

Commodity	Parts per million
* * * *	*
Pea, succulent	0.02
* * * *	*
Salal	3.0
* * * *	*
Vegetable, fruiting, group 8	1.0
* * * *	*

[FR Doc. 05-19062 Filed 9-22-05; 8:45 am]
 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2005-0017; FRL-7736-4]

Kasugamycin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of kasugamycin in or on fruiting vegetables, crop group 8. Arysta Lifescience North American Corporation (previously known as Arvesta Corporation), agent for Hokko Chemical Industry Corporation, requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the

SUPPLEMENTARY INFORMATION. EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0017. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall#2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: waller.mary@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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgrstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly

to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

II. Background and Statutory Findings

In the **Federal Register** of April 8, 2005 (70 FR 17997) (FRL-7704-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6579) by Arysta Lifescience North American Corporation, 100 First Street, Ste. 1700; San Francisco, CA 94105; agent for Hokko Chemical Industry Corporation Ltd., 4-20, Nihonbashi Hongochkucho 4 Chome, Chuo-Ku, Tokyo 103-8341, Japan. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide kasugamycin, 1L-1,3,4/2,5,6-1-deoxy-2,3,4,5,6-pentahydroxycyclohexyl-2-amino-2,3,4,6-tetrahydroxy-4-([α]-iminoglycino)-[α]-D-arabino-hexapyranoside, in or on fruiting vegetables (Crop Group 8) at 0.04 parts per million (ppm), tomato juice at 0.06 ppm, tomato puree at 0.06 ppm, and tomato paste at 0.25 ppm. That notice included a summary of the petition prepared by Arysta Life Science North American Corporation, agent for Hokko Chemical Industry Corporation, LLC, the registrant. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit IV.C. below.

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. . . .”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see <http://>

www.epa.gov/pesticides/factsheets/riskassess.htm

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of kasugamycin on fruiting vegetables (Crop Group 8) at 0.04 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. Specific information on the studies received and the nature of the toxic effects caused by kasugamycin 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.epa.gov/edocket>.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL

was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles of EPA uses in risk characterization at <http://www.epa.gov/oppfead1/trac/science/>.

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 DOSE AND ENDPOINTS FOR KASUGAMYCIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age and general population including infants and children)	None	None	Not Selected No appropriate dose and endpoint could be identified for these population groups
Chronic dietary (all populations)	NOAEL = 11.3 mg/kg/day UF = 100 Chronic RfD = 0.113 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/Special FQPA SF = 0.113 mg/kg/day	Combined chronic toxicity/oncogenicity study in rats LOAEL = 116 mg/kg/day based on increased testicular softening and atrophy
Cancer (oral, dermal, inhalation)	Classification: No oncogenic potential was noted in the mouse oncogenicity or in the rat combined chronic/carcinogenicity studies; additionally, no mutagenic potential was noted in any of the five mutagenicity studies. Classification of kasugamycin is "not likely to be carcinogenic to humans."		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* This final rule reflects the establishment of the first tolerance for kasugamycin. Since there are no registered uses in the United States, the only exposure expected is from imported foods. Risk assessments were conducted by EPA to assess 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. No appropriate dose or endpoint could be identified for acute dietary exposure in the general population or any population subgroup.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The analysis is based on tolerance-level

residues (modified by DEEM default processing factors for tomato processed commodities) and the assumption that 100% of the crop will be treated.

iii. *Cancer.* The Agency classified kasugamycin as "not likely to be carcinogenic to humans," based on the lack of evidence of carcinogenicity in mice and rats. Therefore, a quantitative cancer exposure assessment was not conducted.

2. *Dietary exposure from drinking water.* There is no expectation that kasugamycin residues would occur in surface or ground water sources of drinking water. There are no registered uses of kasugamycin in the United States.

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 use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to kasugamycin and 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 not assumed that kasugamycin has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on

the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* No increased quantitative or qualitative susceptibility was observed in the developmental rat or rabbit studies or in the 2-generation reproduction study. No offspring toxicity was observed at any of the doses tested in these three studies. Reproductive toxicity was noted in the F1 generation of the 2-generation reproduction study. However, because parental toxicity (decreased body weights and body weight gains) occurred at a lower dose than that which resulted in effects on reproduction, there is no increased quantitative or qualitative susceptibility of the offspring. The toxicology database for kasugamycin is complete with respect to prenatal and postnatal toxicity and shows no evidence of increased qualitative or quantitative susceptibility in the offspring. Therefore, there are no residual uncertainties for prenatal and/or postnatal toxicity.

