

List of Subjects in 40 CFR Parts 180 and 186

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

Dated: March 30, 1995.

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

Therefore, it is proposed that chapter I of title 40 of the Code of Federal Regulations be amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follow:

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

b. In § 180.412(a), by amending the table therein by revising the entry for sugar beet, roots, to read as follows:

§ 180.412 2-[1-(Ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one; tolerances for residues.

(a) * * *

Commodity	Part per million
Sugar beet, roots	1.0

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PART 186—[AMENDED]

2. In part 186:

a. The authority citation for part 186 continues to read follows:

Authority: 21 U.S.C. 348.

b. In § 186.2800, by revising the section heading and introductory text and by amending the table therein by revising the entry for sugar beet molasses, to read as follows:

§ 186.2800 2-[1-(Ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one.

Tolerances are established for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following commodities:

Food	Part per million
Sugar beet molasses	10.0

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40 CFR Parts 180, 185, and 186

[PP 9F3731 and FAP 9H5574/P612; FRL-4948-4]

RIN 2070-AC18

Cyfluthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish time-limited tolerances, with an expiration date of November 15, 1997, for residues of the synthetic pyrethroid cyfluthrin in or on the raw agricultural commodities (RAC's) tomatoes; carrots; peppers; radishes; meat, fat, and meat byproducts of cattle, goats, horses, hogs, poultry, and sheep; milkfat; and eggs and in food/feed additive commodities tomato, pomace (dry and wet) and tomato concentrated products. Miles Corp., Animal Products (formerly Mobay Corp.), requested the proposed tolerances and regulations to establish maximum permissible levels for residues of the pesticide.

DATES: Comments, identified by the document control number, [PP 9F3731 and FAP 9H5574/P612], must be received on or before May 12, 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.

Information submitted as a comment 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 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 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 200, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6100.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of March 23, 1989 (54 FR 35434), which announced that Miles Corp. had submitted pesticide petition (PP) 9F3731 and food/feed additive petition (FAP) 9H5574 to EPA.

Pesticide petition (PP) 9F3731 requests that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR 180.436 by increasing tolerances for residues of the insecticide cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)-methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on the raw agricultural commodities alfalfa forage at 5.0 ppm; alfalfa hay at 10.0 ppm; broccoli at 2.0 ppm; brussels sprouts at 0.5 ppm; cabbage at 1.0 ppm; cauliflower at 0.5 ppm; carrots at 0.1 ppm; celery at 1.5 ppm; lettuce at 2.5 ppm; peppers at 0.2 ppm; radishes at 0.5 ppm; spinach at 1.0 ppm; sweet corn at 0.05 ppm; sweet corn forage at 1.0 ppm; sunflower seed at 0.02 ppm; sunflower forage at 1.0 ppm; soybeans at 0.03 ppm; soybean forage at 10.0 ppm; soybean hay at 1.5 ppm; soybean straw at 1.0 ppm; tomato at 0.2 ppm; milk at 0.1 ppm; eggs at 0.01 ppm; meat, fat and meat byproduct of cattle, goats, hogs, horses, and sheep at 1.5 ppm; and meat, fat, and meat byproducts of poultry at 0.01 ppm.

Food/feed additive petition (FAP) 9H5574 requests that the Administrator, pursuant to section 409(e) of the FFDCA (21 U.S.C. 348(e)) amend 40 CFR parts 185 and 186 by establishing a food/feed additive regulation for cyfluthrin in or on processed food commodities tomato concentrated products at 0.5 ppm and feed commodities sweet corn (cannery wastes) at 1.5 ppm; tomato, pomace (wet) at 1.5 ppm; tomato, pomace dry at 5.0 ppm.; soybean hulls at 0.1 ppm; and sunflower hulls at 2.5 ppm.

