

parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by October 27, 1995.

ADDRESSES: Written comments on this action should be addressed to Ms. Jole C. Luehrs, Chief, New Source Review Section, at the EPA Region 6 office listed below. Copies of documents relevant to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least two working days in advance.

U.S. Environmental Protection Agency, Air Programs Branch (6T-A), First Interstate Bank Building, 1445 Ross Avenue, suite 700, Dallas, Texas 75202-2733.

U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center, 401 M Street, SW., Washington, DC 20460.

Texas Natural Resource Conservation Commission, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: Stanley M. Spruiell of the EPA Region 6 Air Programs Branch at (214) 665-7212 and at the above address.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is published in the Rules and Regulations section of this Federal Register.

Authority: 42 U.S.C. 7401-7671q.

Dated: July 10, 1995.

A. Stanley Meiburg,
Deputy Regional Administrator.

[FR Doc. 95-23961 Filed 9-26-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Parts 180 and 185

[PP 5E4429/P631; FRL-4973-9]

RIN 2070-AC18

Oxyfluorfen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish tolerances for residues of the herbicide oxyfluorfen in or on the raw agricultural commodities blackberry and raspberry. 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) pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA). EPA also proposes deleting the metabolites of oxyfluorfen containing the diphenyl ether linkage from certain tolerance expressions.

DATES: Comments, identified by the document control number [PP 5E4429/P631], must be received on or before October 27, 1995.

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 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 5E4429/P631]. 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 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 Hwy., 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) 5E4429 to EPA on behalf of the Agricultural Experiment Stations of Oregon, New York, Virginia, and Washington. 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 180.381 by establishing a tolerance for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the raw agricultural commodities blackberry and raspberry at 0.05 part per million (ppm). The petitioner proposed that use of oxyfluorfen on blackberry and raspberry be geographically limited to Oregon and Washington based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

EPA also proposes to amend established tolerances for oxyfluorfen by deleting the diphenyl ether linkage metabolites from the tolerance expressions under 40 CFR 180.381 and 185.4600. Tolerances are currently established for residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage in or on certain raw agricultural commodities under 40 CFR 180.381 and certain processed foods under 185.4600. EPA has determined that it is no longer necessary to regulate these metabolites in raw agricultural and processed commodities. Metabolism studies with oxyfluorfen show no detectable residues of the diphenyl ether linkage metabolites in plants. Oxyfluorfen per se is the major residue found in meat, meat byproducts, fat, milk, and eggs.

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. A 2-year feeding study in dogs fed diets containing 0, 100, 600, or 2,000 ppm with a no-observed-effect level (NOEL) of 100 ppm (equivalent to 2.5 milligrams (mg)/kilogram (kg)/day). Effects observed in dogs fed diets containing 600 ppm (equivalent to 15 mg/kg/day) were increased liver weight,

increases in alkaline phosphatase, renal tubule vacuolization, and thyroid C-cell hyperplasia.

2. A developmental toxicity study in rats given gavage doses of 0, 18, 183, or 848 mg/kg/day with NOEL's for maternal and developmental toxicity of 18 mg/kg/day. Developmental effects consisting of decreased fetal body weight, increased resorptions, and an increase in the incidence of left carotid artery from the innominate, bent bones of the forelimbs, and other ossification irregularities were observed at the 183-mg/kg/day dose level. These effects were confined to the mid-dose level, since there was 100 percent litter loss in the high-dose groups as a result of maternal mortality and resorptions. The lowest-observed-effect level (LOEL) for maternal toxicity was established at 183 mg/kg/day based on decreased weight gain and food consumption, increased incidences of soft or scant feces, and increased alkaline phosphatase.

3. A developmental toxicity study in rabbits given gavage doses of 0, 10, 30, or 90 mg/kg/day with NOEL's for maternal and developmental toxicity of 10 mg/kg/day. Developmental toxicity (fused sternbrae) and maternal toxicity (anorexia and decreased body weight gain) were observed at the 30-mg/kg/day dose level.

4. A two generation reproduction study in rats fed diets containing 0, 100, 400, or 1,600 ppm with NOEL's for reproductive and systemic effects of 400 ppm (equivalent to 20 mg/kg/day). Reproductive effects observed at the 1,600-ppm dose level were decreased pup body weight during lactation in both the F_{1a} and F_{2a} litters and a decreased litter size at birth in F_{1a} and F_{2a} litters. Systemic effects observed at the 1,600-ppm dose level include pelvic mineralization and pelvic papillary hyperplasia of P₁ and P₂ males and P₂ females and dilation of kidney collecting ductules in both P₂ sexes.

5. Mutagenicity studies including *Salmonella* assays, positive with and without activation in strains TA98, TA100, and TA1537; *Salmonella* assays, negative with and without activation in strains TA98, TA100, TA1535, and TA1537; *in vivo* cytogenetic assay in rats, negative for cytogenetic chromosomal aberrations both with and without metabolic activation; and mouse lymphoma forward mutation assay, positive in the presence of an activation system.

6. A 2-year chronic feeding/carcinogenicity study in rats fed diets containing 0, 2, 40, or 800/1,600 ppm (the 800-ppm dosage level was raised to 1,600 ppm at week 57 of the study) with a NOEL of 40 ppm (equivalent to 2.0

mg/kg/day) based on minimal hypertrophy of liver cells. There were no carcinogenic effects observed under the conditions of the study at any dose level tested.

7. A 20-month carcinogenicity study in CD-1 mice fed diets containing 0, 2, 20, or 200 ppm with a NOEL of 2 ppm (equivalent to 0.3 mg/kg/day) for systemic effects. Oxyfluorfen was associated with significant positive dose-related trends for liver adenoma, carcinoma, and combined adenoma and/or carcinoma in male mice when compared with historical control data from CD-1 mouse studies of 20 to 22 months duration. There was no apparent effect on the latency period for tumor occurrence, and no compound-related increase in tumors were observed in female mice.

Based on a weight-of-the-evidence determination, EPA has classified oxyfluorfen as a possible human carcinogen (Group C) with quantified risk. The qualitative categorization of carcinogenicity is based on the Agency's Guidelines for Carcinogenic Risk Assessment, published in the Federal Register of September 24, 1986 (51 FR 33992).

Although there was no compound-related increase in tumors observed in female mice or in male or female rats, and no evidence for a reduction in latency period for the time-to-liver tumor appearance in male mice, quantification of carcinogenic risk for oxyfluorfen is considered appropriate. The decision supporting a Category C classification with quantified risk is based on the significant positive dose-related trends in liver adenomas, carcinomas, and combined adenomas and/or carcinomas in male CD-1 mice. Supporting evidence includes a strong association of oxyfluorfen with diphenyl ether herbicides (a class of herbicides associated with evidence of carcinogenicity) and evidence of mutagenicity in the *Salmonella* and the mouse lymphoma assays.

A carcinogenic risk assessment for oxyfluorfen has been completed based on the available information. The potential carcinogenic risk from dietary exposure resulting from existing uses of oxyfluorfen is calculated at 1.8×10^{-6} . The dietary risk assessment is based on a potency estimator (Q1*) of 0.13 (mg/kg/day)⁻¹. Dietary exposure is calculated at 0.000014 mg/kg/day based on theoretical maximum residue contribution (TMRC) estimates for some uses and anticipated residue contribution (ARC) estimates for other uses. TMRC values assume that 100 percent of the crops are treated and that the resulting residues are at tolerance

levels. ARC values estimate expected dietary exposure based on actual residue levels that are anticipated on the treated commodities and/or the estimated percent of the crop treated. The potential carcinogenic risk from residues of oxyfluorfen in the diet is expected to be less than calculated since data were not available to estimate the percent of crop treated for several commodities which theoretically contribute significant residues to the diet. In the absence of these data, the Agency has assumed that 100 percent of the crop was treated.

Dietary exposure resulting from tolerance level residues in or on blackberry and raspberry is estimated at 0.000001 mg/kg/day. The potential carcinogenic risk to the proposed tolerance level residues for blackberry and raspberry is calculated at 6×10^{-8} , a negligible increase.

The Reference Dose (RfD) for oxyfluorfen is calculated at 0.003 mg/kg/day, based on a NOEL of 0.30 mg/kg of body weight/day from the 20-month feeding study in mice and an uncertainty factor of 100. Dietary exposure from existing tolerances and the proposed tolerances for blackberry and raspberry utilizes less than 1 percent of the RfD for the general population and for children, aged 1 to 6 years (the subgroup population most highly exposed.)

An adequate analytical method is available for enforcement purposes. The metabolism of oxyfluorfen in plants is adequately understood. An analytical method for enforcing these tolerances has been published in the Pesticide Analytical Manual, Vol. II (PAM II). No secondary residues are expected in meat, milk, poultry, or eggs since blackberry and raspberry are not considered livestock feed commodities.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerances 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 document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCFA.

A record has been established for this rulemaking under docket number [PP 5E4429/P631] (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 Rm. 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 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.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 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 to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Parts 180 and 185

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

Dated: September 18, 1995.

Peter Caulkins,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that parts 180 and 185 be amended as follows:

PART 180—[AMENDED]

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

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

b. In § 180.381, by amending paragraph (a) by revising the introductory text therein and revising paragraph (b), to read as follows:

§ 180.381 Oxyfluorfen; tolerances for residues.

(a) Tolerances are established for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the following raw agricultural commodities:

* * * * *

(b) Tolerances with regional registration are established for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the following raw agricultural commodities:

Commodity	Parts per million
Blackberry	0.05
Garbanzo beans	0.05
Guava	0.05
Papaya	0.05

Commodity	Parts per million
Taro (corms and leaves)	0.05
Raspberry	0.05

PART 185—[AMENDED]

2. In part 185:
a. The authority citation for part 185 continues to read as follows:
Authority: 21 U.S.C. 346a and 348.
b. By amending § 185.4600 by revising the introductory text to read as follows:

§ 185.4600 Oxyfluorfen.

A regulation is established permitting residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the following processed food when present therein as a result of application of the herbicide to growing crops:

* * * * *

[FR Doc. 95-24005 Filed 9-26-95; 8:45 am]

BILLING CODE 6560-50-F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List *Mimulus clivicola* (Bank Monkeyflower)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces a 12-month finding for a petition to list *Mimulus clivicola* (bank monkeyflower) pursuant to the Endangered Species Act of 1973, as amended (Act). After review of all available scientific and commercial data, the Service finds that listing this species is not warranted at this time.

DATES: The finding announced in this document was made on September 19, 1995.

ADDRESSES: Data, information, comments, or questions concerning this petition may be sent to the Field Supervisor, Portland Field Office, U.S. Fish and Wildlife Service, 2600 SE 98th Avenue, Suite 100, Portland, Oregon 97266. The petition finding, supporting data, comments, and materials received will be available for public inspection, by appointment, during normal business hours at the above address.