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 20, 2002.

Marcia E. Mulkey,

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.[380] is amended by removing from the table in paragraph (a) the entries for ''cucumbres'', ''peppers (bell)'', ''stonefruits, except plums/fresh prunes'' and ''strawberries'', and by adding paragraph (e) to read as follows:

§ 180.380 Vinclozolin; tolerances for residues.

* * * * *

(e) *Revoked tolerances subject to the channel of trade provisions.* The following table lists commodities with residues of vinclozolin resulting from lawful use are subject to the channels of trade provisions of section 408(l)(5) of the FFDCA:

Commodity	Parts per million
Cucumbers	1.0
Peppers (bell)	3.0
Stonefruits, except plums/fresh prunes	25.0
Strawberries	10.0

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0082; FRL–7180–8]

Triflusulfuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of triflusulfuron methyl in or on beet, sugar, roots; beet, sugar, tops; and chicory, roots. Interregional Research Project #4 (IR-4) and E. I. Dupont de Nemours & Company requested these tolerances 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 June 12, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0082, must be received on or before August 12, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0082 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins or Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–5697 or (703) 308–9368; e-mail address: tompkins.jim@epa.gov or jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

TABLE 1.—EXAMPLES OF POTENTIALLY AFFECTED ENTITIES

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to 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.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0082. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 22, 1999 (64 FR 71760) (FRL–6391–1) and August 8, 2001 (66 FR 41593) (FRL–6795–4), 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) by IR-4 and E. I. Dupont de Nemours & Company, 681 US Highway #1 South North Brunswick, NJ 08902–3390, and E.I. DuPont de

Nemours & Company, DuPont Agricultural Products, Barley Mill Plaza, Wilmington, DE 19880–0038. This notice included a summary of the petition prepared by E.I. DuPont de Nemours, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.492 be amended by establishing a tolerance for residues of the herbicide, triflusulfuron methyl, methyl 2-[[[[[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]-3-methylbenzoate, in or on chicory, root at 0.05 parts per million (ppm) (PP 0E6214). PP 4F4278 proposed that the currently established time-limited tolerances for sugar beet, root at 0.05 ppm and sugar beet, top at 0.05 ppm be converted to permanent tolerances and to revise the commodities to read beet, sugar, roots at 0.05 ppm and beet, sugar, tops at 0.05 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for tolerances for residues of triflusulfuron methyl on chicory, root at 0.05 ppm; and to convert the time-limited tolerances for beet, sugar, root at 0.05 ppm and beet, sugar, top at 0.05 to permanent tolerances. EPA's assessment of exposures and risks associated with establishing the 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. The nature of the toxic effects caused by triflusulfuron methyl are discussed in Table 2 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 2.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study type	Results
870.3100	90–Day oral toxicity rodents (two studies submitted)	NOAEL = 6.56/7.71 (m/f) mg/kg/day (milligram/kilogram/day) LOAEL = 133/153 (m/f) mg/kg/day based on decreased body weight gain and food efficiency in males; increased incidence of histopathological changes (kidney and spleen) in females. NOAEL = 6.20/7.54 (m/f) mg/kg/day LOAEL = 127/150 (m/f) mg/kg/day; based on decreased mean body weight gain, decreased mean food consumption (f), decreased mean food efficiency, alterations in hematology parameters (m); hemosiderin in kidneys (f)
870.3150	90–Day oral toxicity in nonrodents	NOAEL = 3.9/3.7 (m/f) mg/kg/day LOAEL = 146.9/159.9 (m/f) mg/kg/day based on decreased mean body weight and body weight gain, decreased hematocrit, hemoglobin, RBC's, SGOT, SGPT, ALP, absolute and relative liver and testes weight; microscopic abnormalities of the liver and testes.
870.3200	21/28–Day dermal toxicity	NOAEL = 1,000 mg/kg/day LOAEL = 1,000 mg/kg/day based on limit dose.
870.3700a	Pre-natal developmental in rodents	Maternal NOAEL = 120 mg/kg/day LOAEL = 350 mg/kg/day based on decreased body weight gain, decreased food consumption and lower food efficiency. Developmental NOAEL = >1,000 mg/kg/day limit dose LOAEL = >1,000 mg/kg/day.
870.3700b	Pre-natal developmental in nonrodents	Maternal NOAEL = 90 mg/kg/day LOAEL = 270 mg/kg/day based on clinical signs including absent/reduced stool and stained fur, maternal death, increased abortions, decreased body weight gain, and lower-food efficiency. Developmental NOAEL = 90 mg/kg/day LOAEL = 270 mg/kg/day based on increased abortions.