On July 20, 1993, Miles Corp. requested that the pesticide petition and food/feed additive petition be amended by withdrawing the proposed tolerance

for broccoli, brussels sprouts, cabbage, cauliflower, celery, lettuce, soybeans (straw), spinach and the feed additive regulation for sweet corn (cannery wastes) without prejudice to future filing and by raising the tolerances for carrots, peppers, and radishes to 0.2, 0.5 and 1.5 ppm, respectively. In a letter dated November 18, 1993, Miles amended the petition by withdrawing the crops alfalfa, soybeans, sweet corn, and sunflowers from the subject petitions and proposing them under a separate petition. On June 10, 1994, Miles requested that the pesticide petition be further amended by reducing the tolerance for radishes to 1.0 ppm; proposing one tolerance for wet and dry tomato pomace; reducing the animal commodities to 0.4 ppm; and revising the milk tolerances to be expressed as 2.5 ppm milk fat (reflecting 0.08 ppm in whole milk). This amendment was submitted in response to EPA's preference that an integer tolerance (i.e., one significant figure) rather than a fraction be proposed for radishes; EPA's current practice to set one tolerance on tomato pomace, wet and dry, rather than individual tolerances on the two pomaces; and to make the above tolerances for animal commodities consistent with the feed items in this petition.

The scientific data submitted in the petition and other relevant material have been evaluated. All toxicology data necessary to support these tolerances have been previously submitted, reviewed, and accepted. The toxicology data considered in support of the proposed tolerance include:

1. A 12-month chronic feeding study in dogs with a no-observed-effect level (NOEL) of 4 mg/kg/day. The lowest-effect level (LEL) for this study is established at 16 mg/kg/day, based on slight ataxia, increased vomiting, diarrhea, and decreased body weight.

2. A 24-month chronic feeding/carcinogenicity study in rats with a NOEL of 2.5 mg/kg/day and LEL of 6.2 mg/kg/day, based on decreased body weights in males and females, decreased food consumption in males, and inflammatory foci in the kidneys in females. There were no carcinogenic effects observed under the conditions of the study.

3. A 24-month carcinogenicity study in mice. There were no carcinogenic effects observed under the conditions of the study.

4. An oral developmental toxicity study in rats with a maternal and fetal NOEL of 10 mg/kg/day (highest dose tested). An oral developmental toxicity study in rabbits with a maternal NOEL of 20 mg/kg/day and a maternal LEL of

60 mg/kg/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOEL of 20 mg/kg/day and a fetal LEL of 60 mg/kg/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

5. A developmental toxicity study in rats by the inhalation route of administration with a maternal NOEL of 0.0011 mg/L and an LEL of 0.0047 mg/L, based on reduced mobility, dyspnea, piloerection, ungroomed coats, and eye irritation. The fetal NOEL is 0.00059 mg/L and the fetal LEL is 0.0011 mg/L, based on sternal anomalies and increased incidents in runts. A second developmental toxicity study in rats by the inhalation route of administration is currently under review. The issue of whether cyfluthrin directly induces fetotoxicity under these conditions is unresolved at this time.

6. A three-generation reproduction study in rats with a systemic NOEL of 2.5 mg/kg/day and a systemic LEL of 7.5 mg/kg/day due to decreased parent and pup body weights. The reproductive NOEL and LEL are 7.5 mg/kg/day and 22.5 mg/kg/day, respectively.

7. Mutagenicity tests, including a gene mutation assay (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary (CHO)/(HGPRT)); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All test were negative for genotoxicity.

8. A metabolism study in rats showing that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

A chronic dietary exposure/risk assessment was performed for cyfluthrin using a Reference Dose (RfD) of 0.025 mg/kg bwt/day, based on a NOEL of 50 ppm (2.5 mg/kg bwt/day) and an uncertainty factor of 100. The NOEL was determined in a 2-year rat feeding study. The end-point effects of concern were decreased body weights in males and inflammation of the kidneys in females at the LEL of 150 ppm (6.2 mg/kg/day). The current estimated dietary exposure for the overall U.S. population resulting from established tolerances is 0.001378 mg/kg/bwt day, which represents 5.5 % of the RfD. The current action will increase exposure to 0.002730 mg/kg/ bwt/day or 11% of the RfD. In the subgroup population exposed to the highest risk, nonnursing infants less than 1 year old, the current action will increase exposure to 0.008044 mg/kg bwt/day or 32% of the

RfD. Generally speaking, EPA has no cause for concern if total residue contribution for published and proposed tolerances is less than the RfD. EPA concludes that the chronic dietary risk of cyfluthrin, as estimated by the dietary risk assessment, does not appear to be of concern.

