

specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**IX. Congressional Review Act**

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: January 14, 2005.

**Betty Shackelford,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.535 is amended by alphabetically adding a commodity to the table in paragraph (b) to read as follows:

**§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.**

(b) \* \* \*

Commodity	Parts per million	Expiration/revocation date
* * *	*	* *
Onion .....	0.02	6/30/07
* * *	*	* *

\* \* \* \* \*

[FR Doc. 05-1440 Filed 1-25-05; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2004-0362; FRL-7696-5]

**Chlorfenapyr; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile in or on all foods except fruiting vegetables. BASF Corporation requested this tolerance 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 January 26, 2005. Objections and requests for hearings must be received on or before March 28, 2005.

**ADDRESSES:** To submit a written objection or hearing request, follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2004-0362. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET, or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, D.C. 20460-0001; telephone number: 703 305-6502; e-mail [address:sibold.ann@epa.gov](mailto:address:sibold.ann@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural

producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

**II. Background and Statutory Findings**

In the **Federal Register** of July 16, 2003 (68 FR 42022) (FRL-7312-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6560) by BASF Corporation, 26 Davis Drive, Research Triangle Park, North Carolina 27709. The petition requested that 40 CFR 180.513 be amended by establishing a tolerance for residues of the insecticide 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, chlorfenapyr, in or on all foods at 0.01 parts per million (ppm). That notice included a summary of the petition prepared by BASF Corporation, the registrant. Three public comments (OPP-2003-0205-0001 (Green Party, MI), OPP-2003-0205-0002 (Fluoride Action Network), and

OPP-2003-0205-0003 (BASF Corporation)) were received in response to the registrant's petition. The substantive public comments and corresponding Agency responses are addressed in a separate document available in the docket for this action under Docket identification (ID) number OPP-2004-0362.

The Green Party, MI took exception with the use of a tolerance to provide a "safe" level of pesticide residues in food. The Agency acknowledges this comment but notes that the Agency is authorized by section 408(b)(A)(i) of the Federal Food, Drug, and Cosmetic Act to establish tolerances. The Fluoride Action Network (FAN) provided a number of comments on the Agency's safety determination for chlorfenapyr including raising concerns about: (1) its role in "Mad Cow Disease" (transmissible spongiform encephalopathies), (2) aggregate exposure to chlorfenapyr and other fluorine and bromine containing pesticides and inerts, (3) aggregate exposure to chlorfenapyr and other neurotoxicants, (4) its role in neurodegenerative diseases and disease processes, (5) the status of a conditionally required developmental neurotoxicity study, and (6) public access to risk assessments and other supporting documentation. BASF, the chlorfenapyr registrant, provided a detailed response to the issues raised by FAN.

The substantive public comments and corresponding Agency responses are addressed in a separate document available in the docket for this action under Docket identification (ID) number OPP-2004-0362. The Agency considered all of the substantive comments and saw no basis to support the claims that were made in the public comments. Again, the Agency's complete reasoning is discussed in the comment response document. As to FAN's comments regarding access to Agency documents on chlorfenapyr, EPA would note that there are extensive documents on chlorfenapyr on EPA's website. However, the Agency agrees with the comment that generally more access to information supporting this and other decisions is desirable, and in fact, the Registration Division, Office of Pesticide Programs is currently reviewing its procedures for docketing to address this concern.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of FFDCA 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) of FFDCA, 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) of FFDCA, for a tolerance for residues of chlorfenapyr on all foods except fruiting vegetables at 0.01 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 chlorfenapyr as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 26, 2003 (Vol. 68 No. 187 FR 55519-55527) (FRL-7320-8).

#### 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.

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor" is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand ( $1 \times 10^{-5}$ ), one in a million ( $1 \times 10^{-6}$ ), or one in ten million ( $1 \times 10^{-7}$ ). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this nonlinear 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 ( $MOE_{cancer} = \text{point of departure} / \text{exposures}$ ) is calculated.

A summary of the toxicological endpoints for chlorfenapyr used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 26, 2003 (Vol. 68 No. 187 FR 55519–55527) (FRL–7320–8).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* The tolerance established in 40 CFR 180.513 is further amended to set tolerances for residues of chlorfenapyr in or on all foods except fruiting vegetables at 0.01 ppm. Risk assessments were conducted by EPA to assess dietary exposures from chlorfenapyr 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.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™ Version 2.03), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each food item. The 1994–96, and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as

consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g., apples, peeled fruit - cooked; fresh or baked; or wheat flour - cooked; fresh or baked) using publicly available recipe translation files developed jointly by USDA/Agricultural Research Service (ARS) and EPA. Consumption data are retained as individual consumption events for acute exposure assessment. The following assumptions were made for the acute exposure assessments: Unrefined tier 1 acute dietary exposure assessments using tolerance-level residues and assuming 100% crop treated (CT) for all registered and proposed commodities, and default DEEM™ Version 7.76 processing factors for all commodities were conducted. The acute dietary exposure estimates are below EPA's level of concern (<100% aPAD) at the 95<sup>th</sup> exposure percentile for females 13–49 years old (< 15% aPAD), and the general U.S. population (< 6% of the aPAD), and all other population subgroups. The most highly exposed population subgroup (other than females 13–49 years old) is children 1–2 years old, at < 9% of the aPAD.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each food item. The 1994–96 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g., apples, peeled fruit - cooked; fresh or baked; or wheat flour - cooked; fresh or baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment. The following assumptions were made for the chronic exposure assessments: unrefined, Tier 1 chronic dietary exposure using tolerance-level residues, assuming 100% CT for all registered and proposed commodities. The Agency concluded that the chronic dietary exposure estimates are below HED's level of concern (<100% cPAD for the general U.S. population (< 23% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1–2 years old, at < 45% of the cPAD.

2. *Dietary exposure from drinking water.* There is no concern for exposure to residues of chlorfenapyr in drinking

water based on the approved, pending and proposed directions for use and chlorfenapyr's physical and chemical properties. Approved uses in the United States include applications to ornamental plants inside greenhouses, to a narrow band of soil adjacent to buildings and as a crack-and-crevice and spot treatments inside non-food/feed structures. In food handling areas chlorfenapyr is also applied as a crack-and-crevice and spot treatment inside structures. Chlorfenapyr has extremely low water solubility (120 parts per billion at 25° C) and is also immobile in soil and does not leach because it is strongly adsorbed to all common soil types.

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). Non-dietary exposure to chlorfenapyr is expected to be negligible based on assessments made by EPA for all currently approved uses: ornamentals grown in greenhouses, as a termiticide, and for indoor applications for general pest control. These assessments were based on the physicochemical characteristics of the compound, the intended use patterns, and available information concerning its environmental fate. The vapor pressure of chlorfenapyr is less than  $1 \times 10^{-7}$  mm of mercury (Hg). Therefore, the potential for non-occupational exposure by inhalation is insignificant. These assessments also apply to the use in food/feed handling areas as a crack-crevice and spot treatment.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to chlorfenapyr and any other substances and chlorfenapyr does not appear to produce a toxic metabolite produced by other substances. EPA has also evaluated comments submitted that suggested there might be a common mechanism between chlorfenapyr and other named pesticides that cause brain effects. EPA concluded that the

evidence did not support a finding of common mechanism for chlorfenapyr and the named pesticides. For the purposes of this tolerance action, therefore, EPA has not assumed that chlorfenapyr 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA 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 based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

The Agency previously identified that a developmental neurotoxicity (DNT) study was required for chlorfenapyr, based on the presence of neuropathology (CNS lesions), and neurotoxic signs seen in adult rats (males) and mice (both sexes). Considering the effects seen and the doses at which those effects occurred, the Agency concluded that a 10X safety factor is required until the data are received and evaluated.

2. *Prenatal and postnatal sensitivity.* There is no evidence (qualitative or quantitative) for increased susceptibility following *in utero* exposure in the developmental toxicity studies in rats and rabbits or prenatal/postnatal exposure in the 2-generation reproduction study in rats. In both the rat and rabbit developmental toxicity

studies maternal toxicity included decreased body weight gain. No developmental toxicity was noted in rats up to the highest dose tested of 225 mg/kg/day. Developmental toxicity in rabbits (increased post implantation loss) occurred at a higher dose than maternal toxicity. In the 2-generation reproduction study in rats, parental and offspring toxicity included body weight decrements at similar doses. No reproductive effects were noted up to the highest dose tested.

3. *Conclusion.* EPA evaluated the potential for increased susceptibility of infants and children from exposure to chlorfenapyr. EPA concluded that the toxicology data base was incomplete for FQPA purposes because a required DNT has not been submitted. The DNT was required due to the presence of neuropathology (central nervous system lesions) and neurotoxic signs seen in adult rats (males) and mice (both sexes). Other than lacking the DNT study, EPA identified no residual uncertainties for prenatal/postnatal toxicity. This decision is based on the following:

- There is no evidence (qualitative or quantitative) of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental toxicity studies. There is no evidence (qualitative or quantitative) of increased susceptibility of rat offspring in the multi-generation reproduction toxicity study.
- There are no concerns or residual uncertainties for prenatal and postnatal toxicity in the available developmental and 2-generation reproduction toxicity studies.
- The conservative residue assumptions used in the dietary exposure risk assessments, and the completeness of the residue chemistry database.

