11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule establishes a temporary safety zone to protect the public from fireworks fallout. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–0723 to read as follows:

§ 165.T05–0723 Safety Zone, Shallowbag Bay; Manteo, NC.

(a) *Definitions.* For the purposes of this section, Captain of the Port means the Commander, Sector North Carolina. *Representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized to act on the behalf of the Captain of the Port.

(b) *Location.* The following area is a safety zone: This safety zone will encompass all waters on Shallowbag Bay within a 200 yard radius of a barge anchor in position 35°54′31″ N, longitude 075°39′42″ W. All geographic coordinates are North American Datum 1983 (NAD 83).

(c) *Regulations.* (1) The general regulations contained in § 165.23 of this part apply to the area described in paragraph (b) of this section.

(2) Persons or vessels requiring entry into or passage through any portion of the safety zone must first request authorization from the Captain of the Port, or a designated representative, unless the Captain of the Port previously announced via Marine Safety Radio Broadcast on VHF Marine Band Radio channel 22 (157.1 MHz) that this regulation will not be enforced in that portion of the safety zone. The Captain of the Port can be contacted at telephone number (910) 343–3882 or by radio on VHF Marine Band Radio, channels 13 and 16.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced from 8 p.m. to 10 p.m. on September 26, 2014 unless cancelled earlier by the Captain of the Port.

Dated: August 14, 2014.

S. R. Murtagh,

Captain, U.S. Coast Guard, Captain of the Port North Carolina.

[FR Doc. 2014–20675 Filed 8–28–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0297; FRL–9911–57]

Kasugamycin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of kasugamycin in or on fruit, pome. Arysta LifeScience North America, LLC (Arysta LifeScience), requested a number of tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) which are addressed in this document.

DATES: This regulation is effective August 29, 2014. Objections and requests for hearings must be received on or before October 28, 2014, 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–2010–0297, 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers

determine whether this document applies to them. Potentially affected entities may include:

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0297 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 October 28, 2014. 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–2010–0297, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 19, 2010 (75 FR 28009) (FRL–8823–2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7689) by Arysta LifeScience North America, LLC, 15401 Weston Parkway, Cary, NC 27513. The petition requested that 40 CFR 180.614 be amended by establishing tolerances for residues of the fungicide kasugamycin, in or on fruiting vegetables (crop group 8) at 0.15 parts per million (ppm), pome fruit (crop group 11) at 0.25 ppm, and walnuts at 0.04 ppm. That document referenced a summary of the petition prepared by Arysta LifeScience, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the proposed tolerance levels and the crops for which tolerances will be established. The reasons for these changes are explained in Unit IV.C. The tolerance in imported fruiting vegetables, crop group 8 is not being removed or revised at this time. This regulation additionally deletes the time-limited tolerance for apple, as the tolerance will be superseded by permanent tolerances in the various pome fruits.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for kasugamycin on pome commodities, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with kasugamycin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Kasugamycin is a member of the aminoglycoside family of antibiotics, which also includes streptomycin and gentamicin. These agents inhibit bacterial protein synthesis by binding to the 30S subunit of the bacterial ribosome. Their penetration through the cell membrane of the bacterium depends partly on oxygen-dependent active transport by a polyamine carrier system that seems to be absent in mammalian systems.

Kasugamycin exhibits low acute toxicity, being only a mild dermal and ocular irritant. The major effects observed across species in multiple-dose studies were decreased body weights and body weight gains. The primary target organs identified for kasugamycin were the testes and kidney in the rat and mouse. However, these effects were only seen at higher dose levels, generally at the highest dose tested (HDT). In the combined chronic toxicity/carcinogenicity study in rats, the basis for the lowest-observed-adverse-effect level (LOAEL) was an increased incidence and severity of testicular tubular atrophy, observed during the histopathologic examinations at the end of the 2-year dosing period, as well as at 6 months, and 1 year. Testicular degeneration and atrophy

were observed in adult F1 males in the rat reproductive toxicity study at the highest dose. Testicular tubular dilatation and degeneration were observed in the mouse subchronic study, but at a dose that exceeded the limit dose; the mouse carcinogenicity study tested at much lower doses, and these effects were not observed. In the dog chronic toxicity study, testicular inflammation was reported at the high dose, but was not accompanied by atrophic or degenerative changes, and was not considered a treatment-related adverse effect.

