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: October 22, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

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

§ 180.395 [Amended]

2. Section 180.395, by amending paragraph (b) in the table, by changing the date ''1/31/99'' to read ''5/30/01.''

[FR Doc. 98–31389 Filed 11–24–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300751; FRL 6040–7]

RIN 2070–AB78

Carfentrazone-ethyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of carfentrazone-ethyl and its chloropropionic acid metabolite in or on rice, grain and rice, straw. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on rice. This regulation establishes maximum permissible levels for residues of carfentrazone-ethyl in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on October 31, 1999.

DATES: This regulation is effective November 25, 1998. Objections and requests for hearings must be received by EPA on or before January 25, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, (OPP–300751), 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–300751, 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. 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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number (OPP–300751). 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: Stephen Schaible, 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) 308–9362; e-mail: schaible.stephen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for combined residues of the herbicide carfentrazone-ethyl and its chloropropionic acid metabolite, in or on rice, grain at 0.1 part per million (ppm) and rice, straw at 1.0 ppm. These tolerances will expire and are revoked on October 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

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 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. ''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by

FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

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.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Carfentrazone-ethyl on Rice and FFDCA Tolerances

According to the Applicant, California arrowhead *Sagittaria montevidensis spp. Calcycina* and ricefield bulrush *Scirpus mucronatus* cause economic damage by competing with rice plants for soil, nutrients and sunlight, and by interfering with harvesting equipment to reduce yields. Resistance to the registered alternative herbicide of choice, bensulfuron methyl, has been observed in populations of these weeds. Resistance was first reported in 1992, and a survey conducted in 1995 estimated that 60% of rice fields in California have resistant California arrowhead and 15% have resistant ricefield bulrush. Phenoxy herbicides such as MCPA or 2,4-D may be used on bensulfuron methyl resistant weeds, but are phytotoxic to rice plants. Additionally, manufacturers have announced that they will not supply these products in the Sacramento Valley, due to persistent concerns about off-target applications, drift and damage symptoms on non-target crops, especially cotton. Propanil and triclopyr may offer partial control of these weeds, but neither is labeled for this use. EPA has authorized under FIFRA section 18 the use of carfentrazone-ethyl on rice for control of California arrowhead and ricefield bulrush in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of carfentrazone-ethyl in or on rice, grain and rice, straw. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on October 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on rice, grain and rice, straw after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed the levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether carfentrazone-ethyl meets EPA's registration requirements for use on rice or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of carfentrazone-ethyl by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for carfentrazone-ethyl, contact the Agency's Registration Division at the address provided above.

III. Aggregate Risk Assessment and Determination of Safety

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).

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 time-limited tolerances for combined residues of carfentrazone-ethyl and its chloropropionic acid metabolite on rice, grain and rice, straw at 0.1 ppm and 1.0 ppm, respectively. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

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

1. *Acute toxicity*. For the acute dietary exposure and risk assessment, the acute RfD was established at 5 milligrams/kilogram/day (mg/kg/day). The no observed adverse effect level (NOAEL) of 500 mg/kg/day, taken from the acute neurotoxicity study in rats, was based on clinical observations (i.e., excessive salivation) and motor activity testing at the lowest adverse effect level (LOAEL) of 1,000 mg/kg/day. The acute RfD reflects an uncertainty factor of 100, based on interspecies extrapolation 10x, intraspecies variability 10x, and the Agency determination that the FQPA 10x factor was not required.

2. *Short - and intermediate - term toxicity*. The Agency determined that short- and intermediate-term dermal risk assessments are not required because no systemic toxicity was seen at the limit-dose (1,000 mg/kg/day) in a 21–day dermal toxicity study in rats. In addition, based on the use pattern, long-term dermal exposure is not anticipated, therefore the chronic dermal risk assessment is not required.

Based on the low toxicity and the use pattern (one application at 0.008–0.031 lbs. a.i./acre/season), the Agency also concluded that a risk assessment for inhalation exposure (any time period) is not required.

3. *Chronic toxicity*. EPA has established the RfD for carfentrazone-ethyl at 0.03 (mg/kg/day). This RfD is based on a NOAEL of 3 mg/kg/day taken from the 2–year chronic toxicity study in rats. Effects observed at the LOAEL

of 12 mg/kg/day include histopathology (increases in microscopic red fluorescence of the liver, liver pigment) and total mean urinary porphyrin.

4. *Carcinogenicity*. Carfentrazone-ethyl has been classified by the Agency as a ''not likely'' human carcinogen; there is no evidence of carcinogenicity in reviewed studies.

