§ 430.56 [Corrected]

14. On page 18683, in § 430.56(a)(1) in the table entitled ''SUBPART E [Production of Calcium-, Magnesium-, or Sodium-based Sulfite Pulps],'' in the second column, the first entry is corrected to read ''<ML[a]''.

15. On page 18684, in § 430.56(a)(2)(ii) in the table entitled ''SUBPART E-PRODUCTION OF AMMONIUM-BASED SULFITE PULPS,'' the title in the second column is corrected to read ''PSES (TCF)''.

16. On page 18684, second column, in § 430.56(a)(3)(ii), the reference to ''40 CFR 403.12(b)'' is corrected to read, ''40 CFR 403.12(b), (d), or (e)''.

§ 430.57 [Corrected]

17. On page 18685, in § 430.57, paragraph (a)(2)(ii) is corrected to read:

* * * * *

(a) * * *

(2) * * *

(ii) The following pretreatment standards apply with respect to each new source fiber line operated by an indirect discharger producing ammonium-based sulfite pulps if the indirect discharger discloses to the pretreatment control authority in a report submitted under 40 CFR 403.12(b), (d), or (e) that it uses exclusively TCF bleaching processes at that fiber line:

* * * * *

18. On page 18686, in § 430.57, paragaph (a)(3)(ii) introductory text is corrected to read:

* * * * *

(a) * * *

(3) * * *

(ii) The following pretreatment standards apply with respect to each new source fiber line operated by an indirect discharger producing specialty grade sulfite pulps if the indirect discharger discloses to the pretreatment control authority in a report submitted under 40 CFR 403.12(b), (d), or (e) that it uses exclusively TCF bleaching processes at that fiber line:

* * * * *

[FR Doc. 98–20413 Filed 8–6–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300686; FRL–6018–1]

RIN 2070–AB78

Carfentrazone-ethyl; Temporary Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a temporary tolerance for combined residues of the herbicide carfentrazone-ethyl (fluorobenzenepropanoic acid) in or on wheat raw agricultural commodities: 0.2 ppm in or on wheat hay, 0.2 ppm in or on wheat straw, 0.2 ppm in or on wheat grain; and establishing 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-fluorobenzene-propanoate) and its two major corn metabolites: carfentrazone-ethyl chloropropionic acid (alpha, 2-dichloro-5-[4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid), and 3-desmethyl-FF8426 chloropropionic acid (alpha,2-dichloro-5-[4-difluromethyl)-4,5-dihydro-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid) in or on corn raw agricultural commodities:; 0.15 ppm in or on corn forage, 0.15 ppm in or on corn fodder, 0.15 ppm in or on corn grain. FMC requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1966 (Pub. L. 104-170). The tolerance will expire on May 8, 1999.

DATES: This regulation is effective August 7, 1998. Objections and requests for hearings must be received by EPA on or before October 6, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300686], 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–300686], 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, 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–300686]. 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 PM-23, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 1998 (63 FR 31769) (FRL–5793–1), 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 6G4615) for a tolerance by FMC Corporation, 1735 Market St., 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 extending a temporary 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-fluorobenzene-propanoate), and its metabolite, in or on field corn forage, fodder, and grain at 0.15 parts per million (ppm); and for wheat hay, straw,

and grain at 0.2 ppm. This tolerance will expire on May 8, 1999.

This tolerance request was submitted in a transmittal letter, dated April 29, 1998, along with an application for an experimiental use permit (EUP). This EUP proposes the experimental use of carfentrazone-ethyl on corn and wheat. Under FIFRA, section 516C for experimental use permits, a temporary tolerance level must be established if a pesticide may reasonably be expected to result in any residue on or in food or feed use.

I. Risk Assessment and Statutory Findings

New 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 specialconsideration 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. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population

subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants <1 year old) was not regionally based.

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 temporary tolerance 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-fluorobenzene-propanoate) and its metabolites on wheat at 0.2 ppm and corn at 0.15 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 placed technical carfentrazone in Toxicity Categories III and IV. No evidence of sensitization was observed following dermal application in guinea pigs.

