

residues of *Muscodor albus* strain SA-13 and the volatiles produced on rehydration. Therefore, an exemption from the requirement of a tolerance is established for residues of *Muscodor albus* strain SA-13 and the volatiles produced on rehydration in or on all food commodities when used in accordance with label directions and good agricultural practices.

#### B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### C. Revision to the Requested Tolerance Exemption

One modification has been made to the requested tolerance exemption. When MBI first submitted this petition in 2014, it described the pesticide chemical as “sterile grain inoculated with *Muscodor albus* strain SA-13.” After conducting a review of this petition and evaluating a tolerance exemption established in 2005 for another strain of *Muscodor albus* (QST 20799) (70 FR 56569), which has the same mode of action as *Muscodor albus* strain SA-13, EPA is changing the pesticide chemical name to “*Muscodor albus* strain SA-13 and the volatiles produced on rehydration.” This revision better reflects the possible residues that may occur on food commodities and the data/information submitted to support the petition.

#### IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. 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 exemption in this action, 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 EPA’s 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).

#### V. 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: November 15, 2016.

**Jack Housenger,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

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

■ 2. Add § 180.1340 to subpart D to read as follows:

**§ 180.1340 *Muscodor albus* strain SA-13 and the volatiles produced on rehydration; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of *Muscodor albus* strain SA-13 and the volatiles produced on rehydration in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2016-28884 Filed 11-30-16; 8:45 am]

**BILLING CODE 6560-50-P**

#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 180

[EPA-HQ-OPP-2015-0412; FRL-9950-89]

##### Quizalofop Ethyl; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of quizalofop ethyl in or on crayfish and rice grain. Nissan Chemical Industries, Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 1, 2016. Objections and requests for hearings must be received on or before January 30, 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-2015-0412, 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](mailto: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-id?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-id?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>.

*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-2015-0412 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 January 30, 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-2015-0412, 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 August 26, 2015 (80 FR 51759) (FRL-9931-74), 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 5F8367) by Lewis and Harrison, LLC, 122 C St. NW., Suite 505, Washington, DC 20001 (on behalf of Nissan Chemical Industries, Ltd., 7-1, 3-chome, Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-0054, Japan). The petition requested that 40 CFR 180.441 be amended by establishing tolerances for residues of the herbicide quizalofop-p-ethyl ester, ethyl-(R)-(2-(4-((6-chloroquinoxalin-2-yl)oxy)phenoxy)propanoate), and its acid metabolite quizalofop-P, R-(2-(4-((6-quinoxalin-2-yl)oxy)phenoxy)propanoic acid, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-P-ethyl ester, in or on crayfish at 0.04 parts per million (ppm) and rice, grain at 0.05 ppm. That document referenced a

summary of the petition prepared by Nissan Chemical Industries, Ltd., 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 changed the tolerance expression for rice grain and corrected the commodity definition for crayfish. The reasons for these changes are explained in Unit IV.C.

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

Quizalofop ethyl is a 50/50 racemic mixture of R- and S-enantiomers. Quizalofop-P-ethyl, the purified R-

enantiomer, is the pesticidally-active isomer. Since the toxicological profiles of quizalofop ethyl and quizalofop-P-ethyl are similar, the available toxicity studies are adequate to support both compounds. For the purposes of this final rule, both quizalofop ethyl and quizalofop-P-ethyl are collectively referred to as “quizalofop ethyl”.

Quizalofop ethyl has very low acute toxicity via the oral, dermal, and inhalation routes of exposure, is not an eye or skin irritant, and is not a skin sensitizer. There were no adverse effects observed in the oral toxicity studies that could be attributable to a single-dose exposure.

Repeated-dose toxicity studies indicate the liver as the target organ, as evidenced by increased liver weights and histopathological changes. Following oral administration, quizalofop ethyl is rapidly excreted via urine and feces. In the subchronic oral toxicity rat study, effects of decreased body weight gains, increased liver weight, and centrilobular liver cell enlargement were observed. In the subchronic oral toxicity dog study, an increased incidence of testicular atrophy was observed. In the combined chronic toxicity/carcinogenicity study in rats, an increased incidence of centrilobular liver cell enlargement was observed in both sexes and mild anemia in males.

No dermal toxicity effects were observed in the subchronic dermal toxicity rabbit study at up to the limit dose. Subchronic inhalation toxicity is assumed to be equivalent to oral toxicity. In the chronic oral toxicity dog study, no toxicity effects were observed at the highest dose tested (HDT).

In the rat and rabbit developmental toxicity studies, maternal effects

including decreased body weight gains and food consumption were observed; no developmental effects were observed at up to the HDT. In the two-generation reproduction toxicity study in rats, maternal effects including decreased body weight and body weight gains were observed at the same dose level that resulted in prenatal and postnatal effects (decreased percentage of pups born alive and decreased pup weights).