#### E. Aggregate Risks and Determination of Safety

There are no existing or proposed uses of chlorfenapyr which would result in contamination of drinking water or residential exposures. Therefore, an aggregate-exposure risk assessment was not performed.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Samples of composited meals from the subject study were analyzed for residues of chlorfenapyr using American Cyanamid GC/ECD (Gas Chromatograph/Electron Capture Detector) Method M 2398. This method has undergone a successful petition method validation (PMV). The reported limit of quantitation (LOQ) is 0.01 ppm.

The submitted concurrent recovery data indicate that GC/ECD Method M 2398 is adequate for determining residues of chlorfenapyr *per se* in/on composited meal samples. The data requirement for multiresidue methods has been satisfied pending FDA review and acceptance of the multiresidue methods.

An adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no established Codex, Canadian, or Mexican maximum residue levels (MRLs) for chlorfenapyr on all foods except fruiting vegetables at 0.01 ppm; therefore, harmonization of MRLs and U.S. tolerances is not an issue at this time.

##### C. Conditions

A tolerance has been previously established for Vegetables, fruiting, group 8, at 1.0 ppm. The establishment of additional residue level tolerances for chlorfenapyr on all food (as requested by the petitioner) must therefore, exclude Vegetables, fruiting, group 8. The registrant (BASF) was required to submit a revised Section F, excluding Vegetables, fruiting, group 8 commodity from the petition. The registrant (BASF) has met this condition. In addition, data are required as a condition of registration. These were previously discussed in Unit IV. C. of the final rule published in the **Federal Register** of September 26, 2003 (Vol. 68 No. 187 FR 55519-55527) (FRL-7320-8).

#### V. Conclusion

Therefore, the tolerance is established for residues of 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, chlorfenapyr, in or on all foods except Vegetables, fruiting group 8 at 0.01 ppm.

#### VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use

those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP-2004-0362 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 March 28, 2005.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14<sup>th</sup> St., NW., Washington, DC 20005. 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) 564-6255.

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](mailto: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 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0362, 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 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 under 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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. Congressional Review Act

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: December 24, 2004.

**Betty Shackelford,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

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

■ 2. Section 180.513 is amended in paragraph (a) by designating the text following the paragraph heading *General* as paragraph (a)(1), and by adding paragraph (a)(2) to read as follows:

#### § 180.513 Chlorfenapyr; tolerances for residues.

(a) *General.* (1) \* \* \*

(2) A tolerance of 0.01 parts per million is established for residues of chlorfenapyr in or on all food commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling areas where food/feed products are prepared, held, processed, or served and in accordance with the following prescribed conditions:

(i) Application shall be no greater than a 0.5% active ingredient solution for spot crack and crevice use in food/feed handling establishments, where food and food products are held, processed, prepared and/or served.

(ii) Application may only be undertaken when the facility is not in operation, and provided exposed food has been covered, or removed from the area being treated prior to application.

(iii) Food contact surfaces and equipment should be thoroughly washed with an effective cleaning compound, and rinsed with potable water after each use of the product.

(iv) Contamination of food or food contact surfaces shall be avoided. Application excludes any direct application to any food, food packaging, or any food contact surfaces.

(v) To assure safe use, the label and labeling shall conform to that registered

by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

\* \* \* \* \*

[FR Doc. 05-1439 Filed 1-25-05; 8:45 am]

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#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 73

[DA 05-33; MB Docket No. 04-367, RM-11070]

#### Radio Broadcasting Service; Genoa and Security CO

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Audio Division, at the request of Optima Communications, Inc., substitutes Channel 288C2 for Channel 288C3 at Security, Colorado and modifies Station KSKX(FM)’s license accordingly. To accommodate the upgrade, we also substitute Channel 291C3 for vacant Channel 288C3 at Genoa, Colorado. See 69 FR 60605, published October 12, 2004. Channel 288C2 can be allotted to Security in compliance with the Commission’s minimum distance separation requirements, provided there is a site restriction of 16.12 kilometers (10 miles) southwest of the community at coordinates 38-37-30 North Latitude and 104-49-00 West Longitude. Channel 291C3 can be allotted to Genoa with a site restriction of 18.4 kilometers (11.4 miles) east of the community at coordinates 39-15-35 North Latitude and 103-17-15 West Longitude.

**DATES:** Effective February 25, 2005. A filing window for Channel 291C3 at Genoa, Colorado will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

**ADDRESSES:** Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Helen McLean, Media Bureau, (202) 418-2738.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission’s *Report and Order*, MB Docket No. 04-367, adopted January 5, 2005, and released January 10, 2005. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC’s Reference