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 the 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: September 10, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.553 is amended as follows:

a. By revising the commodities plum, prune, dried and plum, prune, fresh in the table in paragraph (a).

b. By removing the commodity fruit, stone, except plum, prune, fresh in the table in paragraph (a).

c. By alphabetically adding commodities in the table in paragraph (a).

§ 180.553 Fenhexamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cucumber	2.0
Fruit, stone, group 12, except plum, prune, fresh, postharvest	10.0
* * *	* *
Kiwifruit, postharvest	15.0
* * *	* *
Leafy greens, subgroup 4A, except spinach	30.0
* * *	* *
Plum, prune, dried	2.5
Plum, prune, fresh	1.5
* * *	* *
Vegetable, fruiting, group 8, except nonbell pepper	2.0

* * * * *

[FR Doc. 03–24013 Filed 9–25–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0146; FRL–7320–8]

Chlorfenapyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of chlorfenapyr [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] in or on vegetables, fruiting, group 8. BASF Agro Research, now 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 September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0146, must be received on or before November 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6502; e-mail 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 grow fruiting vegetables in commercial greenhouses, consume vegetables that were raised in commercial greenhouses, or provide pest control services to commercial greenhouses. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Pesticide manufacturing (NAICS 32532)
- Other food crops grown under cover (NAICS 111419)
- Entomological services, agricultural; insect control for crops (NAICS 115112)
- Agricultural production or harvesting crews (NAICS 115115)

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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0146. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access*. 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 *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of September 13, 2000 (65 FR 55236) (FRL–6742–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of an amended pesticide petition (PP 6F4716) by BASF Agro Research, now BASF Corporation, P.O. Box 400, Princeton, NJ 08543–0400, now P.O. Box 13528, Research Triangle Park, NC 27709–3528. (The original pesticide petition PP 6F4716 was filed by American Cyanamid (now BASF Agro Research) in 1996). The 2000 notice included a summary of the petition prepared by BASF Agro Research, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.513 be amended by establishing a tolerance for residues of the insecticide chlorfenapyr, [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile], in or on vegetables, fruiting, group 8 at 1.0 parts per million (ppm).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the 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 the 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 the 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 the 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 the FFDCA, for a tolerance for residues of chlorfenapyr on vegetables, fruiting, group 8 at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by chlorfenapyr are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	MRID No. (year)/Classification/Doses	Results
870.3100	90–Day oral toxicity rats	42770219 (1993) Acceptable/guideline 0, 150, 300, 600, 900, 1,200 ppm 0, 11.7, 24.1, 48.4, 72.5, 94.5 mg/kg/day	NOAEL = 24.1 mg/kg/day LOAEL = 48.4, based on spongiform myelopathy in the brain and spinal cord of male rats, decreased body weight gain and increased relative liver weight in males and females, increased absolute liver weight in females, and decreased hemoglobin in females
870.3100	90–Day oral toxicity mouse	43492830 (1994) Acceptable/guideline 0, 40, 80, 160, 320 M: 0, 7.1, 14.8, 27.6, 62.6 mg/kg/day F: 0, 9.2, 19.3, 40, 78 mg/kg/day	NOAEL = 27.6/40, M/F LOAEL = 62.6/78, M/F, based on reduced body weights/body weight gains, and spongiform encephalopathy in both sexes
870.3150	90–Day oral toxicity dog	42770220 (1993) Acceptable/guideline 0, 60, 120,≈247* ppm M: 0, 2.1, 3.9, 6.7 mg/kg/day F: 0, 2.2, 4.5, 6.8 mg/kg/day *High dose animals received 300 ppm during days 1–15, 240 ppm during days 15–25, and 200 ppm during days 25–93	NOAEL = 3.9/4.5 mg/kg/day, M/F LOAEL = 6.7/6.8 mg/kg/day, M/F, based on emaciation, decreased body weight gains, and decreased food efficiency
870.3200	21/28–Day dermal toxicity rabbit	43492831 (1993) Unacceptable/guideline due to incomplete histopathological examination 0, 100, 400, 1,000 mg/kg/day	NOAEL = 100 mg/kg/day LOAEL = 400 mg/kg/day, for both sexes, based on changes in liver chemistry and morphology
870.3700	Prenatal developmental rat	42884202 (1993) Acceptable/guideline 0, 25, 75, 225 mg/kg/day	Maternal NOAEL = 25 mg/kg/day Maternal LOAEL = 75 mg/kg/day, based on decreased body weight gain and relative food consumption during treatment Developmental NOAEL ≥225 mg/kg/day Developmental LOAEL = not identified
870.3700	Prenatal developmental rabbit	42770222 (1993) Acceptable/guideline 0, 5, 15, 30 mg/kg/day	Maternal NOAEL = 5 mg/kg/day Maternal LOAEL = 15 mg/kg/day, based on decreased body weight gain during treatment Developmental NOAEL = 15 mg/kg/day Developmental LOAEL = 30 mg/kg/day, based on increased post implantation loss
870.3800	2–Generation reproduction and fertility effects rat	43492836 (1994) Acceptable/guideline 0, 60, 300, 600 ppm Premating doses for P_1 males/females: 0/0, 4.5/5.0, 22.2/24.5, 44/44.6 mg/kg/day Premating doses for F_1 males/females: 0/0, 4.4/5.1, 22.5/25.6, 44.6/50.7 mg/kg/day	Parental systemic NOAEL = 4.4–4.5 mg/kg/day, M Parental systemic LOAEL = 22.2–22.5 mg/kg/day, M, based on decreased absolute body weight/body weight gains of P_1 males during premating Offspring systemic NOAEL = 4.4–5.1 mg/kg/day Offspring systemic LOAEL = 22.2–25.6 mg/kg/day, based on decreased pup weights at weaning Reproductive NOAEL ≥44–50.7 mg/kg/day Reproductive LOAEL: not identified

