Dated: September 3, 2003.

**Robert E. Roberts,**

*Regional Administrator, Region 8.*

■ 40 CFR part 70, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

## PART 70—[AMENDED]

■ 1. The authority citation for part 70 continues to read as follows:

**Authority:** 42 U.S.C. 7401, *et seq.*

■ 2. In appendix A to part 70 the entry for North Dakota is amended by adding paragraph (c) to read as follows:

**Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs**

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North Dakota

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(c) The North Dakota Department of Health, Environmental Health Section submitted the following program revisions on May 1, 2003: NDAC 33–15–14–06.1(o)(2)(aa), effective November 17, 2003.

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[FR Doc. 03–23751 Filed 9–16–03; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–2003–0286; FRL–7325–1]**

### Trifloxysulfuron; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of trifloxysulfuron in or on almond; almond, hulls; fruit, citrus, group 10; cotton, undelinted seed; cotton, gin byproducts; sugarcane; and tomato. Syngenta Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 17, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0286, must be received on or before November 17, 2003.

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

**FOR FURTHER INFORMATION CONTACT:** Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

*B. How Can I Get Copies of This Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0286. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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

### II. Background and Statutory Findings

In the **Federal Register** of March 21, 2003 (68 FR 13924) (FRL–7296–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F6280) by Syngenta Crop Protection, Inc., Greensboro, NC 27419. That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180 be amended by establishing a tolerance for residues of the herbicide trifloxysulfuron-sodium, [*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino)carbonyl]-3-(2,2,2-trifluoroethoxy)-2-pyridinesulfonamide), in or on sugarcane at 0.01 part per million (ppm); cottonseed at 0.05 ppm; cotton byproducts at 1.0 ppm; citrus at 0.01 ppm; almond hulls at 0.01 ppm; almond nut meat at 0.01 ppm; and tomatoes at 0.01 ppm.

During the course of the review The Agency determined that based on available data and current commodity vocabulary that tolerances should be established for residues of the herbicide trifloxysulfuron *N*-[[4,6-dimethoxy-2-pyrimidinyl)amino)carbonyl]-3-2,2,2-trifluoroethoxy)-2-pyridinesulfonamide in or on the commodities almond at 0.02 ppm; almond, hulls at 0.01 ppm; fruit, citrus, group 10 at 0.03 ppm; cotton, undelinted seed at 0.05 ppm; cotton, gin

byproducts at 1.0 ppm; sugarcane at 0.01 ppm, and tomato at 0.01 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of trifloxysulfuron on almond at 0.02 ppm; almond, hulls at 0.01 ppm; fruit, citrus, group 10 at 0.03 ppm; cotton, undelinted seed at 0.05 ppm; cotton gin byproducts at 1.0 ppm; sugarcane at 0.01 ppm; and tomato at 0.01 ppm. EPAs assessment of exposures and risks associated with establishing the tolerance follows.

