IV. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: July 27, 2000.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.466 [Amended]

2. In § 180.466, amend the table in paragraph (b) by revising the date under the heading ''Expiration/Revocation Date'', ''6/30/00'' to read ''12/31/01'' wherever it appears.

[FR Doc. 00–19661 Filed 8–8–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301025; FRL–6597–7]

RIN 2070–AB78

Carfentrazone-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of carfentrazone-ethyl and its metabolite carfentrazone-chloropropionic acid in or on the cereal grain crop group. In addition, the tolerance expression for the commodity corn, field, forage established in 40 CFR 180.515(a) is being raised from 0.1 parts per million (ppm) to 0.2 ppm to harmonize with the proposed tolerance on corn, sweet, forage under the cereal grain crop group. FMC Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 9, 2000. Objections and requests for hearings, identified by docket control number OPP–301025, must be received by EPA on or before October 10, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301025 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6224; and e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**-Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301025. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of January 30, 1998 (63 FR 4631) (FRL–5766–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition for tolerance by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103. This notice included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.515 be amended by establishing a tolerance for residues of the herbicide carfentrazone-ethyl, (ethyl-alpha-2-dichloro-5-[-4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate), in or on cereal grain at 0.1 ppm; in or on hay at 0.3 ppm; in or on straw at 0.2 ppm; in or on forage at 1.0 ppm; in or on stover at 0.15 ppm; and in or on sweet corn, K + CWHR (kernels plus cob with husk removed) at 0.1 ppm, and in or on the raw agricultural commodities (RACs) soybeans and soybean seed at 0.1 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of carfentrazone-ethyl and its metabolite carfentrazone-chloropropionic acid in or on grain, cereal, group at 0.1 ppm; grain, cereal, forage (excluding corn and sorghum) at 1.0 ppm; grain, cereal, straw (excluding rice) at 0.1 ppm; grain, cereal, stover at 0.3 ppm; grain, cereal, hay at 0.3 ppm; corn, field, forage at 0.2 ppm; corn, sweet, forage at 0.2 ppm; sorghum, forage at 0.2 ppm; rice, straw at 1.0 ppm; corn, sweet, kernel plus cob with husk removed at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by carfentrazone-ethyl are discussed in this unit.

1. A battery of acute toxicity studies places the technical-grade herbicide in Toxicity Categories III and IV. No evidence of sensitization was observed following dermal application in guinea pigs.

2. A 90-day subchronic feeding study was conducted in rats at intake levels of 0, 58, 226, 470, 831 and 1,197 milligrams/kilograms/day (mg/kg/day) for males and 0, 72, 284, 578, 1,008 and 1,427 mg/kg/day in females, respectively. The no observed adverse effect level (NOAEL) was 226 mg/kg/day in males and 284 mg/kg/day in females. The lowest observed adverse effect level (LOAEL) was 470 mg/kg/day in males and 578 mg/kg/day in females based on decreases in body weight, reductions in food consumption and histopathological lesions.

3. A 90-day subchronic feeding study was conducted in mice at dietary intake doses of 0, 143, 571, 1,143, 2,000, and 1,857 mg/kg/day. The LOAEL was 1,143 mg/kg/day based on findings in the liver

pathology. The NOAEL was 571 mg/kg/day.

4. A 90-day subchronic feeding study in dogs administered by dietary intake doses of 0, 50, 150, 500 and 1,000 mg/kg/day. The NOAEL was 50 mg/kg/day and the LOAEL was 150 mg/kg/day based on systemic toxicity (decrease in the rate of weight gain in females and an increase in porphyrin levels in both sexes).

5. An 18-month mouse carcinogenicity study was conducted in mice at dietary intake doses of 0, 10, 110, and 1,090 mg/kg/day for males and 0, 12, 119, and 1,296 mg/kg/day for females. The study found the compound to be noncarcinogenic to mice under the conditions of the study. The systemic NOAEL was 70 ppm (equivalent to 10 mg/kg/day for males and 12 mg/kg/day for females), and the systemic LOAEL was 700 ppm (equivalent to 110 mg/kg/day for males and 119 mg/kg/day for females) based on increased mortality and microscopic signs of hepatotoxicity.