2. A 90-day subchronic toxicity study was conducted in rats, with dietary intake levels of 58, 226, 4,700, 831 and 1,197 milligrams/kilogram/day (mg/kg/day) in males and 72, 284, 578, 1,008 and 1,427 mg/kg/day in females, respectively. A NOEL of 226 mg/kg/day (males) and 5,778 mg/kg/day (females) was established. Lowest observed effect levels (LOELs) of 470 mg/kg/day (males) and 578 mg/kg/day (females) was established based on decreases in body weights and/or gains, reductions in food consumption, alterations in clinical chemistry parameters, and histopathological lesions.

3. A reverse gene mutation assay (*salmonella typhirmurium*) yielded negative results, both with and without metabolic activation.

4. An *in vitro* mutation assay test yielded negative results, there was no indication of an increased incidence of gene mutation at the HGPRT locus as a result of exposure.

5. An *in vitro* mammalian cytogenetic test yielded positive under nonactivated conditions in this assay.

6. An *in vivo* micronucleus cytogenetic assay study was conducted in mice by IP injection of 600, 1,200 and 2,400 mg/kg to groups of 5 males and 5 females. There was no indication of an increased incidence in micronucleated polychromatic erythrocytes associated with exposure to the test material.

7. A 13-week study was conducted on 4 pure breed Beagle dogs/sex/group for 90 days at dietary intake levels of 0, 50, 150, 500 and 1,000 mg/kg/day. NOELs of 500 mg/kg/day for both sexes and the LOEL of 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).

8. An oral prenatal developmental study was administered by gavage to pregnant female New Zealand white rabbits (20/group) on days 7-19 of gestation at dose levels of 0, 10, 40, 150, or 300 mg/kg/day. There was no evidence of treatment-related prenatal developmental toxicity. The developmental LOEL was not determined. The developmental NOEL (greater or equal to sign) of 300 mg/kg/day.

B. Toxicological Endpoints

1. *Acute toxicity*. The Agency does not have a concern for an acute dietary assessment since the available data do not indicate any evidence of significant toxicity from a one day or single event exposure by the oral route, therefore an acute (food and water) risk assessment was not required.

2. *Chronic toxicity*. EPA has established the RfD for carfentrazone-ethyl at 0.06 mg/kg/day. This RfD is based on the NOEL of 60 mg/kg/day from a 90-day rat study with a 1,000 fold uncertainty factor.

3. *Carcinogenicity*. No concern for cancer risks were identified. Data from available studies do not indicate a treatment-related tumor problem, and cancer risk endpoints have not been identified.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have not yet been established (40 CFR 180) for the 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-fluorobenzene-propanoate), and its metabolites, in or on a variety of raw agricultural commodities. Due to the non-quantifiable carfentrazone-ethyl residues in/on the treated RAC's (except wheat forage, however, there is a label feeding restriction) fed to livestock and the limited number of acres involved, there is no expectation of secondary

residues in livestock commodities of meat, meat-by-products, fat, milk, and eggs. Risk assessments were conducted by EPA to assess dietary exposures and risks 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. No short - and intermediate endpoints for occupational and residential exposure were identified.

ii. *Chronic exposure and risk.* The chronic dietary analysis indicates that exposure from the proposed temporary tolerances for use of carfentrazone-ethyl in/on corn and wheat for the U.S. population would account for less than 1% of the RfD. For children (1-6 years), the subgroup with the highest exposure, 1% of the RfD would be utilized.

This chronic analysis for carfentrazone is an upper-bound estimate of dietary exposure with all residues at tolerance level and assuming 100% of the commodities to be treated. Since only 4,000 acres of wheat and 4,000 acres of corn will be treated under this EUP program which represents less than 1% of the total wheat and corn harvested in the United States, this dietary analysis represents an over estimate of the percent RfD that will be utilized by the proposed temporary tolerances. Therefore, the chronic dietary risk resulting from the proposed temporary tolerances for carfentrazone-ethyl will not exceed the Agency's level of concern.