### *A. Toxicological Profile*

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

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3100 | 90–Day oral toxicity rodents (rats) | NOAEL: 507/549 milligrams/kilogram/day (mg/kg/day) Male/Female (M/F)<br>LOAEL: 1052/1128 mg/kg/day (M/F): M = decreased body weight, decreased body weight gain, equivocal increased testicular atrophy at end of recovery phase; F = decreased body weight, decreased body weight gain, equivocal slightly increased histopathology in liver (single cell necrosis, focal necrosis, inflammation, hepatocellular hypertrophy). |
| 870.3100 | 90–Day oral toxicity rodents (mice) | NOAEL: 1,023/1,507 mg/kg/day (M/F)<br>LOAEL: >1,023/>1,507 mg/kg/day (M/F): M = not attained; F = not attained. |
| 870.3150 | 90–Day oral toxicity in nonrodents (dogs) | NOAEL: 19.8/19.6 mg/kg/day (M/F)<br>LOAEL: 164.2/167.3 mg/kg/day (M/F): M = decreased body weight gain (20%), slight hematological effects, clinical chemistry changes suggesting hepatotoxicity, decreased thymus weight, thymic atrophy, increased glycogen in liver, hemorrhage in mesenteric lymph nodes; F = decreased body weight gain (44%), anemia with extramedullary hematopoiesis in liver/spleen and myeloidhyperplasia in bone marrow, clinical chemistry changes suggesting hepatotoxicity, decrease thymus weight, thymic atrophy and hyaline tubular change in kidney. |
| 870.3200 | 21/28–Day dermal toxicity (rats) | NOAEL: 1,000/100 mg/kg/day (M/F)<br>LOAEL: >1,000/1,000 mg/kg/day(M/F): M = not attained; F = decreased body weight gain.<br>No dermal irritation M/F. |
| 870.3700 | Prenatal developmental in rodents (rats) | Maternal NOAEL: 300 mg/kg/day<br>Maternal LOAEL: 1,000 mg/kg/day based on decreased food consumption during treatment, decreased body weight gain during post-treatment.<br>Developmental NOAEL: 300 mg/kg/day<br>Developmental LOAEL: 1,000 mg/kg/day based on slight decrease in fetal weight, increased skeletal anomalies,increased poor/absent skeletal ossification. |
| 870.3700 | Prenatal developmental in nonrodents (rabbit) | Maternal NOAEL: 100 mg/kg/day<br>Maternal LOAEL: 250 mg/kg/day based on increased mortality, increased vaginal/anal bleeding.<br>Developmental NOAEL: 50 mg/kg/day<br>Developmental LOAEL: 100 mg/kg/day based on abnormally shaped heart (one fetus at 100 mg/kg/day and 3 fetuses from 2 litters at 250 mg/kg/day). |

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

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3800 | Reproduction and fertility effects (rat) | Parental systemic NOAEL: 78.8/83.5 mg/kg/day (M/F)<br>Parental systemic LOAEL: 631/676 mg/kg/day (M/F) based on decreased body weight and gain as well as decreased food consumption.<br>Offspring systemic NOAEL: 78.8/83.5 mg/kg/day (M/F)<br>Offspring systemic LOAEL: 631/676 mg/kg/day (M/F): decreased pup weight and weight gain, decreased spleen weight, thymus weight and increased vaginal patency.<br>Reproductive NOAEL: 968/1,030 mg/kg/day (M/F)<br>Reproductive LOAEL: >968/1,030 (M/F) |
| 870.4100 | Chronic toxicity rodents (rat) | See 870.4300 |
| 870.4100 | Chronic toxicity dogs | NOAEL: 51.1/45.3 mg/kg/day (M/F)<br>LOAEL: 123/121 mg/kg/day (M/F): M = gray-white foci in lungs, fibrous thickening of lung pleura, equivocal decreased body weight gain; F = equivocal increased incidence and severity of chronic urinary bladder inflammation. |
| 870.4200 | Carcinogenicity rats | See 870.4300 |
| 870.4200 | Carcinogenicity mice | NOAEL: 854/112 mg/kg/day (M/F)<br>LOAEL: >854/818 mg/kg/day (M/F): M = not determined; F = decreased body weight, body weight gain and food consumption. Negative for carcinogenicity in M and F. |
| 870.4300 | Chronic feeding/carcinogenicity rats | NOAEL: 82.6/23.7 mg/kg/day (M/F)<br>LOAEL: 429/99.3 mg/kg/day (M/F): M = decreased body weight and gains, decreased food consumption and increased Leydig cell hyperplasia in testes; F = increased tubular atrophy in kidneys. At 500 mg/kg/day decreased body weight, body weight gain, food consumption and increased tubular atrophy in kidneys. Negative for carcinogenicity in M and F. |
| 870.5100 | Gene mutation bacterial reverse mutation assay (*S. typhimurium*/*E. coli*) | Negative without and with S-9 activation. |
| 870.5300 | *In vitro* mammalian cell forward gene mutation assay (CHO cells/HGPRT locus) | Negative without and with S-9 activation. |
| 870.5375 | *In vitro* mammalian cytogenetics assay in CHO cells | Negative without and with S-9 activation. |
| 870.5395 | Cytogenetics - mammalian erythrocyte micronucleus test in the mouse | Negative at single oral doses up to 5,000 mg/kg. |
| 870.5500 | *In vitro* unscheduled DNA synthesis (primary rat hepatocytes) | Negative response up to 250 μg/mL. Cytotoxicity at ≥15.63 μg/mL. |
| 870.6200 | Acute neurotoxicity screening battery (rat) | NOAEL: <2,000 mg/kg/day (M/F)<br>LOAEL: 2,000 mg/kg/day (M/F): M and F = decreased motor activity on day 1, histopathological lesions in nervous system tissues. |
| 870.6200 | Acute neurotoxicity screening battery (rat) | NOAEL: 2,000/600 mg/kg/day (M/F)<br>LOAEL: >2,000/2,000 mg/kg/day (M/F): M = not attained; F = decreased motor activity on day 1. |
| 870.6200 | Subchronic neurotoxicity screening battery (rat) | NOAEL: 112/553 mg/kg/day (M/F)<br>LOAEL: 472/1,128 mg/kg/day (M/F): M = decreased body weight, body weight gain and food consumption.; F = decreased body weight. |

