risks, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2019, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on commodities of fruit, citrus, group 10–10 after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because the time-limited tolerance is being approved under emergency

conditions, EPA has not made any decisions about whether oxytetracycline meets FIFRA's registration requirements for use on fruit, citrus, group 10–10, or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registrations of oxytetracycline by a State for special local needs under FIFRA section 24(c). Nor does the tolerance by itself serve as the authority for persons in any State other than Florida to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for oxytetracycline, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D), 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 expected as a result of this emergency exemption use and the time-limited tolerance for residues of oxytetracycline in or on fruit, citrus, group 10–10, at 0.4 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

The information available on the effects of oxytetracycline in humans from pharmaceutical uses, supplemented with the data available on the toxicity of oxytetracycline in laboratory animals is sufficient to evaluate the toxicity of oxytetracycline. Based on the information from these sources, the toxicity and exposure databases for oxytetracycline are considered complete, and exposure estimates are conservative. The emergency exemption allows use of two oxytetracycline compounds: Oxytetracycline hydrochloride and oxytetracycline calcium.

Previously the endpoint for chronic dietary exposures to oxytetracycline was based on the NOAEL of 0.05 milligram/kilogram/day (mg/kg/day) from a special dog study, which demonstrated a change in intestinal flora at the LOAEL of 0.25 mg/kg/day, with a shift from a predominantly drug-susceptible population of enteric lactose-fermenting organisms to a multiple-antibiotic-resistant population. However in 2011, the EPA changed its endpoint selection as recommended by the National Academy of Sciences (NAS) report, *Toxicity Testing in the 21st century: a vision and a strategy.* NAS Press (2007). This report advised selecting toxicity endpoints for assessing human health risk estimates based upon biological perturbations of toxicity pathways that can lead to adverse health outcomes under conditions of human exposure. Based on this NAS report, in the absence of a demonstrable adverse human health outcome, EPA no longer considers the changes in intestinal flora to be an appropriate basis for regulating dietary exposure to antibiotics.

Instead, using a weight-of-the-evidence approach, EPA adopted an NOAEL of 100 mg/kg/day based on minor (toxicologically insignificant) effects seen in two chronic feeding studies in the rat (NOAELs = 50 and 150 mg/kg/day) and two chronic toxicity studies in the dog (NOAELs = 250 mg/kg/day for both, the highest dose tested in these studies), and taking into account a National Cancer Institute rat chronic carcinogenicity study, with an LOAEL of 1250 mg/kg/day (lowest dose tested) based on hyperplasia of the adrenal medulla, and fatty metamorphosis and increases in accessory structures of the liver. To this 100 mg/kg/day NOAEL, EPA applied the customary 100× UF for both interspecies and intraspecies variability resulting in a chronic reference dose (cRfD) of 1.0 mg/kg/day for adults. EPA has applied an additional 10× ''Food Quality Protection Act (FQPA) safety factor'' to provide an additional margin of protection for assessing risks to infants and children, resulting in a chronic population-adjusted dose (cPAD) of 0.1 mg/kg/day. This is further discussed in unit IV.C. of this document.

A summary of the oxytetracycline toxicology data used for human health risk assessment is given in the Table of this unit.

TABLE—OXYTETRACYCLINE TOXICOLOGICAL ENDPOINTS FOR HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	POD, UFs, and FQPA SF	RfD, PAD, and LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	NA	NA	No endpoint was attributable to a single exposure.
Chronic dietary (All populations)	NOAEL = 100 mg/kg/day ..... UF_A = 10× UF_H = 10× FQPA SF = 10×	cRfD = 1 mg/kg/day ..... cPAD = 0.1 mg/kg/day Chronic dietary exposure LOC ≥100% of cPAD.	The NOAEL of 100 mg/kg/day was derived using a weight of evidence (WOE) approach based on 3 rat and 2 dog chronic studies. No specific LOAEL was established.

TABLE—OXYTETRACYCLINE TOXICOLOGICAL ENDPOINTS FOR HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	POD, UFs, and FQPA SF	RfD, PAD, and LOC for risk assessment	Study and toxicological effects
Risk assessments for occupational scenarios are not required because no adverse effects were observed from dermal or inhalation exposures. Evaluation of residential scenarios was not required because there are no registered residential oxytetracycline uses.			
Cancer (Oral, dermal, inhalation) ..	The Agency's Peer Review Committee has classified oxytetracycline as a ''Group D'' carcinogen (''Not Classifiable as to Human Carcinogenicity'').		

NA = Not Applicable. RfD = reference dose. PAD = population adjusted dose (a = acute, c = chronic). LOC-level of concern; mg/kg/day = milligram of pesticide per kilogram of body weight per day. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. WOE = weight of evidence. NCI = National Cancer Institute.

The complete human health risk assessment for this action may be found at *http://www.regulations.gov* in the following three documents ''*Oxytetracycline. Section 18 Emergency Exemption for Citrus Grown in Florida,*'' and ''*Oxytetracycline. Update to Section 18 Emergency Exemption for Citrus Grown in Florida to Consider 10X FQPA,*'' in the docket for ID number EPA–HQ–OPP–2016–0539.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to oxytetracycline, EPA considered exposure under the time-limited tolerances established by this action 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.* No acute dietary effects were identified in the toxicological studies or literature for oxytetracycline; therefore, a quantitative acute dietary exposure assessment is unnecessary and was not conducted.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption data from the US Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey (NHANES). For residue levels in food, EPA assumed one hundred percent crop treated (PCT) and tolerance-level residues for all registered uses plus the subject tolerance of 0.4 ppm in or on all commodities of fruit, citrus, group 10–10. In addition, default processing factors were used for all processed commodities except citrus juice, oil, and peel, since concentration of oxytetracycline was not observed in these commodities. EPA's exposure assessment also included tolerance level residues for livestock commodities owing to use of oxytetracycline as an animal drug. No anticipated residue or PCT refinements were used.

iii. *Cancer.* Based on the information referenced in Unit IV.A., EPA has concluded that oxytetracycline does not pose a cancer risk to humans. No evidence of carcinogenicity was found in a literature search of toxicity in animals. There was no evidence of carcinogenicity for male or female mice fed oxytetracycline at 1,875 mg/kg/day for two years. In the rat carcinogenicity study, there was equivocal evidence for carcinogenicity based upon increased incidences of pheochromocytomas of the adrenal gland at the highest doses tested for males of 2,500 and increased incidences of adenomas of the pituitary gland in females at 1,875 mg/kg/day; both doses are extremely high as compared to expected human exposure and above the limit dose. The mutagenicity assays were all negative except for the mouse lymphoma forward mutation assay which was positive only with metabolic activation. Based upon this information and the weight of the evidence as a whole, the EPA has classified oxytetracycline as a ''Group D'' carcinogen (''Not Classifiable as to Human Carcinogenicity''). A review of the same data by the National Toxicology Program's (NTP) Peer Review Committee was in agreement with this classification. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary and was not conducted.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for oxytetracycline. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models to derive estimated water concentrations for dietary exposure analysis of oxytetracycline exposures through drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of oxytetracycline. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic.*

Based on the Surface Water Calculator, using Pesticide Root Zone Model 5+ and the Variable Volume Water Body Model, the estimated drinking water concentration (EDWC) of oxytetracycline for non-cancer risk assessment due to chronic exposure was 149 parts per billions (ppb) for surface water, based on the highest registered rate for application to peach and nectarine. The PRZM-Ground Water model estimated that no residues of oxytetracycline would result in groundwater in any of the six standard scenarios (use modelled for 100 years), presumably due to the chemical's strong soil sorption. The highest EDWC for surface water of 149 ppb was therefore used to assess chronic dietary exposure contribution from drinking water and was directly entered into the dietary exposure model.

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 or proposed for any specific use patterns that would result in residential exposure (non-dietary), and therefore this risk assessment was not performed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at*: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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.'' EPA has not found oxytetracycline to share a common mechanism of toxicity with 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 assumed that oxytetracycline does not have 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 Web site at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) 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, required under the Food Quality Protection Act, is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Considering the toxicity database for oxytetracycline, the mouse prenatal development study did not identify adverse effects up to the highest dose tested (HDT), 2100 mg/kg/day. In addition, the effects seen in the rat prenatal development study occurred only at levels above the limit dose. However, clinical use of tetracyclines administered to pregnant women, infants and children have resulted in discoloration of the teeth, enamel hypoplasia, and bone developmental effects in fetuses and children. A decrease in fibula growth in premature infants has been observed after an oral dose of 25 mg/kg every six hours, equivalent to a total dose of 100 mg/kg/day (though these effects reversed quickly after discontinuation of dosing). For these reasons, the FDA recommends not administering oral doses of tetracycline to children under 8 years of age. In addition, tetracyclines cross the placenta and should not be taken during the last half of pregnancy. The effect in premature infants dosed with tetracycline was observed at 100 mg/kg/day, the same level as that used as the POD for chronic risk assessment (derived from laboratory animal toxicity data). Thus, EPA concluded that some uncertainty remains regarding the potential sensitivity to infants, children under 8 years of age, and pregnant women based upon the literature database for therapeutic uses of oxytetracycline, and decided to retain the 10× FQPA SF to assure adequate protection for these populations.

3. *Conclusion.* The existing database, together with the extensive literature and study reports available on oxytetracycline, including studies submitted to and reviewed by the EPA, the National Toxicology Program, and World Health Organization, the FDA and open literature studies, are adequate for characterizing toxicity and quantification of risk from the proposed and existing uses of oxytetracycline. EPA has determined that reliable data indicate that retaining the 10× FQPA SF will adequately protect the safety of infants and children. That decision is based on the following findings:

i. The toxicity database for oxytetracycline is complete and there are no data gaps.

ii. There is no indication that oxytetracycline is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although the guideline toxicity studies did not suggest an increased lifestage sensitivity/susceptibility (no effects at the highest doses tested or effects only above the limit dose), data from the pharmaceutical literature suggests that infants and children may be more susceptible to oxytetracycline side-effects than adults, and FDA does not recommend administering oral doses of tetracycline to children under 8 years of age or pregnant women. Therefore, a 10× FQPA SF has been retained.

iv. There are no residual uncertainties with regard to the exposure databases. The dietary assessment overestimates actual exposures to oxytetracycline because it assumed 100% crop treated, and incorporated tolerance-level residues and default processing factors (PFs). EPA also made conservative (protective, high-end) assumptions in the environmental water modeling used to estimate potential levels of oxytetracycline in drinking water. All of the assumptions used for the exposure and risk estimates are likely to overestimate exposures that may actually occur. Therefore, these assessments will not underestimate the exposure and risks posed by oxytetracycline.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified (no acute dietary endpoint was determined). Therefore, oxytetracycline is not expected to pose an acute risk and no acute risk assessment was necessary.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to oxytetracycline from food and water will utilize 40% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for oxytetracycline. Although exposure may occur through therapeutic use of oxytetracycline as a drug, such pharmaceutical use is not included in this aggregate exposure assessment for agricultural uses of oxytetracycline as a pesticide. However, potential exposure through clinical drug use of oxytetracycline was considered and compared to the exposure estimates from the agricultural use, which is further discussed in Unit IV.D.6. below.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential (non-dietary, non-occupational) exposure plus chronic exposure to food and water (considered to be a background exposure level). Oxytetracycline is not registered for any use patterns that would result in short-term residential exposure. Further, because no short-term adverse effect was identified, oxytetracycline is not expected to pose a short-term risk and the chronic risk assessment will be protective for any short-term exposures.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term

residential (non-dietary, non-occupational) exposure plus chronic exposure to food and water (considered to be a background exposure level). Oxytetracycline is not registered for any use patterns that would result in intermediate-term residential exposure. Further, because no intermediate-term adverse effect was identified, oxytetracycline is not expected to pose an intermediate-term risk and the chronic risk assessment will be protective for any intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, oxytetracycline is not expected to pose a cancer risk to humans and no cancer risk assessment was necessary.

