

Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 4, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

1. The authority citation for part 180 continues to read as follows:
Authority: 21 U.S.C. 346a and 371.
2. Section 180.471 is revised to read as follows:

§ 180.471 3-Dichloroacetyl-5-(2-furanyl)-2,2-dimethyloxazolidine; tolerances for residues.

Time-limited tolerances are established for residues of 3-

dichloroacetyl-5-(2-furanyl)-2,2-dimethyloxazolidine (CAS Reg. No. 121776-33-8) when used as an inert ingredient (safener) in pesticide formulations in or on the following agricultural commodities:

Commodity	Parts per million	Expiration date
Corn, fodder (field)	0.01	June 30, 1998
Corn, forage (field)	0.01	June 30, 1998
Corn, grain (field)	0.01	June 30, 1998

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BILLING CODE 6560-50-F

40 CFR Part 180

[PP 6E4652/P664; FRL-5377-1]

RIN 2070-AC18

Quizalofop ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish tolerances for the combined residues of the herbicide quizalofop-p ethyl ester, its acid metabolite quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p-ethyl ester, in or on the raw agricultural commodities peppermint tops and spearmint tops. The proposed regulation to establish maximum permissible levels for residues of the herbicide was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4).

DATES: Comments, identified by the docket number [PP 6E4652/P664], must be received on or before July 19, 1996.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted to OPP by sending electronic mail (e-mail) to:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form

of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 6E4652/P664]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the "SUPPLEMENTARY INFORMATION" section of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308-8783; e-mail: jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP)

6E4652 to EPA on behalf of the Oregon Agricultural Experiment Station.

This petition requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.441 by establishing tolerances for the combined residues of the herbicide quizalofop-p ethyl ester [ethyl (R)-(2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy] propionate)], its acid metabolite quizalofop-p [R-(2-[4-((6-chloroquinoxalin-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 the raw agricultural commodities peppermint tops and spearmint tops at 2 parts per million (ppm).

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. Several acute toxicology studies placing technical-grade quizalofop ethyl in toxicity Category III.

2. An 18-month carcinogenicity study with CD-1 mice fed diets containing 0, 2, 10, 80 and 320 ppm (equivalent to 0, 0.2, 1.5, 12, and 48 mg/kg/day) with no carcinogenic effects observed under the conditions of the study at levels up to and including 80 ppm. There was an elevated incidence of hepatocellular adenomas and carcinomas combined in CD-1 male mice at the 320 ppm dose level, which exceeded the maximum tolerated dose (MTD).

3. A 2-year chronic toxicity/carcinogenicity study in rats fed diets containing 0, 25, 100 and 400 ppm (equivalent to 0, 0.9, 3.7, and 15.5 mg/kg/day for males and 0, 1.1, 4.6, and 18.6 mg/kg/day for females) with no carcinogenic effects observed under the conditions of the study. The NOEL for systemic toxicity is established at 25

ppm (0.9 mg/kg/day) based on red blood cell destruction in males, and slight/minimal centrilobular enlargement of the liver in females at the 100 ppm dose level.

4. A 1-year feeding study in dogs fed diets containing 0, 0.625, 2.5, and 10 mg/kg/day with a NOEL of 10 mg/kg/day (HDT).

5. A developmental toxicity study in rats fed dosage levels of 0, 30, 100, and 300 mg/kg/day, with no developmental effects observed under the conditions of the study. The NOEL for maternal toxicity is established at 30 mg/kg/day.

6. A developmental toxicity study in rabbits fed dosage levels of 0, 7, 20, and 60 mg/kg/day with no developmental effects observed under the conditions of the study. The NOEL for maternal toxicity is established at 20 mg/kg/day based on decreases in food consumption and body weight gain at 60 mg/kg/day (HDT).

7. A two-generation reproduction study in rats fed diets containing 0, 25, 100 and 400 ppm (equivalent to 0, 1.25, 5, and 20 mg/kg/day) with a NOEL for developmental toxicity at 25 ppm based on an increase in liver weight and an increase in the incidence of eosinophilic changes in the liver at 100 ppm. The NOEL for parental toxicity is established at 100 ppm based on decreased body weight and premating weight gain in males at the 400 ppm dose level.