B. Exposures and Risks

1. *From food and feed uses.* Permanent tolerances for field corn, soybean and wheat commodities were published in the **Federal Register** on September 30, 1998. An amendment to add the remaining commodities in the cereal grain crop group is pending with the Agency. Secondary residues in animal commodities resulting from this section 18 use are expected to be negligible. 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. Tolerance level residues and 100% crop treated were assumed to derive TMRC exposure values; these values should be viewed as conservative risk estimates; further refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

The existing and proposed food uses of carfentrazone-ethyl result in an acute dietary exposure of 0.002 mg/kg/day for the U.S. population (0.04% of the acute RfD), 0.003 mg/kg/day for non-nursing infants (< 1 year) (0.06% of the acute RfD), and 0.001 mg/kg/day for females 13+ years (0.02% of the acute RfD).

ii. *Chronic exposure and risk.* In estimating chronic dietary exposure from food uses of carfentrazone-ethyl, it was assumed that 100% of rice and all other commodities having carfentrazone-ethyl tolerances will contain residues and those residues would be at the level of the tolerance; these assumptions lead to overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, the Agency is taking into account this conservative exposure assessment.

Existing and proposed carfentrazone-ethyl food uses result in a TMRC of 0.0003 mg/kg/day (1% of the RfD) for the U.S. population, and 0.0007 mg/kg/day (2% of the RfD) for both non-nursing infants (< 1 year old) and children (1–6 years old), the two subgroups having the highest exposure.

2. *From drinking water.* The Agency has calculated drinking water levels of concern (DWLOCs) for acute and chronic exposure to carfentrazone-ethyl in surface and groundwater. The DWLOCs are calculated by subtracting from the RfD (acute or chronic) the respective acute or chronic dietary exposure attributable to food to obtain the acceptable exposure to carfentrazone in drinking water; as there are no residential uses of carfentrazone-ethyl at this time, this component is not reflected in the calculation. Default body weights (70 kg for males, 60 kg for females, and 10 kg for non-nursing infants < 1 year old) and default drinking water consumption estimates (2 L/day for adults, 1 L/day for non-nursing infants) are then used to calculate the actual DWLOCs. The DWLOC represents the concentration level in surface water or groundwater at which aggregate exposure to the chemical is not of concern.

Using generic expected environmental concentration (GENEEC) (surface water) and SCI-GROW (groundwater) models, the Agency has calculated acute and chronic Tier I estimated environmental concentrations (EECs) for carfentrazone-ethyl for use in human health risk assessments. These values represent the upper bound estimates of the concentrations of carfentrazone-ethyl that might be found in surface and ground water assuming the maximum application rate allowed on the label. The EECs from these models are compared to the DWLOCs to make the safety determination.

i. *Acute exposure and risk.* Acute DWLOCs were calculated to be 175 ppm for the U.S. population, 150 ppm for females 13+ years, and 50 ppm for non-nursing infants less than 1 year old. Using the GENEEC model, the calculated acute EECs in surface water for carfentrazone-ethyl and its chloropropionic acid degradate were 1.2 parts per billion (ppb) and 2.88 ppb, respectively. Using the SCI-GROW model, the acute EECs in groundwater were calculated to be 0.000181 ppb for carfentrazone-ethyl and 0.016065 ppb for chloropropionic acid.

ii. *Chronic exposure and risk.* Chronic DWLOCs were calculated by the Agency to be 1040 ppb for the U.S. population, 891 ppb for females 13+ years, and 293 ppb for non-nursing infants less than 1 year old. Using the GENEEC model, the calculated chronic EECs in surface water for carfentrazone-ethyl and its chloropropionic acid degradate were 0.02 ppb and 2.46 ppb, respectively. Using the SCI-GROW model, the chronic EECs in groundwater were calculated to be 0.000181 ppb for carfentrazone-ethyl and 0.016065 for chloropropionic acid.

3. *From non-dietary exposure.* Carfentrazone-ethyl is a new chemical with no registered residential uses. There is no concern for non-dietary exposure via the dermal or inhalation routes.

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

EPA does not have, at this time, available data to determine whether carfentrazone-ethyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, carfentrazone-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that carfentrazone-ethyl has a common mechanism of toxicity with other substances. For more 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)(FRL–5754–7).

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

1. *Acute risk.* Using the TMRC assumptions described above, acute dietary exposure from existing and proposed uses of carfentrazone-ethyl was calculated to represent 0.4% of the acute RfD for the U.S. population and 0.02% of the RfD for females 13+ years. Estimated acute or peak EECs in surface water and groundwater of both carfentrazone-ethyl and its chloropropionic acid degradate are well below the acute DWLOCs calculated by the Agency for all population subgroups of concern.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to carfentrazone-ethyl from food will utilize 1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate

exposure is non-nursing infants less than 1 year old (discussed below). 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. Estimated chronic EECs in surface water and groundwater of both carfentrazone-ethyl and its chloropropionic acid degradate are well below the chronic DWLOCs calculated by the Agency for all population subgroups of concern.

3. *Aggregate cancer risk for U.S. population*. Carfentrazone-ethyl has been classified by the Agency as a ''not likely'' human carcinogen; there is no evidence of carcinogenicity in reviewed studies. This risk assessment was not required.

