40 CFR Parts 180 and 186

[PP 3F4204 and FAP 3H5670/R2145; FRL–4960–8]

RIN 2070–AB78

Cyfluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes time-limited tolerances with an expiration date of November 15, 1997, for residues of the synthetic pyrethroid cyfluthrin in or on the raw agricultural commodity (RAC) sugarcane at 0.05 ppm and in or on the processed feed sugarcane molasses at 0.2 ppm. Bayer Corp., Animal Products (formerly Miles Corp.), requested the regulations to establish maximum permissible levels for residues of the insecticide.

EFFECTIVE DATE: This regulation becomes effective June 28, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 3F4204 and FAP 3H5670/R2145], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted 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 copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number, [PP 3F4024 and FAP 3H5670/R2145]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this 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: 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; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of October 21, 1993 (58 FR 54353), which announced that the Bayer Corp. had submitted pesticide petition (PP) 3F4204 and feed additive petition (FAP) 3H5670 to EPA requesting that the Administrator, pursuant to sections 408(d) and 409(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) and 348(b), establish tolerances for residues of the insecticide cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)-methyl-3-(2,2-dicloroethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on the raw agricultural commodities sugarcane at 0.05 ppm and the feed commodities sugarcane bagasse (0.2 ppm) and sugarcane molasses (0.2 ppm). The proposed tolerance for sugarcane bagasse was subsequently withdrawn since bagasse in not considered a feed item.

No comments were received in response to the notice of filing.

The data base for cyfluthrin is essentially complete. Data lacking but desirable are a new 21-day subchronic dermal study, an acute neurotoxicity study in rats, and a 90-day neurotoxicity study in rats. Although these data are lacking, the Agency believes it has sufficient toxicity data to support the proposed tolerance, and these missing data will not significantly change its risk assessment. In a letter dated April 20, 1995, Bayer Corp. has committed to submit the 21-day subchronic dermal study by June 1996, the acute neurotoxicity study by December 1996, and the 90-day neurotoxicity study by May 1997.

In addition, the Agency is requiring submission of a processing study for blackstrap molasses. The submitted sugarcane processing studies show that only molasses was produced. No residue data were submitted for blackstrap molasses. In commercial processing, as molasses is further concentrated to recover more sugar, blackstrap is produced. Although blackstrap is an animal feed commodity (about 10% of diet), minor amounts can enter the human diet. In a letter dated January 25, 1995, Bayer Corp. submitted additional information confirming that residues of cyfluthrin do not concentrate in molasses. Thus it is unlikely residues will be concentrated in blackstrap. However, Bayer Corp has initiated an additional sugarcane processing study to obtain residue data for blackstrap which will be submitted by December 31, 1996. In the interim, Bayer Corp. proposes that the 0.2 ppm tolerance in molasses should cover any potential for the concentration of residues in blackstrap.

Based upon the submitted data in molasses, the Agency does not believe that residues will concentrate in blackstrap; however, since there is a potential for concentration, the Agency will establish a time-limited tolerance in molasses. After submission and evaluation of the blackstrap processing study, the Agency will determine the need for a permanent feed additive tolerance.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicology data submitted in support of the 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 resorption 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 incidence of 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 several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary(CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All tests 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 no-observed-effect level (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 endpoint 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 0.002730 mg/kg/bwt day, which represents 11% of the RfD. Established tolerances utilize 32% of the RfD in the subgroup population with the highest exposure levels, nonnursing infants less than 1-year old. The proposed use on sugarcane would not significantly contribute to the dietary exposure of the overall U.S. population or nonnursing infants. 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 rabbit developmental toxicity study with a maternal NOEL of 20 mg/kg/day 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 established tolerances of 0.40 ppm for residues of cyfluthrin in/on fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep and 0.01 ppm in/on fat, meat, and meat byproducts of poultry and eggs are adequate to cover secondary residues resulting from the proposed use as delineated in 40 CFR 180.6(a)(2).

The metabolism of cyfluthrin in plants and livestock for this use is adequately understood. The residue of concern is cyfluthrin per se. 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** of 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 timelimited 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 establish a time-limited tolerance on sugarcane and sugarcane molasses with an expiration date of November 15, 1997, to cover residues expected to result from use during the period of conditional registration.

Residues remaining in or on the above commodities after expiration of these tolerances will not be considered actionable if the pesticide is legally applied during the term of and in accordance with provisions of the conditional registration.

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

The pesticide is considered useful for the purposes for which it is sought and capable of achieving its intended physical or technical effect. 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 and that use of the pesticide in accordance with the tolerance established by amending 40 CFR part 186 would be safe. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing

requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 3F4204 and FAP 3H5670/R2145] (including objections and hearing requests 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.

Written objections and hearing requests, identified by the document control number [PP 3F4204 and FAP 3H5670/R2145], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk 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 any objections and hearing requests 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 objections and hearing requests 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, October 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, or establishing or raising food additive regulations 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 186

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

Dated: June 9, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

1. In part 180:

a. The authority citation of part 180 continues to read as follows:

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

b. By amending § 180.436 in the table therein, by adding and alphabetically inserting an entry for the commodity sugarcane, to read as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

* * * * *

Commodity	Parts per million	Expiration date
* * * * *		
Sugarcane	0.05	Do.
* * * * *		

PART 186—[AMENDED]

2. 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 amending paragraph (a) in the table therein by adding and alphabetically inserting an entry for the commodity sugarcane molasses as follows:

§ 186.1250 Cyfluthrin.

(a) * * *

Commodity	Parts per million	Expiration date
* * * * *		
Sugarcane, molasses	0.2	Do.
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[FR Doc. 95–15578 Filed 6–27–95; 8:45 am]

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