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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0665; FRL-10020-34]

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 multiple commodities which are identified and discussed later in this document. The Interregional Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], 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-2019-0665, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide

remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, 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 Publishing 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-2019-0665 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2019-0665, 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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets*. 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 8, 2020 (85 FR 27346) (FRL-10008-38), 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 9E8803) by IR-4, Rutgers, the State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.441 be amended by establishing tolerances for residues of the herbicide quizalofop ethyl convertible to

2-methoxy-6-chloroquinoxaline, expressed as quizalofop ethyl, in or on carinata at 1.5 parts per million (ppm); cottonseed subgroup 20C at 0.1 ppm; fruit, pome, group 11-10 at 0.1 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13 07F at 0.1 ppm; fruit, stone, group 12-12 at 0.1 ppm; pennycress, meal at 2 ppm; pennycress, seed at 1.5 ppm; and sunflower subgroup 20B at 3 ppm. Additionally, the petition requested, upon approval of the above tolerances, to remove the existing tolerances in 40 CFR 180.441(a) in or on cotton, undelinted seed at 0.1 ppm and sunflower, seed at 1.9 ppm. That document referenced a summary of the petition prepared by AMVAC Chemical Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. Two 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 corrected several tolerance definitions and is not establishing a tolerance on pennycress, meal, as proposed by the petitioner. The reasons 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 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.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for quizalofop ethyl, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to quizalofop ethyl and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of quizalofop ethyl, see Unit III.A. of the February 23, 2018 rulemaking (83 FR 8006) (FRL-9972-30).

Toxicological Points of Departure/Levels of Concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the December 1, 2016 rulemaking (81 FR 86581) (FRL-9950-89).

Exposure Assessment. Much of the exposure assessment remains the same, although updates have occurred to accommodate exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the February 23, 2018 rulemaking.

EPA’s dietary exposure assessments have been updated to include the additional exposure from the new uses of quizalofop ethyl on brassica carinata; fruit, pome, group 11-10; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; fruit, stone, group 12-12; and pennycress and the

crop subgroup expansions for cottonseed subgroup 20C and sunflower subgroup 20B. The assessment used the same assumptions as the February 23, 2018 final rule concerning tolerance level residues and default processing factors for all processed commodities except sunflower oil, where an empirical factor was used.

Updated average percent crop treated values were used for the following crops that are currently registered for quizalofop-ethyl: beans, green: 2.5%; canola: 5%; cotton: 1%; dry beans/peas: 15%; peas, green: 2.5%; soybeans: 2.5%; sugar beets: 1%; and sunflowers: 5%; and 100% crop treated for other registered and new uses of quizalofop ethyl.

Anticipated residue and PCT information. Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average

PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that Conditions a, b, and c discussed above have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which quizalofop-ethyl may be applied in a particular area.

Drinking water, non-occupational, and cumulative exposures. Drinking water exposures and residential (non-occupational) exposures are not impacted by the new uses, and thus have not changed since the last assessment. EPA's conclusions concerning cumulative risk remain unchanged from the February 23, 2018 rulemaking.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the February 23, 2018 rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate Risks and Determination of Safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the

acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not conducted as toxicological effects attributable to a single dose were not identified. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: they are 92% of the cPAD for all infants less than 1-year old, the population subgroup with the highest exposure estimate. Quizalofop-ethyl is classified as a Category D chemical, i.e. "Not Classifiable as to Human Carcinogenicity;" therefore, quantification of chronic risks using a non-linear approach will adequately account for all chronic toxicity, including any potential carcinogenicity that would result from exposure. There are no registered or new uses of quizalofop ethyl that would result in residential exposure, therefore the aggregate risk estimates are equivalent to the chronic dietary (food and water) risk estimates and are not of concern.

Therefore, based on the risk assessments and information described above, EPA concludes 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. More detailed information about the Agency's analysis can be found at *http://www.regulations.gov* in the documents titled "Quizalofop-P-ethyl. Human-Health Risk Assessment in Support of the Proposed New Uses on Carinata, Pennycress, Pome Fruit (Group 11-10), Stone Fruit (Group 12-12), and Small Vine-climbing Fruit, Except Fuzzy Kiwifruit (Subgroup 13-07F); and Use Expansions for Sunflower and Cottonseed (Subgroups 20B and 20C)" in docket ID number EPA-HQ-OPP-2019-0665.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the February 23, 2018 rulemaking.

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 has not established MRLs for quizalofop ethyl.

C. Response to Comments

Although two comments were submitted to the docket in response to the May 8, 2020 Notice of Filing, only one specifically related to this tolerance action. The commenter requested that EPA deny IR-4's request for tolerances for quizalofop ethyl on cotton sunflower seeds out of a concern for the general health impacts of pesticides.

Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the quizalofop ethyl tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

The commodity definition for carinata has been revised to brassica carinata, seed; and brassica carinata, meal. The tolerance for brassica carinata, seed will be established at 1.5 ppm; and the tolerance for brassica carinata, meal will be established at 2 ppm. EPA is not establishing a tolerance for pennycress, meal as requested by the petitioner because the glucosinolates in pennycress meal restrict its use to a livestock feedstuff, not a human food. EPA's current

practice is to set tolerances for livestock feedstuffs only if they are significant, which is not the case for pennycress meal.

V. Conclusion

Therefore, tolerances are established for residues of quizalofop ethyl convertible to 2-methoxy-6-chloroquinoxaline, expressed as quizalofop ethyl, in or on brassica carinata, meal at 2 ppm; brassica carinata, seed at 1.5 ppm; cottonseed subgroup 20C at 0.1 ppm; fruit, pome, group 11–10 at 0.1 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.1 ppm; fruit, stone, group 12–12 at 0.1 ppm; pennycress, seed at 1.5 ppm; and sunflower subgroup 20B at 3 ppm. Upon establishment of the above tolerances, the established tolerances for cotton, undelinted seed at 0.1 ppm; and sunflower, seed at 1.9 ppm will be removed as they are superseded by the new tolerances on subgroups 20C and 20B, respectively.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to petitions 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), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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 tolerances 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: March 2, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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, amend the table in paragraph (a)(1) as follows:

i. Add a table heading.

ii. Add alphabetically the entries “Brassica carinata, meal”; and “Brassica carinata, seed”.

iii. Remove the entry for “Cotton, undelinted seed”.

iv. Add alphabetically the entries “Cottonseed subgroup 20C”; “Fruit, pome, group 11-10”; “Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F”; “Fruit, stone, group 12-12”; and “Pennycress, seed”.

v. Remove the entry for “Sunflower, seed”.

vi. Add alphabetically the entry “Sunflower subgroup 20B”.

The additions read as follows:

§180.441 Quizalofop ethyl; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * * * *	
Brassica carinata, meal	2
Brassica carinata, seed	1.5
* * * * * * *	
Cottonseed subgroup 20C	0.1
* * * * * * *	
Fruit, pome, group 11-10	0.1
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.1
Fruit, stone, group 12-12	0.1
* * * * * * *	
Pennycress, seed	1.5
* * * * * * *	
Sunflower subgroup 20B	3
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[FR Doc. 2021-04720 Filed: 3/5/2021 8:45 am; Publication Date: 3/8/2021]