

not subject to OMB review under the Executive Order.

#### B. Unfunded Mandates Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) requires that the Agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year. Section 203 requires the Agency to establish a plan for obtaining input from and informing, educating, and advising any small governments that may be significantly or uniquely affected by the rule.

Under section 205 of the Unfunded Mandates Act, the Agency must identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a budgetary impact statement must be prepared. The Agency must select from those alternatives the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule, unless the Agency explains why this alternative is not selected or the selection of this alternative is inconsistent with law.

This order merely extends the current reclamation requirements for a very limited time. Therefore, there are no mandates to the states.

#### C. Paperwork Reduction Act

There is no additional information collection requirements associated with this order; therefore, EPA has determined that the Paperwork Reduction Act does not apply. The initial § 608 final rulemaking did address all recordkeeping associated with the refrigerant purity provisions. An Information Collection Request (ICR) document was prepared by EPA and approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. This ICR is contained in the public docket A-92-01.

#### D. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601-602, requires that Federal agencies examine the impacts of their regulations on small entities. Under 5 U.S.C. 604(a), whenever an agency is required to publish a general notice of proposed rulemaking, it must prepare and make available for public comment an initial regulatory flexibility analysis (RFA). Such an analysis is not required if the head of an agency certifies that an action will not have a significant

economic impact on a substantial number of small entities, pursuant to 5 U.S.C. 605(b).

EPA believes that since this action merely extends a current requirement designed to protect purity of refrigerants temporarily, there will be no adverse effects for the regulated community, including small entities. An examination of the impacts of these provisions was discussed in the initial final rule promulgated under § 608 (58 FR 28660). That final rule assessed the impact the rule may have on small entities. A separate regulatory impact analysis was developed. That impact analysis accompanied the final rule and is contained in Docket A-92-01.

I certify that this temporary order will not have any additional negative economic impacts on any small entities.

#### List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Hydrochlorofluorocarbons, Interstate commerce, Reporting and reclamation, Reporting and recordkeeping Requirements, Refrigerant purity, Recycling, Stratospheric ozone layer.

Dated: March 11, 1996.

Carol M. Browner,  
*Administrator.*

Part 82, chapter I, title 40, of the Code of Federal Regulations, is amended to read as follows:

#### PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671-7671q.

2. Section 82.154 is amended by revising paragraphs (g) and (h) to read as follows:

#### § 82.154 Prohibitions.

\* \* \* \* \*

(g) Effective from March 15, 1996 until no later than May 30, 1996, no person may sell or offer for sale for use as a refrigerant any class I or class II substance consisting wholly or in part of used refrigerant unless:

(1) The class I or class II substance has been reclaimed as defined at § 82.152;

(2) The class I or class II substance was used only in an MVAC or MVAC-like appliance and is to be used only in an MVAC or MVAC-like appliance; or

(3) The class I or class II substance is contained in an appliance that is sold or offered for sale together with the class I or class II substance.

(h) Effective from March 15, 1996 until no later than May 30, 1996, no person may sell or offer for sale for use as a refrigerant any class I or class II substance consisting wholly or in part of used refrigerant unless:

(1) The class I or class II substance has been reclaimed by a person who has been certified as a reclaimer pursuant to § 82.164;

(2) The class I or class II substance was used only in an MVAC or MVAC-like appliance and is to be used only in an MVAC or MVAC-like appliance; or

(3) The class I or class II substance is contained in an appliance that is sold or offered for sale together with the class I or class II substance.

\* \* \* \* \*

[FR Doc. 96-6219 Filed 3-14-96; 8:45 am]

BILLING CODE 6560-50-P

#### 40 CFR Parts 180

[PP 4F4309/R2216; FRL-5354-9]

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 commodities (RAC's) alfalfa, sunflowers, and fat of cattle, goats, horses, hogs, and sheep; and an expiration date of July 5, 1999 for residues of cyfluthrin in or on sweet corn. The proposed tolerances and regulations to establish a maximum permissible level for residues of the pesticide was requested in a petition submitted by Bayer Corp. (formerly Miles Corp.).

**EFFECTIVE DATE:** This regulation becomes effective March 15, 1996.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 4F4309/R2216], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. 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. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 4F4309/R2216]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic 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 public notice, published in the Federal Register of July 13, 1994 (59 FR 35719), which announced that Bayer Corp. had submitted pesticide petition (PP) 4F4309 and feed additive petition (FAP) 4H5686 to EPA.

Pesticide petition (PP) 4F4309 requests that the Administrator, pursuant to sections 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) and 348(b), amend 40 CFR 180.436 by establishing 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 (RACs) sweet corn, forage at 54.0 ppm; alfalfa, hay at 10.0 ppm; soybean, forage at 10.0 ppm; alfalfa, forage at 5.0 ppm; soybean, hay at 1.5 ppm; sunflower, forage at 1.0 ppm; sweet corn at 0.05

ppm; soybeans at 0.03 ppm and sunflower, seed at 0.02 ppm.