8. Mutagenicity data included gene mutation assays with *E. coli* and *S. typhimurium* (negative); DNA damage assays with *B. subtilis* (negative); and a chromosomal aberration test in Chinese hamster cells (negative).

OPP's Health Effects Division, Carcinogenicity Peer Review Committee (CPRC) has evaluated the rat and mouse cancer studies for quizalofop ethyl along with other relevant short-term toxicity studies, mutagenicity studies, and structure-activity relationships. The CPRC has classified quizalofop ethyl as a Group D carcinogen (not classifiable as to human cancer potential). The Group D classification is based on an approximate doubling in the incidence of male mice liver tumors between controls and the high dose. This finding was not considered strong enough to warrant the classification of a Category C (possible human carcinogen); the increase was of marginal statistical significance, occurred at a high dose which exceeded the predicted MTD, and occurred in a study in which the concurrent control for liver tumors was somewhat low as compared to the historical controls, while the high dose control group was at the upper end of previous historical control groups. No

new cancer studies are required for quizalofop ethyl at this time.

The Reference Dose (RfD) for quizalofop ethyl is calculated at 0.009 mg/kg of body weight/day. The RfD is based on the NOEL of 0.9 mg/kg/day from the 2-year rat feeding study, and an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) from existing tolerances and the proposed tolerance for mint tops utilizes 5 percent of the RfD for the overall U.S. population and 18.5 percent of the RfD for non-nursing infants (the population subgroup most highly exposed). EPA generally has no concern for dietary exposures below 100 percent of the RfD.

The nature of the residue in plants is adequately understood. An adequate analytical method (HPLC-UV) is available for enforcement purposes. Prior to its publication in the Pesticide Analytical Manual, Volume II (PAM II), the enforcement method is being made available in the interim to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202 (703)305-5805.

There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat of livestock and poultry since there are no significant livestock feed commodities associated with this action. Data submitted with the petition demonstrate that residues of quizalofop ethyl do not concentrate in mint oil. The proposed tolerances for peppermint and spearmint tops is adequate to cover residues in mint oil.

There are presently no actions pending against the continued registration of this chemical. The pesticide is considered useful for the purpose for which the tolerance is sought.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal

Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the docket number [PP 6E4652/P664].

A record has been established for this rulemaking under docket number [PP 6E4652/P664] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or

otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

This action does not impose any enforceable duty, or contain any "unfunded mandates" as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement explaining the factual basis for this determination was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 10, 1996.

Stephen L. Johnson,
Director, Registration Division, Office of
Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.441, by revising paragraph (c) to read as follows:

§ 180.441 Quizalofop ethyl; tolerances for residues.

* * * *

(c) Tolerances are established for the combined residues of the herbicide quizalofop-p ethyl ester [ethyl (R)-(2-[4-(6-chloroquinoxalin-2-yl)oxy]phenoxy)]

propionate], its acid metabolite quizalofop-p [R-(2-[4-((6-chloroquinoxalin-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 the following raw agricultural commodities:

Commodity	Parts per million
Cottonseed	0.05
Peppermint, tops	2
Spearmint, tops	2

[FR Doc. 96-15595 Filed 6-18-96; 8:45 am]

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40 CFR Parts 180 and 185

[OPP-300431; FRL-5379-7]

RIN 2070-AC18

Triadimefon; Revocation of Pesticide Tolerances and a Food Additive Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke the pesticide tolerances for triadimefon on barley grain, green forage and straw and the food additive regulation for triadimefon on milled fractions of barley (except flour) because there are no longer registered uses of triadimefon on barley. EPA is proposing that the revocation of the tolerance become effective as of May 23, 1997.

DATES: Written comments, identified by the docket number OPP-300431, must be received on or before July 19, 1996. This revocation is proposed to become effective on May 23, 1997.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA. Information submitted and any comment(s) concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment(s) that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential

may be disclosed publicly by EPA without prior notice to the submitter. Information on the proposed action and any written comments will be available for public inspection in Rm. 1132 at the Virginia address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300431]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail, Lisa Nisenson, Special Review Branch (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 3rd floor, Crystal Station, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8031; e-mail: nisenson.lisa@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Background

The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as "tolerances." Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342.

The FFDCA has separate provisions for tolerances for pesticide residues on raw agricultural commodities (RACs) and tolerances on processed food. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409, which pertains to "food additives." 21 U.S.C. 348. Maximum residue