Although tumors were observed in male and female mice after exposure to quizalofop, the overall evidence for carcinogenicity is weak, as discussed in supporting documents. Additionally, the point of departure used for establishing the chronic reference dose for quizalofop is significantly lower (30X) than the dose that induced tumors in male and female mice. EPA has determined that quantification of cancer risk using a non-linear approach would adequately account for all chronic toxicity, including carcinogenicity, which could result from exposure to quizalofop ethyl.

Quizalofop ethyl does not show evidence of neurotoxicity, based on no evidence of neurotoxicity or neuropathology in the available toxicology studies. There was also no evidence of adverse effects on the functional development of pups observed in the rat reproduction toxicity study. Quizalofop ethyl showed no evidence of immunotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by quizalofop ethyl 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,

“Quizalofop-P-ethyl. Human Health Risk Assessment in Support of the Proposed New Use on Rice” in docket ID number EPA-HQ-OPP-2015-0412.

#### *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 the NOAEL and the LOAEL are identified. Uncertainty/safety factors (UF) 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-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

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

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR QUIZALOFOP ETHYL 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 (all populations) .....	No hazard attributable to a single-dose exposure was identified.		
Chronic dietary (all populations) ....	NOAEL = 0.9 mg/kg/day ..... UF <sub>A</sub> = 10x ..... UF <sub>H</sub> = 10x ..... FQPA SF = 1x .....	Chronic RfD = 0.009 mg/kg/day ... cPAD = 0.009 mg/kg/day .....	<i>Combined Chronic Toxicity/Carcinogenicity Rat Study</i> LOAEL = 3.7 mg/kg/day based on mild anemia in males and increased number of liver masses and centrilobular enlargement of the liver in both sexes

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = 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 quizalofop ethyl, EPA considered exposure under the petitioned-for tolerances as well as all existing quizalofop ethyl tolerances in 40 CFR 180.441. EPA assessed dietary exposures from quizalofop ethyl 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 one-day or single exposure. No such effects were identified in the toxicological studies for quizalofop ethyl; 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 USDA 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA incorporated tolerance-level residues, 100 percent crop treated (PCT) for all commodities, and default processing factors for all processed commodities except sunflower oil.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that quizalofop ethyl 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 percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for quizalofop ethyl. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

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

Based on the Modified Tier 1 Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW) model, the estimated drinking water concentrations (EDWCs) of quizalofop ethyl for chronic exposures for non-cancer assessments

are estimated to be 127 parts per billion (ppb) for surface water and 89 ppb 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 value of 127 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). Quizalofop ethyl is not registered for any specific use patterns that would result in residential exposure.

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

EPA has not found quizalofop ethyl to share a common mechanism of toxicity with any other substances, and quizalofop ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that quizalofop ethyl does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <http://www.epa.gov/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 Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable

data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* As summarized in Unit III.A., results from the rat and rabbit developmental toxicity and the two-generation rat reproduction toxicity studies indicated no qualitative or quantitative evidence of increased susceptibility in developing fetuses or in the offspring following prenatal and/or postnatal exposure to quizalofop ethyl.

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 quizalofop ethyl is complete.

ii. There is no indication that quizalofop ethyl 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 qualitative or quantitative evidence that quizalofop ethyl results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

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 quizalofop ethyl in drinking water. These assessments will not underestimate the exposure and risks posed by quizalofop ethyl.

### 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. Since there are no residential uses for quizalofop ethyl, the aggregate risk assessment only includes exposure estimates from dietary consumption of food and drinking water.

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-dose exposure was identified and no acute dietary endpoint was selected. Therefore, quizalofop ethyl 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 quizalofop ethyl from food and water will utilize 97% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

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

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

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

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodologies (Modified Meth-147, liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) for plant commodities including rice; Modified BASF Method Number D1416 (LC-MS/MS) for crustaceans; and AMR-515-86, AMR-623-86, AMR-627-86, AMR-845-87, and AMR-846-87, all High Performance Liquid Chromatography (HPLC) methods using ultraviolet detection for livestock commodities) 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; email address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural

practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for quizalofop ethyl.

##### C. Revisions to Petitioned-For Tolerances

EPA changed the proposed tolerance expression for rice grain from the detection of “quizalofop-P-ethyl and its acid metabolite quizalofop-P, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-P-ethyl ester” to “quizalofop ethyl residues convertible to 2-methoxy-6-chloroquinoxaline, expressed as the stoichiometric equivalent of quizalofop ethyl” to match the expression of the other existing plant commodities since the same common moiety analytical method is used for enforcement. EPA also changed the proposed commodity name from “crayfish” to the correct definition of “fish-shellfish, crustacean”.

#### V. Conclusion

Therefore, tolerances are established for residues of quizalofop ethyl in or on fish-shellfish, crustacean at 0.04 ppm and rice, grain at 0.05 ppm.

