ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180


Acequinocyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acequinocyl in or on bean, edible podded; hop, dried cones; okra and vegetable, fruiting, group 8. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 17, 2010. Objections and requests for hearings must be received on or before January 18, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 327 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0812. All documents in the docket are listed in the docket index available at http://www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at http://www.regulations.gov or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: jackson.sidney@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 those engaged in the following activities:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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

| Section 200.9, Table 1 (Part 231 references), | 3/5/09 | 11/17/10, [Insert FR page citation]. | EPA is approving reference documents that are not already Federally enforceable. |
| Sections 200.6, 200.7 and 200.9, | 2/25/00 | 4/22/08, 73 FR 21548 | EPA is approving reference documents that are not already Federally enforceable. |
| Subpart 201–2.1(b)(21), Definitions. | 3/5/09 | 11/17/10, [Insert FR page citation]. | EPA is including the definition of “Major stationary source or major source or major facility” with the understanding that the definition applies only to provisions of Part 231. |
| Part 231, New Source Review for New and Modified Facilities. | 3/5/09 | 11/17/10, [Insert FR page citation]. | Partial approval; no action taken on provisions that may require PSD permits for sources of greenhouse gas (GHG) emissions with emissions below the thresholds identified in EPA’s final PSD and Title V GHG Tailoring Rule at 75 FR 31514, 31666 (June 3, 2010). |

§ 52.1689 [Reserved]

4. Section 52.1689 is removed and reserved.

FR Doc. 2010–28964 Filed 11–16–10; 8:45 am
BILLING CODE 6560–50–P

Federal Register / Vol. 75, No. 221 / Wednesday, November 17, 2010 / Rules and Regulations 70143

New York State regulation State effective date Latest EPA approval date Comments

Redesignation of non-attainment areas to attainment areas (200.1(av)) does not relieve a source from compliance with previously applicable requirements as per letter of Nov. 13, 1981 from H. Hovey, NYSDEC.

Changes in definitions are acceptable to EPA unless a previously approved definition is necessary for implementation of an existing SIP regulation.

EPA is including the definition of “Federally enforceable” with the understanding that (1) the definition applies to provisions of a Title V permit that are correctly identified as Federally enforceable, and (2) a source accepts operating limits and conditions to lower its potential to emit to become a minor source, not to “avoid” applicable requirements.

EPA is approving reference documents that are not already Federally enforceable.

EPA is approving reference documents that are not already Federally enforceable.

EPA is including the definition of “Major stationary source or major source or major facility” with the understanding that the definition applies only to provisions of Part 231.
the person listed under FOR FURTHER INFORMATION CONTACT.

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


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 include your name and principal business address 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 January 18, 2011. 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 that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 is available in the public docket. Submit a copy of your non-CBI objection or hearing request, identified by docket number EPA–HQ–OPP–2009–0812, by one of the following methods:

- 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 Facility’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. Summary of Petitioned-for Tolerance

In the Federal Register of January 6, 2010 (75 FR 868) (FRL–8801–5), 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 967598) by IR–4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.599 be amended by establishing a tolerance of 3.5 ppm for residues of the insecticide acequinocyl, 2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione, and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, calculated as the stoichiometric equivalent of acequinocyl and by establishing a tolerance for the residues of acequinocyl, including its metabolites and degradates in or on vegetable, fruiting, and nonfrooting, group 8 at 0.7 parts per million (ppm); okra at 0.7 ppm; bean, edible podded at 0.25 ppm and hop, dried cone at 3.5 ppm. That notice referenced a summary of the petition prepared on behalf of IR–4 by Arya LifeScience North America LLC, the registrant, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance for hop dried cones from 3.5 ppm to 4.0 ppm and available data submitted support the higher tolerance. The reason(s) for these changes are 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 section 408(b)(2)[D] of FFDCA, and the factors specified in 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 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 their 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.

Acequinocyl exhibits low acute toxicity in oral, dermal and inhalation routes of exposure, as well as, primary eye and primary skin irritation studies. It is not a dermal sensitizer.

In rat studies including a subchronic oral toxicity study, a 28-day dermal toxicity study, and a chronic feeding/oncogenicity study, acequinocyl increased prothrombin and activated partial thromboplastin. Internal hemorrhages were observed in both a rat and rabbit developmental toxicity study, a mouse subchronic/chronic toxicity study, and in a 2-generation reproduction rat study. In a combined chronic toxicity/oncogenicity study in rats, enlarged eyeballs were observed. Hepatotoxicity in the mouse was evidenced by histopathology and increased liver enzymes.

