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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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: May 6, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.670 is added to subpart C to read as follows:

§ 180.670 Sulfoxaflor; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide sulfoxaflor, including its metabolites and degradate, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only sulfoxaflor (*N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-γ^4-sulfanylidene]cyanamide).

Commodity	Parts per million
Almond, hulls	6.0
Barley, grain	0.40
Barley, hay	1.0
Barley, straw	2.0
Bean, dry seed	0.20
Bean, succulent	4.0
Beet, sugar, dried pulp	0.07
Beet, sugar, molasses	0.25
Berry, low growing, subgroup 13–07G	0.70
Cattle, fat	0.10
Cattle, meat	0.15
Cattle, meat byproducts	0.40
Cauliflower	0.08
Citrus, dried pulp	3.6
Cotton, gin byproducts	6.0
Cotton, hulls	0.35
Cottonseed subgroup 20C	0.20
Fruit, citrus, group 10–10	0.70
Fruit, pome, group 11–10	0.50
Fruit, small, vine climbing, subgroup 13–07F, except fuzzy kiwi fruit	2.0
Fruit, stone, group 12	3.0
Goat, fat	0.10
Goat, meat	0.15
Goat, meat byproducts	0.40
Grain, aspirated fractions	20.0
Grape, raisin	6.0
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.10
Horse, meat	0.15
Horse, meat byproducts	0.40
Leafy greens, subgroup 4A	6.0
Leafy petiole, subgroup 4B	2.0
Milk	0.15
Nuts, tree, group 14	0.015
Onion, bulb, subgroup 3–07A	0.01
Onion, green, subgroup 3–07B	0.70
Pistachio	0.015
Poultry, eggs	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Rapeseed, meal	0.50
Rapeseed subgroup 20A	0.40
Sheep, fat	0.10
Sheep, meat	0.15
Sheep, meat byproducts	0.40
Soybean, seed	0.20
Tomato, paste	2.60
Tomato, puree	1.20
Vegetable, *brassica,* leafy, group 5, except cauliflower	2.0
Vegetable, cucurbit, group 9	0.40
Vegetable, fruiting, group 8–10	0.70
Vegetable, leaves of root and tuber, group 2	3.0
Vegetable, legume, group 7	3.0
Vegetable, root and tuber, group 1	0.05
Watercress	6.0
Wheat, forage	1.0
Wheat, grain	0.08
Wheat, hay	1.5
Wheat, straw	2.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent registrations.* [Reserved]

[FR Doc. 2013–11824 Filed 5–16–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0852; FRL–9385–3]

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 grapefruit and grapefruit, 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 on grapefruit. This regulation establishes maximum permissible levels for residues of streptomycin in or on these commodities. The time-limited tolerances expire on December 31, 2015.

DATES: This regulation is effective May 17, 2013. Objections and requests for hearings must be received on or before July 16, 2013 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–2011–0852, 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), EPA West 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: Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; email address: *conrath.andrea@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://ecfr.gpoaccess.gov/cgi/t/text/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–2011–0852 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 July 16, 2013. 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–2011–0852, 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.htm.* 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, 5-(2,4-diguanidino-3,5,6-trihydroxy-cyclohexoxy)-4-[4,5-dihydroxy-6-(hydroxymethyl)-3-methylamino-tetrahydropyran-2-yl] oxy-3-hydroxy-2-methyl-tetrahydrofuran-3-carbaldehyde, in or on grapefruit at 0.15 parts per million (ppm) and dried grapefruit pulp at 0.40 ppm. Streptomycin is an antibiotic of the aminoglycoside class and is produced by the bacteria streptomyces. The active pesticide ingredient, streptomycin sulfate, dissociates in water to streptomycin, but otherwise is relatively stable in crops, animals, and humans. Therefore, compliance with the tolerance levels is determined by measuring the residues of streptomycin only and there are no toxicologically significant metabolites and/or degradates. Streptomycin and streptomycin sulfate are considered equivalent in this document and both are referred to as streptomycin. These time-limited tolerances expire on December 31, 2015.