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

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.6300 | Developmental neurotoxicity (rat) | No study performed. Not Required. |
| 870.7485 | Metabolism and pharmacokinetics (rat) | Rapidly absorbed and exceted. Most (>87%) of the administered dose (AD) was excreted within 24 hours. After 7 days, very little (≤0.3% of AD) remained in the tissues. Urine was the primary route of excretion in males (50-61% of AD) and in females (70-80% of AD). Unchanged parent in males (11-20% of AD) and in females (37-47% of AD) was excreted almost entirely in the urine and only trace amounts were found in the feces. With the exception of the parent, the metabolite profile was similar between the urine and feces. The 2 primary metabolites in both urine and feces were Metabolite J (desmethyl parent, up to 26% of AD) and Metabolite K (5'hydroxy-pyrimidine of parent, up to 19% of AD). Other metabolites were Metabolites X, N, F, A and D, each up to 8.2% of the AD in males and up to 4.7% of the AD in females. Several minor metabolites were also identified as Metabolite Q, Metabolite P, guanidine, CGA-382997 and CGA-368732 (each ≤4.4% of the AD). |
| 870.7485 | Biliary metabolism (rat) | In bile duct cannulated rats, absorption was 84-88% of the Administered Dose (AD) at 48 hours. Nearly all of the AD was excreted within 48 hours. Excretion in urine ranged from 58-76%, in bile from 5-27%, and in feces was about 6% of the AD. There was no evidence for an enterohepatic circulation. Biotransformation was similar to that in the conventional rat metabolism study. The metabolite profiles in urine, bile fluid and feces were all similar. |
| 870.7600 | Dermal penetration (rat) | No study performed. Not Required. |

*B. Toxicological Endpoints*

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

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

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as $1 \times 10^{-6}$ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer}$ = point of departure/exposures) is calculated. A summary of the toxicological endpoints for trifloxysulfuron used for human risk assessment is shown in Table 2 of this unit:

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

| Exposure Scenario | Dose Used in Risk Assessment, UF | Special FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute dietary (females 13-49) | Developmental NOAEL = 50 mg/kg/dayUF = 100<br>Acute RfD =0.5 mg/kg | Special FQPA SF = 1<br>aPAD =<br>acute RfD/Special FQPA SF = 0.5 mg/kg | Developmental Toxicity Study in Rabbits.<br>Developmental LOAEL = 100 mg/kg/day based on increased incidence of abnormal shaped hearts in fetuses. |
| Acute dietary (general population) | NOAEL = 600 mg/kg UF = 100<br>Acute RfD =6.0 mg/kg | Special FQPA SF = 1<br>aPAD =<br>acute RfD/Special FQPA SF = 6.0 mg/kg | Acute Neurotoxicity Studies in Rats.<br>LOAEL = 2,000 mg/kg based on decreased motor activity on day 1 and histopathological lesions in nervous system tissues of males and females. |
| Chronic dietary (all populations) | NOAEL= 23.7 mg/kg/day UF = 100<br>Chronic RfD = 0.237 mg/kg/day | Special FQPA SF = 1<br>cPAD =<br>chronic RfD/Special FQPA SF = 0.237 mg/kg/day | Combined Chronic Toxicity/Carcinogenicity Study in Rats.<br>LOAEL = 99.3 mg/kg/day based on increased tubular atrophy in the kidneys of females (developing after 12 months). |
| Incidental oral short-term (1 - 30 days) | Offspring NOAEL = 78.8/83.5 (M/F) mg/kg/day | Residential LOC for MOE = 100 | 2–Generation Reproduction Study in Rats.<br>Offspring LOAEL = 631/676 (M/F) mg/kg/day based on decreased pup body weights on day 21. |
| Dermal short-term (1 - 30 days) | Dermal study<br>Systemic NOAEL= 100 mg/kg/day | Residential LOC for MOE = 100 | 28–Day Dermal Toxicity Study in Rats.<br>Systemic LOAEL = 1,000 mg/kg/day based on decreased body weight gain in females. |
| Inhalation short-term (1 - 30 days) | Oral study<br>NOAEL= 50 mg/kg/day (inhalation absorption factor = 100%) | Residential LOC for MOE = 100 | Developmental Toxicity Study in Rabbits.<br>LOAEL = 100 mg/kg/day based on increased incidence of abnormal shaped hearts in fetuses. |
| Cancer (oral, dermal, inhalation) | Classification: Not Likely to be carcinogenic to humans | | |

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

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* No tolerances have been previously established for trifloxysulfuron. Tolerances being established under § 180.591 include almond; almond hulls; cotton, undelinted seed; cotton, gin byproducts; fruit, citrus, Group 10; sugarcane, and tomato. No tolerances are required for meat, milk, poultry or eggs. Risk assessments were conducted by EPA to assess dietary exposures from trifloxysulfuron in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the 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: 100% of the crops from registered uses are treated and that residues of trifloxysulfuron are at tolerance levels. Anticipated residues were not used.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% of the crops from registered uses are treated and that residues of trifloxysulfuron are at tolerance levels. Anticipated residues were not used.

iii. *Cancer.* Trifloxysulfuron has been classified as ''not likely to be carcinogenic in humans.'' Therefore a quantitative assessment of aggregate cancer risk was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for trifloxysulfuron 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 trifloxysulfuron.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in

Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to trfloxysulfuron they are further discussed in the aggregate risk sections Unit E.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of trifloxysulfuron and its metabolites of concern for acute exposures are estimated to be 6.47 parts per billion (ppb) for surface water and 0.054 ppb for ground water. The EECs for chronic exposures are estimated to be 0.52 ppb for surface water and 0.054 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).

Trifloxysulfuron will be registered for use on the following non-dietary sites: Turf—golfcourses. The risk assessment was conducted using the following exposure assumptions: The Agency has examined the potential postapplication exposure to individuals over 12 years of age from the proposed use of trifloxysulfuron on golf courses. Duration of such exposure is anticipated to be short-term. The short-term dermal post-application exposure for golfing was estimated to be 0.0005 mg/kg/day. The estimate assumes that 18 holes of golf are played in 4 hours, that there are 0.015 µg ai/cm$^2$ of turf, that the transfer coefficient for turf is 500 cm$^2$/hour, and that the average golfer weighs 60 kg. Transfer coefficients are based on surrogate data, from chlorothalonil and chlorpyrifos, describing actual, median-value exposures to golfers.

The vapor pressure of trifloxysulfuron is very low and, therefore, inhalation exposure to trifloxysulfuron vapor is not expected to occur. The Agency has not assessed inhalation exposure to trifloxysulfuron due to residential activities.