#### 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: November 10, 2016.

**Michael Goodis,**

*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 § 180.441:

■ a. Add alphabetically the commodity in the table in paragraph (a)(1).

■ b. Add paragraph (a)(3).

The additions read as follows:

**§ 180.441 Quizalofop ethyl; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
Rice, grain .....	0.05

\* \* \*

(3) Tolerances are established for residues of the herbicide quizalofop-P-ethyl, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring quizalofop ethyl and quizalofop acid, expressed as the stoichiometric equivalent of quizalofop ethyl, in or on the commodity.

Commodity	Parts per million
Fish-shellfish, crustacean .....	0.04

\* \* \*

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**BILLING CODE 6560-50-P**

**FEDERAL COMMUNICATIONS COMMISSION****47 CFR Parts 1, 25, 73 and 74**

[GN Docket No. 15-236; FCC 16-128]

**Review of Foreign Ownership Policies for Broadcast, Common Carrier and Aeronautical Radio Licensees**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this Report and Order, the Federal Communications Commission (Commission) extends its streamlined foreign ownership rules and procedures that apply to common carrier and certain aeronautical licensees under Section 310(b)(4) of the Communications Act of 1934, as amended (the “Act”) to broadcast licensees, with certain modifications to tailor them to the broadcast context. The Commission also reforms the methodology used by both common carrier and broadcast licensees that are, or are controlled by, U.S. public companies to assess compliance with the 20 percent foreign ownership limit in Section 310(b)(3), and the 25 percent foreign ownership benchmark in Section 310(b)(4) of the Act, in order to reduce regulatory burdens on applicants and licensees. Finally, the Commission makes certain technical corrections and clarifications to its foreign ownership rules.

**DATES:** Effective January 30, 2017, except for the amendments to 47 CFR 1.5000 through 1.5004, 25.105, 73.1010 and 74.5 which will be effective upon approval of information collection requirements by the Office of Management and Budget (OMB). The Commission will publish a separate document in the **Federal Register** announcing the effective date of these rule changes.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. The Commission will seek comments from the Office of Management and Budget (OMB), other Federal agencies and the general public on the Paperwork Reduction Act (PRA) information collection requirements contained herein in a separate notice to be published in **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Cook or Francis Gutierrez, Telecommunications and Analysis Division, International Bureau, FCC, (202) 418-1480 or via email to [Kimberly.Cook@fcc.gov](mailto:Kimberly.Cook@fcc.gov), [Francis.Gutierrez@fcc.gov](mailto:Francis.Gutierrez@fcc.gov). On PRA

matters, contact Cathy Williams, Office of the Managing Director, FCC, (202) 418-2918 or via email to [Cathy.Williams@fcc.gov](mailto:Cathy.Williams@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Report and Order in GN Docket No. 15-236, FCC 16-128, adopted September 29, 2016 and released on September 30, 2016. The full text of the Report and Order is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Washington, DC 20554. The document also is available for download over the Internet at [http://transition.fcc.gov/Daily\\_Releases/Daily\\_Business/2016/db0930/FCC-16-128A1.pdf](http://transition.fcc.gov/Daily_Releases/Daily_Business/2016/db0930/FCC-16-128A1.pdf).

**Synopsis of Report and Order**

1. The Report and Order modifies the foreign ownership filing and review process for broadcast licensees by extending the streamlined rules and procedures developed for foreign ownership reviews for common carrier and certain aeronautical licensees under Section 310(b)(4) of the Communications Act of 1934, as amended (the “Act”), to the broadcast context with certain limited exceptions.<sup>1</sup> Recognizing the difficulty U.S. public companies face in ascertaining their foreign ownership, this Report and Order also reforms the methodology used by both common carrier and broadcast licensees that are, or are controlled by, U.S. public companies to assess compliance with the foreign ownership limits in Sections 310(b)(3) and 310(b)(4) of the Act, respectively. In particular, the reformed methodology provides a framework for a publicly traded licensee or controlling U.S. parent to ascertain its foreign ownership using information that is “known or reasonably should be known” to the company in the ordinary

<sup>1</sup> For ease of reference, this Report and Order refers to broadcast, common carrier, aeronautical en route and aeronautical fixed radio station applicants and licensees (including broadcast permittees) and to common carrier spectrum lessees collectively as “licensees” unless the context warrants otherwise. This Report and Order also uses the term “common carrier” or “common carrier licensees” to encompass common carrier, aeronautical en route and aeronautical fixed radio station applicants and licensees unless the context applies only to common carrier licensees. “Spectrum lessees” are defined in Section 1.9003 of Part 1, Subpart X (“Spectrum Leasing”). 47 CFR 1.9003. This Report and Order also refers to aeronautical en route and aeronautical fixed licensees collectively as “aeronautical” licensees. In using this shorthand, this Report and Order does not include other types of aeronautical radio station licenses issued by the Commission.