of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 7, 2017.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2017–05068 Filed 3–14–17; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0540; FRL–9957–65]

Streptomycin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of streptomycin in or on fruit, citrus, group 10–10, for both fresh fruit and dried pulp. 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 maximum permissible levels for residues of streptomycin in or on these commodities. The time-limited tolerances expire on December 31, 2019.

DATES: This regulation is effective March 15, 2017. Objections and requests for hearings must be received on or before May 15, 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–2016–0540, 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–2016–0540 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 15, 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–2016–0540, 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. 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 time-limited tolerances for residues of streptomycin, expressed as only streptomycin ((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 2 parts per million (ppm), and the dried pulp of these commodities at 6 ppm. These time-limited tolerances expire 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 any 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 Streptomycin on Citrus and FFDCA Tolerances

The Florida Department of Agriculture and Consumer Services (FDACS) asserted that an emergency situation exists in accordance with the criteria for approval of an emergency exemption, and requested the use of streptomycin (and oxytetracycline, addressed in a separate document) in citrus to suppress the *Candidatus Liberibacter asiaticus* (*C*Las) bacterium that causes Huanglongbing (HLB) also known as citrus greening. HLB is a newly-introduced disease, 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. Currently there is no cure. 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 tree. FDACS states that use of streptomycin, along with other management measures, may suppress HLB symptoms, and prolong the productive life of infected trees, allowing citrus producers to remain in business while researchers continue to explore and evaluate new treatments for the disease.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, 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 streptomycin on citrus to suppress the CLas bacterium that causes HLB disease in Florida.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of streptomycin in or on citrus fruit commodities. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances 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 these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2019, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on citrus fruit commodities 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 levels that were authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether streptomycin meets FIFRA's registration requirements for use on citrus fruit or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as bases for registrations of streptomycin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves 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 streptomycin, 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 tolerances for residues of streptomycin on fruit, citrus, group 10–10 at 2 ppm, and the dried pulp of these commodities at 6 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerances 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 to use in evaluating the risks to humans from 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, EPA assumes that any amount of exposure will lead to some degree of risk. Thus, the EPA 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/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for streptomycin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR STREPTOMYCIN 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 (Any population)	NA	NA	Toxicity from single dose was not identified.
Chronic dietary (All populations)	NOAEL= 5 mg/kg/day UF_A = 10 UF_H = 10 FQPA SF = 1X	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	Two-year feeding study in rats. LOAEL = 10 mg/kg/day based on reduced body weight in males.
Inhalation (All durations)	NOAEL = 5 mg/kg/day. FQPA SF = 1X	LOC ≤ MOE of 100	Two-year feeding study in rats. LOAEL = 10 mg/kg/day based on reduced body weight in males.
Cancer	Classification—There is not enough information in line with EPA's guidelines for toxicological studies of pesticides to classify carcinogenic potential. The toxicological data requirements have been waived due to the extensive human database from streptomycin drug use. A 2-year rat carcinogenicity study, used by FDA and the World Health Organization to set tolerances for animal drug residues, is available and did not demonstrate evidence of carcinogenicity. Also, a literature search for streptomycin toxicity in animals and humans did not result in any data indicating evidence of 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. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among the human population (intraspecies).

The complete human risk assessment for this action can be found at *http://www.regulations.gov* in the document ''Streptomycin. Section 18 Emergency Exemption for Citrus Grown in Florida'' in the docket for ID number EPA–HQ–OPP–2016–0450.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to streptomycin, EPA considered exposure under the time-limited tolerances established by this action as well as all existing streptomycin tolerances in 40 CFR 180.245. EPA assessed dietary exposures from streptomycin in food as follows:

i. *Acute exposure.* No acute effects were identified in the toxicological studies for streptomycin; 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 2003–2008 US Department of Agriculture (USDA) National Health and Nutrition Examination Survey (NHANES). For residue levels in food, EPA assumed tolerance level residues for all registered uses plus the new tolerances of 2 ppm in citrus fruit and 6 ppm in the dried pulp of these commodities. In addition, default processing factors were used for all processed commodities, except citrus juice, oil, and tomato puree since concentration was not observed in these commodities. One hundred percent crop treated (PCT) was assumed for all commodities. EPA's exposure assessment included tolerance level residues in livestock commodities owing to use of streptomycin as an animal drug as well. No anticipated residue or PCT refinements were used.

iii. *Cancer.* Based on the data summarized in Unit IV.A., EPA has concluded that streptomycin 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 percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for streptomycin. Tolerance level residues and 100% CT 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 streptomycin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of streptomycin. 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/about-water-exposure-models-used-pesticide.*

Potential residues resulting in surface water and groundwater were modeled based upon registered and new uses. The estimated drinking water concentrations (EDWCs) for ground water were higher than for surface water, and thus were used for estimating exposure from drinking water consumption, as the most conservative (worst case) estimate. Based on the Pesticide Root Zone Model, Ground Water, the EDWC in groundwater (the highest modeled value) for streptomycin for acute exposures is estimated to be 932 parts per billion (ppb), and for chronic exposures (non-cancer) is estimated at 760 ppb. No acute assessment was required as discussed earlier in this document. The modeled estimate of drinking water concentration for chronic exposure was directly entered into the dietary exposure model used to estimate chronic risks presented by potential residues in food and 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).

