§ 180.1254 Aspergillus flavus NRRL 21882 on peanut; exemption from requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* NRRL 21882 in or on peanut; peanut hay; peanut, meal; peanut, refined oil.

■ 30. Section 180.1258 is revised to read as follows:

§ 180.1258 Acetic acid; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide acetic acid when used as a preservative on post-harvest agricultural commodities intended for animal feed, including Alfalfa, seed; alfalfa, hay; barley, grain; bermudagrass, hay; bluegrass, hay; bromegrass, hay; clover, hay; corn, field, grain; corn, pop, grain; cowpea, hay; fescue, hay; lespedeza, hay; lupin; oat, grain; orchardgrass, hay; peanut, hay; timothy, hay; vetch, hay; and wheat, grain, or commodities described as grain or hay.

■ 31. Section 180.1261 is revised to read as follows:

§ 180.1261 Xanthomonas campestris pv. vesicatoria and Pseudomonas syringae pv. tomato specific Bacteriophages.

An exemption from the requirement of a tolerance is established for residues of *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. tomato* specific bacteriophages in or on pepper and tomato.

■ 32. In § 180.1274, by revising the introductory text to read as follows:

§ 180.1274 Tris (2-ethylhexyl) phosphate; exemption from the requirement of a tolerance.

Tris (2-ethylhexyl) phosphate (TEHP, CAS Reg. No. 78–42–2) is exempt from the requirement of a tolerance for residues in grain, aspirated fractions; barley, grain, barley, hay, barley, straw; wheat, grain; wheat, forage; wheat, hay; wheat, straw when used under the following conditions:

■ 33. Section 180.1276 is revised to read as follows:

§ 180.1276 Tobacco mild green mosaic tobamovirus (TMGMV); temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of tobacco mild green mosaic tobamovirus in or on all grass, forage and grass, hay.

■ 34. Section 180.1279 is revised to read as follows:

§ 180.1279 Zucchini yellow mosaic virus—weak strain; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the ZYMV–WK strain in or on all raw cucurbit when applied/used in accordance with label directions.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0312; FRL–8414–6]

Triflumizole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline (FA-1-1) moiety, calculated as the parent compound, in or on leafy greens subgroup 4A, except spinach; Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; cilantro leaves; Swiss chard; pineapple; papaya; black sapote; canistel; mamey sapote; mango; sapodilla; star apple; hops, dried cones; and turnip greens. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also deletes the following time-limited tolerances, as permanent tolerances supersede them: Collards, kale and mustard greens, as residues on these commodities will be covered by the Brassica, leafy greens, subgroup 5B tolerance; broccoli, since residues will be covered by the Brassica, head and stem, subgroup 5A tolerance; dandelion leaves and parsley leaves, since residues will be covered by the leafy greens subgroup 4A tolerance; Swiss chard and turnip greens, as the time-limited tolerances will be superseded by permanent tolerances; and coriander leaves, as the cilantro leaves tolerance supersedes it and is the preferred commodity definition.

DATES: This regulation is effective June 3, 2009. Objections and requests for hearings must be received on or before August 3, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0312. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0312 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 as required by 40 CFR part 178 on or before August 3, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0312, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petitions for Tolerance

In the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL–8133–4), 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 7E7183) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. 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)-1 *H*-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on Brassica, leafy greens, subgroup 5B at 20.0 parts per million (ppm). That notice referenced a summary of the petition prepared on behalf of IR-4 by Chemtura USA Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of February 6, 2008 (73 FR 6964) (FRL–8350–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 7E7258 and 7E7286) by IR-4. The petition requested that 40 CFR 180.476 be amended by establishing tolerances for combined residues of the fungicide triflumizole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on food commodities for PP 7E7258: Leafy greens subgroup 4A, except spinach, at 35 ppm; cilantro, leaves at 35 ppm; Swiss chard at 18 ppm; pineapple at 4.0 ppm; papaya at 2.5 ppm; sapote, black at 2.5 ppm; canistel at 2.5 ppm; sapote, mamey at 2.5 ppm; mango at 2.5 ppm; sapodilla at 2.5 ppm; star apple at 2.5 ppm; and hop, dried cones at 50.0 ppm; and for PP 7E7286: Brassica, head and stem, subgroup 5A at 5.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Chemtura USA Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to this notice of filing.

In the **Federal Register** of May 16, 2008 (73 FR 28461) (FRL–8361–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the amendment of pesticide petition (PP 7E7258) by IR-4. The petition requested that 40 CFR 180.476 be amended by additionally establishing a tolerance for combined residues of the fungicide triflumizole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on the food commodity turnip, greens at 40 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Chemtura USA Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to this notice of filing.

Based upon review of the data supporting these petitions, EPA has determined that some of the proposed tolerance levels should be increased and has also revised the tolerance expression. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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. . . . ''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for combined residues of triflumizole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, on leafy greens subgroup 4A, except spinach at 35 parts per million (ppm); Brassica, head and stem, subgroup 5A at 8.0 ppm; Brassica, leafy greens, subgroup 5B at 40.0 ppm; cilantro

leaves at 35 ppm; Swiss chard at 18 ppm; pineapple at 4.0 ppm; papaya at 2.5 ppm; black sapote at 2.5 ppm; canistel at 2.5 ppm; mamey sapote at 2.5 ppm; mango at 2.5 ppm; sapodilla at 2.5 ppm; star apple at 2.5 ppm; hop, dried cones at 50.0 ppm; and turnip greens at 40 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Triflumizole has low acute toxicity via the oral, dermal, and inhalation routes. It is a mild eye irritant and dermal sensitizer, but is not a dermal irritant. The primary target organ affected by triflumizole is the liver. Liver effects were seen in rat and mouse subchronic and chronic/carcinogenicity studies. Subchronic effects included increased absolute and relative liver weights, accumulation of fat droplets, and slight hepatocyte centrilobular swelling. With increased length of exposure, the types of microscopic lesions noted increased in number and severity. Chronic effects included hepatocyte fatty vacuolization; hepatocyte hypertrophy, focal inflammation, and necrosis; fatty degeneration; eosinophilic foci of hepatocyte alteration; hepatic nodules; bile duct hyperplasia; and hyaline degeneration/fibrosis of the bile duct. The dog was less sensitive to the effects of triflumizole. In the dog chronic study, effects included increased liver weights, increased serum alkaline phosphatase levels, and a macroscopic hepatic lobular pattern and granular texture. A very mild, macrocytic anemia was also noted and was most likely secondary to liver effects.

A special microsomal enzyme induction study showed that triflumizole can induce hepatic microsomal enzymes when administered orally at high doses. Kidney weights were increased in the rat and mouse also, but the only pathology seen microscopically was in the rat chronic/carcinogenicity study in which cortical cysts were noted. Other organ effects were observed microscopically at the highest dose tested (HDT) in the chronic rat study, which mainly involved cystic or hyperplastic lesions in endocrine glands and/or lymph nodes. Body weight decrements were noted in the rat and/or mouse subchronic, chronic and carcinogenicity studies and the developmental and reproduction studies.

Long-term dietary administration of triflumizole did not result in an overall treatment-related increase in incidence of tumor formation in rats or mice. Based upon the lack of evidence of carcinogenicity in rats and mice, EPA classified triflumizole as ''not likely to be carcinogenic to humans'' by all routes of exposure. Further, triflumizole did not show evidence of mutagenicity in *in vitro* or *in vivo* studies.

Signs of neurotoxicity were seen in the acute oral toxicity studies in the rat and mouse and an acute inhalation study in the rat. Neurotoxic signs were also observed in the acute neurotoxicity study based on functional-observational-battery (FOB) findings (neuromuscular impairment) and decreased locomotor activity. By day 8 of the observation period treated males and females were comparable to the controls. Although there was a statistically significant increase in hindlimb splay of low-dose females, this effect does not appear to be of great toxicological significance, since no other FOB effects were observed in low-dose females. No evidence of neurotoxicity was seen in the rat subchronic oral toxicity study or the mouse subchronic oral toxicity and carcinogenicity studies.

In oral rat developmental studies, fetal effects (decreased numbers of viable fetuses, increased dead or resorbed fetuses, increased numbers of late resorptions, decreased fetal body weight and increased incidences of cervical ribs) were seen at the same doses where less severe maternal effects were noted (decreases in body weight gain and food consumption and increases in placental, spleen and liver weights). Fetal effects in the rabbit developmental study (decreased 24–hour survival, increased fetal and litter incidences of lumbar ribs and decreased placental weights) were noted at the same dose as maternal toxic effects (decreased food consumption, and decreased placental weights). In a multi-generation study in rats, offspring effects included decreased pup weights, survival indices, and litter sizes in both F3 litters, reduced litter size in the F1a litter, increased total-litter mortality in the F3a litter, and developmental effects in the F1b and F2b progeny. Reproductive toxicity, manifested as increased gestation length, was increased at the high dose.

Specific information on the studies received and the nature of the adverse 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.regulations.gov* in document ''Triflumizole: Second Amended Human Health Risk Assessment for Proposed Uses on Leafy Greens (Subgroup 4A) Except Spinach, Head and Stem Brassica (Subgroup 5A), Cilantro, Swiss Chard, Pineapple, Papaya, Black Sapote, Canistel, Mamey Sapote, Mango, Sapodilla, Star Apple, and Hops'' pages 51–55 in docket ID number EPA–HQ–OPP–2007–0312.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment

process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

EPA identified an acute effect for the general population (neuromuscular impairment and decreased locomotor activity seen in the rat acute neurotoxicity study) and for females 13 to 49 years old (decreased numbers of viable fetuses, increased dead or resorbed fetuses, increased numbers of late resorptions, decreased fetal body weight, and increased incidence of cervical ribs in the rat developmental toxicity study that are presumed to occur after a single exposure). The aPAD for the general population has been established at 0.25 milligrams/kilogram/day (mg/kg/day); whereas, the aPAD for females 13 to 49 years old is lower (0.1 mg/kg/day) due to the more sensitive endpoint on which it is based.

In previous risk assessments for triflumizole, the chronic reference dose (cRfD) for the general population was derived from the NOAEL of 1.5 mg/kg/day from the multi-generation rat reproduction study. However, the Registrant requested that the Agency consider historical control data in relation to the rat reproductive study. Based on evaluation of the historical control data it was determined that the NOAEL should be 3.5 mg/kg/day (previously classified as the LOAEL). The NOAEL of 3.5 mg/kg/day was based on decreased pup body weight, mortality, reduced litter size and increased incidence of hydroureter and space between the body wall and organs observed at 8.5 mg/kg/day (NOAEL= 3.5 mg/kg/day). In addition, gestation length was increased in the dams of F1a, F2a, and F3a intervals at the LOAEL of 8.5 mg/kg/day (NOAEL = 3.5 mg/kg/day).

Based on a re-evaluation of the toxicity database, it was determined that the most suitable endpoint for the derivation of a cRfD was a LOAEL of 3.5 mg/kg/day (a NOAEL was not determined) identified in a chronic rat study and based on liver toxicity. The revised NOAEL of 3.5 mg/kg/day in the rat reproduction study would not be protective of potential liver toxicity associated with triflumizole. It was determined that the LOAEL of 3.5 mg/kg/day from the Combined Chronic Toxicity/Carcinogenicity (based on liver effects) was protective with an additional safety factor.

A summary of the toxicological endpoints for triflumizole used for human risk assessment can be found at *http://www.regulations.gov* in document ''Triflumizole: Second Amended Human Health Risk Assessment for Proposed Uses on Leafy Greens (Subgroup 4A) Except Spinach, Head and Stem Brassica (Subgroup 5A), Cilantro, Swiss Chard, Pineapple, Papaya, Black Sapote, Canistel, Mamey Sapote, Mango, Sapodilla, Star Apple, and Hops'' pages 30-32 in docket ID number EPA–HQ–OPP–2007–0312.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to triflumizole, EPA considered exposure under the petitioned-for tolerances as well as all existing triflumizole tolerances in 40 CFR 180.476. EPA assessed 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all existing and new uses of triflumizole.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used average field trial residues as anticipated residues (ARs) for apple, grape, pear, cherry, cucurbit, strawberry, leafy greens (subgroup 4A) except spinach, head and stem Brassica (subgroup 5A), cilantro, Swiss chard, pineapple, papaya, black sapote, canistel, mamey sapote, mango, sapodilla, star apple and hops. For all other commodities, the assessment used tolerance level residues. The EPA used PCT information for apples, cantaloupes, cherries, cucumbers, grapes, hazelnuts (filberts), honeydew melons, pears, pumpkins, squash, strawberries and watermelons. 100 PCT information was used for the remaining registered and proposed uses.

iii. *Cancer*. Based on absence of significant tumor increases in two rodent carcinogenicity studies, EPA has classified triflumizole as ''not likely to be carcinogenic to humans;'' therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

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 residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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:

- Condition a: 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information for chronic assessments as follows:

Apples 20%; Cantaloupe 10%; Cherries 15%; Cucumbers 5%; Grapes 5%; Hazelnuts (Filberts) 15%; Honeydew melons 15%; Pears 40%; Pumpkin 5%; Squash 1%; Strawberry 15%; and Watermelon 5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The

maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which triflumizole may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for triflumizole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) for surface water and Screening Concentration in Ground Water (SCI-GROW) models for ground water, the estimated drinking water concentrations (EDWCs) of triflumizole and its metabolites containing the 4-chloro-2-trifluoromethyl aniline moiety for surface water are estimated to be 37.4 parts per billion (ppb) for acute exposures; 15.8 ppb for chronic exposures for non-cancer assessments. For ground water, the EDWCs for all of the above exposure scenarios are estimated to be 3.11 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 37 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 16 ppb was used to assess the contribution to 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).

Triflumizole is currently registered for use on ornamental plants including trees, shrubs and vines in residential areas. Since residential applications of triflumizole are to be made by commercial applicators, residential handler exposures are not expected to occur. In addition, post-application exposures of adults and children from this use have been determined to be negligible. Therefore, a residential exposure assessment is not necessary for triflumizole and was not conducted.

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.''

EPA has not found triflumizole to share a common mechanism of toxicity with 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 assumed that triflumizole does not have 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for triflumizole includes prenatal developmental toxicity studies in rats and rabbits and a multi-generation reproduction toxicity study in rats. There is no evidence of increased quantitative or qualitative susceptibility of rabbit fetuses following *in utero* exposure to triflumizole. Although 24–hour fetal survival was reduced in this study, 24–hour fetal survival is more an indicator of fetal endurance after being removed from the womb rather than a measurement of treatment-related effects on fetal viability and, thus, is not appropriate to use to ascertain fetal susceptibility. In the multi-generation rat reproduction study, reproductive toxicity (increased gestation length and increased vaginal bleeding and dystocias) was increased at the high dose. However, these effects may be a result of endocrine effects on the reproductive system. Comparison of offspring toxicity to reproductive toxicity is more appropriate to evaluate susceptibility because the increased gestation length in the dams is a true parental effect and may affect the dam or the offspring; therefore, there is no increased susceptibility of offspring following prenatal and postnatal exposure in the rat reproduction study.

There was evidence of increased qualitative susceptibility following *in utero* exposure of rats in a developmental study. Developmental toxicity resulted in decreased pup viability, increased dead or resorbed fetuses and an increased incidence of cervical ribs at doses that resulted in less severe maternal toxicity (decreases in body weight gain and food consumption and increases in placental, spleen and liver weights). There are no residual uncertainties for developmental toxicity, and the use of the developmental NOAEL and the endpoint for the acute reference dose (aRfD) for females 13-49 is considered protective of the prenatal toxicity following an acute dietary exposure.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3X for all repeated exposure scenarios and 1X for single

exposure scenarios. That decision is based on the following findings.

i. The toxicity database for triflumizole is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. In the toxicity database for triflumizole, there was some indication of possible immunotoxicity in the form of non-neoplastic lesions, characterized as dilated cyctic sinuses in the thymic lymph node following dietary administration for 2 years. However, these lesions were seen only in male rats at the HDT and only at the termination of the study. This indicates that these lesions are non-specific, are due to the age of the rats, and thus are not attributable to frank immunotoxicity. There were no other corroborative changes, such as changes in the thymus weights, in this study or in the thymus and spleen in the other studies (i.e., subchronic and chronic studies in dogs). Moreover, triflumizole belongs to the imidazole class of compounds, which are not known to be immunotoxicants. Based on the considerations in this unit, the Agency does not believe that conducting the immunotoxicity study will result in a dose less than the point of departure already used in this risk assessment and an additional database uncertainty factor for potential immunotoxicity does not need to be applied.

ii. There is no need for a developmental neurotoxicity (DNT) study or additional UFs to account for neurotoxicity based on the following considerations:

Signs of neurotoxicity were observed in the acute neurotoxicity study based on FOB findings (neuromuscular impairment) and decreased locomotor activity. By day 8 of the observation period treated males and females were comparable to the controls. Although there was a statistically significant increase in hindlimb splay of low-dose females, this effect does not appear to be of great toxicological significance, as no other FOB effects were observed in low-dose females. In a combined subchronic oral toxicity/subchronic neurotoxicity study there was no evidence of neurotoxicity at any dose tested. Further, there were no signs of neurotoxicity and no indications of increased susceptibility of *in utero* rats or rabbits or offspring in the developmental and reproduction studies for triflumizole. There was evidence of qualitative toxicity in the rat developmental toxicity study, but only at doses that were maternally toxic. The evidence does not support the need for a developmental neurotoxicity study. This conclusion is supported by:

- No neurotoxic signs noted in the rat subchronic study at any dose;
- No neurotoxic signs in the adult or offspring in the developmental and reproduction studies; and
- No neurotoxicity noted in any developmental toxicity study.

iii. There is no evidence that triflumizole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study. Although there is evidence of increased qualitative susceptibility in the prenatal developmental study in rats, the Agency did not identify any residual uncertainties after establishing toxicity endpoints, traditional UFs for single exposure scenarios, and an additional 3X SF for repeated exposures to triflumizole (to address concerns for the use of a LOAEL instead of a NOAEL to derive the cRfD.

iv. The chronic POD is derived from the use of a LOAEL (based on liver toxicity; aseosinophilic foci in male rats and fatty vacuolation and inflammation and necrosis in female rats) established in the combined chronic toxicity/carcinogenicity study in rats. Although use of a LOAEL as a POD raises uncertainty, here the uncertainty is relatively low indicating that a 3X FQPA safety factor will be adequate. That conclusion is based on the following weight of evidence considerations:

- The most sensitive endpoint in the target organ (liver) for this class of compounds (imidazole fungicide) is used for assessing chronic risk;
- There is low concern for the observed effects since the lesions did not progress into malignancy;
- The response was marginal at the LOAEL;
- The available data do not show this chemical to be a potent toxicant, as clear NOAELs were established following dietary administrations in all other studies, such as the 2–generation reproduction study in rat (3.5 mg/kg/day); subchronic rat (15.3 mg/kg/day) and mouse (33.1 mg/kg/day) studies; chronic dog study (10 mg/kg/day); and mouse carcinogenicity (16.2 mg/kg/day) study; and
- The extrapolated NOAEL of 1.2 mg/kg/day is supported by a comparable NOAEL (2.5 mg/kg/day) used to derive the cRfD for a structurally-related chemical (Imazalil).

Based on these weight-of-evidence considerations, EPA is confident that the 3X FQPA SF is adequate to address the concerns for the lack of a NOAEL in the rat combined chronic toxicity/carcinogenicity study and that the cRfD would not underestimate dietary risk from chronic exposure to triflumizole. Specific information regarding the additional FQPA safety factor for chronic exposure to triflumizole can be found at *http://www.regulations.gov* in document ''Triflumizole: A Short History of the Chronic Endpoint'' in docket ID number EPA–HQ–OPP–2007–0312.

v. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The chronic dietary food exposure assessment utilized tolerance-level residues or anticipated residues that are based on reliable field trial data. For several currently registered commodities, the chronic assessment also utilized PCT data that have a valid basis and are considered to be reliable. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to triflumizole in drinking water. At this time, residential exposure of infants and children is expected to be negligible from the use of triflumizole. These assessments will not underestimate the exposure and risks posed by triflumizole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute

exposure, EPA performed separate acute risk assessments for females 13 to 49 years old and for the general population, including infants and children, based on different endpoints and aPADs. For females aged 13–49, acute dietary exposure to triflumizole from food and water will occupy 67% of the aPAD chosen for that population subgroup. For the general population and population subgroups other than females aged 13–49, acute dietary exposure to triflumizole is greatest for children 1-2 years old. That subgroup will occupy 40% of the applicable aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to triflumizole from food and water will utilize 44% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of triflumizole is not expected.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Although triflumizole is registered for commercial use on ornamentals in residential areas, this use is not expected to result in significant short-term or intermediate-term exposures of adults or children. Therefore, the short-term and intermediate-term aggregate risk is the sum of the risk from exposure to triflumizole through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Based on the absence of significant tumor increases in two rodent carcinogenicity studies, triflumizole was classified as ''not likely to be carcinogenic to humans,'' and is not expected to pose a cancer risk to humans.

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, or to infants and children from aggregate exposure to triflumizole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate Gas Chromatography/Nitrogen Phosphorus Detector (GC/NPD) method is available in Pesticide Analytical Methods (PAM) Vol. II (Method I, section 180.476) for determining the combined residues of triflumizole and its metabolites containing the FA-1-1 moiety in plant commodities. The method limit of quantitation (LOQ) is 0.5 ppm for plant commodities.

B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits (MRLs) established for residues of triflumizole in or on commodities associated with this petition.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA revised the proposed tolerances for the following commodities: Brassica, leafy greens, subgroup 5B from 20 ppm to 40 ppm; and Brassica, head and stem, subgroup 5A from 5.0 ppm to 8.0 ppm. EPA revised the tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance Italicize Guiidance for Setting Pesticide Tolerances Based on Field Trial Data. EPA also revised the tolerance expression to clarify 1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of triflumizole not specifically mentioned; and 2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. This change was made to both the tolerance expressions for plant commodities and animal commodities because it makes no substantive change to the meaning of the tolerance but rather only clarifies the existing language.

V. Conclusion

Therefore, tolerances are established for combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1 *H* -imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on leafy greens subgroup 4A, except spinach at 35 ppm; Brassica, head and stem, subgroup 5A at 8.0 ppm; Brassica, leafy greens, subgroup 5B at 40.0 ppm; cilantro, leaves at 35 ppm; Swiss chard at 18 ppm; pineapple at 4.0 ppm; papaya at 2.5 ppm; sapote, black at 2.5 ppm; canistel at 2.5 ppm; sapote, mamey at 2.5 ppm; mango at 2.5 ppm; sapodilla at 2.5 ppm; star apple at 2.5 ppm; hop, dried cones at 50.0 ppm; and turnip, greens at 40 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: May 22, 2009.

Daniel J. Rosenblatt,

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.

■ Section 180.476 is amended by revising the introductory text for paragraph (a)(1); by alphabetically adding the following commodities to the table in paragraph (a)(1); by revising the introductory text for paragraph (a)(2); and by removing the entries for Broccoli; Collards; Coriander, leaves; Dandelion, leaves; Kale; Mustard, greens; Parsley, leaves; Swiss chard; and Turnip, greens from the table in paragraph (b) to read as follows:

§ 180.476 Triflumizole; tolerances for residues

(a) *General.* (1) Tolerances are established for residues of the fungicide triflumizole, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the parent compound triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1 *H* -imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as stoichiometric equivalent of the parent compound.

Commodity	Parts per million
* * * * *	
Brassica, head and stem, subgroup 5A	8.0
Brassica, leafy greens, subgroup 5B	40
Canistel	2.5
* * * * *	
Cilantro, leaves	35
* * * * *	
Hop, dried cones	50
Leafy greens subgroup 4A, except spinach	35
Mango	2.5
Papaya	2.5
* * * * *	
Pineapple	4.0
Sapodilla	2.5
Sapote, black	2.5
Sapote, mamey	2.5
Star apple	2.5
* * * * *	
Swiss chard	18
Turnip, greens	40
* * * * *	

(2) Tolerances are established for residues of the fungicide triflumizole, including its metabolites and degradates, in or on the commodities of animal origin listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the parent compound triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-propoxyethyl)-1 *H* -imidazole, the metabolite 4-chloro-2-hydroxy-6-trifluoromethylaniline sulfate, and other metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound.

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0158; FRL–8416–7]

Aspergillus flavus AF36 on Pistachio; Extension of Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the temporary exemption from the requirement of a tolerance for residues of the *Aspergillus flavus* AF36 (*A. flavus* AF36) on pistachio when applied/used