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 Grapefruit and FFDCA Tolerances

The Florida Department of Agriculture and Consumer Services (FDACS) requested an emergency exemption for use of streptomycin on up to 54,000 acres of fresh-market grapefruit to combat citrus canker, a disease caused by the bacteria *Xanthomonas citri.* Citrus canker was once limited to localized areas in Florida, but several recent severe hurricane seasons have spread the disease throughout the citrus growing areas and widespread treatment to control the disease throughout the season has become necessary. The FDACS requested a maximum of 2 applications of streptomycin, by ground equipment only, at a rate of 0.448 pounds of active ingredient per acre per application, during the hottest part of the season when the risk of fruit injury from the alternative controls is the greatest. 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 grapefruit for control of citrus canker 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 grapefruit. In doing so, 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 these time-limited tolerances expire on December 31, 2015, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on grapefruit and grapefruit, dried pulp 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 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 grapefruit 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 registration of streptomycin by a State for special local needs under FIFRA section 24(c). Nor does this 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 streptomycin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Specific information on the studies reviewed and the nature of the adverse effects caused by streptomycin 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,* under docket ID number EPA–HQ–OPP–2011–0852, in the document titled ''Streptomycin sulfate. Section 18 Petition by the Florida Department of Agriculture and Consumer Services for use on Grapefruit.''

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, the aggregate exposures expected as a result of this emergency exemption request and the time-limited tolerances for residues of streptomycin in or on grapefruit at 0.15 ppm, and grapefruit, dried pulp at 0.40 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 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 non-threshold risk in terms of the probability of an occurrence of the adverse effect during 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://www.epa.gov/pesticides/factsheets/riskassess.htm.*

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

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 exposure 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 gain.
Cancer	NA—EPA Waived its toxicology data requirements		

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 members of the human population (intraspecies).

The human risk assessment for this action can be found at *http://www.regulations.gov* in the document ''Streptomycin sulfate. Section 18 Petition by the Florida Department of Agriculture and Consumer Services for Use on Grapefruit'' in the docket for ID number EPA-HQ–OPP–2011–0852.

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 such acute adverse 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 food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues for all registered commodities, and the proposed tolerance levels of 0.15 ppm for grapefruit and grapefruit juice. In addition, default processing factors were used for all commodities except grapefruit juice. One hundred percent crop treated (PCT) was assumed for all crops.

iii. *Cancer.* No concern for carcinogenicity is expected for streptomycin based on the weight of evidence of available information. Streptomycin has been used for decades as a human drug at doses much higher than those expected from pesticidal uses, without findings of an association with cancer. Based on this information combined with the lack of tumors reported in the 2-year rat study assessed by FDA, and the properties of the molecule (e.g., minimal metabolism and large molecular size restricting interaction of the chemical with typical carcinogenic receptors) EPA has waived its toxicological data requirements for streptomycin. EPA has concluded that streptomycin does not pose a cancer risk to humans and a quantitative data requirements for streptomycin dietary exposure assessment for assessing cancer risk was not conducted.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for streptomycin. 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 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 *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI–GROW) models, for surface and ground water, respectively, the estimated drinking water concentrations (EDWCs) of streptomycin for ground and surface water were calculated as 1.2 parts per billion (ppb) and 51.4 ppb, respectively. The EDWCs are based on aerial application to apple orchards, which is the highest rate allowed by the label.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the EDWC value of 51.4 ppb for surface water was used to assess the dietary exposure contribution from 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 the following uses that could result in residential exposures: Use in residential areas on trees and shrubs to control the same diseases (e.g., blight, various rots) for which it is used in commercial greenhouse and agricultural settings.

EPA assessed residential nondietary exposure using the following assumptions: Since streptomycin is not significantly absorbed through dermal route, only inhalation exposures were assessed for residential scenarios of homeowner application to fruit trees and shrubs using a low pressure handwand. Although a quantitative residential post-application inhalation exposure assessment was not performed, an occupational inhalation exposure assessment for handlers was performed which is representative of a higher-end, more intensive inhalation exposure. Thus, this assessment is also protective for evaluating any potential residential post-application inhalation exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 Food Quality Protection Act (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 available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In a rabbit developmental toxicity study, no teratogenic effects were observed at the highest dose tested (10 milligrams/kilogram/day (mg/kg/day) orally). However, women receiving clinical treatment at doses of approximately 15 mg/kg/day by intramuscular injection of streptomycin during pregnancy have been known to give birth to children with hearing loss or vestibular problems; no other teratogenic effects have been attributed to streptomycin treatment. Because only about 1% of an oral dose of streptomycin is absorbed by the body, that intramuscular injection corresponds to approximately 1,500 mg/kg/day by the oral route. Thus the pharmacological dose at which these prenatal effects have been observed is about 150 times higher than the no observed adverse effect level in the rabbit developmental toxicity study, and

approximately 30,000 times higher than the dose that produced the reduced weight gain endpoint used in establishing the chronic RfD, EPA is confident that the RfD will protect against teratogenic effects.

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 1. That decision is based on the following findings:

i. 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 (based upon anticipated maximum exposures) is based upon a toxicity endpoint (decreased weight gain in test animals) that occurs at a much lower oral dose than the injected dose at which prenatal effects occur in humans, there are no residual concerns and the FQPA safety factor was reduced to 1x.

ii. There is some indication that streptomycin may be neurotoxic at the very high doses when injected as a drug. Injury to the 8th cranial nerve has been noted in some patients receiving streptomycin injections. However, this injury occurs because streptomycin accumulates in the inner ear and is not indicative of systemic injury to the nervous system. Other rare conditions reported in patients treated with streptomycin injections at clinical doses include neuromuscular blockade associated with anesthesia, enlarged blind spots of the eye, and paresthesia or abnormal sensations. Again, these responses are rare and occurred with large pharmacological doses at approximately 30,000 times higher than the RfD for streptomycin. A developmental neurotoxicity study is therefore not recommended, and there is no need for additional UFs to account for neurotoxicity.

iii. There was no evidence that *in utero* rabbits have increased susceptibility to streptomycin in the prenatal developmental study. A reproductive toxicity study has been waived and is therefore not available. Some children of mothers treated during pregnancy with streptomycin have been born with hearing deficits, which may indicate that the developing fetus is more sensitive than the mother to streptomycin-induced inner ear toxicity. However, these effects occurred after treatment with a directly injected pharmacological dose which is comparable to a dose about 150 times higher than the no observed adverse effect level in the rabbit developmental toxicity study, and approximately 30,000 times the chronic RfD EPA has selected for risk management purposes. At the much lower dose that EPA is using for risk management, there are no residual concerns. Therefore there are no concerns for prenatal effects.

iv. There are no residual uncertainties identified in the exposure databases; all guideline toxicity data requirements were waived because of the extensive clinical information available for streptomycin from decades of use as a drug in humans and animals. The dietary food exposure assessments were performed based on 100 PCT 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 assess 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 experiencing 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 adverse effect endpoint was identified. Therefore, streptomycin 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 dietary exposure to streptomycin from food and water will utilize 13% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in the unit regarding residential use patterns, chronic residential exposure to residues of streptomycin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Streptomycin is currently registered for uses that could result in short-term residential exposure. However, no such effects were identified in the studies for streptomycin. The Agency has determined that the chronic risk assessment is adequately protective for short-term exposures, and it is appropriate to aggregate chronic exposure through food and water (considered background exposure) with short-term residential exposures to streptomycin. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures from the highest exposure scenario result in an aggregate MOE of 2,100. Because EPA's level of concern for streptomycin is an MOE of 100 or below, this MOE is not of concern. Although a quantitative residential post-application inhalation exposure assessment was not performed, the occupational inhalation exposure assessment performed for handlers is representative of a worse case inhalation exposure and therefore protective of any potential post-application inhalation exposure in residential scenarios. The lowest MOE from the occupational assessments was 560, and assumed no use of protective equipment such as a respirator. Since this is higher than EPA's level of concern of an MOE of 100 or below it is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Streptomycin is not registered for any use patterns that would result in intermediate-term residential exposure and no intermediate-term adverse effects have been identified. Because there is no intermediate-term residential exposure or adverse effects identified, 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for streptomycin.

5. *Aggregate cancer risk for U.S. population.* A quantitative cancer

assessment is unnecessary. Available data suggest there are no concerns for cancer from exposure to streptomycin, and EPA has concluded that streptomycin is not expected to pose a cancer risk to humans.

6. *Antibiotic resistance risk.* EPA estimated the potential for development of antibiotic resistance in pathogenic bacteria, in consideration of factors recommended by public health experts to sustain the effectiveness of antibiotic materials. EPA conducted a qualitative analysis of this use as outlined in FDA's Guidance for Industry (GFI) #152. FDA's GFI #152 addresses expansion of antibiotic uses outside clinical settings with respect to potential impact on resistance development. Existing resistance to streptomycin has diminished its use in clinical settings, although it is still used as a second line treatment for tuberculosis and used for several other bacterial diseases. However, based upon the limitations of the use under an emergency exemption, both in terms of rate and geographic area, EPA concluded that the use is expected to result in low risks of release into the environment, and subsequently low exposures. Thus, EPA determined that the overall rating for risks of resistance development from this emergency exemption use under an emergency exemption is ''low.'' The analysis, ''Review of Florida Department of Agriculture/AgroSource's Analysis of Streptomycin's Safety with Regard to Its Microbiological Effect on Bacteria of Human Health Concern (FDA/CVM Guidance to Industry #152)'', as well as FDA's GFI #152, may be found at *http://www.regulations.gov,* under docket ID number EPA–HQ–OPP–2011–0852.