Streptomycin is currently registered for uses on residential gardens and trees which could result in residential exposures. EPA considered residential exposures from these uses and determined the following: Since there is no dermal hazard identified for streptomycin, residential dermal exposures were not assessed. Non-dietary incidental ingestion and inhalation from post-application residential exposures are assumed to be negligible, based upon the use scenarios and chemical properties of streptomycin. However, residential handler inhalation exposures may occur based on the use sites, equipment, and in particular, the lack of personal protective equipment (PPE) requirements on certain product labels for residential uses. Risk was therefore evaluated from short- and intermediate-term inhalation exposures for residential (non-professional) handlers/applicators. 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 streptomycin to share a common mechanism of toxicity with any other substances, and streptomycin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that streptomycin 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 *http://www.epa.gov/pesticides/cumulative.*

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 (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 SF when reliable data are available to EPA which support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There were no teratogenic effects noted in a rabbit developmental study at the high dose of 10 mg/kg/day. Although children born to mothers treated with streptomycin injections have sometimes had hearing loss, no teratogenic effects have been attributed to streptomycin treatment. The injected dose at which these effects occurred in humans is equivalent to approximately 150 times higher than the NOAEL from the rabbit study and approximately 30,000 times higher than the dose that produced the reduced body weight endpoint used in establishing the chronic RfD. Additionally, none of the available toxicity data for streptomycin indicate any pre- or post-natal susceptibility. Therefore there are no residual concerns, EPA is confident that the chronic RfD is sufficiently protective for teratogenic effects, and the Food Quality Protection Act (FQPA) safety factor was reduced to 1X.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for streptomycin is complete. An extensive database exists from drug use of streptomycin in humans and animals and all guideline toxicity data requirements for streptomycin have been waived. The toxicity of streptomycin was assessed using toxicity reviews provided by the FDA and from the published literature on drug use. Because the dose selected for risk assessment from agricultural use is based upon a toxicity endpoint (decreased body weight in test animals) that occurs at a much lower oral dose than the injected dose at which prenatal hearing effects occurred in humans, there are no residual concerns and the FQPA safety factor is reduced to 1X.

ii. The extensive database in animals and humans does not demonstrate any potential for streptomycin to cause either peripheral or central nervous system toxicity and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no direct evidence of sensitivity/susceptibility in the developing or young animal. No teratogenic effects were observed in the rabbit. As noted previously, children born to mothers treated with streptomycin injections have sometimes had hearing loss but no teratogenic effects have been attributed to direct streptomycin treatment. Chosen points of departure are expected to be protective of any possible hearing loss effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to streptomycin in drinking water. EPA used similarly conservative assumptions to consider potential for post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by streptomycin.

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.* No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, streptomycin is not expected to pose an acute risk.

2. *Chronic risk.* Based on the explanation in the unit regarding residential use patterns, chronic residential exposures to residues of streptomycin are not expected.

Therefore chronic aggregate risk was assessed considering only dietary exposures from potential residues in food and drinking water. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to streptomycin from potential residues in food and drinking water will not result in risks of concern (*i.e.,* are <100% of the cPAD) for all population groups

considered. The population group with the greatest dietary exposure is Infants ≤1 year old, with 90% of the cPAD occupied by chronic dietary exposure. Estimates for chronic dietary exposure contributed by residues in food occupy ≤32% of the cPAD for all population subgroups, indicating that the main contribution to dietary exposure is from potential residues in drinking water. The most conservative assumptions were made in the drinking water analysis, which likely resulted in overestimated exposures. Refinements could be made which would likely decrease the EDWCs, thereby further reducing the estimates of exposure and risk from potential residues in drinking water. However, assessment using these unrefined worst-case exposure scenarios provided chronic exposure estimates which would not result in risks of concern (*i.e.,* were <100% of the cPAD).

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposures take into account short and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The dermal route of exposure was not assessed because no dermal hazard exists for streptomycin. Non-dietary incidental ingestion and inhalation from post-application residential exposures are assumed to be negligible, based upon the chemical properties and the use scenarios for streptomycin. Intermediate-term residential exposure is not expected from the residential use patterns registered for streptomycin, and therefore was not assessed. However, short-term inhalation exposures may occur for residential handlers applying streptomycin, and therefore this route of exposure was assessed. For all residential handler scenarios considered, the estimated inhalation exposures did not present risks of concern (*i.e.,* MOEs ≥ EPA's LOC of 100). The lowest calculated MOE was 86,000 from the highest exposure scenario of the handler using hand wand/backpack and no PPE. The adult population group with the highest dietary exposure was adults 20 to 49 years old, with 38% of the cPAD occupied. Therefore, aggregate short- and intermediate-term exposure included dietary (food and water) and inhalation routes from residential handler exposure. Using these two highest-exposure scenarios, the short-term exposure estimate resulted in an MOE of 270, which does not present a risk of concern (MOE ≥ LOC of 100). Although residential exposures to children may occur through incidental oral and inhalation routes during residential application and post-application activities, they are assumed to be negligible and thus were not quantitatively assessed. Therefore, the child aggregate assessment included only contributions from chronic exposure to food and drinking water, which was previously presented in this document, and did not result in risks of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in the streptomycin database, no cancer risk is expected from streptomycin and a cancer risk assessment was not needed.