Food/feed additive petition (FAP) 4H5686 requests that the Administrator pursuant to section 409(e) of the FFDCA (21 U.S.C. 348(e)) amend 40 CFR 186.1250 by establishing a food/feed additive regulation for cyfluthrin in or on sunflower hulls at 2.5 ppm and soybean hulls at 0.1 ppm.

On September 18, 1995, Bayer Corp. requested (60 FR 64059, December 13, 1995) that the pesticide petition (4F4309) be amended by decreasing the proposed tolerances on sweet corn forage from 54.0 ppm to 30.0 ppm; increasing tolerances for fat of cattle, goats, hogs, horses and sheep from 0.05 ppm to 5.0 ppm; establishing a tolerance of 15.0 ppm for milkfat (representing 0.5 ppm in whole milk); and withdrawing proposed tolerances for soybean forage, soybean hay, and soybeans; and the food/feed additive regulation petition (3H5686) for sunflower hulls at 2.5 ppm and soybeans hulls at 0.1 ppm without prejudice to future filing. On November 3, 1995, Bayer Corp. requested that the pesticide petition (4F4309) be further amended by reducing the tolerances for fat of cattle, goats, hogs, horses and sheep from 5.0 ppm to 1.0 ppm; and withdrawing the tolerance for milkfat. An increased milkfat tolerance was established in (59 FR 53130, May 31, 1995) at 2.5 ppm (reflecting 0.08 ppm in whole milk) which adequately addresses secondary tolerances for this proposed action. This amendment also addressed EPA's preference for the sweet corn tolerance to be expressed in terms of kernel plus cob with husk removed (K+CWHR).

There were no comments or requests to the advisory committee received in response to the initial and amended notices 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 and a dermal sensitization study on the end use product Baythroid 2. 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. On October 12, 1995, Bayer Corp submitted to the Agency a dermal sensitization study on Baythroid 2.

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, 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 3-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 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 0.003403 mg/kg bwt/day, which represents 13.6% of the RfD. The current action will increase exposure to 0.003766 mg/kg/bwt/day of 15% of the RfD. The current estimated dietary exposure for the subgroup population exposed to the highest risk, non-nursing infants less than 1 year old, is 0.010622 mg/kg bwt/day, which represents 42.5% of the RfD. The current action will increase exposure to 0.010850 mg/kg bwt/day or 43.4% 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 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 666. Generally speaking, MOE's greater than 100 for data derived from animal studies are regarded as showing no appreciable risk.

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 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 establish a time-limited tolerance on alfalfa (forage and hay), sunflowers (forage and hay) and livestock animal commodities with an expiration date of November 15, 1997, to cover residues expected to result from use during the period of conditional registration.

On July 5, 1995 EPA issued a conditional registration and time-limited tolerance for cyfluthrin use in or on corn (field, pop and sweet) in combination with another insecticide *O*-[2-(1-dimethylethyl)-5-pyrimidinyl]*O*-ethyl-*O*-(1-methylethyl)phosphorothioate with an expiration date of July 5, 1999. See the Federal Register of Wednesday, July 5, 1995 (60 FR 34874). Because of the lack of mammalian neurotoxicity studies for the other insecticide, the Agency limited the period of time that the regulation is to be in effect to allow time for submission and evaluation of the data. To be consistent with the conditional registration and the regulation for establishing a time-limited tolerance for the other insecticide, the Agency is issuing a time-limited tolerance with an expiration date of July 5, 1999 for residues of cyfluthrin in or on sweet corn, forage and fodder.

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 4F4309/R2216] (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 4F4309/R2216], 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 Part 180

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

Dated: March 6, 1996.

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]**

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

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

b. In § 180.436, the table to paragraph (a) by adding alphabetically entries for "alfalfa, forage", "alfalfa, hay", "sunflower, forage", and "sunflower, seed", and by revising the entries "cattle, fat", "goats, fat", "hogs, fat", "horses, fat", and "sheep, fat", and in paragraph (b) by revising the table, to read as follows:

**§ 180.436 Cyfluthrin, tolerances for residues.**

(a) *				
Commodity	Parts per million		Expiration date	
*	*	*	*	*
Alfalfa, forage .....	5.00		Nov. 15, 1997	
alfalfa, hay .....	10.00		Do.	
Cattle, fat .....	1.00		Do.	
Goats, fat .....	1.00		Do.	
Hogs, fat .....	1.00		Do.	
Horses, fat .....	1.00		Do.	
Sheep, fat .....	1.00		Do.	
Sunflower, forage ..	1.00		Do.	
Sunflower, seed ....	0.02		Do.	
*	*	*	*	*

(b) *				
Commodity	Parts per million		Expiration date	
Corn, forage and fodder, field and pop .....	0.01		July 5, 1999	
Corn, grain, field and pop .....	0.01		Do.	
Corn, sweet, (K+CWHR) ....	0.05		Do	
Corn, sweet, fodder .....	15.00		Do.	
Corn, sweet, forage .....	30.00		Do.	

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**40 CFR Part 180**

[PP 5F4549/R2213; FRL-5354-6]

RIN 2070-AB78

**Pesticide Tolerances for Dimethenamid**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes tolerances for residues of the herbicide,