Kidney toxicity is often associated with exposure to aminoglycoside antibiotics, and the metabolism study indicated higher levels of radioactivity in the kidneys than other tissues. In male F1 rats in the reproductive toxicity study, dilatation of the kidney, and an increased incidence of chronic progressive nephropathy were observed. In the subchronic rat study, an increased incidence of eosinophilic bodies (graded slight for severity) in the renal proximal tubular cells was reported in males at several dose levels. These effects were considered treatment related, but not adverse due to their low severity grade, and lack of associated findings. However, in female rats, increased epithelial cells in the urinary sediment, along with decreased urine pH (decreased pH was also seen in males), were observed at the high dose, and considered evidence of possible kidney toxicity. Lipofuscin deposition (slight) was observed in the rat combined chronic toxicity/carcinogenicity study, but was not considered adverse due to the lack of other related findings; this study tested up to the no-observed-adverse-effect level (NOAEL) of the subchronic study. In the mouse, following subchronic exposure, minimal to severe basophilia/hyperplasia in the renal *pars recta* in females was observed. No renal effects were reported in the mouse carcinogenicity study at lower doses, or in the dog subchronic or chronic studies.

There was no evidence that exposure to kasugamycin results in neurotoxicity, and a developmental neurotoxicity (DNT) study is not required. Also, there was no evidence of immune system effects based on the review of a submitted immunotoxicity study. Although a 28-day rat inhalation toxicity study was not submitted, EPA has determined that it is not required based on available hazard and exposure information.

The database is complete with respect to pre- and postnatal toxicity, and shows no evidence of increased qualitative or quantitative susceptibility in the offspring, or in the developing fetus. There was no evidence of carcinogenicity in male and female mice, nor in male and female rats at doses that were adequate to assess the carcinogenic potential of kasugamycin. There was no evidence of mutagenicity. Based on the overall weight of the evidence, kasugamycin is classified as ''not likely to be carcinogenic to humans.''

Although antimicrobial drug residues present in or on food may cause adverse effects on the ecology of the intestinal microflora of consumers, the Agency does not believe this is a concern for kasugamycin because of the use pattern (application occurring prior to fruit development) and low residue detection in field trials.

Specific information on the studies received and the nature of the adverse effects caused by kasugamycin as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document ''Kasugamycin. Human Health Risk Assessment for the Proposed Use of the Fungicide on Fruiting Vegetables, Pome Fruits, and Walnuts'' at pp. 15–21 in docket ID number EPA–HQ–OPP–2010–0297.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for kasugamycin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR KASUGAMYCIN RELEVANT TO FFDCA ANALYSIS

Exposure scenario	Point of departure	Uncertainty and FQPA SF	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (all populations)	An appropriate dose and endpoint for this risk assessment scenario was not identified, based on a lack of single-dose effects in the database.			
Chronic dietary (all populations including infants and children, and females age 13 to 49).	NOAEL = 11 mg/kg/day.	UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.11 mg/kg/day. cPAD = 0.11 mg/kg/day.	Combined chronic toxicity/carcinogenicity study in the rat. LOAEL = 116 mg/kg/day, based on testicular atrophy and softening.
Cancer (oral, dermal, inhalation)	Classification: ''Not likely to be carcinogenic to humans.''			

Point of Departure = a data point or estimated point derived from observed dose-response data, which is used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. NOAEL = no-observed-adverse-effect level. LOAEL = lowest-observed-adverse-effect level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to kasugamycin, EPA considered exposure under the petitioned-for tolerances as well as all existing kasugamycin tolerances in 40 CFR 180.614. EPA assessed dietary exposures from kasugamycin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for kasugamycin; 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 United States Department of Agriculture (USDA) 1994–1996 and the 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). An unrefined chronic aggregate dietary (food and drinking water) exposure and risk assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™), Version 2.03. The residue inputs into the dietary model were the recommended tolerance level residues and default processing factors were used, with the exception of the apple juice processing factor, for which the 1.5X data-derived processing factor was used. EPA assumed 100% crop treated (PCT) for all proposed uses.

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

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for kasugamycin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of kasugamycin. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) the estimated drinking water concentrations (EDWCs) of kasugamycin for chronic exposures for non-cancer assessments are estimated to be 0.001178 ppm for surface water. EDWCs of kasugamycin for ground water were estimated to be 0.000116 ppm via the Screening Concentration in Ground Water (SCI–GROW) system. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.001178 ppm was used to assess the contribution to drinking water.