2. *From drinking water.* A chronic dietary risk assessment from drinking water was not conducted because of the short duration of the EUP (2 years) and the small percentage of treated acres for corn and wheat as a result of the proposed use (<1% of the total U.S. production for both commodities).

3. *Acute exposure and risk.* As part of the hazard assessment process, the Agency reviews the available toxicological database to determine the endpoints of concern for acute dietary risk. There is no concern since the available data do not indicate any evidence of significant toxicity from a one day or single event exposure by the oral route. Therefore an acute dietary risk assessment was not required.

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 NOEL'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.

4. *From non-dietary exposure.* The proposed uses for this pesticide does not include uses that would result in a non-dietary, non-occupational exposure.

5. *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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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.

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

1. *Acute risk.* The Agency does not have a concern for acute dietary assessment since the available data do not indicate any evidence of significant toxicity from a one day or single event exposure by the oral route. An acute dietary risk assessment was not required.

2. *Chronic risk.* The chronic dietary analysis indicates that exposure from the proposed temporary tolerances for use of carfentrazone-ethyl in/on corn and wheat for the U.S. population would account for less than 1% of the RfD. For children (1-6 years), the subgroup with the highest exposure, 1% of the RfD would be utilized. A chronic dietary risk (food and water) was not conducted for the following reasons: the short duration of this EUP, the small percentage of treated acres for corn and

wheat as a result of the proposed use (<1% of the total U.S. production for both commodities; and the fact that these commodities are blended before consumption). This chronic analysis for carfentrazone-ethyl is an upper-bound estimate of dietary exposure with all residues at tolerance level and assuming 100% of the commodities to be treated. Since only 4,000 acres of wheat and 4,000 acres of corn will be treated under this EUP program, which represents less than 1% of the total wheat and corn harvested in the United States, this dietary analysis represents an over estimate of the percent RfD that will be utilized by the proposed temporary tolerances. Therefore, the chronic dietary risk resulting from the proposed temporary tolerances for carfentrazone-ethyl will not exceed the Agency's level of concern. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to carfentrazone-ethyl residues.

E. Aggregate Cancer Risk for U.S. Population

The chronic dietary analysis indicates that exposure from the proposed temporary tolerances for use of carfentrazone-ethyl in/on corn and wheat for the U.S. population would account for less than 1% RfD. There is no concern for cancer risks identified. Data from available studies do not indicate a treatment-related tumor problem, and cancer endpoints have not been identified.

F. 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. Developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. 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 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 MOE and 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. *Developmental toxicity studies— a. Rabbits.* A prenatal oral developmental toxicity study in rabbits with dose levels of 0, 10, 40, 150, or 300 mg/kg/day with a maternal LOEL of 300/mg/kg/day and the maternal NOEL of ≧ 150 mg/kg/day. There was not evidence of treatment-related prenatal developmental toxicity.

b. *Rat.* A prenatal oral developmental toxicity study in the rat at dose levels of 0, 100, 600, or 1,250 mg/kg/day with a maternal LOEL of 600 m g/kg/day based on staining of the abdominogential area and of the cage pan liner; and with the maternal NOEL of 100 mg/kg/day. The developmental NOEL of 1,250 mg/kg/day was based upon a significant increase in the litter incidences of wavy and thickened ribs and with the developmental NOEL of 600 mg/kg/day.

iii. *Reproductive toxicity study.* Under Title 40 of the Code of Federal Regulations, part 158, § 158.340, a 2-generation reproduction study is not required for an EUP when the TMRC is less than 50% of the RfD. Exposure from the proposed temporary tolerance of carfentrazone-ethyl from use on wheat and corn will account for less than 1% of the RfD.

iv. *Pre- and post-natal sensitivity.* There was no evidence of pre-and post-natal sensitivity in the prenatal oral developmental studies discussed above.

v. *Conclusion.* All required toxicology studies have been completed for this phase of the registration process. The required developmental studies show no pre-natal sensitivity. Based on these findings as well as the generally low toxicity seen in all of the carfentrazone studies, EPA concludes there is reliable data supporting not using an additional 10-fold safety factor for the protection of infants and children. EPA believes the 1,000-fold safety factor used in assessing the carfentrazone risk is adequate to protect all consumers. The 1,000-fold safety factor includes a 100-fold factor for intra- and inter-species differences and a 10-fold factor because the RfD was based on subchronic study.

2. *Chronic risk.* EPA has concluded that aggregate exposure to carfentrazone-ethyl from food will utilize 1% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to carfentrazone-ethyl in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. 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

The metabolism of carfentrazone-ethyl in plants is adequately understood for the purposes of these tolerances. For the purposes of this EUP, the residues of concern are the parent carfentrazone-ethyl and its two major metabolites. The nature of the residue in animals has not been reported. Due to the non-quantifiable carfentrazone-ethyl residues in/on the treated RACs, except wheat forage (there is a label feeding restriction in this EUP) fed to livestock and the limited number of acres involved, there is no expectation of secondary residues in livestock commodities of meat, meat-by-products, fat, milk, and eggs.

B. Analytical Enforcement Methodology

There is a practical analytical method for detecting and measuring levels of carfentrazone 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. For the parent carfentrazone-ethyl, acceptable method recoveries were established at a limit of quantitation (LOQ) of 0.05 ppm, and a limit of detection (LOD) was set at 0.01 ppm for all the field corn and wheat crop matrices. The methodology can also be used to determine major plant metabolites with similar LOQs and LODs. No analytical method for meat, milk and eggs has been submitted by the registrant. Since no temporary tolerances have been proposed for animal RACs, an analytical enforcement

method for animals is not required for this EUP.

C. Magnitude of Residues

The magnitude of the residue in animals has not been reported. These data will not be required for this EUP due to the non-quantifiable carfentrazone-ethyl residues in/on treated RACs (corn forage, fodder, and grain, and wheat hay, straw, and grain) fed to livestock and the limited number of acres involved. Residues were only found in wheat forage, therefore for this EUP only, a grazing restriction must be included to prohibit the grazing and harvesting of wheat forage as a feedstuff.

D. International Residue Limits

There is no Codex proposal, no Canadian or Mexican limits for residues of carfentrazone-ethyl in corn or wheat. A compatibility issue is not relevant to the proposed tolerances for either crop.

IV. Conclusion

Therefore, the temporary tolerance is extended for combined residues of carfentrazone (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoate) and its metabolites in wheat at 0.20 ppm and corn at 0.15 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 October 6, 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 prescribed by 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–300686] (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 Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, 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

This final rule extends a temporary 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 any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the temporary 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.

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: July 29, 1998.

Arnold E. Layne,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180–[AMENDED]

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

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

§ 180.515 [AMENDED]

2. In § 180.515 by amending the table in paragraph (a) for all of the commodities by changing the date ''5/8/98'' to read ''5/8/99.''

[FR Doc. 98–21201 Filed 8–6–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300694; FRL–6021–2]
RIN 2070–AB78

Avermectin; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the insecticide and miticide avermectin B1 and its delta-8,9-isomer in or on spinach and celeriac at 0.05 part per million (ppm) for an additional 18 month period, to January 31, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on spinach and celeriac. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective August 7, 1998. Objections and requests for hearings must be received by EPA, on or before October 6, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300694], 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–300694], 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 #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. Follow the instructions in Unit II. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel J. Rosenblatt, 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: Rm. 280, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308–9375; e-mail: rosenblatt.dan@epamail.epa.gov. .

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of August 19, 1997 (62 FR 44089) (FRL-5737-1), which announced that on its own initiative and under section 408(e) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), it established a time-limited tolerance for the residues of avermectin and its metabolites in or on spinach and celeriac at 0.05 ppm, with an expiration date of July 31, 1998. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of avermectin on spinach and celeriac for this year's growing season due to the yield losses associated with the two-spotted spider mite in celeriac and the leafminer in spinach. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of avermectin on spinach and celeriac.

EPA assessed the potential risks presented by residues of avermectin in or on spinach and celeriac. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of August 19, 1997 (62 FR 44089). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 18 month period. Although this tolerance will expire and is revoked on January 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on spinach and celeriac after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.