Because there was a sign of developmental effects seen in animal studies, the Agency used the rat developmental toxicity study (with a NOEL of 0.00059 mg/L by the inhalation route of exposure) to assess acute dietary exposure and determine a margin of exposure (MOE) for the overall U.S. population and certain subgroups. Since the toxicological end-point pertains to developmental toxicity, the population group of concern for this analysis is women aged 13 and above, the subgroup which most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOEL to the exposure. For this analysis the Agency calculated the MOE for women ages 13 and above to be 1,250. Generally speaking, MOE's greater than 100 for data derived from animal studies are acceptable to the Agency.

The metabolism of the chemical in animals for this use is adequately understood. An adequate analytical method, gas-liquid chromatography, is available for enforcement purposes. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency 401 M St., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5232.

On August 5, 1988, EPA issued a conditional registration and time-limited tolerance for cyfluthrin for use on cottonseed with an expiration date of October 31, 1991 (see the Federal Register of August 15, 1988 (53 FR 30676)). On November 12, 1992, the conditional registration was amended and extended to November 15, 1993, and the tolerance on cottonseed extended to November 15, 1994 (see the Federal Registers October 20, 1993 (58 FR 54094) and February 22, 1994 (54 FR 9411)). On November 15, 1993, EPA amended the conditional registration on

cottonseed by extending the expiration date to November 15, 1996, and extending the time-limited tolerance to November 15, 1997. The conditional registration was amended and extended to allow time for submission and evaluation of additional environmental effects data. In order to evaluate the effects of cyfluthrin on fish and aquatic organisms and its fate in the environment, additional data were required to be collected and submitted during the period of conditional registration. Such requirements included a sediment bioavailability and toxicity study and a small-plot runoff study that must be submitted to the Agency by July 1, 1996. To be consistent with the conditional registration and extension on cottonseed, the Agency is proposing to issue a conditional registration with an expiration date of November 15, 1996, and establishing a time-limited tolerance on tomatoes, carrots, peppers, radishes, meat, milk, and egg tolerances with an expiration date of November 15, 1997, to cover residues expected to result from use during the period of conditional registration.

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

The pesticide is considered useful for the purposes for which it is sought. Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR parts 180, 185, and 186 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 FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 9F3731 and FAP 9H5574/P612]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4

p.m., Monday through Friday, except legal holidays.

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, 185, and 186

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

Dated: April 5, 1995.

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

Therefore, it is proposed that chapter I of title 40 of the Code of Federal Regulations 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. By amending § 180.436, by revising the table therein, to read as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

Commodities	Parts per million	Expiration date
Carrots	0.20	Nov. 15, 1997
Cattle, fat	0.40	Do.
Cattle, meat	0.40	Do.
Cattle, mby	0.40	Do.
Cottonseed	1.0	Do.
Eggs	0.01	Do.
Goats, fat	0.40	Do.
Goats, meat	0.40	Do.
Goats, mby	0.40	Do.
Hogs, fat	0.40	Do.
Hogs, meat	0.40	Do.
Hogs, mby	0.40	Do.
Hops, fresh	4.0	None
Horses, fat	0.40	Nov. 15, 1997
Horses, meat	0.40	Do.
Horses, mby	0.40	Do.
Milkfat (reflecting 0.08 ppm in whole milk)	2.50	Do.
Peppers	0.50	Do.
Poultry, fat	0.01	Do.
Poultry, meat	0.01	Do.
Poultry, mby	0.01	Do.
Radishes	1.00	Do.
Sheep, fat	0.40	Do.
Sheep, meat	0.40	Do.
Sheep, mby	0.40	Do.
Tomato	0.20	Do.

