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).

For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does 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 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 10, 2001.

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), 346(a) and 371.

2. Section 180.425 is amended by alphabetically adding the commodity Sugar cane, cane, to the table in paragraph (a) to read as follows:

§ 180.425 Clomazone; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * *	*
*	*
Sugar cane, cane.	0.05.
* * *	*
*	*

* * * * *

[FR Doc. 01–19172 Filed 7–31–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301149; FRL–6790–9]

RIN 2070–AB78

Carfentrazone-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of carfentrazone-ethyl in or on the caneberry subgroup and cotton. The Interregional Research Project Number 4 (IR-4) and FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 1, 2001. Objections and requests for hearings, identified by docket control number OPP–301149, must be received by EPA on or before October 1, 2001.

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–301149 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703)–308–3194; and e-mail address: brothers.shaja@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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301149. 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 March 19, 2001 (66 FR 15459) (FRL–6766–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP 0E6183) for tolerance by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. 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 combined residues of the herbicide carfentrazone-ethyl, (ethyl-alpha,-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate), in or on the caneberry subgroup at 0.10 part per million (ppm).

In the **Federal Register** of April 12, 2001 (66 FR 18931) (FRL–6776–9), EPA issued a notice pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d) as amended by the FQPA (Publilc Law 104–170) announcing the filing of a pesticide petition (PP 7F4795) for tolerance by FMC Corporation, Agricultural Products Group, 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 part 180 be amended by establishing a tolerance for residues of carfentrazone-ethyl (ethyl-alpha,-2-dichloro-5[-4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-l-yl]-4-fluorobenzene-propanoate) and the metabolite carfentrazone-ethyl chloropropionic acid (,2-dichloro-5[-4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid) in or on the raw agricultural commodity (RAC) cotton at 3.5 parts per million (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 a tolerance for combined residues of carfentrazone-ethyl on the caneberry subgroup at 0.1 ppm and cotton, undelinted seed (0.20 ppm); cotton, gin byproducts (10 ppm); cottonseed, hulls (0.60 ppm); cottonseed meal (0.35 ppm); and cottonseed, refined oil (1.0 ppm). EPA's assessment of 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 in the Unit III.A. of the Final Rule on Carfentrazone-ethyl published in the **Federal Register** of August 9, 2000 (65 FR 48620) (FRL–6597–7).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where

the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer}= point of departure/exposures) is calculated. A summary of the toxicological endpoints for carfentrazone-ethyl used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CARFENTRAZONE-ETHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF (mg/kg/day)	FQPA SF and Endpoint for Risk Aassessment (mg/kg/day)	Study and Toxicological Effects
Acute dietary	NOAEL=500 UF[1]=100 aRfD=5	FQPA SF=1 aPAD=aRfD/FQPA SF aPAD=5	Acute neurotoxicity-rat; clinical observations (salivation) and decreased motor activity
Chronic dietary	NOAEL=3 UF[1]=100 cRfD=0.03	FQPA SF=1 cPAD=cRfD/FQPA SF cPAD=3	Chronic toxicity-rat; observations of liver histopathology and total urinary porphyrin
Short-term incidental oral	NOAEL=500 UF[1]=100	FQPA SF=1 LOC for MOE[2]=100	Acute neurotoxicity-rat; clinical signs (such as salivation), changes in motor activity
Intermediate-term incidental oral	NOAEL=50 UF[1]=100	FQPA SF=1 LOC for MOE[2]=100	Subchronic toxicity-dog; decreased body weight gain, increased porphyrin levels
Long-term incidental oral	Not applicable	Due to nature of incidental exposure, long-term incidental oral is not anticipated	
Short-term (dermal) and Intermediate-term (dermal)	Not applicable	No systemic toxicity was seen at the limit-dose (1000 mg/kg/day) in a 21–day dermal toxicity study in rats; therefore, these risk assessments are not required	
Long-term (dermal)	Not applicable	Based on the use pattern, long-term dermal exposure is not anticipated	
Short-term inhalation	NOAEL=500 UF[1]=100	FQPA SF=1 LOC for MOE[2]=100	Acute neurotoxicity-rat; clinical signs (such as salivation), changes in motor activity
Intermediate-term inhalation	NOAEL = 50 mg/kg/day UF[1]=100	FQPA SF=1 LOC for MOE[2]=100	Subchronic oral-dog; decreased body weight gain, increased porphyrin levels
Long-term inhalation	NOAEL=3 UF[1]=100	FQPA SF=1 LOC for MOE[2]=100	Chronic toxicity-rat; observations of liver histopathology and total urinary porphyrin