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

EPA does not have, at this time, available data to determine whether trifloxysulfuron has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to trifloxysulfuron and any other substances and trifloxysulfuron 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 trifloxysulfuron 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://epa.gov/pesticides/cumulative/*.

*D. Safety Factor for Infants and Children*

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity study in rats or in the 2–generation reproduction study in rats. In the developmental toxicity study in rabbits, there was an increase in quantitative susceptibility based upon the presence of abnormally shaped heart in one fetus at 100 mg/kg/day. Three additional fetuses from two litters at 250 mg/kg/day also had abnormally shaped hearts. The degree of concern for this finding was low because there was a clear NOAEL for this effect, only 1 fetus had the effect at the LOAEL, and this effect was used as a toxicological endpoint in appropriate risk assessments. There are no residual uncertainties for prenatal and/or postnatal toxicity.

3. *Conclusion*. There is a complete toxicity data base for trifloxysulfuron and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X. This determination was based on the following:

- The toxicological data base is complete for FQPA assessment.
- There was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity study in rats. At the limit dose, maternal effects were decreased food consumption during treatment and decreased body weight gain during post-treatment. The only fetal findings noted at the limit dose were a slight decrease in fetal body weights, and an increase in minimal skeletal findings and poor/absent skeletal ossification.
- There was evidence of increased quantitative susceptibility in the developmental toxicity study in rabbits. The maternal NOAEL was 100 mg/kg/day based on increased mortality and

increased vaginal/anal bleeding at the LOAEL of 250 mg/kg/day. The developmental NOAEL was 50 mg/kg/day based on an increased incidence of abnormally shaped hearts at the LOAEL of 100 mg/kg/day (one fetus at 100 mg/kg/day). Three additional fetuses from two litters at 250 mg/kg/day also had abnormally shaped hearts. In historical control data provided by the registrant, there were no reported instances of abnormally shaped hearts. The degree of concern is low for the quantitative evidence of susceptibility seen in the rabbit developmental study because there was a clear NOAEL for this effect, only one fetus had the effect at the LOAEL, this effect was used as a toxicological endpoint in appropriate risk assessments.

- There was no evidence of increased quantitative or qualitative susceptibility in the 2–generation reproduction study in rats.
- There are no residual uncertainties for prenatal and/or postnatal toxicity.
- A developmental neurotoxicity study in rats is not required.
- The acute and chronic dietary food exposure assessments assumed tolerance level residue data and 100% crop treated. The acute and chronic risk assessments will not underestimate exposure or risk since the exposures are based on reliable data derived from studies designed to produce worst-case residues.
- The dietary drinking water assessment used 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. Furthermore, EPA used a highly conservative technique to estimate concentrations of non-parent residues of concern.
- The non-dietary exposure assessment will not underestimate postapplication exposure to golfers resulting from the use of trifloxysulfuron-sodium on golf course turf.

*E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to trifloxysulfuron will occupy <1% of the aPAD for the U.S. population, <1% of the aPAD for females 13-49 years, <1% of the aPAD for all infants > 1 year old and <1% of the aPAD for children 1–12 year old. In addition, there is potential for acute dietary exposure to trifloxysulfuron in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLOXYSULFURON

| Population Subgroup | aPAD (mg/kg) | % aPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Acute DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. population | 6.0 | <1 | 6.47 | 0.054 | 210,000 |
| All infants < 1 year old | 6.0 | <1 | 6.47 | 0.054 | 60,000 |
| Children 1-2 year old | 6.0 | <1 | 6.47 | 0.054 | 60,000 |
| Females 13-49 years old | 0.05 | <1 | 6.47 | 0.054 | 15,000 |

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to trifloxysulfuron from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for females 13–49 years, <1% of the cPAD for all infants > 1 year old and <1% of the cPAD for children 1–2 years old. Based the use pattern, chronic residential exposure to residues of trifloxysulfuron is not expected. In addition, there is potential for chronic dietary exposure to trifloxysulfuron 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 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRIFLOXYSULFURON

| Population Subgroup | cPAD mg/kg/day | % cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. population | 0.237 | <1 | 0.52 | 0.054 | 8300 |
| All infants < 1 year old | 0.237 | <1 | 0.52 | 0.054 | 2,400 |
| Children 1–2 years old | 0.237 | <1 | 0.52 | 0.054 | 2,400 |
| Females 13–49 years old | 0.237 | <1 | 0.52 | 0.054 | 7,100 |

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Trifloxysulfuron is proposed for a use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for trifloxysulfuron.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 20,000 for all affected populations including the general U. S. population, youth 13–19 years old, adults 20–49 years old, and females 13–49 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of trifloxysulfuron in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO TRIFLOXYSULFURON

| Population Subgroup | Aggregate MOE (Food + Residential) | Aggregate Level of Concern (LOC) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Short-Term DWLOC (ppb) |
|---|---|---|---|---|---|
| U. S. population | 170,000 | 100 | 0.52 | 0.054 | 28,000 |
| Youth 13–19 years old | 170,000 | 100 | 0.52 | 0.054 | 24,000 |
| Adults 20–49 years old | 180,000 | 100 | 0.52 | 0.054 | 28,000 |
| Females 13–49 years old | 180,000 | 100 | 0.52 | 0.054 | 24,000 |

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Trifloxysulfuron is not registered for use any sites that would result in any intermediate residential exposure. Therefore, the aggregate risk has not been assessed for intermediate scenarios.

5. *Aggregate cancer risk for U.S. population*. Trifloxysulfuron has been classified as ''not likely to be carcinogenic to humans.'' Therefore, no cancer risk is expected.

6. *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 trifloxysulfuron residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology high performance liquid chromatography/ultravoilet (HPLC/UV) 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 Canadian, Mexican, or Codex maximum residue limits (MRLs) established for trifloxysulfuron. Therefore, international harmonization is not an issue with the proposed uses.

### *C. Conditions*

No conditions are required to support these tolerances.

## V. Conclusion

Therefore, the tolerance is established for residues of trifloxysulfuron, *N*-[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]-3-(2,2,2-trifluoroethoxy)-2-pyridinesulfonamide, in or on almond at 0.02 ppm; almond, hulls at 0.01 ppm; fruit, citrus, group 10 at 0.03 ppm; cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 1.0 ppm; sugarcane at 0.01 ppm, and tomato at 0.01 ppm.

## VI. Objections and Hearing Requests

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

appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

*A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0286 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 17, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0286. to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

## VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### VIII. Congressional Review Act

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

### List of Subjects in 40 CFR Part 180

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

Dated: September 4, 2003.

**James Jones,**

*Director, Office of Pesticide Programs.*

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

## PART 180—[AMENDED]

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

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

■ 2. Section 180.591 is added to read as follows:

### § 180.591 Trifloxysulfuron; tolerances for residues

(a) *General.* Tolerances are established for residues of the herbicide trifloxysulfuron, *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(2,2,2-trifluoroethoxy)-2-pyridinesulfonamide in or on the following raw agricultural commodities.

| Commodity | Parts per million |
|---|---|
| Almond | 0.02 |
| Almond, hulls | 0.01 |
| Fruit, citrus, Group 10 | 0.03 |
| Cotton, undelinted seed | 0.05 |
| Cotton, gin byproducts | 1.0 |
| Sugarcane | 0.01 |
| Tomato | 0.01 |

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

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

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

[FR Doc. 03–23428 Filed 9–16–03; 8:45am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–2003–0306; FRL–7327–5]**

## Thiamethoxam; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite in or on imported coffee, pecan, stone fruit, succulent bean, and sunflower. Syngenta Crop Protection, Inc. and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

**DATES:** This regulation is effective September 17, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0306, must be received on or before November 17, 2003.

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

**FOR FURTHER INFORMATION CONTACT:** Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5409; e-mail address: *daniel.dani@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