7. *Pharmaceutical aggregate risk.* Section 408 of the FFDCA requires EPA to consider potential sources of exposure to a pesticide and related substances in addition to the dietary sources expected to result from a pesticide use subject to the tolerance. In order to determine whether to maintain a pesticide tolerance, EPA must ''determine that there is a reasonable certainty of no harm.'' Under FFDCA section 505, the Food and Drug Administration reviews human drugs for safety and effectiveness and may approve a drug notwithstanding the possibility that some users may experience adverse side effects. EPA does not believe that, for purposes of the section 408 dietary risk assessment, it is compelled to treat a pharmaceutical user the same as a non-user, or to assume that combined exposures to pesticide and pharmaceutical residues that lead to a physiological effect in the user constitutes ''harm'' under the meaning of section 408 of the FFDCA.

Rather, EPA believes the appropriate way to consider the pharmaceutical use of 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 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 approximately 375,000 times the highest dietary exposure estimate of 0.004 mg/kg/day (the food and water exposure estimate for the highest-exposed population (children 1–2 years 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 contribution of streptomycin exposure 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 no harm will result from the potential dietary pesticide exposure of a user being treated therapeutically with streptomycin.

8. *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 streptomycin residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology, ''Confirmation of Aminoglycosides by HPCL–MS/MS''; United States Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science, SOP No: CLG–AMG1.02, using high performance liquid chromatography with tandem mass spectrometry for detection (HPLC–MS/MS), is available to enforce the tolerance expression.

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 an MRL for streptomycin on grapefruit.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of streptomycin, in or on grapefruit at 0.15 ppm and grapefruit, dried pulp at 0.40 ppm. These tolerances expire on December 31, 2015.

VII. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule does not

contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established 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 final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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 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: May 9, 2013.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.245 is amended by adding paragraph (b) to read as follows:

§ 180.245 Streptomycin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of streptomycin, in or on the agricultural commodities, as specified in the following table, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels listed in the following table is to be determined by measuring the levels of streptomycin only, in or on the commodities listed in the table. The tolerances expire on the dates specified in the table.

Commodity	Parts per million	Expiration date
Grapefruit	0.15	12/31/2015
Grapefruit, dried pulp	0.40	12/31/2015

* * * * *

[FR Doc. 2013–11858 Filed 5–16–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1007

[OIG–1203–F]

State Medicaid Fraud Control Units; Data Mining

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends a provision in HHS regulations prohibiting State Medicaid Fraud Control Units (MFCU) from using Federal matching funds to identify fraud through screening and analyzing State Medicaid data, known as data mining. To support and modernize MFCU efforts to effectively pursue Medicaid provider fraud, we finalize proposals to permit Federal financial participation (FFP) in costs of defined data mining activities under specified circumstances. In addition, we finalize requirements that MFCUs annually report costs and results of approved data mining activities to OIG.

DATES: These regulations are effective on June 17, 2013.

FOR FURTHER INFORMATION CONTACT: Richard Stern, Department of Health and Human Services, Office of Inspector General, (202) 619–0480.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

In 1977, the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95–142) were enacted to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs. Section 17(a) of the statute amended section 1903(a) of the Social Security Act (the Act) to provide for Federal participation in the costs attributable to establishing and operating a MFCU. The requirements for operating a MFCU appear at section 1903(q) of the Act. Promulgated in 1978, regulations implementing the MFCU authority appear at 42 CFR part 1007.

Section 1903(a)(6) of the Act requires the Secretary of Health and Human Services (the Secretary) to pay FFP to a State for MFCU costs ''attributable to the establishment and operation of a MFCU'' and ''found necessary by the Secretary for the elimination of fraud in the provision and administration of medical assistance provided under the State plan.'' Under the section, States receive 90 percent FFP for an initial 3-year period for the costs of establishing and operating a MFCU, including the costs of training, and 75 percent FFP thereafter. Currently, all States with MFCUs receive FFP at a 75-percent rate. In accordance with section 1903(q) of the Act, MFCUs must be separate and distinct from the State's Medicaid agency. For a State Medicaid agency, general administrative costs of operating a State Medicaid program are reimbursed at a rate of 50 percent, although enhanced FFP rates are available for certain activities specified by statute, including those associated with Medicaid management information systems (MMIS).