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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0820; FRL-9986-87]

Oxytetracycline; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of oxytetracycline in or on fruit, citrus, crop group 10-10. Geo Logic Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**] 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-2015-0820, 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 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 EPA's tolerance regulations at 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 FFDCA section 408(g), 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-2015-0820 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2015-0820, 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 consider 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/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 16, 2016 (81 FR 14030) (FRL-9942-86), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8415) by Geo Logic Corporation, P.O. Box 3091, Tequesta, FL 33469. The

petition requested that 40 CFR 180.337 be amended by establishing tolerances for residues of the bactericide 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, crop group 10-10 at 0.01 parts per million (ppm).

That document referenced a summary of the petition prepared by Geo Logic Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

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…."

Consistent with FFDCA section 408(b)(2)(D), and 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 for oxytetracycline including exposure resulting from the

tolerances established by this action. EPA's assessment of exposures and risks associated with oxytetracycline 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.

At high doses, the target organ of tetracycline toxicity is the liver. The most common effect in intermediate- or long-term oral exposures in rats and mice was a decrease in body weight. In the prenatal developmental study in rats, clinical signs included increased incidences of respiratory signs and rough hair coat in the dams, in addition to increased mortality and a decreased percentage of dams found pregnant. Also identified was a decrease in fetal body weight. In the mouse prenatal developmental study, there was no toxicity identified in the dams or fetuses. In all of the above animal studies, adverse effects were seen at doses that exceed the limit dose. There is no adequate reproductive toxicity study available in the database, however, the data requirement was waived based on the lack of reproductive effects reported during the history of use as a drug. No evidence of neurotoxicity was observed in any guideline study. A rat immunotoxicity study demonstrated immunosuppression at doses lower than those for systemic toxicity. Tetracyclines are known to inhibit bone growth in developing tissue. When oxytetracycline was administered orally as a single dose to two female infant rhesus monkeys, zygomatic arch bone (lateral surface of temporal bone) growth was inhibited for ~12.5 days with no recovery observed by 21 days. Effects on bone growth are consistent with oxytetracycline's ability to chelate calcium, and so are not unexpected. Bone developmental effects were also

observed after administration of chlortetracycline and demethylchlortetracycline in adult rhesus monkeys highlighting the consistency of tetracycline treatment across this class of chemicals.

The Agency has classified oxytetracycline as "Group D: *Not Classifiable as to Human Carcinogenicity*". Oxytetracycline has low acute toxicity, being Toxicity Category IV for oral toxicity, the only acute lethality study available in the database.

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* in document "*Oxytetracycline/Oxytetracycline Hydrochloride/Oxytetracycline Calcium: Draft Human Health Risk Assessment in Support of Registration Review and Tolerance Establishment in/on Citrus Fruit Crop Group 10- 10*" in docket ID number EPA-HQ-OPP-2015-0820.

B. 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 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 *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

Table 1. -- Summary of Toxicological Doses and Endpoints for Oxytetracycline for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	None selected	N/A	No appropriate endpoint for females age 13-49 or for the general population attributable to a single exposure.
Chronic dietary (All populations)	NOAEL= 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 10x	Chronic RfD = 1 mg/kg/day cPAD = 0.10 mg/kg/day	WOE from 3 rats and 2 dogs chronic studies. The NOAEL of 100 mg/kg/day was derived from these studies and no specific LOAEL was established.
Cancer	Classified as a Group D carcinogen—not classifiable as to human carcinogenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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 2003-2008 food consumption data from the USDA's National Health and Nutrition Examination Survey/What We Eat in America. As to residue levels in food, EPA used tolerance-level residues, default processing factors (PFs), and assumed 100 percent crop treated (PCT).

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that oxytetracycline does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for oxytetracycline in 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 *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model version 5.02/Variable Volume Water Body Model (VVWM V1.02) and Pesticide Root Zone Model Ground Water (PRZMGW), EDWCs of oxytetracycline for chronic exposures for non-cancer assessments are estimated to be 2.85 ppb for surface water and 0.323 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 2.85 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 any specific use patterns that would result in residential exposure.

Tetracycline hydrochloride (97% chemical similarity to oxytetracycline) is approved by FDA for use as an oral antibiotic to treat certain bacterial and parasitic infections. EPA examined the impact that additional pesticide exposures to oxytetracycline would have on a person who has been prescribed the antibiotic. EPA determined that the additional pesticide exposure would not have more than a minimal impact on the total dose to the pharmaceutical patient, and thus concludes that there is a reasonable certainty that the additional exposure from pesticide uses of oxytetracycline would result in no harm finding to a user being treated therapeutically.