6. A 2-year rat chronic toxicity/carcinogenicity study was conducted in rats at intake levels of 0, 2, 9, 37, and 188 mg/kg/day for males and 0, 3, 12, 49, and 242 mg/kg/day for females. The study found the compound to be noncarcinogenic to rats under the conditions of the study. The NOAEL was 200 ppm (9 mg/kg/day) for males and 50 ppm (3 mg/kg/day) for females. The LOAEL was 800 ppm (37 mg/kg/day) for males and 200 ppm (12 mg/kg/day) for females, based on liver histopathology and total urinary porphyrin.

7. A 1–year feeding study in dogs dosed at levels of 0, 50, 150, 500, and 1,000 mg/kg/day in both sexes with a NOAEL of 50 mg/kg/day and a LOAEL of 150 mg/kg/day, based on an increase mean total urinary porphyrins.

8. A developmental toxicity study in rats was conducted in rats at dose levels of 0, 100, 600, and 1,250 mg/kg/day in females, with a maternal LOAEL of 600 mg/kg/day based on staining of the abdominogenital area and a maternal NOAEL of 100 mg/kg/day; a developmental LOAEL of 1,250 mg/kg/day based upon a significant increase in the litter incidences of wavy and thickened ribs; and a developmental NOAEL of 600 mg/kg/day.

9. A developmental toxicity study in rabbits was conducted at gavage dose levels of 0, 10, 40, 150, and 300 mg/kg/day. Evidence of treatment-related maternal toxicity consisted of unthriftiness and emaciation in two does at 300 mg/kg/day. There were no treatment-related mortalities or gross pathological findings. No effects on body weight, body weight change, or organ weight data were identified at any treatment level. However, when considered in conjunction with the findings of the two pilot dose-setting studies, which were conducted at higher dose levels and which identified a steep dose-response curve with maternal mortality occurring at doses of 350 mg/kg/day and above, it was determined that 300 mg/kg/day provided an adequate high-dose assessment of maternal toxicity in rabbits. The maternal toxicity NOAEL is greater than/equal to 150 mg/kg/day and maternal LOAEL of 300 mg/kg/day. There was no evidence of treatment-related prenatal development toxicity, the developmental LOAEL was not determined and the developmental NOAEL is greater than/equal to 300 mg/kg/day.

10. A 2-generation reproduction study in the rat at dietary levels of 0, 8.6, 42.4, 127, 343 mg/kg/day for males, and 0, 9.5, 47.8, 142, and 387 mg/kg/day for females established a parental NOAEL for systemic and reproductive/developmental parameters of 127 mg/kg/day for males and 142 mg/kg/day for female. The parental LOAEL for systemic and reproductive development parameters was 343 mg/kg/day for males and 387 mg/kg/day for females. There was no systemic toxicity demonstrated at dose levels of less than/equal to 1,500 ppm. There were no treatment-related clinical signs of toxicity or increases in mortality at any dose levels. The offspring NOAEL was 142 mg/kg/day and the LOAEL was 387 mg/kg/day. The NOAEL for reproductive toxicity was greater than/equal to 387 mg/kg/day; the highest dose tested. There were no clinical signs of toxicity reported for the pups of either generation.

11. In an acute neurotoxicity study in rats at gavage doses of 0, 500, 1,000, and 2,000 mg/kg, a NOAEL of 500 mg/kg and a LOAEL of 1,000 mg/kg were based upon clinical observations (i.e., salivation) and motor activity. There was no evidence of neuropathology.

12. A 90-day subchronic neurotoxicity study in the rat was conducted at dietary levels of 0, 59, 603, and 1,178 mg/kg/day for males and 0, 71, 718, and 1,434 mg/kg/day for females, with a NOAEL of 59 mg/kg/day for males and 71 mg/kg/day for females. The LOAEL was 603 mg/kg/day for males and 718 mg/kg/day for females based on decreased body weight.

13. Two reverse gene mutation assays (*salmonella typhimurium*) at dose yielded negative results, both with and without metabolic activation.

14. An *in vitro* mammalian cell forward gene mutation assay in CHO cells yielded negative results both with and without activation.

15. An *in vitro* chromosomal abberation assay yielded positive results under nonactivated conditions following doses of 3.75, 12.5, 37.5, and 125 micrograms/milliliter (mu;g/mL). There were consistent and statistically significant increased incidences of cells with aberrations at 125 mu;g/mL, the highest dose tested in the absence of metabolic activation.

16. An *in vivo* mouse micronucleus cytogenic assay test was negative for clastogenic and/or aneugenic activity, following intraperitoneal injection doses of 600, 1,200, and 2,400 mg/kg. Dosed animals showed no reduction in the ratio of polychromatic erythrocytes to total erythrocytes. There was no evidence of polychromatic erythrocytes associated with exposure to the test material.

17. An unscheduled *in vivo/in vitro* DNA synthesis assay was negative following a single IP injection doses of 750, 1,500, 3,000 mg/kg. Slight lethargy was seen in the high dose animals. Higher levels (4,000 mg/kg/) were lethal in a preliminary study. Cytotoxicity for the hepatocytes was not apparent at any dose. The results obtained with the positive controls confirmed the sensitivity of the test system to detect unscheduled DNA synthesis (UDS). There was, however, no evidence that the test material induced agenotoxic response at any dose or sacrifice time.

18. A metabolism study in rats indicated that approximately 72.4 to 87% of the administered dose of carfentrazone-ethyl was rapidly absorbed and excreted in the urine within 24 hours after dosing. The major metabolites in both the urine and feces were F8426-chloropropionic acid (48.4 to 66.06%). The proposed metabolic pathway appeared to be the conversion of the parent compound by hydrolysis of the ester moiety to form F8426-chloropropionic acid, followed by oxidative hydroxylation of the methyl group to form 3-hydroxymethyl-F8426-chloropropionic acid, or dehydrochlorination to form F8426-cinnamic acid.

B. Toxicological Endpoints

1. *Acute toxicity.* The acute population adjusted dose (aPAD) is based on the acute neurotoxicity study in rats. The NOAEL of 500 mg/kg/day, was based on clinical observations (i.e., salivation) and decreased motor activity at the LOAEL of 1,000 mg/kg/day. The aPAD of 5 mg/kg/day is based on interspecies extrapolation (10x), intraspecies variability (10x), and the FQPA 1x factor.

2. *Short- and intermediate-term toxicity.* No systemic toxicity was seen at the limit-dose 1,000 mg/kg/day in a 21-day dermal toxicity study in rats.

3. *Chronic toxicity.* The chronic PAD (cPAD) is based on a 2-year chronic toxicity study in rats. The NOAEL of 3 mg/kg/day was based on liver histopathology (increases in microscopic red fluorescence of the liver, liver pigment) and total mean urinary porphyrin observed at the LOAEL of 12 mg/kg/day. The cPAD of 0.03 mg/kg/day is based on interspecies extrapolation (10x), intraspecies variability (10x), and the FQPA 1x factor.

4. *Carcinogenicity.* EPA classified carfentrazone-ethyl as a ''not likely'' human carcinogen according to EPA's Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996).

C. Exposures and Risks

1. *From food and feed.* Tolerances have been established (40 CFR 180.515) for the combined residues of carfentrazone-ethyl and its chloropropionic acid, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures in food from carfentrazone-ethyl as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The acute dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM TM ver. 7.075) and consumption data from the U.S. Department of Agriculture (USDA) 1989–92 Nationwide Continuing Surveys of Food Intake by Individuals (CSF II). The acute analysis assumed tolerance level residues and 100% crop treated for all registered and proposed uses. The acute dietary food exposure estimates to carfentrazone-ethyl were less than the Agency's level of concern (less than 100% aPAD) for the general U.S. population and all population subgroups.

ii. *Chronic exposure and risk.* A chronic dietary exposure analysis was conducted using the Dietary Exposure Evaluation Model (DEEM TM ver. 7.075) and consumption data from the USDA 1989–92 Nationwide Continuing Surveys of Food Intake by Individuals (CSF II). The chronic analysis assumed tolerance level residues and 100% crop treated for all registered and proposed uses. The chronic dietary food exposure estimates to carfentrazone-ethyl, for all population subgroups, were less than the Agency's level of concern (less than 100% cPAD).

2. *From drinking water.* Carfentrazone-ethyl breaks down rapidly in the environment to carfentrazone-chloropropionic acid (F8426–ClPAc). The chloropropionic acid degradate subsequently breaks down to F8426-cinnamic acid, F8426-propionic acid, F8426-benzoic acid, and 3-hyroxymethyl-F8426-benzoic acid at slower rates than the parent compound. Aquatic dissipation and anerobic soil metabolism studies suggest that residues in the subsurface may be longer lived than residues in surface water. Ground and surface water estimated environmental concentrations (EECs) for carfentrazone-ethyl and degradates (F8426-cinnamic acid, F8426-propionic acid, F8426-benzoic acid, and 3-hyroxymethyl F8426-benzoic acid) were generated using screening models GENEEC (surface water) and SCI–GROW (ground water). Both models assumed an application rate of 0.031 lbs ai/acre. The surface water estimates are 1.69 µg/L; peak concentration (0.65 µg/L; 56-day average). The ground water estimate is 6.55 µg/L. Carfentrazone-ethyl may also be applied to flooded rice fields and the treated water subsequently released to surface water. Based on the aquatic dissipation study submitted by the petitioner, the concentration of carfentrazone-ethyl and degradates on day zero was 409 µg/L. The time weighted average of carfentrazone-ethyl plus degradates in treated rice water was 14.2 µg/L. Assuming a two-fold dilution of paddy water into receiving waters, the acute and chronic surface water concentration for carfentrazone-ethyl and its degradates, as a result of the application to a flooded rice field, are 205 µg/L and 7.1 µg/L.

i. *Acute exposure and risk.* For the acute scenario, the drinking water levels of comparison (DWLOCs) are 170,000, 50,000, 50,000 and 50,000 parts per billion (ppb) for the U.S. population, all infants (less than 1 year), children (1–6 years), and children (7–12 years), respectively.

ii. *Chronic exposure and risk.* For the chronic scenario, the DWLOCs are 1,000, 290, 290, and 290 ppb for the U.S. population, all infants (less than 1 year), children (1–6 years), and children (7–12 years), respectively.

3. *From non-dietary exposure.* There are no registered or proposed residential uses for carfentrazone-ethyl.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether carfentrazone-ethyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, carfentrazone-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that carfentrazone-ethyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

Aggregate exposures are calculated by summing dietary (food and water) and residential exposures. Carfentrazone-ethyl is not registered for residential uses. Therefore aggregate exposures are only concerned with food and water. Since EPA does not have ground and surface water monitoring data to calculate a quantitative aggregate exposure, drinking water levels of comparison (DWLOC) were calculated. The DWLOC is the theoretical upper limit of a chemical's concentration in drinking water that will result in an aggregate exposure less than a specified PAD. The DWLOC is used as a point of comparison against model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water.

1. *Acute risk.* The acute dietary exposure analysis assumed tolerance level residues and 100% crop treated for all registered and proposed commodities (Tier 1). Dietary exposures from food for all population subgroups were less than 1% of the aPAD. The DWLOC for the U.S. population is 170,000 ppb. The EECs for surface water (205 ppb) and ground water (6.6 ppb) are less than the DWLOC. Therefore, acute exposure to carfentrazone-ethyl, as a result of all registered and proposed uses, is below the Agency's level of concern.