3. *Conclusion.* There is a complete toxicity data base for kasugamycin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Additionally, a developmental neurotoxicity study is not required because there was no evidence of neurotoxicity in any studies. Based on the above information, EPA concludes that it has reliable data that supports the conclusion that it is safe to remove the additional children's safety factor.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* No appropriate dose or endpoint was identified for acute dietary exposure in the general population or any population subgroup. Therefore, no acute risk is expected from exposure to Kasugamycin.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to kasugamycin from food will utilize < 1% of the cPAD for the U.S. population, < 1% of the cPAD for all infants < 1-year, and < 1% of the cPAD for children 1-2 years. There are no residential uses for kasugamycin that result in chronic residential exposure to kasugamycin, and no exposure is expected from drinking water. EPA does not expect the aggregate exposure (dietary only) to exceed 100% of the cPAD as shown in Table 2 of this unit.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO KASUGAMYCIN

Population/Subgroup	cPAD (mg/kg/day)	%cPAD (Food)
U.S. population	0.113	<1
All Infants (< 1 yr)	0.113	<1
Children 1-2 yrs	0.113	<1

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level.)

Kasugamycin is not registered for use on any sites that would result in residential exposure, and the tolerance in this rule is for imported fruiting vegetables (crop group 8). No exposure is expected from drinking water. Therefore, the aggregate risk is from food only, and which does not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Kasugamycin is not registered for use on any sites that would result in residential exposure, and the tolerance in this rule is for imported fruiting vegetables (crop group 8). No exposure is expected from drinking water. Therefore, the aggregate risk is from food only, and which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Kasugamycin has not been shown to be carcinogenic. Therefore, kasugamycin is not expected to pose a cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

The analytical enforcement method uses ion exchange resins for clean up and reverse-phase ion-pairing liquid chromatography with ultra-violet detection (HPLC/UV). This method was validated by an independent laboratory. The Agency's laboratory also conducted a laboratory trial of this method and has determined the method performance to

be useful as an enforcement method with the incorporated revisions recommended by the petitioner.

The method (HPLC/UV) may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican MRLs for kasugamycin.

C. Response to Comments

Comments were received from a private citizen on the notice of filing for kasugamycin on April 17, 2005 objecting to this proposed tolerance. The comments further stated that not enough tests have been completed (long term or tests on how it combines) and that there is little indication of safety.

The Agency response is as follows: The Agency has a complete toxicity database on kasugamycin, including several long-term or chronic studies. Further, EPA has not made a common mechanism of toxicity finding as to kasugamycin and any other substances and kasugamycin does not appear to produce a toxic metabolite produced by other substances. The commenter submitted no scientific information or contention in support of the commenter's claims.

V. Conclusion

Therefore, the tolerance is established for residues of kasugamycin, [3-O-[2-amino-4-[[[carboxyimino(methyl)amino]-2,3,4,6-tetrahydroxy- α -D-arabino-hexopyranosyl]-D-chiro-inositol]], in or on fruiting vegetables (Crop Group 8) at 0.04 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new

section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2005-0017 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 22, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2005-0017, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). 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); or OMB review or any Agency action under Executive Order 13045,

entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal

Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: September 15, 2005.

James Jones,
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 180.614 is added to read as follows:

§ 180.614 Kasugamycin; tolerances for residues.

(a) *General.* Tolerances are established for residues of kasugamycin, 3-O-[2-amino-4-[(carboxyiminomethyl)amino]-2,3,4,6-tetraoxy- α -D-arabino-hexopyranosyl]-D-chiro-inositol in or on the following raw agricultural commodity:

Commodity	Parts per million
Vegetable, fruiting group 8 ¹	0.04

¹There 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. 05–19061 Filed 9–22–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0185; FRL–7736–3]

Amicarbazone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of amicarbazone and its metabolites in or on field corn and livestock commodities and indirect or inadvertent residues of amicarbazone and its metabolites in alfalfa, cotton, soybean and wheat. Arysta Lifescience North American Corporation (previously known as Arvesta Corporation) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0185. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm.