

the use of the food commodities in this paragraph when treated in accordance with the provisions of the experimental use permit 67979-EUP-4 which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked October 15, 2007; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0103; FRL-7765-3]

Triflumizole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino-2-propoxyethyl)-1H-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on filberts. Interregional Research Project Number 4 (IR-4) 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 March 15, 2006. Objections and requests for hearings must be received on or before May 15, 2006.

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 EPA-HQ-OPP-2006-0103. All documents in the docket are listed on the <http://www.regulations.gov> Web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) 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:

Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: madden.barbara@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- 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 on 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.html>.

II. Background and Statutory Findings

In the **Federal Register** of January 18, 2006 (71 FR 2930) (FRL-7757-1), 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 3E6535) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902. The petition requested that 40 CFR 180.476 be amended by establishing a tolerance for combined residues of the fungicide triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino-2-propoxyethyl)-1H-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on filberts at 0.05 parts per million (ppm). That notice included a summary of the petition prepared by Chemtura, the registrant. There were no comments received in response to the notice of filing.

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 <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

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 combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino-2-propoxyethyl)-1H-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on filbert at 0.05 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. Specific information on the studies received and the nature of the toxic effects caused by triflumizole as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at <http://www.epa.gov/EPA-PEST/2002/June/Day-12/p14768.htm>

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>.

A summary of the toxicological endpoints for triflumizole used for human risk assessment is discussed in Unit VI.A. of the final rule published in the **Federal Register** of April 8, 2005 (70 FR 17908) (FRL-7701-6).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.476) for the combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino-2-propoxyethyl)-1H-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on a variety of raw agricultural commodities. In addition, tolerances for livestock commodities have been established for the combined residues of triflumizole, the metabolite 4-chloro-2-hydroxy-6-trifluoromethylaniline sulfate, and other metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as parent compound, in/on milk; eggs; meat, fat, and meat byproducts (mbyp) of cattle, goats, hogs, horses, and sheep; and in/on meat, and mbyp of poultry. Risk assessments were conducted by EPA to assess dietary exposures from triflumizole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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.

Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID™) (ver. 2.03) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (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 and 100 percent crop treated (PCT) information for all registered and proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM software with the DEEM-FCID™, which incorporates food consumption data 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: A refined, chronic dietary exposure assessment was performed using anticipated residues (ARs) from average field trial residues for apple, grape, pear, cherry, cucumber, strawberry, and milk commodities; registered and proposed tolerance for all other commodities; PCT information for apples, grapes and pear commodities; and 100 PCT information for all other uses.

iii. *Cancer.* Triflumizole is classified as a "Group E" (evidence of non-carcinogenicity in humans) chemical based on adequate studies in two species of animal. Therefore, a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue;

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Apples of 18%, grapes of 13%, pears of 29%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

This method of projecting PCT for a new pesticide use, with or without regard to specific pest(s), produces an upper-end projection that is unlikely, in most cases, to be exceeded in actuality because the dominant pesticide is well-established and accepted by farmers. Factors that bear on whether a projection based on the dominant pesticide could be exceeded are whether the new pesticide is more efficacious or controls a broader spectrum of pests than the dominant pesticide, whether it is more cost-effective than the dominant pesticide, and whether it is likely to be readily accepted by growers and experts. These factors have been considered for this pesticide new use, and they indicate that it is unlikely that actual PCT for this new use will exceed the PCT for the dominant pesticide in the next 5 years.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a

comprehensive dietary exposure analysis and risk assessment for triflumizole in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of triflumizole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool and Screening Concentrations in Groundwater models, the estimated environmental concentrations (EECs) of triflumizole for acute exposures are estimated to be 191 parts per billion (ppb) for surface water and 0.12 ppb for ground water. The EECs for chronic exposures are estimated to be 40 ppb for surface water and 0.12 ppb for ground 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). Triflumizole is not registered for use on any sites that would result in residential exposure.

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 triflumizole and any other substances, and triflumizole 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 triflumizole 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.

2. *Prenatal and postnatal sensitivity.* There is qualitative evidence of increased susceptibility demonstrated in the oral prenatal developmental toxicity studies in rats. Developmental toxicity resulted in fetal death as compared to maternal toxicity which included decreases in body weight gain and food consumption and increases in placental, spleen and liver weights at the same dosages. No quantitative or qualitative evidence of increased susceptibility was demonstrated in the prenatal developmental toxicity studies in rabbits or the multi-generation reproduction studies in rats. In the rabbit developmental studies, 24-hour fetal survival was decreased at the highest dose tested. This endpoint is not a recommended guideline parameter and is generally believed to have limited value in the assessment of development toxicity; rather, it is more an indicator of fetal endurance in the absence of critical maternal care, following removal from the uterus. The Agency did not consider this effect to be a measurement of treatment-related effects on fetal viability and, thus, did not consider it to be relevant to the assessment of fetal susceptibility. There was no evidence of quantitative or qualitative susceptibility in the 2-generation reproduction study in rats. In that study, increased gestation length was observed at the study LOAEL. In rats, this alteration in normal reproductive function can result in

equally adverse consequences (i.e., mortality) in both dams and offspring.

3. *Conclusion.* In the Agency's previous triflumizole human health risk assessments (refer to <http://www.epa.gov/EPA-PEST/2002/June/Day-12/p14768.htm>) the following toxicity studies were determined to be data gaps: A 28-day rat inhalation study (OPPTS Harmonized Guideline Number 870.3465), acute rat neurotoxicity study (OPPTS Harmonized Guideline 870.6200), and subchronic rat neurotoxicity study (OPPTS Harmonized Guideline 870.6200). The acute and sub-chronic neurotoxicity studies have been submitted, reviewed by the Agency and determined to be acceptable.

The Agency has re-evaluated the quality of the exposure and hazard data; and, based on these data, concluded that the additional 10X FQPA safety factor should be removed (previously, a 3X FQPA safety factor was retained). The conclusion is based on the following:

- The toxicity database is complete for FQPA assessment.
- There was no quantitative or qualitative evidence of increased susceptibility in the rabbit fetuses following *in utero* exposure or the rat following prenatal and postnatal exposure in the rat reproduction study.

- There was evidence of qualitative susceptibility in the developmental rat study; however, there are no residual uncertainties, and the use of the developmental NOAEL and the endpoint for the acute RfD for females 13 to 50 would be protective of the prenatal toxicity following an acute dietary exposure.

- The acute dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100 PCT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

- The chronic dietary food exposure assessment utilizes ARs and PCT data verified for several existing uses. For all proposed use, tolerance-level residue and 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.

- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded.

- There are no registered or proposed uses of triflumizole that would result in residential exposure.

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 triflumizole will occupy 6% of the aPAD for the U.S. population, 9% of the aPAD for females 13 years and older, 11% of the aPAD for all infants (<1 year old), and 21% of the aPAD for children 1–2 years old, the subpopulation at greatest exposure. In addition, there is potential for acute dietary exposure to triflumizole in drinking water. To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against EECs. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at <http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf>. After calculating drinking water level of concentration DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLUMIZOLE

Population Subgroup	aPAD (mg/kg)	%aPAD/ (Food)	Surface Water EEC/ (ppb)	Ground Water EEC/ (ppb)	Acute DWLOC/ (ppb)
U.S. population	0.25	6	191	0.12	8,300
Females (13 years and older)	0.1	9	191	0.12	2,700
All infants (<1 year)	0.25	11	191	0.12	2,200
Children (1–2 years old)	0.25	21	191	0.12	2,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to triflumizole from food will utilize 5% of the chronic Population adjusted dose (cPAD) for the U.S. population, 4% of the cPAD for all

infants (<1 year old), and 13% of the cPAD for children 1–2 years old, the subpopulation at greatest exposure. There are no residential uses for triflumizole. There is potential for chronic dietary exposure to triflumizole in drinking water. After calculating

DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRIFLUMIZOLE

Population/Subgroup	cPAD/mg/kg/day	%cPAD/ (Food)	Surface Water EEC/ (ppb)	Ground Water EEC/ (ppb)	Chronic DWLOC (ppb)
U.S. population	0.015	5	40	0.12	500
All infants (<1 year)	0.015	4	40	0.12	140
Children (1–2 years old)	0.015	13	40	0.12	130

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Triflumizole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Triflumizole has been classified as not likely to be carcinogenic to humans. Therefore, triflumizole is expected to pose at most a negligible cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology gas chromatography/mass spectrometry detector (GC/MSD) method (Morse Method METH-115, Revision #3) 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 limits (MRLs) for triflumizole in/on filberts. Therefore, harmonization is not an issue at this time.

V. Conclusion

Therefore, the tolerance is established for combined residues of triflumizole, 1-(1-(4-chloro-2-(trifluoromethyl)phenyl)imino-2-propoxyethyl)-1H-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on filbert at 0.05 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 EPA-HQ-OPP-2006-0103 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 May 15, 2006.

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 issue(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 14th 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. *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 EPA-HQ-OPP-2006-0103, to: Public Information and Records Integrity Branch, Information Technology and Resources Management 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**. 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 issue(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: March 3, 2006.

Lois Rossi,
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 180.476 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows:

§ 180.476 Triflumizole; tolerances for residues.

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

Commodity	Parts per million
* * *	* * *
Filbert	0.05
* * *	* * *

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[WT Docket No. 03-66; RM-10586; FCC 04-135]

Facilitating the Provision of Fixed and Mobile Broadband Access, Educational and Other Advanced Services in the 2150-2162 and 2500-2690 MHz Bands

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations, which were published in the **Federal Register** on Friday, December 10, 2004, (69 FR 72020). The Commission published final rules in the *Report and Order*, that renamed the Instructional Television Fixed Service (ITFS) as the Educational Broadband Service (EBS) and renames the Multichannel Multipoint Distribution Service (MMDS) and the Multipoint Distribution Service (MDS) as the Broadband Radio Service (BRS). This document corrects the final regulations by revising Section 1.1307.

DATES: Effective January 10, 2005.

FOR FURTHER INFORMATION CONTACT: Nancy J. Brooks, Office of Engineering and Technology, (202) 418-2454 e-mail: *Nancy.Brooks@fcc.gov*.

SUPPLEMENTARY INFORMATION: The final regulations that are the subject of this correction relate to final rules in the *Report and Order*, which transformed the rules and policies governing the licensing of the Instructional Television Fixed Service (ITFS) the Multichannel Multipoint Distribution Service (MMDS) and the Multipoint Distribution Service (MDS), in the 2500-2690 bands.

Need for Correction

As published, the final regulations contain errors, which require immediate correction.