2. *Chronic risk.* The chronic dietary exposure analysis assumed tolerance level residues and 100% crop treated for

all registered and proposed commodities (Tier 1). Dietary exposures from food for all population subgroups were less than or equal to 3% of the cPAD. The DWLOC for the U.S. population is 1,000 ppb. The EECs for surface water (7.1 ppb) and ground water (6.6 ppb) are less than the DWLOC. Therefore, chronic exposure to carfentrazone-ethyl, as a result of all registered and proposed uses, is below the Agency's level of concern.

3. *Short- and intermediate-term risk.* The Agency concludes with reasonable certainty that residues of carfentrazone-ethyl and its chloropropionic acid metabolite would not result in unacceptable levels of short- and intermediate-term human health risk. There are no residential uses or exposure scenarios and no toxicological endpoints were identified for short- and intermediate-term exposure scenarios.

4. *Aggregate cancer risk for U.S. population.* Carfentrazone-ethyl is classified as a ''not likely'' human carcinogen according to EPA's Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996).

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to carfentrazone-ethyl residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of carfentrazone-ethyl, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Prenatal and postnatal sensitivity.* There was no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to the chemical. The toxicological data base is complete.

iii. *Conclusion.* There is a complete toxicity data base for carfentrazone-ethyl, and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that a 10x safety factor was not required. The rationale is based on the following: there was no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to the chemical; the toxicological data base is complete; and the fact that there are no registered residential products, in conjunction with the use of generally high quality data, conservative models and/or assumptions in the exposure assessment provide adequate protection for infants and children.

2. *Acute risk.* Dietary exposure for all of the population subgroups were less than 1% of the aPAD. Surface water and ground water EECs for all population subgroups were 205.0 and 6.6 ppb, respectively. The acute DWLOC for the subgroups: All infants (less than 1–year), children (1–6 years), children (7–12 years) was 50,000 ppb. Since the EECs are less than the DWLOC, acute exposure to carfentrazone-ethyl, as a result of all registered and proposed uses, is below the Agency's level of concern.

3. *Chronic risk.* Dietary exposure for all of the population subgroups were less than 3% of the cPAD. Surface water and ground water EECs for all population subgroups were 7.1 and 6.6 ppb, respectively. The chronic DWLOC for the subgroups: All infants (less than 1–year), children (1–6 years) and children (7–12 years) was 290 ppb. Since the EECs are less than the DWLOC, chronic exposure to carfentrazone-ethyl, as a result of all registered and proposed uses, is below the Agency's level of concern.

4. *Short- or intermediate-term risk.* There are no residential uses or exposure scenarios and no toxicological endpoints were identified for short- and intermediate-term exposure scenarios.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to carfentrazone-ethyl residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

Metabolism studies performed on soybeans, corn, wheat, lactating goats, and laying hens were previously reviewed and presented to the Metabolism Assessment and Review Committee (MARC). The MARC determined that considering the crops for which the petitioner was requesting registration (corn, wheat, soybeans), the appropriate tolerance expression for livestock and plant commodities was carfentrazone-ethyl and its chloropropionic acid metabolite (F8426–ClPAc). In addition, these two compounds were sufficient for the dietary risk assessment. However, since the hydroxyl metabolite, 3–OH–F8426–Cl–PAc, was found as the major residue in soybean forage and hay, the registrant was instructed to monitor for this metabolite in all field trials of additional future crops.

B. Analytical Enforcement Methodology

There is a practical method for detecting and measuring levels of carfentrazone-ethyl and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. The proposed analytical method for determining residues is hydrolysis followed by gas chromatography with electron capture detection for the parent, and hydrolysis and derivitization followed by gas chromatography with mass selective detection for the metabolites.

The method may be requested from: The Analytical Chemistry Branch (ACB), BEAD (7503C), Environmental Science Center, 701 Mapes Road, Fort George G. Meade, MD 20755–5350; contact Francis D. Griffith, Jr. telephone (410) 305–2905, e-mail: griffith.francis@epa.gov. The analytical standards for these methods are also available from the EPA National Pesticide Standard Repository at the same location.

C. Magnitude of Residues

The residue data submitted support the establishment of the following tolerances; grain, cereal, group at 0.10 ppm; grain, cereal, forage (excluding corn and sorghum) at 1.0 ppm; grain,

cereal, straw (excluding rice) at 0.10 ppm; grain, cereal, stover at 0.30 ppm; grain, cereal, hay at 0.30 ppm; corn, field, forage at 0.20 ppm; corn, sweet, forage at 0.20 ppm; sorghum, forage at 0.20 ppm; rice, straw at 1.0 ppm; corn, sweet, kernel plus cob with husk removed at 0.10 ppm.

D. International Residue Limits

There are no Codex, Canadian, or Mexican tolerances or maximum residue limits established for carfentrazone-ethyl in/on cereal grains. There are no compatibility problems that exists between the proposed U.S. and Codex tolerances.

E. Rotational Crop Restrictions

Based on the confined accumulation in rotational crops study, the MARC determined that the carfentrazone-ethyl and F8426–CIPAc are the residues of concern in rotational crops. The committee also expressed concern for the residues of the benzoic acid compounds if the levels found are similar to or greater than the parent and the metabolite. The confined rotational crop study demonstrated that the combined residues of carfentrazone-ethyl and the chloropropionic acid metabolite were less than 0.01 ppm at all plant-back intervals for lettuce, radishes, wheat grain, and wheat forage. Parent was found at detectable levels in wheat straw at 32 days after treatment (DAT: 0.012–0.013 ppm) and at 277 DAT (0.017–0.048 ppm). Based on the confined rotational crop study, the labeling will require the following rotational crop restrictions are appropriate: soybean and cereal grains—no waiting period, root and leafy vegetables—30 days; all other crops—12 months.

V. Conclusion

Therefore, the tolerances are established for combined residues of carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[-4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1yl]-4-fluorobenzene-propanoate) and its metabolite: carfentrazone-chloropropionic acid (alpha, 2-dichloro-5-[4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-yl]-4-fluorobenzenepropanoic acid) in or on grain, cereal, group at 0.10 ppm; grain, cereal, forage (excluding corn and sorghum) at 1.0 ppm; grain, cereal, straw (excluding rice) at 0.10 ppm; grain, cereal, stover at 0.30 ppm; grain, cereal, hay at 0.30 ppm; corn, field, forage at 0.20 ppm; corn, sweet, forage at 0.20 ppm; sorghum, forage at 0.20 ppm; rice, straw at 1.0 ppm; corn, sweet, kernel plus cob with husk removed at 0.10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301025 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 10, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301025, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: Opp-docket@epa.gov. Please use an ASCII file format and avoid 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 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy.

You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register.** This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: July 20, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. In § 180.515, by revising paragraph (a) to read as follows:

§ 180.515 Carfentrazone-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[-4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]-4-fluorobenzene propanoate) and its metabolite: carfentrazone-chloropropionic acid (alpha, 2-dichloro-5-[-4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid) in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.20
Corn, sweet, forage	0.20
Corn, sweet, kernel plus cob with husk removed	0.10
Grain, cereal, forage (excluding corn and sorghum)	1.0
Grain, cereal, hay	0.30
Grain, cereal, group	0.10
Grain, cereal, stover	0.30
Grain, cereal, straw (excluding rice)	0.10
Rice, straw	1.0
Sorghum, forage	0.20

* * * * *

[FR Doc. 00–19793 Filed 8–8–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301033; FRL–6599–2]

RIN 2070–AB78

Pymetrozine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pymetrozine 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene)amino] in or on cucurbit vegetables (Crop Group 8) at 0.05 parts per million (ppm) and fruiting vegetables (Crop Group 9) at 0.05 ppm. Novartis Crop Protection, Inc. of Greensboro, NC 27419 requested this