6. *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 issue or maintain a pesticide tolerance, EPA must ''determine that there is a reasonable certainty of no harm'' resulting from the pesticide use subject to the tolerance. 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 assume that combined exposures to pesticide and pharmaceutical residues that lead to a physiological effect in the user necessarily constitutes ''harm'' under the meaning of section 408 of 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 the same, or a related chemical substance. Where the additional pesticide exposure has no more than a minimal impact on the pharmaceutical user, EPA can 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'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. The typical pharmaceutical oxytetracycline dose for children is 25 mg/kg/day. This dose is approximately 1,262 times greater than the dietary exposure estimate of 0.019809 mg/kg/day, the food and water exposure estimate for children 6–12 years old. This group represents the potential highest exposed population group, in terms of considering therapeutic use of oxytetracycline (children under 8 yrs old are not given therapeutic oxytetracycline). 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 no harm will result from the potential dietary pesticide exposure of a user being treated therapeutically with oxytetracycline.

7. *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.

V. Other Considerations

A. Analytical Enforcement Methodology

The analytical method used to derive the citrus residue data for determining the appropriate tolerance levels was based on Method STM2028.06, which was found to be scientifically acceptable for enforcement of tolerances of oxytetracycline on apple, pear and peach. This method employs liquid chromatography with tandem mass spectrometry (LC/MS/MS) using turbo ion spray in the positive ion mode, monitoring two ion transitions for confirmation of oxytetracycline, and was adequately validated for the quantitation and confirmation of ion transitions using samples of apple and nectarine. A successful independent laboratory validation was performed as well using samples of apple, pear, peach, and nectarine. Since the method used for citrus was similar to this and provided adequate recoveries for citrus fruits, it is considered adequate to support the emergency exemption use and enforce the tolerance expression of oxytetracycline in or on commodities of fruit, citrus, group 10–10. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for oxytetracycline.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of oxytetracycline and its metabolites and degradates, expressed as only oxytetracycline, (4S,4aR,5S,5aR,6S,12aS)-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide, in or on fruit, citrus, group 10–10 at 0.4 ppm. This tolerance expires on December 31, 2019.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA sections 408(e) and 408(l)(6). 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''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 action 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 in accordance with FFDCA sections 408(e) and 408(l)(6), 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 action 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 FFDCA section 408(n)(4). 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 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA submitted 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 the rule in the **Federal Register**. This action 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: February 23, 2017,

Michael Goodis,

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. In § 180.337 revise paragraph (b) to read as follows:

§ 180.337 Oxytetracycline; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the fungicide/bactericide oxytetracycline, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only oxytetracycline, (4S,4aR,5S,5aR,6S,12aS)-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the dates specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Fruit, citrus, group 10–10	0.40	12/31/2019

* * * * *

[FR Doc. 2017–04795 Filed 3–9–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0557; FRL–9958–75]

Flupyradifurone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of flupyradifurone [4-[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]-2(5*H*)-furanone] in or on sweet sorghum, forage and sorghum, syrup resulting from use of flupyradifurone in accordance with the terms of crisis exemptions issued under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This action is in response to the issuance of crisis emergency exemptions under FIFRA section 18 authorizing use of the pesticide on sweet sorghum. This regulation establishes maximum permissible levels for residues of flupyradifurone in or on sweet sorghum forage and sorghum syrup. These time-limited tolerances expire on December 31, 2019.

DATES: This regulation is effective March 10, 2017. Objections and requests for hearings must be received on or before May 9, 2017, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0557, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC),West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review