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. In § 185.1250, by revising paragraph (a) and removing paragraph (b) and designating it as reserved, as follows:

§ 185.1250 Cyfluthrin.

(a) A tolerance, to expire on November 15, 1997 is established for residue of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethyl)-2,2-dimethylcyclopropanecarboxylate) in or on the following food commodities:

Commodity	Parts per million	Expiration date
Cottonseed oil	2.0	Nov. 15, 1997
Tomato, concentrated products	0.5	Do.

(b) [Reserved]

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PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 348.

b. In § 186.1250, by revising paragraph (a) and removing paragraph (b) and designating it as reserved, as follows:

§ 186.1250 Cyfluthrin.

(a) A tolerance, to expire on November 15, 1997, is established for residues of the insecticide cyfluthrin

(cyano[4-fluoro-3-phenoxyphenyl]methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the following feed commodities:

Commodity	Parts per million	Expiration date
Cottonseed, hulls	2.0	November 15, 1997
Tomato, pomace (dry and wet)	5.0	Do.

(b) [Reserved]

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[FR Doc. 95-9149 Filed 4-10-95; 1:53 pm]

BILLING CODE 6560-50-F

40 CFR Part 300

[FRL-5188-1]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete Hamilton Island (Site) from the National Priorities List. Request for comments.

SUMMARY: The Environmental Protection Agency (EPA) Region 10 announces its intent to delete the Hamilton Island site from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended. EPA and the State of Washington Department of Ecology (Ecology) have determined that the Site poses no significant threat to public health or the environment and, therefore, remedial measures pursuant to CERCLA are not appropriate.

DATES: Comments concerning this Site may be submitted on or before May 12, 1995.

ADDRESSES: Comments may be mailed to: Christopher Cora, U.S. Environmental Protection Agency, 1200

Sixth Avenue, Mail Stop: HW-124, Seattle, Washington 98101.

Comprehensive information on this Site is available through the U.S. Army Corps of Engineers public docket which is available for viewing at the Hamilton Island repositories at the following locations:

North Bonneville City Hall/Community Library North Bonneville, Washington
 Bonneville Dam Second Powerhouse and Bradford Island Visitor Center, Skamania County, Washington
 U.S. Army Corps of Engineers, Portland District, 333 S.W. First Street, Portland, Oregon 97204

FOR FURTHER INFORMATION CONTACT: Christopher Cora, U.S. Environmental Protection Agency, 1200 Sixth Avenue, Mail Stop: HW-124, Seattle, Washington 98101, (206) 553-1148.

SUPPLEMENTARY INFORMATION:

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- IV. Basis of Intended Site Deletion

I. Introduction

The Environmental Protection Agency (EPA) Region 10 announces its intent to delete Hamilton Island from the National Priorities List (NPL), appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300, and requests comments on this deletion. EPA identifies sites that appear to present a significant risk to human health or the environment and maintains the NPL as a list of those sites. As described in § 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions in the unlikely event that conditions at the site warrant such actions.

EPA will accept comments on the proposal to delete this Site for thirty days after publication of this notice in the Federal Register.

Section II of this notice explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Hamilton Island Site and explains how the Site meets the deletion criteria.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that releases may be deleted from, or recategorized on the NPL where no further response is appropriate. In making a determination to delete a release from the NPL, EPA shall consider, in consultation with the state, whether any of the following criteria have been met:

- (i) Responsible parties or other persons have implemented all appropriate response actions required;
- (ii) All appropriate response under CERCLA have been implemented, and no further action by responsible parties is appropriate, or
- (iii) The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

Even if a site is deleted from the NPL, where hazardous substances, pollutants, or contaminants remain at the site above levels that allow for unlimited use and unrestricted exposure, EPA's policy is that a subsequent review of the site will be conducted at least every five years after the initiation of the remedial action at the site to ensure that the site remains protective of public health and the environment. In the case of this Site, where no hazardous wastes are above health based levels and future access does not require restriction, operation