will use to determine and record the time and cause of the alarm as well as the corrective actions taken to minimize emissions as specified in paragraphs (e)(4)(i) and (ii) of this section.

* * * * *

(ii) The cause of the alarm must be alleviated by taking the necessary corrective action(s) that may include, but not be limited to, those listed in paragraphs (e)(4)(ii)(A) through (F) of this section.

* * * * *

(h) *Shop building opacity.* In order to demonstrate continuous compliance with the opacity standards in § 63.1623, you must comply with the requirements § 63.1625(d)(1) and one of the monitoring options in paragraphs (h)(1) or (2) of this section. The selected option must be consistent with that selected during the initial performance test described in § 63.1625(d)(2). Alternatively, you may use the provisions of § 63.8(f) to request approval to use an alternative monitoring method.

* * * * *

(j) *Requirements for sources using CMS.* If you demonstrate compliance with any applicable emissions limit through use of a continuous monitoring system (CMS), where a CMS includes a continuous parameter monitoring system (CPMS) as well as a continuous emissions monitoring system (CEMS), you must develop a site-specific monitoring plan and submit this site-specific monitoring plan, if requested, at least 60 days before your initial performance evaluation (where applicable) of your CMS. Your site-specific monitoring plan must address the monitoring system design, data collection and the quality assurance and quality control elements outlined in this paragraph and in § 63.8(d). You must install, operate and maintain each CMS according to the procedures in your approved site-specific monitoring plan. Using the process described in § 63.8(f)(4), you may request approval of monitoring system quality assurance and quality control procedures alternative to those specified in paragraphs (j)(1) through (6) of this section in your site-specific monitoring plan.

* * * * *

(k) If you have an operating limit that requires the use of a CPMS, you must install, operate and maintain each continuous parameter monitoring system according to the procedures in paragraphs (k)(1) through (7) of this section.

* * * * *

(p) *Particulate Matter CEMS.* If you are using a CEMS to measure particulate matter emissions to meet requirements of this subpart, you must install, certify, operate and maintain the particulate matter CEMS as specified in paragraphs (p)(1) through (4) of this section.

* * * * *

■ 5. Section 63.1656 is amended by revising paragraphs (b)(7) introductory text, (b)(7)(i) and (ii), and (b)(7)(v) to read as follows:

§ 63.1656 Performance testing, test methods, and compliance demonstrations.

* * * * *

(b) * * *

(7) Method 9 of appendix A–4 of 40 CFR part 60 to determine opacity. ASTM D7520–16, ''Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere'' may be used (incorporated by reference, see § 63.14) with the following conditions:

(i) During the digital camera opacity technique (DCOT) certification procedure outlined in Section 9.2 of ASTM D7520–16, the owner or operator or the DCOT vendor must present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees and mixed backgrounds (clouds and/or a sparse tree stand).

(ii) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520–16.

* * * * *

(v) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software and operator in accordance with ASTM D7520–16 and these requirements is on the facility, DCOT operator and DCOT vendor.

* * * * *

[FR Doc. 2017–00156 Filed 1–17–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0829; FRL–9956–85]

Acequinocyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acequinocyl in or on multiple commodities which are identified and discussed later in this document. Interregional Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 18, 2017. Objections and requests for hearings must be received on or before March 20, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0829, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under 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–2015–0829 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 March 20, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0829, 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, 2016 (81 FR 31581) (FRL–9946–02), 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 5E8422) by Interregional Research Project Number 4 (IR–4), Rutgers University, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.599 be amended by establishing tolerances for residues of the insecticide acequinocyl in or on avocado at 0.4 parts per million (ppm); bean, dry, seed at 0.03 ppm; vegetable, cucurbit, group 9 at 0.2 ppm; tea, plucked leaves at 40 ppm; cherry subgroup 12–12A at 1.0 ppm; fruit, citrus, group 10–10 at 0.20 ppm; fruit, pome, group 11–10 at 0.40 ppm; nut, tree, group 14–12 at 0.02 ppm; and vegetable, fruiting, group 8–10 at 0.70 ppm. The petition also requested that upon establishment of the above tolerances, to remove the existing tolerances for cucumber at 0.15 ppm; melon, subgroup 9A at 0.15 ppm; cherry, sweet at 0.50 ppm; cherry, tart at 1.0 ppm; fruit, citrus, group 10 at 0.20 ppm; fruit, pome, group 11 at 0.40 ppm; nut, tree, group 14 at 0.02 ppm; pistachio at 0.02 ppm; vegetable, fruiting, group 8 at 0.70 ppm; and okra at 0.70 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.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established. The reason for these changes is explained in Unit IV.D.

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 acequinocyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acequinocyl 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.

The target organs of acequinocyl are the liver (hepatocyte vacuolization, brown pigmented cells and perivascular inflammatory cells in liver) and hematopoietic system (hemorrhage, increased clotting factor times and increased platelet counts). There was no evidence of neurotoxicity and immunotoxicity and there was no evidence of carcinogenic potential in either the rat or mouse, or in the genotoxicity and mutagenicity studies.

In rats and rabbits, there was no evidence of increased quantitative or qualitative fetal susceptibility. In both species there were clinical signs and gross necropsy findings seen in maternal animals at similar or lower doses than those producing resorptions. In rabbits, there were increased incidences of late resorptions at the highest dose tested. In the rat two-generation reproductive toxicity study, there was evidence of apparent increased quantitative postnatal susceptibility. Offspring effects at the mid- and high-doses consisted of swollen body parts, protruding eyes, clinical signs, delays in pupil development, and increased mortality occurring mainly after weaning. No parental effects were observed up to the highest dose tested; however, hematological parameters, such as changes in partial and activated partial

thromboplastin times, were not measured in parental animals and changes in these parameters would have been expected at the same doses as offspring effects based on rat studies in the acequinocyl toxicological database. There were no effects on reproductive parameters.

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 can be found at *http://www.regulations.gov* in the document titled ''*Acequinocyl. Human Health Risk Assessment To Support the Petition for Tolerance for Residues in/on Dry Beans, Cucurbit Vegetables, Group 9, Avocado and Tea (Without U.S. Registration) and Crop Group Conversions for Citrus Fruit Group 10–10, Tree Nut Group 14–12, and Fruiting Vegetable Group 8–10*'' at page 30 in docket ID number EPA–HQ–OPP–2015–0829.

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 to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

Since the last assessment for acequinocyl (**Federal Register** of April 13, 2016, (81 FR 21752) (FRL–9944–34)), the endpoints for acequinocyl were revisited and updated based upon the available data. An acute dietary endpoint for the general population has been selected to be consistent with current Agency practices. A summary of the updated toxicological endpoints for acequinocyl used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ACEQUINOCYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 7.3 mg/kg/day UF_A = 10×. UF_H = 10× FQPA SF = 1×	Acute RfD = 0.073 mg/kg/day. aPAD = 0.073 mg/kg/day	Reproduction and fertility effects in rats Offspring LOAEL (M/F) = 58.9 based on hemorrhagic effects, swollen body parts, protruding eyes, clinical signs, delays in pupil development and increased mortality post weaning.
Chronic dietary (All populations)	NOAEL = 2.7 mg/kg/day UF_A = 10×. UF_H = 10× FQPA SF = 1×	Chronic RfD = 0.027 mg/kg/day. cPAD = 0.027 mg/kg/day LOC for MOE = 100	18-month carcinogenicity study in mice; LOAEL = 7.0 mg/kg/day based on clinical chemistry and microscopic non-neoplastic lesions (brown pigmented cells and perivascular inflammatory cells in liver).
Dermal short-term (1 to 30 days).	Dermal study NOAEL = 200 mg/kg/day. UF_A = 10× UF_H = 10× FQPA SF = 1×		28-dermal toxicity in rats. LOAEL (M/F) = 1000 mg/kg/day based on increased clotting factor times in males.
Cancer (Oral, dermal, inhalation).	Classification: Not likely to be carcinogenic to humans.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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.

Such effects were identified for acequinocyl. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all proposed and registered uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance level residues and 100 PCT for all proposed and registered uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that acequinocyl does not pose a cancer risk to humans. Therefore,

a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acequinocyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acequinocyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), Provisional Cranberry Model, and Screening Concentration in Ground Water (SCI–GROW) Model, the estimated drinking water concentrations (EDWCs) of acequinocyl for acute exposures are estimated to be 6.69 parts per billion (ppb) for surface water and 3.6×10^{-3} ppb for ground water, and for chronic exposures are estimated to be 6.69 ppb for surface water and $\geq 3.6 \times 10^{-3}$ ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 6.69 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 6.69 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 uses that could result in residential exposures: use on ornamentals for landscapes, gardens, and trees. EPA assessed residential exposure using the following assumptions: There is a potential for residential exposure associated with handler (*i.e.,* mixing, loading and applying); however, all registered acequinocyl product labels with residential use sites (*e.g.,* ornamentals for landscapes, gardens, and trees) require that handlers wear specific clothing (*e.g.,* long-sleeve shirt/long pants) and/or use personal protective equipment (PPE). Therefore, the Agency has made the assumption that these products are not for homeowner use, and has not conducted a quantitative residential handler assessment.

Only short-term post-application dermal exposure is anticipated for the registered residential uses. The quantitative exposure/risk assessment for residential post-application exposures assessed dermal exposures to adults for activities associated with gardening, dermal exposures to children (6 to <11 years old) for activities associated with playing in and around gardens and gardening, dermal exposures to adults associated with handling trees and retail plants, and dermal exposures to children (6 to <11 years old) for activities associated with playing in and around trees and retail plants.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found acequinocyl to share a common mechanism of toxicity with 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 assumed that acequinocyl 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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 FQPA Safety Factor (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 is no evidence of an increased quantitative or qualitative fetal susceptibility in rats or rabbits. In isolation, there was evidence of increased quantitative offspring susceptibility in the two-generation reproductive study; however, but the concern is low since: (1) The effects in pups are well characterized with a clear NOAEL; and (2) the effects are protected for by the selected endpoints. Therefore, there are no residual uncertainties for pre-/post-natal toxicity. Additionally, taking into consideration the full database, there would be no susceptibility to offspring since assessment of parental animals in the two-generation reproductive toxicity study were limited. If additional evaluations had been performed, including all hematological measurements, then it would be expected that effects on the hematopoietic system observed in the other oral rat studies would have been seen at the same doses eliciting offspring effects. Therefore, using a weight-of-evidence approach that puts the offspring findings in the two-generation reproductive toxicity study in context with the full toxicological database, there is no concern for susceptibility to offspring since parental toxicity would be anticipated at the same dose as offspring effects.

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. That decision is based on the following findings:

i. The toxicity database for acequinocyl is complete.

ii. There is no indication that acequinocyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence of an increased quantitative or qualitative fetal susceptibility in rats or rabbits, but in isolation there was evidence of increased quantitative offspring susceptibility in the two-generation reproductive study. However, the

concern is low for the reasons outlined above in section III.D.2.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acequinocyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by acequinocyl.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acequinocyl will occupy 71% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acequinocyl from food and water will utilize 70% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of acequinocyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acequinocyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to acequinocyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1200 for adults and 890 for children 6–12 years old. Because EPA's level of concern for acequinocyl is a MOE of 100 or below, these MOEs are not of concern.

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

An intermediate-term adverse effect was identified; however, acequinocyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for acequinocyl.

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

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

Adequate enforcement methodology (two high-performance liquid chromatography methods with tandem mass-spectroscopy detection (HPLC/MS/MS) for determining residues in/on fruit and nut commodities (Morse Methods Meth-133 and Meth-135) 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 any MRLs for acequinocyl.

C. Response to Comments

A comment was submitted by the Center for Biological Diversity and was primarily concerned about EPA's consideration of the impacts of acequinocyl on the environment, pollinators, and endangered species. This comment is not relevant to the Agency's evaluation of safety of the acequinocyl tolerances under section 408 of the FFDCA, which requires the Agency to evaluate the potential harms to human health, not effects on the environment.

Two other comments were submitted in response to the Notice of Filing that stated, in part, that this chemical ''should not be used at all in America or anywhere in the world'' and that ''no residue should be permitted on any food or other plant.'' The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The citizens' comments appear to be directed at the underlying statute and not EPA's implementation of it; the citizens have made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance of 0.4 for residues on avocado is being increased to 0.50 ppm as EPA corrected some residue levels in the field trials for degradation during storage and declared two of the trials to be replicates. The

data that EPA used in Organization for Economic Co-operation and Development (OECD) Maximum Residue Limits (MRL) Tolerance Worksheet for avocado was thus slightly different from the petitioner's data. The tolerance level of 0.15 ppm for residues in dry beans is based upon the OECD MRL tolerance worksheet. The difference is based on EPA using slightly different residue levels that were corrected for degradation during storage. The tolerance level of 0.30 ppm for residues in/on cucurbit vegetables is based upon the OECD MRL tolerance worksheet. The difference is based on EPA using slightly different residue levels that were corrected for degradation during storage. The data that EPA used in MRL tolerance spreadsheet for summer squash was slightly different from the petitioner's data. Concerning the crop group conversions, the tolerance level for residues in/on citrus fruit was modified to be harmonized with the Canadian MRL.

V. Conclusion

Therefore, tolerances are established for residues of acequinocyl, including its metabolites and degradates, in or on avocado at 0.50 ppm; bean, dry, seed at 0.15 ppm; cherry, subgroup 12–12A at 1.0 ppm; fruit, citrus, group 10–10 at 0.35 ppm; fruit, pome, group 11–10 at 0.40 ppm; nut, tree, group 14–12 at 0.02 ppm; tea, plucked leaves at 40 ppm; vegetable, cucurbit, group 9 at 0.30 ppm; and vegetable, fruiting, group 8–10 at 0.70 ppm. In addition, the existing tolerances on cherry, sweet; cherry, tart; cucumber; fruit, citrus, group 10; fruit, pome, group 11; melon, subgroup 9A; nut, tree, group 14; okra; pistachio; and vegetable, fruiting, group 8 are removed as unnecessary since they are now covered by the new tolerances.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established 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 action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

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: December 15, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.599, in the table in paragraph (a);

■ a. Add alphabetically the entries ''Avocado''; ''Bean, dry, seed''; ''Cherry, subgroup 12–12A''; ''Fruit, citrus, group 10–10''; ''Fruit, pome, group 11–10''; ''Nut, tree, group 14–12''; ''Tea, plucked leaves'' (and a footnote); ''Vegetable, cucurbit, group 9''; and ''Vegetable, fruiting, group 8–10''; and

■ b. Remove the entries for ''cherry, sweet''; ''cherry, tart''; ''cucumber''; ''fruit, citrus, group 10''; ''fruit, pome, group 11''; ''melon, subgroup 9A''; ''nut, tree, group 14''; ''okra''; ''pistachio''; and ''vegetable, fruiting, group 8'' from the table in paragraph (a).

The additions read as follows:

§ 180.599 Acequinocyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * *	
Avocado	0.50
Bean, dry, seed	0.15
* * * *	
Cherry, subgroup 12–12A	1.0
* * * *	
Fruit, citrus, group 10–10	0.35
Fruit, pome, group 11–10	0.40
* * * *	
Nut, tree, group 14–12	0.02
* * * *	
Tea, plucked leaves [1]	40
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8–10	0.70

[1] There are no U.S. registrations as of January 18, 2017 for use on tea.

* * * * *

[FR Doc. 2016–31823 Filed 1–17–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 438

[CMS–2402–F]

RIN 0938–AT10

Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This rule finalizes changes to the pass-through payment transition periods and the maximum amount of pass-through payments permitted annually during the transition periods under Medicaid managed care contract(s) and rate certification(s). This final rule prevents increases in pass-through payments and the addition of new pass-through payments beyond those in place when the pass-through payment transition periods were established, in the final Medicaid managed care regulations effective July 5, 2016.

DATES: *Effective Date:* These regulations are effective on March 20, 2017.

FOR FURTHER INFORMATION CONTACT: John Giles, (410) 786–1255.

SUPPLEMENTARY INFORMATION:

I. Background

In the June 1, 2015 **Federal Register** (80 FR 31098), we published the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability'' proposed rule (''June 1, 2015 proposed rule''). As part of the actuarial soundness proposals, we proposed to define actuarially sound capitation rates as those sufficient to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract, including furnishing of covered services and operation of the managed care plan for the duration of the contract. Among the proposals was a general rule that the state may not direct the managed care organization's (MCO's), prepaid inpatient health plan's (PIHP's), or prepaid ambulatory health plan's (PAHP's) expenditures under the contract.

In the May 6, 2016 **Federal Register** (81 FR 27498), we published the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability'' final rule (''May 6, 2016 final rule''), which finalized the June 1, 2015 proposed rule. In the final rule, we finalized, with some revisions, the proposal which limited state direction of payments, including pass-through payments as defined below.

In the November 22, 2016 **Federal Register** (81 FR 83777), we published the ''Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems'' proposed rule (''November 22, 2016 proposed rule''). This rule finalizes the November 22, 2016 proposed rule as discussed below. This final rule is consistent with the intent of the May 6, 2016 final rule to provide transition periods for states that already use pass-through payments—these transition periods allow states to implement changes to existing pass-through payments over a period of time to minimize disruption and to ensure continued financial support for safety-net providers. As we discussed in the November 22, 2016 proposed rule, this final rule is also consistent with the CMCS Informational Bulletin (CIB) concerning ''The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems,'' which was published on July 29, 2016.

A. Summary of the Medicaid Managed Care May 6, 2016 Final Rule

We finalized a policy to limit state direction of payments, including pass-through payments, at § 438.6(c) and (d) in the May 6, 2016 final rule (81 FR 27587 through 27592). Specifically, under the final rule (81 FR 27588), we defined pass-through payments at § 438.6(a) as any amount required by the state (and considered in calculating the actuarially sound capitation rate) to be added to the contracted payment rates paid by the MCO, PIHP, or PAHP to hospitals, physicians, or nursing facilities that is not for the following purposes: A specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under § 438.6(c)(1)(i) through (iii) for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; graduate medical education (GME) payments; or federally-qualified health center (FQHC) or rural health clinic (RHC) wrap around payments. We noted that section 1903(m)(2)(A) of the Social Security Act (the Act) requires that capitation payments to managed care plans be actuarially sound; we interpret this requirement to mean that payments under the managed care contract must align with the provision of services to beneficiaries covered under the contract. We provided that these pass-through payments are not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services. The final rule contains a detailed description of the policy rationale (81 FR 27587 through 27592).

In an effort to provide a smooth transition for network providers, to support access for the beneficiaries they serve, and to provide states and managed care plans with adequate time to design and implement payment systems that link provider reimbursement with services covered under the contract or associated quality outcomes, we finalized transition periods related to pass-through payments for the specified provider types to which states make most pass-through payments under Medicaid managed care programs: Hospitals, physicians, and nursing homes (81 FR 27590 through 27592). As finalized, § 438.6(d)(2) and (3) provide a 10-year transition period for hospitals, subject to limitations on the amount of pass-through payments. For MCO, PIHP, or PAHP contracts beginning on or after July 1, 2027, states will not be permitted to require pass-through payments for hospitals. The final rule also provides a 5-year transition period for pass-through payments to physicians and nursing facilities. For MCO, PIHP, or PAHP contracts beginning on or after July 1, 2022, states will not be permitted to require pass-through payments for physicians or nursing facilities. These transition periods provide states, network providers, and managed care plans significant time and flexibility to integrate current pass-through payment arrangements into allowable payment structures under actuarially sound capitation rates, including enhanced fee schedules or the other approaches consistent with § 438.6(c).

As finalized in the May 6, 2016 final rule, § 438.6(d) limits the amount of pass-through payments to hospitals as a percentage of the ''base amount,'' which is defined in paragraph (a) and