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

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Petition for Tolerance

In the **Federal Register** of August 11, 2006 (71 FR 46223) (FRL-8085-8), 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 6F7040) by Arysta LifeScience North America Corporation, 15401 Weston Pkwy., Suite 150, Cary, NC 27513. The petition requested that 40 CFR 180.599 be amended by establishing a tolerance for combined residues of the insecticide acequinocyl and its metabolite 2-dodecyl-3-hydroxy-1,4-naphthoquinone (acequinocyl-OH) expressed as acequinocyl equivalents in or on tree nuts (crop group 14) at 0.02 parts per million (ppm). That notice referenced a summary of the petition prepared by Arysta LifeScience North America Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C. below. In the **Federal Register** of January 23, 2008 (73 FR 3964) (FRL-8345-7), 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 7F7176) by Arysta LifeScience North America Corporation. The petition requested that 40 CFR 180.599 be amended by establishing a tolerance for acequinocyl and its

metabolite acequinocyl-OH expressed as acequinocyl equivalents in or on grapes at 7.0 parts per million (ppm), grape juice at 0.05 ppm and raisins at 0.1 ppm. The proposed grape tolerance of 7.0 ppm was subsequently amended by the petitioner to 1.0 ppm.

Based upon review of the data supporting the petition, EPA has revised the tolerances proposed for grape, grape juice and raisin; and changed the commodity definition for tree nuts (crop group 14). The appropriate tolerance for grape was calculated to be 1.6 ppm. The grape processing data provided for grape juice and raisins showed the combined residues of acequinocyl and acequinocyl-OH did not concentrate in either of these commodities and, thus separate tolerances are not required for grape juice or raisins. The recommended tolerance level for grape was determined considering Agency guidance (Guidance for Setting Pesticide Tolerances Based on Field Trial Data). The commodity definition for tree nuts (crop group 14) has been changed to nut, tree, group 14.

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. . . ." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 the petitioned-for tolerance for combined residues of acequinocyl and its metabolite

acequinocyl-OH expressed as acequinocyl equivalents on nut, tree, group 14 and grape at 0.02 ppm and 1.6 ppm, respectively. 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 adverse effects caused by acequinocyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the acequinocyl final rule published in the **Federal Register** of July 21, 2004 (69 FR 43525) (FRL-7364-1).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which the NOAEL are observed in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which the LOAEL of concern are identified is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the level of concern (LOC) to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted (aPAD) dose and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are

considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for acequinocyl used for human risk assessment can be found at <http://www.regulations.gov> in the document "Human Health Risk Assessment for Use of Acequinocyl on Grapes, the Tree Nut Crop Group, and Residential Sites (Ornamentals)" on pages 13 and 14 in docket ID number EPA-HQ-OPP-2006-0678-0006.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acequinocyl, EPA considered exposure under the petitioned-for tolerances as well as all existing acequinocyl tolerances in 40 CFR 180.599. EPA assessed dietary exposures from acequinocyl 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 acequinocyl; 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 1998; CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

Anticipated residues were not used.

iii. *Cancer.* The Agency classified acequinocyl as a "not likely carcinogen". Therefore, an exposure assessment for the purpose of estimating cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* The Agency did not use anticipated residue estimates or PCT information in the acequinocyl dietary exposure assessment.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for acequinocyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or

modeling taking into account data on the environmental fate characteristics of acequinocyl. 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) with the index reservoir scenarios model, the estimated drinking water concentrations (EDWCs) of acequinocyl only and of the combined residues of acequinocyl and its metabolite (acequinocyl-OH) for chronic exposures are estimated to be 2.73 and 0.37 parts per billion (ppb), respectively for surface water. Based on the Screening Concentration in Ground Water (SCI-GROW) model, for chronic ground water exposure, the EDWC value for the combined residues of acequinocyl and its metabolite (acequinocyl-OH) is 0.0036 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. Acute dietary risk assessments were not conducted because an end point of concern attributable to a single dose was not identified. For chronic dietary risk assessment, the water concentration value of 2.73 ppb was used to assess the contribution to drinking water.

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

Acequinocyl is currently registered for the following residential non-dietary sites: Ornamental plants. EPA assessed residential exposure using the following assumptions: Exposure is considered to be short term only, due to the infrequent use patterns associated with homeowner products; and individuals are wearing shorts, short-sleeved shirts, socks, and shoes. The estimates of exposure to residential handlers are based on surrogate data available from the Outdoor Residential Exposure Task Force (ORETF) and the Pesticide Handlers Exposure Data (PHED) (August, 1998). The residential exposure assessed was exposure to adults from residential application of acequinocyl. Short-term inhalation and dermal exposure estimates were generated for residential adult handlers during the mixing, loading and application of acequinocyl in residential settings. Based on the use pattern, no significant post application exposure in residential settings is anticipated.

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."

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 acequinocyl and any other substances and acequinocyl 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 acequinocyl 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 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 (10X) 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased quantitative susceptibility following *in utero* exposure to acequinocyl in rat or rabbit developmental studies or following prenatal and/or postnatal exposure to acequinocyl in a two-generation reproduction study in rats. There is an apparent qualitative increase in susceptibility in the rat and rabbit developmental studies as indicated by increases in resorptions that occurred at the same or higher dose that caused maternal toxicity, but the concern is low since: (1) The fetal effects were noted in the presence of maternal toxicity; and (2) the effects are well-characterized in

that a clear NOAEL was identified. An increase in mortality in the offsprings of F1 and/or F2 generation was identified in the two-generation reproduction study; however, EPA does not consider this as evidence for increased susceptibility because the mortality occurred after weaning (day 21) during days 22 to 55 when food intake by the pups substantially increases, substantially increasing the administered dose of pesticide. In any event these effects occurred in the presence of maternal toxicity and a clear NOAEL was identified. There are no residual uncertainties and low concern for prenatal and/or postnatal toxicity following exposure to acequinocyl.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for acequinocyl is complete.

ii. Though two studies showed effects that could be indicative of neurotoxicity, EPA concluded that exposure to acequinocyl does not pose a neurotoxicity concern and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. First, acequinocyl is a known Vitamin K antagonist; neurotoxic compounds of similar structure were not identified. Second, the study effects are considered as secondary because they were observed at very high doses (58.9/69.2 milligrams/kilogram/day (mg/kg/day) and 111.2/133.5 mg/kg/day in the rat reproduction study and 252.7/286.0 mg/kg/day in the rat subchronic study.) In the two-generation reproduction study, significant reduction in startle response in F2 pups was observed in the high dose groups. However, other functional development studies (such as a papillary reflex test at 21 days post partum, an open field exploration test at 35 to 48 days post partum) that were performed on pups did not show significant differences as compared to control values even at the highest dosage rate.

iii. There is no evidence that acequinocyl results in increased quantitative susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study. As discussed above, there is low concern for any potential qualitative sensitivity observed in these studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level

residues. Conservative ground water and surface water modeling estimates were used. No significant post application exposure to children is anticipated from the registered use of acequinocyl on ornamental plants. These assessments will not underestimate the exposure and risks posed by acequinocyl.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* No acute risk is expected because an endpoint of concern attributable to a single dose was not identified.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to acequinocyl from food and water will utilize 41% of the cPAD for the population group children 1 to 2 years old, the most highly exposed population subgroup. Based on the use pattern, chronic residential exposure to residues of Acequinocyl is not expected.

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).

Acequinocyl is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for acequinocyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 2,700 for adult residential handlers 50+ years old mixing, loading and applying acequinocyl in residential settings. The adult 50+ years old population is the highest exposed population group and the MOE of 2,700 is considered protective of the other adult population groups. Based on the use pattern, no significant post application exposure is anticipated, therefore, no residential post application assessment was conducted.

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).

Acequinocyl is not registered for use on any sites that would result in intermediate-term residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Acequinocyl is not considered to be a carcinogen and thus 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, or to infants and children from aggregate exposure to acequinocyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Analytical enforcement methods include liquid chromatography with tandem mass spectrometric detection (LC/MS/MS). The limit of quantitation (LOQ) is 0.01 ppm for each analyte in plant and livestock commodities and the reported limit of detection (LOD) is 0.003 ppm for each analyte in plant commodities.

Adequate enforcement methodology (two liquid chromatography with tandem mass spectrometric detection LC/MS/MS) methods (Morse Methods Meth-133 revision #4 and Meth-135, revision #2 for grape and tree nuts, respectively) are available to enforce the tolerance expression. The methods 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 no established or proposed CODEX, Canadian, or Mexican maximum residue limits (MRLs) for acequinocyl.

C. Response to Comments

One comment was received from a private citizen opposing the "manufacturing, selling or use" of acequinocyl. The commenter further stated that it was their wish that no exemptions be issued and that no tolerances should be approved. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides

should be banned completely. However, under the existing framework provided by section 408 of the FFDCA, EPA is required to establish pesticide tolerances or exemptions where persons seeking such tolerances have demonstrated that the pesticide meets the safety standard imposed by that statute. The commenter has not provided the Agency with specific rationale nor additional information pertaining to the legal standards in FFDCA section 408 for opposing the establishment of a tolerance for acequinocyl. In the absence of any additional information of a factual nature, the Agency can not effectively respond to the commenter's disagreement with the Agency's decision.

V. Conclusion

Therefore, the tolerances are established for combined residues of acequinocyl and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone expressed as acequinocyl equivalents, in or on grape and nut, tree, group 14 at 1.6 ppm and 0.02 ppm, respectively.

VI. 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, 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) 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 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.

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 section 408(n)(4) of FFDCA. 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 6, 2000) do not apply to this rule. In addition, This 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) (Public Law 104-4).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: March 20, 2008.

Lois Rossi,

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 180.599 is amended by removing from the table in paragraph (a) the entry for almond, and adding new commodities to the table to read as follows:

§ 180.599 Acequinocyl; Tolerances for residues.

(a) * * *

Commodity	Parts per million
Grape	1.6
Nut, tree, group 14	0.02

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0479; FRL-8347-9]

Ferric Citrate; Inert Ingredient; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance under 40 CFR 180.910 for residues of ferric citrate (CAS Reg. No. 2338-05-8) in or on raw agricultural commodities when applied/used as inert ingredients in pesticide formulations. The Shepherd Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ferric citrate.

DATES: This regulation is effective April 2, 2008. Objections and requests for