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 assessed the potential for oxytetracycline to share a common mechanism of toxicity with any other substances. Based on its assessment of the available toxicological data, EPA has determined that oxytetracycline does not share a similar toxicological profile with other pesticides, and no further cumulative evaluation is necessary for oxytetracycline.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor 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), 2,100 mg/kg/day. In addition, the effects seen in the rat prenatal development study occurred only at levels above the limit dose. Although guideline toxicity studies do not suggest an increased lifestage sensitivity/susceptibility (effects above the limit dose or no effects at the highest doses tested), data from the literature suggests that developing

infants and children may be more susceptible to oxytetracycline side-effects than adults. When oxytetracycline was administered orally, as a single dose, to two female infant rhesus monkeys, zygomatic arch bone (lateral surface of temporal bone) growth was inhibited for ~12.5 days with no recovery observed by 21 days. The delayed bone growth occurs as a result of chelation of calcium, the mineral needed for bone growth. When the monkeys are treated with a very high dose of oxytetracycline (80 mg/kg), the calcium can be bound up for several days, leading to a delay in bone growth during that short time frame. However, once the oxytetracycline levels diminish, bone growth continues resulting in normal bones at maturity.

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, is adequate for characterizing toxicity and quantification of risk from the proposed and existing uses of oxytetracycline. EPA is retaining the 10X FQPA SF because of the potential for pre-natal toxicity. The Agency concludes that this safety factor will be protective of potential toxicity to infants and children based on the following findings:

i. The toxicity database for oxytetracycline is complete.

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. There is no evidence that oxytetracycline results in increased susceptibility in *in utero* rats in the prenatal developmental studies. Within the toxicity database, the mouse prenatal developmental study did not identify adverse effects up to the highest does tested (HDT), 2,100 mg/kg/day. Based on the adverse effects seen in infant rhesus monkeys after oral administration of oxytetracycline, the Food Quality Protection Act (FQPA) Safety Factor (SF) is being retained at 10X.

iv. There are no residual uncertainties identified in the exposure databases. The dietary assessment overestimates actual exposures to oxytetracycline as it incorporated tolerance-level residues, default PFs, assumed that 100% of the proposed and existing crops are treated with oxytetracycline, and included high-end ground and surface drinking water modeling estimates. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to oxytetracycline in drinking water. These assessments will not underestimate the exposure and risks posed by oxytetracycline.

E. 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 and no acute dietary endpoint was selected. 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 chronic exposure to oxytetracycline from food and water will utilize 33% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential pesticide uses for oxytetracycline.

3. *Short-term risk and Intermediate-term risk*. Short-term and intermediate-term aggregate exposures take into account short-term residential exposure plus chronic exposure to

food and water (considered to be a background exposure level) and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level), respectively. Short and intermediate-term adverse effects were identified; however, oxytetracycline is not registered for any residential pesticide uses that would result in short or intermediate-term residential exposures. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure and intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there are no short-term or intermediate-term residential exposures and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for oxytetracycline.

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

5. *Pharmaceutical aggregate risk for U.S. population.* 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 and determine that "there is a reasonable certainty of no harm" from those exposures. Because the Food and Drug Administration (FDA) may approve pharmaceutical drugs under FFDCA section 505, notwithstanding the possibility that some users may experience adverse side effects. EPA examines the impact that the additional pesticide exposures would have to a pharmaceutical user exposed to a related (or, in some cases, the same) compound in assessing the potential of harm to the

pharmaceutical user. Where the additional pesticide exposure has no more than a minimal impact on the pharmaceutical user, EPA has concluded that it can make a reasonable certainty of no harm finding for the pesticide tolerances of that compound under section 408 of the FFDCA.

For oxytetracycline, EPA's pesticide exposure assessment has taken into consideration the appropriate population, exposure route, and exposure duration for comparison with pharmaceutical exposure to oxytetracycline. EPA estimates that the pharmaceutical exposure a person is expected to receive from a typical therapeutic dose (25 mg/kg/day for children) is 750 to 2,800 times greater than the estimated dietary exposure from the pesticidal sources of oxytetracycline (0.0089334 mg/kg/day). Therefore, because the pesticide exposure has no more than a minimal impact on the total dose to a pharmaceutical user, EPA concludes that there is a reasonable certainty that the potential pesticide exposure will result in no harm to a person being treated therapeutically with oxytetracycline.

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

Adequate enforcement methods are available for determining oxytetracycline residues in/on plant commodities. A high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS) has been proposed for tolerance enforcement.

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 Alimentarius 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.

C. Response to Comments

One comment was received generally opposing the use of any pesticides in or on food. The Agency recognizes that some individuals oppose the use of pesticides in or on food, but the FFDCA authorizes the Agency to establish tolerances for residues of pesticides in or on food if the Agency determines that the tolerance is safe. EPA has examined all the available data and determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. The commenter has provided no information to support a finding that the tolerances would not be safe.

V. Conclusion

Therefore, tolerances are established for residues of oxytetracycline, in or on fruit, citrus, group 10-10 at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) 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 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); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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 on the basis of a petition under FFDCA section 408(d), 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).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 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: November 23, 2018.

Michael Goodis,
Director, Registration Division, Office of Pesticide Program.

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, add alphabetically the entry for "Fruit, citrus, group 10-10" to the table in paragraph (a) to read as follows:

§ 180.337 Oxytetracycline; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Fruit, citrus, group 10-10	0.01
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[FR Doc. 2018-26343 Filed: 12/3/2018 8:45 am; Publication Date: 12/4/2018]