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	MRID No. (year)/Classification/Doses	Results
870.4100	Chronic toxicity dog	43492834 (1994) Acceptable/guideline 0, 60, 120, 240 ppm M: 0, 2.1, 4.0, 8.7 mg/kg/day F: 0, 2.3, 4.5, 10.1 mg/kg/day	NOAEL = 4.0/4.5 mg/kg/day, M/F LOAEL = 8.7/10.1 mg/kg/day, M/F, based on decreased body weight/body weight gains
870.4200	Carcinogenicity mouse	43492838 (1994) Acceptable/guideline 0, 20, 120, 240 ppm M: 0, 2.8, 16.6, 34.5 mg/kg/day F: 0, 3.7, 21.9, 44.5 mg/kg/day	NOAEL = 2.8/3.7 mg/kg/day, M/F LOAEL = 16.6/21.9 mg/kg/day, M/F, based on decreased body weight gains, brain vacuolation, and scabbing of the skin (males) No evidence of carcinogenicity
870.4300	Combined chronic/carcinogenicity in rat	43492837 (1994) Acceptable/guideline 0, 60, 300, 600 ppm M: 0, 2.9, 15.0, 30.8 mg/kg/day F: 0, 3.6, 18.6, 37 mg/kg/day	NOAEL = 15 mg/kg/day, males LOAEL = 30.8 mg/kg/day, males, based on anemia NOAEL = 3.6 mg/kg/day, females LOAEL = 18.6 mg/kg/day, females, based on decreased body weight/body weight gain Classification: ''Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential'' based on significant trends in liver tumors (adenomas and combined adenomas/carcinomas), malignant histiocytic sarcomas, and testicular cell tumors in male rats and uterine polyps in female rats seen at the highest dose
870.5100	Bacterial reverse mutation	42770223 (1993) Acceptable/Guideline	Negative for reverse mutation in *S. typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, TA 1538 and *E. coli* strain WP2 uvrA- exposed up to cytotoxicity (50 µg/plate, +/- S9)
870.5300	*In vitro* mammalian cell gene mutation in Chinese hamster ovary cells (CHO/HGPRT)	42770224, 43187601 (1993) Acceptable/Guideline	Independently performed tests were negative up to a cytotoxic and precipitating concentration (500 µg/ml) in the presence of S9 activation or the solubility limit (250 µg/ml) without S9 activation
870.5375	*In vitro* mammalian chromosome aberration (CHO)	43492843 (1994) Acceptable	The test was negative up to 100 µg/ml -S9 or 25 µg/ml +S9; higher doses with or without S9 activation were cytotoxic
870.5385	*In vitro* chromosome aberration assay in Chinese hamster lung (CHL) cells	43492839 (1994) Acceptable/Guideline	The test was negative up to a precipitating level without S9 activation (225 µg/ml) or a concentration range of 3.5–14.1 µg/ml +S9. Higher S9-activated doses (≥28 µg/ml) were cytotoxic
870.5395	Mammalian micronucleus (mouse)	42770225, 43187602 (1993, 1994) Acceptable/Guideline	The test was negative in mice administered single oral gavage doses of 7.5–30 mg/kg (males) or 5–20 mg/kg (females). Clinical toxicity (deaths in males and diarrhea in females) was seen at the HDT. There was, however, no evidence of cytotoxicity for the target organ
870.5550	Unscheduled DNA synthesis	42770226 (1993) Acceptable/Guideline	Negative for inducing unscheduled DNA synthesis in primary rat hepatocyte cultures exposed up to severely toxic concentrations (≥30 µg/ml)
870.6200	Acute neurotoxicity screening battery rat	43492829 (1994) Acceptable/guideline 0, 45, 90, 180 mg/kg	NOAEL = 45 mg/kg/day LOAEL = 90 mg/kg/day, based on lethargy in male rats on the day of treatment
870.6200	Chronic neurotoxicity rat	43492833 (1994) Acceptable/Guideline 0, 60, 300, 600 ppm M: 0, 2.6, 13.6, 28.2 mg/kg/day F: 0, 3.4, 18, 37.4 mg/kg/day	NOAEL = 2.6/3.4 mg/kg/day, M/F LOAEL = 13.6/18 mg/kg/day, M/F, based on the presence of myelinopathic alterations in the central nervous system (CNS) in male rats and decreased average body weights/body weight gains, food efficiency, absolute food consumption (females) and water consumption (males)

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	MRID No. (year)/Classification/Doses	Results
870.7485	Metabolism and pharmacokinetics rat	43492844 (1994) Acceptable/guideline 20, 200 mg/kg/day	Low recoveries of the radioactive dose in urine and tissues indicate limited absorption of CL 303,630 (chlorfenapyr) by rats. The radioactivity in urine, as a percent of administered dose, from the high dosed rats was about half that from the single and multiple-low dosed rats. More than 80% of the doses were eliminated in the feces. Most of the radioactivity was eliminated in the feces and urine within 48 hours of dosing. After 7 days, 89–121% of the dosed radioactivity was recovered. At sacrifice, female rats had greater (about twice) recovery of radioactivity in the carcass, blood, and fat at all doses than did males. The highest recovery of radioactivity from a single organ was from the liver (0.15–0.48% of dose) Metabolite and parent compound accounted for 72–91% of the radioactive doses. Parent compound was the major radioactive component found in excreta, accounting for approximately 40–70% of the administered doses. Minor amounts of eight primary and conjugated metabolites and four unidentified isolated components were detected, each at less than 10% of the dosed radioactivity. Liver and kidney contained several primary and conjugated metabolites and only minor levels of the parent compound (≤8.3% of the radioactivity in the sample). Based on the metabolites identified, the major deposition route of orally administered chlorfenapyr is fecal excretion of unaltered parent compound. Other pathways include cleavage of the ethoxymethyl side-chain, followed by de-alkylation and ring hydroxylation, and some degree of conjugation of the de-alkylated, ring-hydroxylated metabolite. The two rings of the molecule are not cleaved. Metabolites are excreted primarily in urine; accumulation in tissues is minimal

B. Toxicological Endpoints

The dose at which 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 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. An additional safety factor (SF) may be required if the data base is incomplete. For chlorfenapyr EPA concluded that a developmental neurotoxicity (DNT) study is required based on the presence of neuropathology (CNS lesions) and neurotoxic signs seen in adult rats (males) and mice (both sexes). EPA further concluded that a UF of 10X is required until the data are received and evaluated. EPA does not have sufficient reliable data justifying the selection of a factor lower than the default 10X value for the additional SF for the protection or infants and children for this data gap.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional SF is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

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.

A summary of the toxicological endpoints for chlorfenapyr used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CHLORFENAPYR FOR USE IN HUMAN RISK ASSESSMENT.

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 15 mg/kg UF = 1,000 aRfD = 0.015 mg/kg	Special FQPA SF = 1X aPAD = aRfD ÷ FQPA SF = 0.015 mg/kg	Developmental toxicity study - rabbit LOAEL = 30 mg/kg/day based on increased post-implantation loss

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CHLORFENAPYR FOR USE IN HUMAN RISK ASSESSMENT.—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	NOAEL = 45 mg/kg UF = 1,000 aRfD = 0.045 mg/kg	Special FQPA SF = 1X aPAD = aRfD ÷ FQPA SF = 0.045 mg/kg	Acute neurotoxicity study - rat LOAEL = 90 mg/kg/day based on lethargy in male rats
Chronic Dietary (All populations)	NOAEL= 2.6 mg/kg/day UF = 1,000 cRfD = 0.003 mg/kg/day	Special FQPA SF = 1X cPAD = cRfD ÷ FQPA SF = 0.003 mg/kg/day	Chronic neurotoxicity study - rat LOAEL = 13.6/18 mg/kg/day, M/F, based on the presence of myelinopathic alterations in the CNS in male rats and decreased average body weights, body weigh gains, food efficiency, absolute food consumption (F), and water consumption (M) Supporting this endpoint are similar CNS lesions and skin lesions observed in the mouse carcinogenicity study (NOAEL = 2.8)

*The reference to the special FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* 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 1–day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption 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 commodity. The following assumptions were made for the acute exposure assessments: Tolerance-level residues (not anticipated residues); 100% crop treated for all registered and proposed commodities; and default DEEM® Version 7.76 processing factors for all commodities. EPA selected separate acute dietary endpoints for females 13–50 years old and the general U.S. population (including infants and children). Therefore, two separate acute dietary exposure assessments were performed for females 13–49 years old and for the general U.S. population and various population subgroups. These assessments conclude that the acute dietary exposure estimates are below EPA's LOC (<100% aPAD) at the 95th 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 12% of the aPAD.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996, and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance-level residues (not anticipated residues); 100% crop treated for all registered and proposed commodities; and default DEEM® Version 7.76 processing factors for all commodities. An assessment of the general U.S. population and various population subgroups was conducted. This assessment concludes that the chronic dietary exposure estimates are below EPA's LOC (<100% cPAD) for the general U.S. population (24% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1–2 years old, at 47% of the cPAD.

2. *Dietary exposure from drinking water.* The registered uses of chlorfenapyr include: Termiticide use, crack and crevice use, and use on ornamental plants grown in greenhouses. The proposed use is for vegetable crops grown in greenhouses. When used according to label directions, these uses are not expected to result in contamination of drinking water.

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). Chlorfenapyr is registered for residential crack and crevice use and in-ground termite use. EPA has addressed the issues of possible residential exposures to chlorfenapyr when used according to label directions, either as a termiticide or as a crack and crevice treatment. EPA concluded that there is essentially no incidental-oral or dermal exposures. Further, the low vapor pressure of chlorfenapyr makes inhalation exposure negligible.

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

EPA does not have, at this time, available data to determine whether chlorfenapyr has a common mechanism of toxicity with other substances. 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. 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 the 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 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.

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.