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.515) for the combined residues of carfentrazone-ethyl, in or on corn (field corn, sweet corn, and popcorn), wheat, barley, oats, grain sorghum, rice, and soybeans and carfentrazone-chloropropionic acid (40 CFR 180.515) ranging from 0.1 ppm (cereal grain) to 1.0 (rice straw). Preplant and post-emergence applications with ground and/or aerial equipment are permitted with rates ranging from 0.015 lbs ai/acre (grain sorghum) to 0.15 lbs ai/acre (rice). Risk assessments were conducted by EPA to assess dietary exposures from carfentrazone-ethyl in food as follows:

i. *Acute exposure.* 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 Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992– nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An acute analysis was performed for each population subgroup using tolerance level residues, 100% crop treated, and DEEM™ default processing factors for all registered and proposed commodities.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992– nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic analysis was performed for the general U.S. population and all population subgroups using tolerance level residues, 100% crop treated, and

DEEM™ default processing factors for all registered and proposed commodities.

iii. *Cancer*. Carfentrazone-ethyl is classified as ''not likely'' to be a human carcinogen.

iv. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows: The Agency believes that the three conditions listed [above] have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which carfentrazone-ethyl may be applied in a particular area.

2. *Dietary exposure 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.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for carfentrazone-ethyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical c haracteristics of carfentrazone-ethyl.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to carfentrazone-ethyl they are further discussed in the aggregate risk sections below.

The residues of concern in water are carfentrazone-ethyl, F8426-ClPAc, and F8126-CAc. Due to the hydrolysis and metabolic half-life of carfentrazone-ethyl, F8426-ClPAc and F8126-CAc, the agency concluded that the combined EECs for these three compounds would not be significantly different from the EECs for F8426-ClPAc alone. Therefore, a Tier I was provided for ground water (SCI-GROW) and surface water (GENEEC) EECs for only F8426-ClPAc. Both models assumed a seasonal application rate of 0.4 lbs ai/acre (highest proposed and registered rate).

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of carfentrazone-ethyl exposure for surface water is estimated to be 21 part per billions (ppb) for the peak concentration, and exposure for ground water is estimated to be 13.4 ppb.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Carfentrazone-ethyl is not registered for use on any sites that would result in residential exposure.

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. Safety Factor for Infants and Children

1. *In general*. 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 on toxicity and exposure 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.

2. *Prenatal and postnatal sensitivity*. Based on the developmental and 2–generation reproduction study, there was no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to the chemical. Therefore, Carfentrazone-ethyl is not a developmental or reproductive toxicant.

3. *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 the 10X safety factor to protect infants and children should be removed. The FQPA safety factor was reduced to 1X. The rationale was 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.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. A Tier 1 acute dietary exposure analysis for carfentrazone-ethyl was performed using existing and proposed tolerance level residues, 100 CT for all commodities, and DEEM™ default processing factors. The acute analysis was performed for the U.S. population and population subgroups. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to carfentrazone-ethyl will occupy <1 % of aPAD for all population subgroups at the 95th percentile. In addition, there is potential for acute dietary exposure to carfentrazone-ethyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CARFENTRAZONE-ETHYL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC2 (ppb)	Ground Water EEC2 (ppb)	Acute DWLOC3 (ppb)
U.S. pop - all seasons	5	0.001070	21	13.4	1.8e+05
All Infants (<1 year) year)old)	5	0.001674	21	13.4	5.0e+04
Children (1–6 years old)	5	0.001860	21	13.4	5.0e+04
Children (7–12 years old)	5	0.001270	21	13.4	5.0e+04
Females (13–50 years old)	5	0.000656	21	13.4	1.5e+05
Males (13–19 years old)	5	0.000961	21	13.4	1.8e+05
Males (20+ years old)	5	0.000725	21	13.4	1.8e+05
Seniors (55+ years old)	5	0.000535	21	13.4	1.8e+05

2. *Chronic risk*. A Tier 1 chronic dietary exposure analysis for carfentrazone-ethyl was performed using existing and proposed tolerance level residues, 100 CT for all commodities, and DEEM™ default processing factors. The chronic analysis was performed for U.S. population and population subgroups. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to carfentrazone-ethyl from food will utilize < 4% of the cPAD for all population subgroups. There are no residential uses for carfentrazone-ethyl that result in chronic residential exposure to carfentrazone-ethyl. In addition, there is potential for chronic dietary exposure to carfentrazone-ethyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CARFENTRAZONE-ETHYL

Population Subgroup	cPAD mg/kg/day	% cPAD (food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	DWLOC (ppb)
U.S. pop - all seasons	0.03	0.000409	6.6	13.4	1.0e+03
All Infants (<1 year old)	0.03	0.000740	6.6	13.4	1.0e+03
Children (1–6 years old)	0.03	0.000921	6.6	13.4	1.0e+03
Children (7–12 years old)	0.03	0.000656	6.6	13.4	1.0e+03
Females (13–50 years old)	0.03	0.000308	6.6	13.4	1.0e+03
Males (13–19 years old)	0.03	0.000455	6.6	13.4	1.0e+03
Males (20+ years old)	0.03	0.000326	6.6	13.4	1.0e+03
Seniors (55+ years old)	0.03	0.000260	6.6	13.4	1.0e+03

3. *Aggregate cancer risk for U.S. population*. EPA has classified carfentrazone-ethyl as a ''not likely'' to be a human carcinogen; therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to carefentrazone-ethyl residues.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

The methods used in the field trial study for caneberry and cotton have been validated and are adequate for data gathering purposes. The method may be requested from: Francis Griffith, Analytical Chemical Branch, Environmental Science Center, 701 Mapes Road, Fort George G. Mead, Maryland, 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits for residues of carfentrazone-ethyl and F8426-Cl-PAc in/on caneberry, cotton gin byproducts, cottonseed, cottonseed hulls, cottonseed oil, or cottonseed meal.

C. Conditions

IR-4's petition for carfentrazone-ethyl in/on the caneberry subgroup at 0.1 ppm has been made conditional. Additional caneberry field trials and the proposed caneberry enforcement method must be submitted and validated by the agency before unconditional registration is granted.

FMC's must submit a cottonseed processing study. Unconditional registration may be granted upon submission and review of the requested cotton processing study.

V. Conclusion

Therefore, these tolerances are established for combined residues of carfentrazone-ethyl, (ethyl-alpha,-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate) and carfentrazone-ethyl chloropropionic acid (oc, 2-dichloro-5-[4-(difluromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene propanoic acid), in or on caneberry subgroup at 0.1 ppm, cotton, undelinted seed (0.20 ppm); cotton, gin byproducts (10 ppm); cottonseed, hulls (0.6 ppm); cottonseed, meal (0.35 ppm); and cottonseed, refined oil (1.0 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–301149 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 1, 2001.

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, Waterside Mall, 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–301149, 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 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 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 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 13, 2001.

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), 346(a) and 371.

2. Section 180.515 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.515 Carfentrazone-ethyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Caneberry subgroup	0.1
* * *	* *
Cotton, gin by products	10
Cotton, undelinted seed	0.20
Cottonseed, hulls	0.60
Cottonseed, meals	0.35
Cottonseed, refined oil	1.0
* * *	* *

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[FR Doc. 01–19171 Filed 7–31–01; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–1766, MM Docket No. 00–116, RM–9877]

Digital Television Broadcast Service; Kansas City, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of KMBC Hearst-Argyle Television, licensee of station KMBC(TV), substitutes DTV channel 7 for DTV channel 14 at Kansas City, Missouri. *See* 65 FR 41035, July 3, 2000. DTV channel 7 can be allotted to Kansas City in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates (39–05–01 N. and 94–30–57 W.) with a power of 115, HAAT of 357 meters and with a DTV service population of 2086 thousand. With is action, this proceeding is terminated.

DATES: Effective September 10, 2001.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 00–116, adopted July 24, 2001, and released July 27, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Television, Digital television broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.622 [Amended]

2. Section 73.622(b), the Table of Digital Television Allotments under Missouri, is amended by removing DTV channel 14 and adding DTV channel 7 at Kansas City.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 01–19148 Filed 7–31–01; 8:45 am]

BILLING CODE 6712–01–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–1765, MM Docket No. 01–15, RM–10030]

Digital Television Broadcast Service; Missoula, MT

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of KPAX Communications, Inc., licensee of station KPAX–TV, substitutes DTV channel 7 for DTV channel 35 at Missoula, Montana. *See* 66 FR 8557, February 1, 2001. DTV channel 7 can be allotted to Missoula in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates (37–01–06 N. and 114–00–41 W.) with a power of 28.0, HAAT of 623 meters and with a DTV service population of 134 thousand. Since Missoula is located within 400 kilometers of the U.S.-Canadian border, concurrence by the Canadian government has been obtained for this allotment. With this action, this proceeding is terminated.

DATES: Effective September 10, 2001.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 01–15, adopted July 24, 2001, and released July 27, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Television, Digital television broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.622 [Amended]

2. Section 73.622(b), the Table of Digital Television Allotments under Montana, is amended by removing DTV channel 35 and adding DTV channel 7 at Missoula.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 01–19147 Filed 7–31–01; 8:45 am]

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