In both rat and rabbit developmental toxicity studies, acequinocyl increased the number of resorptions. Developmental effects (i.e., resorptions) occurred at a dose that was higher than or the same as the dose that caused maternal toxicity. In the 2-generation reproduction toxicity study in the rat, there was no evidence of reproductive toxicity, though there were notable toxic effects observed in offspring that were not observed in adults including swollen body parts, protruding eyes, clinical signs, delays in pup development and increased mortality occurring mainly after weaning.

There was no evidence of carcinogenic potential in either the rat or mouse carcinogenicity study, indicating that acequinocyl is “not likely” to be carcinogenic to humans. There was no concern for mutagenic activity as indicated by several
mutagenicity studies. Acequinocyl is classified as "Not likely to be Carcinogenic to Humans."

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 document, “Acequinocyl: Human-Health Risk Assessment for Proposed Section 3 Uses on Fruiting Vegetables, Hops, Okra, and Edible-Podded Beans” dated August 26, 2010, at pp. 32–35 in docket ID number EPA–HQ–OPP–2009–0812–0004.

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

A summary of the toxicological endpoints for acequinocyl used for human risk assessment is shown in Table 1 of this unit.

<table>
<thead>
<tr>
<th>Exposure/Scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RTD, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary (General population including infants and children)</td>
<td>N/A</td>
<td>N/A</td>
<td>An endpoint attributable to a single dose was not identified in the database.</td>
</tr>
<tr>
<td>Chronic dietary (All populations)</td>
<td>NOAEL = 2.7 mg/kg/day</td>
<td>Chronic RfD = 0.027 mg/kg/day</td>
<td>Carcinogenicity study in mice (18 month); LOAEL = 7.0 mg/kg/day based on the clinical chemistry and microscopic nonneoplastic lesions (brown pigmented cells and perivascular inflammatory cells in liver).</td>
</tr>
<tr>
<td>Short-term (1 to 30 days) and intermediate-term (1–6 months) dermal.</td>
<td>UF A = 10x</td>
<td>Chronic RfD = 0.027 mg/kg/day</td>
<td>28-day dermal study in rats; LOAEL = 1000 mg/kg/day based on increased clotting factor times.</td>
</tr>
<tr>
<td>Short-term (1 to 30 days) inhalation</td>
<td>Oral NOAEL = 60 mg/kg/day (inhalation absorption rate = 100%)</td>
<td>LOC (occupational/residential) for MOE = &lt;100.</td>
<td>Developmental toxicity study in rabbits; Maternal LOAEL = 120 mg/kg/day based on clinical signs (hematuria, reduced fecal output, body weight loss, and reduced food consumption) and gross necropsy findings (pale lungs and liver, hemorrhaging uterus, fluid in the cecum, fur in the stomach, blood stained vaginal opening, blood-stained urinary bladder contents/urine).</td>
</tr>
<tr>
<td>Cancer (oral, dermal, inhalation)</td>
<td>Classification: “Not likely to be Carcinogenic to Humans.”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 U.S. Department of Agriculture (USDA) 1994–1996 and 1998 and the Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted a chronic dietary exposure analysis of acequinocyl based on the assumption of tolerance level residues and 100 percent crops treated (PCT) for all existing and proposed 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 exposure 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 models for residential exposure 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://www.epa.gov/oppefed1/models/water/index.htm.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of acequinocyl for chronic exposures for non-cancer assessments are estimated to be 2.45 parts per billion (ppb) acequinocyl for surface water and 0.0036 ppb (acequinocyl and its metabolite, acequinocyl-OH) for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model for chronic dietary risk assessment. The water concentration of 2.45 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, termiteicides, and flea and tick control on pets). Acequinocyl is currently registered for the following uses that could result in residential exposures: Landscape ornamentals in residential and public areas for use by commercial applicators and homeowners. EPA assessed residential exposure using the following assumptions: In assessing residential exposure/risk, the homeowner handlers are expected to complete all tasks associated with the use of a pesticide product, including mixing and loading (if needed), and application. No chemical-specific data were available with which to assess potential exposure to pesticide handlers. The estimates of exposure to pesticide handlers are based upon surrogate study data available from the Outdoor Residential Exposure Task Force (ORETF) and the Pesticide Handlers Exposure Data (PHED). Homeowner handler assessments are based on the assumption that individuals are wearing shorts, short-sleeved shirts, socks, and shoes. Residential handler exposure scenarios are considered to be short-term only, due to infrequent use patterns associated with homeowner products. Based upon the proposed use pattern, the following residential handler scenarios have been assessed:

(1) Mixing/loading/applying liquids with low-pressure handwand (ORETF-fruit trees and ornamentals).

(2) Mixing/loading/applying liquids with hose-end sprayer (ORETF-fruit trees and ornamentals).

No significant dermal post-application exposure is expected from landscape ornamentals uses.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(iv) 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 website at http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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. In the rat prenatal developmental toxicity study, developmental toxicity was indicated by increased resorptions and fetal variations. The developmental toxicity study in rabbits identified an increased number of complete resorptions. In the rat two-generation reproductive toxicity study, both the maternal and reproductive toxicity LOAEs were not observed, however the LOAEL for parental males was 58.9/69.2 mg/kg/day based on hemorrhagic effects. The offspring systemic LOAEL was also 58.9 mg/kg/day. Though the offspring LOAEL was similar to that of parental male’s, there were effects specific to the pups which in addition to the hemorrhagic effects noted in both generations, included swollen body parts, protruding eyes, clinical signs, delays in pupil development and increased mortality occurring mainly after weaning.

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. At this time, the Agency is making permanent registration of these new uses conditional pending resolution of toxicological issues and has identified the following studies needed, including: (1) A 28-day inhalation study; (2) an immunotoxicity study; and (3) acute and subchronic neurotoxicity studies. Except for the 28-day inhalation study, the remaining studies are required under new EPA regulations. The toxicology database for acequinocyl does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. An immunotoxicity study is required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower point of departure (POD) than that currently in use for overall risk assessment. The database uncertainty factor (UFDB) is not needed to account for lack of this study.
Although a 28-day inhalation study is not available, EPA has determined that the additional FQPA SF is not needed. Residential inhalation risk was estimated by calculating exposure using the Agency’s Residential SOPs. For chemicals with low vapor pressure (7.5 x 10^{-5} mmHg or below for outdoor uses at 20–30 °C), these standard assumptions are expected to overestimate the exposure via the inhalation route. Acequinocyl is such a compound (1.69 x 10^{-1} mmHg at 25 °C) and exposure through the inhalation route is expected to be minimal. Therefore, the risk estimate is conservative and is considered protective and the additional FQPA SF is not needed. Since all calculated inhalation MOEs for residential handlers are significantly greater than the Agency’s LOC (MOE >100), even retaining the FQPA SF would not affect EPA’s conclusion on safety.

There is potential evidence of neurotoxicity or neuropathology in the 2-generation reproduction study as well as the rat subchronic oral toxicity study, however these toxicities are not considered to be primary effects since they occur in the presence of more severe systemic effects in both studies. Therefore, although an acute and subchronic neurotoxicity studies are now required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration, the agency does not believe that conducting these studies will result in a lower point of departure (POD) than that currently used for risk assessment.

ii. There is no evidence that acequinocyl results in increased susceptibility in in utero rat or rabbit fetuses in the prenatal developmental studies or in young rats in the 2-generation reproduction study. In the 2-generation rat reproduction study, more severe effects were observed in the offspring, however these effects were observed at the same doses as parental effects, and a clear NOAEL was established which is being used in endpoint selection.

iii. 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 water and surface water modeling used to assess exposure to acequinocyl in drinking water. The residential use (ornamentals) is not expected to result in post-application exposure to infants and 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 and non-linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acequinocyl from food and water will utilize 45% of the cPAD for children 1–2 years old of the population group receiving the greatest exposure. 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 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 that the combined short-term food, drinking water, andermal and inhalation residential exposures result in aggregate MOE of 2.700 for adults 50+ years old, the highest exposed population. Because EPA’s level of concern for chemical name 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). 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, 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 methodologies are available for enforcing tolerances for acequinocyl residues of concern in/on the proposed/registered plant commodities. Methods include two high-performance liquid chromatography methods with tandem mass-spectroscopy detection (HPLC/MS/MS).

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

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 U.N. 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 U.S. 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 MRLs for acequinocyl.

C. Revisions to Petitioned-for Tolerances

The Agency revised the 3.5 ppm proposed tolerance on hop, dried cones to 4.0 ppm. The Agency’s tolerance spreadsheet as specified by the Guidance for Setting Tolerances Based on Field Trial Data SOP (August 2009 version) was used to determine appropriate tolerance levels.

EPA has revised the tolerance expression for acequinocyl to clarify
1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of acequinocyl not specifically mentioned; and
2. That compliance with the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of acequinocyl including its metabolites and degradates in or on bean, edible podded at 0.25 ppm, hop, dried cones at 4.0 ppm, okra at 0.70 ppm, and vegetable, fruiting, group 8 at 0.70 ppm. Compliance with the tolerance levels specified is to be determined by measuring only the sum of acequinocyl [2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione] and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, calculated as the stoichiometric equivalent of acequinocyl, in or on the commodity.

VI. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under 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 relationship 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 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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: November 4, 2010.

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:


2. Section 180.599 is amended by revising paragraph (a) introductory text and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.599 Acequinocyl; tolerance for residues.

(a) General. Tolerances are established for residues of acequinocyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of acequinocyl [2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione] and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, calculated as the stoichiometric equivalent of acequinocyl, in or on the commodity.


**SUPPLEMENTARY INFORMATION:**

On April 19, 2000, OMB approved the information collection requirements contained in § 54.703(c) of title 47 of the United States Code as a revision to OMB Control Number 3060–0876. OMB had previously temporarily approved this information collection several times.

On March 16, 2004, OMB approved the information collection requirements contained in §§ 54.609(d)(2) and 54.621 of title 47 of the United States Code as a revision to OMB Control Number 3060–0804.

On July 13, 2004, OMB approved the information collection requirements contained in § 54.513(c) of title 47 of the United States Code as a part of OMB Control Number 3060–1062.

On November 12, 2004, OMB approved the information collection requirements contained in § 54.514(b) of title 47 of the United States Code as a revision to OMB Control Number 3060–0806.

On May 12, 2005, OMB approved the information collection requirements contained in §§ 54.409(d), 54.410, and 54.416 of title 47 of the United States Code as a revision to OMB Control Number 3060–0819.

On June 28, 2005, OMB approved the information collection requirements contained in §§ 54.609(e) of title 47 of the United States Code as a revision to OMB Control Number 3060–0804.

On March 19, 2007, OMB approved the information collection requirements contained in §§ 54.5, 54.708, and 54.712 of title 47 of the United States Code as a revision to OMB Control Number 3060–0855. OMB had previously temporarily approved these information collections on October 20, 2006.

These information collection requirements required OMB approval in order to become effective. The Commission publishes this document as an announcement of those approvals. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Thomas Butler, Federal Communications Commission, Room 5–C457, 445 12th Street, SW., Washington, DC 20554. Please include the OMB Control Numbers, 3060–0804, 3060–0806, 3060–0819, 3060–0855, 3060–0876, and 3060–1062, in your correspondence. The Commission will also accept your comments via the Internet if you send them to PRA@fcc.gov.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

**Synopsis**

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval for the information collection requirements described above. The OMB Control Numbers are 3060–0804, 3060–0806, 3060–0819, 3060–0855, 3060–0876, and 3060–1062. The total annual reporting burden for respondents for these collections of information, including the time for gathering and maintaining the collection of information, has been most recently approved to be:

For 3060–0804: 59,464 responses, for a total annual burden of 67,468 hours, and no annual costs.

For 3060–0806: 221,000 responses, for a total annual burden of 525,003 hours, and no annual costs.

For 3060–0819: 227,055 responses, for a total annual burden of 61,788 hours, and no annual costs.

For 3060–0855: 36,068 responses, for a total annual burden of 273,129 hours, and no annual costs.

For 3060–0876: 22 responses, for a total annual burden of 560 hours, and no annual costs.

For 3060–1062: 100 responses, for a total annual burden of 100 hours, and no annual costs.

An agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act, which does not display a current, valid OMB Control Number. The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

**List of Subjects in 47 CFR Part 54**

Telecommunications, Universal service.

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

[FR Doc. 2010–29016 Filed 11–16–10; 8:45 am]

BILLING CODE 6712–01–P

---

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Bean, edible podded ..........</td>
<td>0.25</td>
</tr>
<tr>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Hop, dried cones ............</td>
<td>4.0</td>
</tr>
<tr>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Okra ........................</td>
<td>0.70</td>
</tr>
<tr>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Vegetable, fruiting, group</td>
<td>0.70</td>
</tr>
<tr>
<td>8</td>
<td>*</td>
</tr>
</tbody>
</table>

[FR Doc. 2010–28973 Filed 11–16–10; 8:45 am]

BILLING CODE 6560–50–P

---

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 54**

**Universal Service Support Mechanisms**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; announcement of effective date.

**SUMMARY:** The Federal Communications Commission has published a number of requirements related to the universal service support mechanisms. This document announces the approval of the Office of Management and Budget (OMB) for information collection requirements contained in the sections outlined in the **DATES** section.

**DATES:** Effective November 17, 2010, the following regulations have been approved by OMB:

- 54.5—71 FR 38796, July 10, 2006.
- 54.514(b)—68 FR 36942, June 20, 2003.
- 54.609(e)—70 FR 6373, Feb. 7, 2005.
- 54.703(c)—63 FR 70753, Dec. 21, 1998.

**FOR FURTHER INFORMATION CONTACT:** Nicholas Degani, Telecommunications Access Policy Division, Wireline Competition Bureau, at (202) 418–7400.