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

Kasugamycin is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has not found kasugamycin to share a common mechanism of toxicity with any other substances, and kasugamycin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that kasugamycin 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.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased quantitative or qualitative susceptibility in rat or rabbit developmental toxicity studies, or in the rat reproductive study. No developmental effects were seen in the rat developmental study, whereas maternal toxicity (decreased body weight gain, food consumption, and feed efficiency) was observed at the highest dose. Although no maternal or developmental toxicity was observed in the main rabbit developmental toxicity study, in the dose range-finding study, maternal weight loss, reduced food consumption during dosing, and abortions (occurring at GD 18 or later) were observed at higher doses. Fetal weight was decreased at the maternally toxic dose but, due to abortions or maternal death, was not evaluated at the higher doses. In the rat reproductive toxicity study, parental toxicity included decreased parental body weight/weight gain at the mid and high doses. No offspring toxicity was observed. Reproductive toxicity was observed only at the highest dose tested (above the parental LOAEL), with testicular atrophy, decreased fertility and fecundity in the F1 parents for both litters, and an increased pre-coital interval during the mating period for the F2b litter.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for the following reasons:

i. The toxicity database for kasugamycin is complete, including rat acute and subchronic neurotoxicity screening studies and a mouse immunotoxicity study. Based on the lack of observed neurotoxicity, a DNT study is not required. Furthermore, a 28-day inhalation study is not required based on the available hazard and exposure information and proposed and existing uses for kasugamycin.

ii. There is no evidence of increased quantitative or qualitative pre- and/or postnatal susceptibility observed in developmental toxicity studies in the rat and rabbit, or in a 2-generation reproduction study in the rat.

iii. The exposure assessment for food and drinking water will not underestimate potential dietary exposure to kasugamycin. There are no proposed or existing residential uses for kasugamycin.

E. Aggregate Risks and Determination of Safety

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

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

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to kasugamycin from food and water are below HED's LOC of 100% of the cPAD for all population subgroups. The most highly exposed population subgroup, children 1–2 years old, had a risk estimate of 1.7% cPAD. There are no residential uses for kasugamycin to aggregate with chronic exposure to kasugamycin from food and water.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential uses for kasugamycin, kasugamycin is not expected to pose a short- or intermediate-term risk.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, kasugamycin is not expected to pose a cancer risk to humans.

5. *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 kasugamycin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology high-performance liquid chromatography with ultraviolet detection (HPLC/UV) 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 a MRL for kasugamycin.

C. Revisions to Petitioned-For Tolerances

As EPA explained in its latest crop group rulemaking published in the **Federal Register** of August 22, 2012 (77 FR 50617) (FRL–9354–3), EPA will attempt to conform petitions seeking tolerances for crop groups to the newer established crop groups, rather than establish new tolerances under the pre-existing crop groups, as part of its effort to eventually convert tolerances for any pre-existing crop group to tolerances with coverage under the revised crop group. Therefore, although the petitioner requested tolerances for crop group 11 (pome fruit), EPA evaluated tolerances for crop group 11–10 (pome fruit).

Based on the available residue data and using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedure, EPA is establishing a tolerance of 0.20 ppm for residues of kasugamycin in or on fruit, pome (crop group 11–10).

EPA also is not establishing tolerances for walnuts and fruiting vegetables because the petitioner withdrew its tolerance requests for those commodities.

The Agency has revised the tolerance expression in 40 CFR 180.614(a) to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of kasugamycin not specifically mentioned.

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of kasugamycin, in or on pome fruits (crop group 11–10) at 0.20 ppm. This regulation additionally deletes the time-limited tolerance for apple, as the tolerance will be superseded by permanent tolerances in the various pome fruits.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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 on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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).

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: August 20, 2014.

Marty Monell,

Acting 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. Revise § 180.614 to read as follows:

§ 180.614 Kasugamycin; tolerances for residues.

(a) *General.* Tolerances are established for residues of kasugamycin, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified is to be determined by measuring only kasugamycin (3-*O*-[2-amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetradeoxy-α-*D-arabino*-hexopyranosyl]-*D-chiro*-inositol) in or on the commodity.

Commodity	Parts per million
Fruit, pome, group 11–10	0.20
Vegetable, fruiting, group 8[1]	0.04

[1] There is no U.S. registration as of September 1, 2005.

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

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

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

[FR Doc. 2014–20502 Filed 8–28–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–9915–97–Region–6; EPA–R06–RCRA–2013–0785]

Oklahoma: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: Oklahoma Department of Environmental Quality (ODEQ) has applied to the Environmental Protection Agency (EPA) for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for Final authorization, and is authorizing the State's changes through this immediate final action. The EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize Oklahoma's changes to its hazardous waste program will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

DATES: This final authorization will become effective on October 28, 2014 unless the EPA receives adverse written comment by September 29, 2014. If the EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

ADDRESSES: Submit your comments by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. *Email: patterson.alima@epa.gov.*

3. *Mail:* Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733.

4. *Hand Delivery or Courier.* Deliver your comments to Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733.

Instructions: Do not submit information that you consider to be CBI or otherwise protected through *regulations.gov,* or email. The Federal regulations.gov Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

You can view and copy Oklahoma's application and associated publicly