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

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 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 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 streptomycin 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.

Injected drug doses of streptomycin are approximately 15 mg/kg/day. Because the oral absorption of streptomycin is <1%, this corresponds to an oral equivalent dose of 1,500 mg/kg/day. This oral equivalent dose is over 30,000 times the highest dietary exposure estimate of 0.045 mg/kg/day, the food and water exposure estimate for the highest-exposed population (infants <1 year old). Therefore, dietary exposure from pesticide uses of streptomycin is negligible compared to drug exposure and would not contribute to drug toxicity, so there are no concerns for risks from dietary exposure contribution of streptomycin from pesticide use, in patients receiving streptomycin drug injections. 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 streptomycin.

V. Other Considerations

A. Analytical Enforcement Methodology. An adequate enforcement methodology is available to enforce the tolerance expression. The method uses high performance liquid chromatography with tandem mass spectrometry for detection (HPLC–MS/MS). The method is detailed in ''Confirmation of Aminoglycosides by HPLC/MS/MS; United States Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science SOP No: CLG–AMG1.02,'' which 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 any MRLs for streptomycin in/on citrus fruit commodities.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of streptomycin in or on fruit, citrus, group 10–10, at 2 ppm, and the dried pulp of these commodities at 6 ppm. These tolerances expire on December 31, 2019.

VII. Statutory and Executive Order Reviews

This action establishes tolerances 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 tolerances 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 9, 2017.

Michael L. 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 § 180.245, add alphabetically the entries ''Fruit, citrus, Group 10–10'' and ''Fruit, citrus, Group 10–10, dried pulp'' to the table in paragraph (b) to read as follows:

§ 180.245 Streptomycin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration date
Fruit, citrus, Group 10–10	2.0	December 31, 2019.
Fruit, citrus, Group 10–10, dried pulp	6.0	December 31, 2019.
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[FR Doc. 2017–04779 Filed 3–14–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 160929897–7222–02]

RIN 0648–BG37

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Russian River Estuary Management Activities

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS, upon request from the Sonoma County Water Agency (SCWA), issues these regulations pursuant to the Marine Mammal Protection Act (MMPA) to govern the incidental taking of marine mammals incidental to Russian River estuary management activities in Sonoma County, California, over the course of five years (2017–2022). These regulations, which allow for the issuance of Letters of Authorization (LOA) for the incidental take of marine mammals during the described activities and specified timeframes, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, and establish requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from April 21, 2017, through April 20, 2022.

ADDRESSES: A copy of SCWA's application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Regulatory Action

These regulations, issued under the authority of the MMPA (16 U.S.C. 1361 *et seq.*), establish a framework for authorizing the take of marine mammals incidental to SCWA's estuary management activities at the mouth of the Russian River in Sonoma County, CA. SCWA plans to manage the naturally-formed barrier beach at the mouth of the Russian River in order to minimize potential for flooding adjacent to the estuary and to enhance habitat for juvenile salmonids, as well as to conduct biological and physical monitoring of the barrier beach and estuary. Breaching of the naturally-formed barrier beach at the mouth of the Russian River requires the use of heavy equipment and increased human presence, and monitoring in the estuary requires the use of small boats.

We received an application from SCWA requesting five-year regulations and authorization to take multiple species of marine mammals. Take is anticipated to occur by Level B harassment incidental to estuary management activities due to disturbance of hauled pinnipeds. The regulations are valid from 2017 to 2022. Please see ''Background'' below for definitions of harassment.

Legal Authority for the Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for issuing this final rule containing five-year regulations, and for any subsequent Letters of Authorization. As directed by this legal authority, this final rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Final Rule

The following provides a summary of some of the major provisions within the final rulemaking for SCWA estuary management activities. We have determined that SCWA's adherence to the planned mitigation, monitoring, and reporting measures listed below will achieve the least practicable adverse impact on the affected marine mammals. They include:

- Measures to minimize the number and intensity of incidental takes during sensitive times of year and to minimize the duration of disturbances.
- Measures designed to eliminate startling reactions.
- Eliminating or altering management activities on the beach when pups are present, and setting limits on the frequency and duration of events during pupping season.

Background

Paragraphs 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1371 (a)(5)(A) and (D)) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s); will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant); and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On September 2, 2016, we received an adequate and complete request from SCWA for authorization to take marine mammals incidental to estuary management activities. On September 20, 2016 (81 FR 64440), we published a notice of receipt of SCWA's application