EPA concluded that a FQPA SF in the form of UFDB of 10X is required until the data from the DNT study are received and evaluated. EPA does not have sufficient reliable data justifying the selection of a factor lower than the default 10X value for this data gap.

E. Aggregate Risks and Determination of Safety.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to chlorfenapyr will occupy 6% of the aPAD for the U.S. population, 15% of the aPAD for females 13 years and older, 12% of the aPAD for children 1–2 years old and 3% of the aPAD for infants < 1 year old. As explained in Unit III.C.2., there is no potential for acute dietary exposure to chlorfenapyr in drinking water. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to chlorfenapyr from food will utilize 24% of the cPAD for the U.S. population, 10% of the cPAD for infants < 1 year old and 47% of the cPAD for children 1–2 years old. Based on the use pattern, chronic residential exposure to residues of chlorfenapyr is not expected. There is no potential for chronic dietary exposure to chlorfenapyr in drinking water. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Chlorfenapyr is registered for use on sites that would result in negligible residential exposure and no exposure from drinking water. Therefore, the aggregate risk is equal to the risk from food, and does not exceed the Agency's LOC.

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Residue analytical methods*. The proposed enforcement method is M2427, a gas chromatography/electron capture detection (GC/ECD) method with an limit of quantitation (LOQ) of 0.05 ppm. Method M2427 has been subjected to a successful independent laboratory validation (ILV) as well as an acceptable radiovalidation using samples obtained from lettuce and tomato metabolism studies. A version of this method, M2284 was sent to EPA's Analytical Chemistry Branch (ACB) in Beltsville, MD for a petition method validation (PMV) on oranges and citrus oil. Although the PMV was successful, minor revisions were required. A new version of analytical method M2284 with the recommended revisions has not been submitted. The Agency's review of PP 6F4716 concluded that method M2427 is adequate for data collection and tolerance enforcement purposes pending submission of the rewritten method M2284. Since M2427 is similar to M2284, the petitioner was directed to rewrite Method M2427 following the ACB comments regarding M2284. The petitioner has submitted Method 2427.02, which contains the requested revisions.

2. *Multiresidue method (MRM)*. The data requirement for MRM is satisfied pending U.S. Food and Drug Administration (FDA) review and acceptance of the MRM results. The petitioner previously submitted MRM recovery data for chlorfenapyr through FDA Protocols A through E. Protocols A and B were not applicable to chlorfenapyr. In Protocol C, chlorfenapyr gave a good response with the electron capture detector on three different GC columns. In Protocol D, using pears as a non-fatty food representative, the 5% OV-101 column gave the greatest sensitivity at 0.05 and 0.50 ppm. In Protocol E, chlorfenapyr eluted well on Florisil in both the ethyl ether/petroleum ether system and the alternate hexane/acetonitrile/methylene chloride system and gave acceptable recovery.

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*.

B. International Residue Limits

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

C. Conditions

The following data are required as a condition of registration: A developmental neurotoxicity study to determine the cause/relationship of potential central nervous system/ myelinopathic alterations to neurotoxicity in the developing young.

V. Conclusion

Therefore, the tolerance is established for residues of chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, in or on vegetables, fruiting, group 8 at 1.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the 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–2003–0146 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 November 25, 2003.

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 (1900C), 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 Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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

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 Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0146, 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 Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 the 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 the 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: September 22, 2003.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. A new section heading and text are added to § 180.513 to read as follows:

§ 180.513 Chlorfenapyr; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide chlorfenapyr [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] in or on the following raw agricultural commodities:

Commodity	Parts per million
Vegetables, fruiting, group 8	1.0

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

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2175–CN]

RIN 0938–AM20

Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects the effective date of a final rule with comment period published in the **Federal Register** on August 29, 2003 (68 FR 51912). That rule finalizes separately, in an accelerated timeframe, two specific provisions of the September 19, 1995 proposed rule. It establishes new recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program. It also sets forth a 3-year time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to us. In addition, it announces the pressing need for codification of fundamental recordkeeping requirements. It also announces our intention to continue to work on finalizing the complete drug