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

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 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*. In the rat study, the maternal (systemic) NOAEL was 100 mg/kg/day based on abdominogenital and cage liner staining at the LOAEL of 600 mg/kg/day. The developmental (fetal) NOAEL was 600 mg/kg/day based on wavy or thickened ribs at the LOAEL of 1,250 mg/kg/day. In the rabbit developmental toxicity study, the maternal (systemic) NOAEL was ≥150 mg/kg/day based on unthriftiness and emaciation in two doses in the current study at the LOAEL of 300 mg/kg/day, as well as, dyspnea, decreased locomotion, lacrimation, abdominogenital staining, loss of righting reflex, nasal discharge, unthriftiness, and dehydration reported in pilot studies at 350 and 700 mg/kg/day. The developmental (fetal) NOAEL was ≥300 mg/kg/day, the highest dose tested.

iii. *Reproductive toxicity study*. In the 2-generation rat reproduction study, the maternal (systemic) NOAEL was 127 mg/kg/day in males and 142 mg/kg/day in females based on decreased body weight gains, increased liver weights, liver and bile duct histopathology, and reductions in the mean cell volume, hematocrit, and hemoglobin at the LOAEL of 343 mg/kg/day in males and 387 mg/kg/day in females.

iv. *Pre- and post-natal sensitivity*. Based on the developmental and reproductive toxicity studies for carfentrazone-ethyl there does not appear to be an extra sensitivity for pre- or post-natal effects. Therefore, the Agency has concluded that the 10x safety factor to account for potential sensitivity by infants and children to carfentrazone-ethyl should be removed.

v. *Conclusion*. There is a complete toxicity database for carfentrazone-ethyl and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. Using the TMRC assumptions described above, acute dietary exposure from existing and proposed uses of carfentrazone-ethyl was calculated to represent 0.06% of the RfD for non-nursing infants less than 1 year old, the infant and children subgroup most highly exposed. Estimated acute or peak EECs in surface water and groundwater of both carfentrazone-ethyl and its chloropropionic acid degradate are well below the acute DWLOCs calculated by the Agency for all population subgroups of concern.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to carfentrazone-ethyl from food will utilize 2% 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. Estimated chronic EECs in surface water and groundwater of both carfentrazone-ethyl and its chloropropionic acid degradate are well below the chronic DWLOCs calculated by the Agency for all population subgroups of concern.

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

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residue of concern is the parent compound carfentrazone-ethyl and its chloropropionic acid metabolite.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available from the Agency, (associated with PP#7F4795) to enforce the proposed tolerance on rice. This enforcement method is a GC method that uses ECD (electron capture detection), MSD (mass selective detection), ELCD (electrolytic conductivity detection), or MS/NCI (negative ion chemical ionization mass spectrometry). The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

Data on multi-residue methods has been submitted pertaining multi-residue methods testing for carfentrazone-ethyl. Carfentrazone-ethyl was detected under Protocol C using either an ECD or NPD detector. Better sensitivity was achieved with ECD detection. Carfentrazone-ethyl metabolites were tested using Protocols B and C with ECD detection. These data have been forwarded to FDA to be included in PAM I, Appendix I.

C. Magnitude of Residues

Residues of carfentrazone-ethyl and its chloropropionic acid metabolite are not expected to exceed 0.10 ppm in/on

rice, grain and 1.0 ppm in/on rice, straw as a result of this section 18 use.

D. International Residue Limits

No Codex, Canadian, and Mexican tolerances are established for carfentrazone-ethyl. Therefore, no compatibility problems exist between the proposed U.S. and Codex tolerances.

E. Rotational Crop Restrictions

A 30–day plant-back interval is to be required on the label. The recommended time-limited tolerances reflect this restriction.

V. Conclusion

Therefore, the tolerance is established for combined residues of carfentrazone-ethyl and its chloropropionic acid metabolite in rice, grain at 0.1 ppm and rice, straw at 1.0 ppm.

VI. 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 January 25, 1999, 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 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number (OPP–300751) (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.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). 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 tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

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

C. Executive Order 13084

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

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

IX. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: October 21, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

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

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

2. In §180.515 is amended by revising paragraph (b) to read as follows:

§ 180.515 Carfentrazone-ethyl; tolerances for residues

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide carfentrazone-ethyl and its chloropropionic acid metabolite in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Rice, grain	0.1	10/31/99
Rice, straw	1.0	10/31/99

* * * * *

[FR Doc. 98–31546 Filed 11–24–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300759; FRL 6045–4]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of azoxystrobin or methyl (*E*)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl)-3-methoxyacrylate) and its *Z isomer* in or on sugar beets and soybeans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on sugar beets and soybeans. This regulation establishes maximum permissible levels for residues of azoxystrobin in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and will be revoked on June 30, 2000.

DATES: This regulation is effective November 25, 1998. Objections and requests for hearings must be received by EPA on or before January 25, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300759], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing