a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. 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 the rule in the **Federal Register**. This 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: September 22, 1998.

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. 346a and 371.

2. In § 180.482 by adding alphabetically an entry for ''cranberries,'' to the table in paragraph (b) to read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* ***

Commodity	Parts per million	Expiration/ Revocation Date
* * *	*	*
Cranberries	0.5	9/30/99
* * *	*	*

* * * * *

[FR Doc. 98–26001 Filed 9–29–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300718; FRL–6032–1]

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 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-ethyl chloropropionic acid (alpha, 2-dichloro-5–[4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-l-y]-4-fluorobenzenepropanoic acid) in or on these raw agricultural commodities: corn, field, grain at 0.1ppm; corn, field, forage at 0.1ppm; corn, field, fodder at 0.1 ppm; soybean seed at 0.1 ppm; wheat grain at 0.1 ppm; wheat forage at 1.0 ppm; wheat hay at 0.3 ppm; and wheat straw at 0.2 ppm. FMC Corporation requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective September 30, 1998. Objections and requests for hearings must be received by EPA on or before November 30, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300718], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests 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 identified by the docket control number, [OPP–300718], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall (CM)

#2, 1921 Jefferson Davis Hwy., Arlington, VA.

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 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300718]. 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.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: 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(e) announcing the filing of a pesticide petition (PP) for tolerance by FMC Corporation. 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 part 180 be amended by establishing tolerances for the herbicide, in or on corn, field, grain at 0.1 parts per million (ppm); corn, field, forage at 0.1 ppm; corn, field, fodder at 0.1 ppm; soybean seed at 0.1 ppm; wheat grain at 0.1 ppm; wheat forage at 1.0 ppm; wheat hay at 0.3 ppm; and wheat straw at 0.2 ppm.

I. Risk Assessment and Statutory Findings

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 published in the **Federal Register** of November 26, 1997 (62 FR 62961)(FRL–5754–7).

II. 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 Carfentrazone-ethyl and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance on corn, field, grain at 0.1 part ppm; corn, field, forage at 0.1 ppm; corn, field, fodder at 0.1 ppm; soybean seed at 0.1 ppm; wheat grain at 0.1 ppm; wheat forage at 1.0 ppm; wheat hay at 0.3 ppm; and wheat straw at 0.2 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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 below.

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 miligrams/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-Effect-Level (LOEL) 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 LOEL 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 admix doses of 0, 50, 150, 500 and 1,000 mg/kg/day. The NOAEL was 50 mg/kg/day and the LOEL 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 LOEL 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 respectively and the LOEL 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 LOEL 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 LOEL of 600 mg/kg/day based on staining of the abdominogenital area and maternal NOAEL of 100 mg/kg/day, and a developmental LOEL 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-reponse curve with maternal mortality occuring 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 LOEL of 300 mg/kg/day. There was no evidence of treatment-related prenatal development toxicity, the developmental LOEL 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 females. The parental LOEL 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 LOEL 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 LOEL 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 LOEL 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. *In vitro* mammalian cell forward gene mutation assay in Chinse hampster Ovary (CHO) cells yielded negative results both with and without activation.

15. *In vitro* chromosomal abberation assay yielded positive results under nonactivated conditions following doses of 3.75, 12.5, 37.5 and 125 µg/ml. There were consistent and statistically significant increased incidences of cells with aberrations at 125 µg/ml, the highest dose tested in the absence of metabolic activation.

16. *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 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 carefentrazone-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*. In an acute neurotoxicity study in rats and using an uncertainty factor of 100 (10× for inter-species extrapolation, 10× for intra-species variability, an acute referenced dose (RfD) of 5 mg/kg/day was established, based on a NOAEL of 500 mg/kg/day. A LOEL of 1,000 mg/kg/day was based on clinical observations and motor activity testing.

A developmental toxicity study resulted in a NOAEL of 100 mg/kg/day and the LOEL was 600 mg/kg/day. The finding was a result of the interference of Carfentrazone-ethyl with porphyrin metabolism. It is obvious that repeated doses of 600 mg/kg/day caused that interference; one dose will cause interference also but the effect will not be pronounced. Therefore, the NOAEL was not selected for this risk assessment (i.e., for acute exposure).

2. *Short - and intermediate - term toxicity.* No dermal or systemic toxicity was seen following repeated dermal application at 0, 100, 500 and 1,000 mg/kg/day, 6 hours/day, 5 days/week for 21 consecutive days to male and female Sprague-Dawley rats. Also, in the oral developmental toxicity study, no developmental toxicity was seen in rabbits and rats. In the rabbits, the developmental NOAEL was 300 mg/kg/day (the highest dose tested). In the rats, the developmental NOAEL was 600 mg/kg/day and the developmental LOEL was 1,250 mg/kg/day (slightly higher than the Limit-Dose) based on increase in the litter incidence of wavy and thickened ribs. Therefore, based on the lack of systemic toxicity via the dermal route and the occurrence of developmental toxicity only at high doses in rats, the Health Effects Division's Hazard Identification Assessment Review Committee (HED HIARC) determined that there are no toxicological endpoints of concern for dermal risk assessments.

3. *Chronic toxicity*. EPA has established the RfD for Carfentrazone-ethyl at 0.03 mg/kg/day. This RfD is based on the NOAEL of 3 mg/kg/day established in a 2-year chronic toxicity/carcinogenicity study in rats and using an uncertainty factor of 100 (10× for inter-species extrapolation, 10× for intra-species variability. The LOEL of 12 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 both sexes.

4. *Carcinogenicity*. The Office of Pesticide Programs' HED HIARC classified Carfentrazone-ethyl as a ''not likely'' human carcinogen according to EPA Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996).

C. Exposures and Risks

1. *From food and feed uses.* No previous tolerances have been established for the combined residues of Carfentrazone-ethyl and its chloropropionic acid. Risk assessments were conducted by EPA to assessed dietary exposures 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 one day or single exposure. The Dietary Risk Evaluation System (DRES) acute dietary exposure analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1989–92 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of Carfentrazone-ethyl in the commodity supply. The acute percentages of the RfD were <1% for the U.S. population and all subgroups. This is also a highly conservative risk estimate in which 100% crop treated and tolerance level residues were used.

ii. *Chronic exposure and risk.* A chronic dietary exposure analysis from food source was conducted using tolerance level residues and 100% crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. The TRMC for the general population represents 1% of the RfD, 1.3% for all infants (<1 year), 0.4% for nursing infants (<1 year), 1.7% for non-nursing infants (<1 year), 2.3% for children (1–6 years), 1.7% for children (7–12 years), 0.9% for females (13+/nursing), and 1.2% for males (13–19 years). This is a highly conservative risk estimate. No refinements for percent crop treated or anticipated residues were made.

2. *From drinking water.* Carfentrazone-ethyl is moderately soluble in water (12 ppm). Its mobility in soil could not be determined in the aged leaching study because of its rapid breakdown. The major degradate chloropropionic acid has a high water solubility (910 ppm) and is very mobile (K_{ads} = 0.4; K_{oc} = 30–48).

EPA estimates exposure Carfentrazone-ethyl and its degradate chloropropionic acid for both surface and groundwater based on available modeling. Since there are no registered uses for Carfentrazone-ethyl in the U.S., there are no monitoring data to compare against the modeling. Environmental concentrations for surface water were estimated using Generic expected environmental concentration (GENEEC), a single event model. Groundwater calculations for parent Carfentrazone-ethyl and degradate chloropropionic acid was based on the SCI-GROW method.

i. *Acute exposure and risk*. Drinking water levels of concern (DWLOC) were calculated for surface water for the parent compound and its chloropropionic acid metabolite at 1.8×10^5 for adults and 5×10^4 parts per billion (ppb) for infants and children. Using the GENEEC model, available environmental fate data, and very conservative assumptions, the estimated environmental concentrations calculated were 1.2 ppb for parent Carfentrazone-ethyl and 2.88 ppb for the chloropropionic acid metabolite. These values are well below EPA's level of concern. DWLOC's for groundwater were not calculated since the estimated environmental concentrations calculated for groundwater using SCI-GROW model were all less than 1 ppb.

ii. *Chronic exposure and risk*. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOAEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause Carfentrazone-ethyl to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with Carfentrazone-ethyl in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

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

4. *Cumulative exposure to substances with 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

1. *Acute risk*. EPA concludes with reasonable certainty that residues of Carfentrazone-ethyl and its chloropropionic acid metabolite would not result in unacceptable levels of aggregrate acute human health risk at this time. Acute risk estimates associated with exposure to Carfentrazone-ethyl in food and water do not exceed EPA's level of concern. Acute percentages of the RfD (from food sources only) were less than 1% for the U.S. population and all subgroups. DWLOC's calculated for surface water for the parent compound and its chloropropionic acid metabolite were 1.8×10^5 ppb for adults and 5×10^4 ppb

for infants and children. Using the GENEEC model, available environmental fate data, and very conservative assumptions, the estimated environmental concentrations calculated were 1.2 ppb for parent Carfentrazone-ethyl and 2.88 ppb for chloropropionic acid metabolite. These values are well below EPA's level of concern. DWLOC's for groundwater were not calculated since the estimated environmental concentrations calculated for groundwater using SCI-GROW model were all less than 1 ppb.

2. *Chronic risk*. EPA concludes with reasonable certainty that residues of Carfentrazone-ethyl and its chloropropionic acid metabolite would not result in unacceptable levels of aggregate chronic human health risk at this time. Chronic risk estimates associated with exposure to Carfentrazone-ethyl in food and water do not exceed EPA's level of concern. The chronic exposure analysis performed using tolerance level residues and 100% crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups yielded TMRC's for the general population that represents 1% of the RfD, 1.3% for all infants (<1 year), 0.4% for nursing infants (<1year), 1.7% for non-nursing infants (<1 year), 2.3% for children (1–6 years), 1.7% for children (7–12 years), 0.9% for females (13+/ nursing), and 1.2% for males (13–19 years). The estimated average concentration in surface water for Carfentrazone-ethyl (0.02 ppb) and for the chloropropionic acid (2.46 ppb) does not exceed DWLOC's of 1×10^3 ppb for adults and 3×10^2 ppb for children. Conservative model estimates (SCI-GROW) of the concentration of Carfentrazone-ethyl and its chloropropionic acid in groundwater indicate that exposure will be minimal, therefore DWLOC's for chronic groundwater were not calculated.

3. *Short- and intermediate-term risk*. HED 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. *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 two-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 pre-and post-natal toxicity and the completeness of the database 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 inter- and intra-species 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. *Pre- and post-natal sensitivity*. EPA determined that a 10× safety factor for enhanced sensitivity to infants and children 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 database is complete; and the fact that there are no registered residential products, in conjunction with the use of generally high qualitiy data, conservative models and/or assumptions in the exposure assessment provide adequate protection for infants and children.

2. *Acute risk*. EPA concludes with reasonable certainty that residues of Carfentrazone-ethyl and its chloropropionic acid metabolite would not result in unacceptable levels of aggregate acute human health risk at this time.

3. *Chronic risk*. EPA concludes with reasonable certainty that residues of Carfentrazone-ethyl and its chloropropionic acid metabolite would not result in unacceptable levels of aggregate chronic human health risk at this time. Chronic risk estimates associated with exposure to Carfentrazone-ethyl in food and water do not exceed EPA's level of concern.

4. *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.

III. Other Considerations

A. Metabolism In Plants and Animals

EPA decided that for the present crops (corn, wheat, soybeans), the proposed tolerance expression for the combined residues of the herbicide carfentrazone-ethyl (F8426) and its chloropropionic acid metabolite is adquate for the plant and animal commodities. However, since the hydroxyl metabolite, 3-OH-F8426-Cl-PAc, was found as the major residue in soybean forage and hay, the registrant must also monitor for this metabolite in all field trials of additional future crops.

B. Analytical Enforcement Methodology

There is a practical analytical 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 chromatographic separation.

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. International Residue Limits

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

D. Rotational Crop Restrictions

The labeling will require a 30 day plant-back interval for crops other than small grains.

IV. Conclusion

Therefore, the tolerance is established for 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-ethyl chloropropionic acid (alpha, 2-dichloro-5-[4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-l-y]-4-fluorobenzenepropanoic acid) in or on corn grain, corn forage, corn fodder, soybean seed, and wheat grain at 0.1ppm, wheat forage at 1.0 ppm, wheat hay at 0.3 ppm, and wheat straw at 0.2 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 30, 1998, file written objections to any aspect of this 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 or a request for a fee waiver as specified in 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (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 issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300718] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of 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 comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in **ADDRESSES** at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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) (Pub. L. 104–4). Nor does it require 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must

provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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 the rule in the **Federal Register**. This 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: September 23, 1998.

Marcia E. Mulkey,

Director, 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. 346a and 371.

2. Section 180.515 is revised 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-ethyl chloropropionic acid (alpha, 2-dichloro-5–[4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-l-y]-4-fluorobenzenepropanoic acid) in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field	0.1
Corn, field, fodder	0.1
Corn, field, forage	0.1
Soybean seed	0.1
Wheat forage	1.0
Wheat grain	0.1
Wheat hay	0.3
Wheat straw	0.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 98–26162 Filed 9–29–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6167–9]

Massachusetts: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The Commonwealth of Massachusetts has applied for Final Authorization of a revision to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). Massachusetts' revision addresses the Satellite Accumulation Rule contained in Non-HSWA Cluster I. This optional rule was promulgated on December 20, 1984 and amended the hazardous waste rules to allow accumulation of waste at satellite areas at the generator's facility. The specific provisions relating to the Satellite Accumulation Rule for which Massachusetts is seeking authorization are listed in the table in section B of this document. The EPA has reviewed The Commonwealth of Massachusetts' application and determined that its hazardous waste program revisions relating to the Satellite Accumulation Rule satisfy all of the requirements necessary to qualify for final authorization. Unless adverse written comments are received during the review and comment period, EPA's decision to authorize Massachusetts' hazardous waste program revision will take effect as provided below.

DATES: This Immediate Final Rule will become effective on November 30, 1998 without further notice, unless EPA receives relevant adverse comments by October 30, 1998. Should EPA receive