TABLE 2.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study type	Results
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 5.81/7.75 (m/f) mg/kg/day LOAEL = 44/58 mg/kg/day based on decreased body weight, decreased body weight gain, decreased food consumption, and decreased-food efficiency. Reproductive NOAEL = 89.5/115 (m/f) mg/kg/day based on the absence of reproductive effects at the highest dose tested (HDT). LOAEL = >115 mg/kg/day. Offspring NOAEL = 5.81/7.75 (m/f) mg/kg/day LOAEL = 44/58 (m/f) mg/kg/day based on decreased F1 pup body weight on days 14 and 21 due to exposure via milk and in the diet.
870.4100a	Chronic toxicity rodents	NOAEL = 2.44 mg/kg/day LOAEL = 30.6 mg/kg/day based on decreased body weight and body weight gain, alteration in hematology (mainly males) and increased incidences of interstitial cell hyperplasia in testes.
870.4100b	Chronic toxicity dogs	NOAEL = 26.9 mg/kg/day LOAEL = 116.6 mg/kg/day based on increased liver weight, alkaline phosphatase, and hepatocellular hypertrophy.
870.4200	Carcino-genicity rats	NOAEL = 2.44 mg/kg/day LOAEL = 30.6 mg/kg/day based on decreased body weight and body weight gain, alteration in hematology (mainly males) and increased incidences of interstitial cell hyperplasia in the testes. (Possible) evidence of carcinogenicity
870.4300	Carcino-genicity mice	NOAEL = 14.6 mg/kg/day LOAEL = 349 mg/kg/day based on increased liver weight and increased hepatic cell tumors (adenomas and/or carcinomas combined. (Possible) evidence of carcinogenicity
870.5100	Gene Mutation	No genotoxic effect in Ames assay using S. typhimurium. (two studies)
870.5375	Cytogenetics	No genotoxic effect in Chinese hampster ovary (CHO) gene mutation assay
870.5375 870.5395	Other Effects	Positive effects in the presence of metabolic activation, but inconclusive in the absence of metabolic activation in a chromosomal aberration/human lymphocyte study. Mouse micronucleus assay negative for genotoxic effects.
870.6200a	Acute neurotoxicity screening battery	NOAEL = >2,000 mg/kg/day HDT LOAEL = Not established
870.6200b	Subchronic neurotoxicity screening battery	NOAEL = 92.7/7.1 (m/f) mg/kg/day LOAEL = 186.2/51.6 (m/f) mg/kg/day based on decreased body weight and body weight gain.
870.7485	Metabolism and pharmacokinetics	Urine major route of excretion at low doses and the feces at high doses. *N*-desmethyl triflusulfuron methyl, the upper urinary metabolite composed between 25–44% of the dose at the low dose level (single and repeated). Parent was the major component in the high dose feces and liver.
870.7600	Dermal penetration	No dermal absorption studies were available. A 27% absorption was calculated from a ratio of the LOAEL from a developmental and 21–day dermal toxicity studies in rabbits.
	Special studies: *In vivo* and *in vitro* mechanic studies	The purpose of these studies was to investigate the mechanism of Leydig cell tumor induction in the testes of male rats. A dose-dependent decrease in aromatase enzyme activity was seen *in vitro*, but was inconclusive *in vivo*.

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 factor 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 safety factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-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 triflusulfuron methyl used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLUSULFURON METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and LOC for risk assessment	Study and toxicological effects
Acute Dietary (all population subgroups)	N/A		No toxicological effects attributable to a single exposure (dose) were observed in oral toxicity studies. Therefore, an acute RfD can not be established and an acute dietary risk assessment will not be conducted for the general population.
Chronic Dietary (all populations)	NOAEL = 2.44 mg/kg/day UF = 100 Chronic RfD = 0.024 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD ÷ FQPA SF = 0.024 mg/kg/day	Chronic Toxicity in Rats LOAEL = 30.6 mg/kg/day based on decreased body weight and body weight gain, alter. In hematology (mainly males), increased incidence of interstitial cell hyperplasia in testes.
Cancer (oral, dermal, inhalation)			Triflusulfuron methyl is classified as a Group C—possible human carcinogen chemical.

* The reference to the FQPA safety factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.492) for the residues of triflusulfuron methyl in or on sugar beet, root and sugar beet, top. Risk assessments were conducted by EPA to assess dietary exposures from triflusulfuron methyl 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. There are no effects attributable to a single, oral dose of triflusulfuron methyl. Therefore, an acute dietary risk assessment was not conducted.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture 1989–1992 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 chronic exposure assessments: Tolerance level residues and that 100% of the crop is treated. Because suitable data depicting residues of triflusulfuron methyl in drinking were not available for incorporation into the dietary exposure model, the dietary exposure estimates do not include potential exposure from drinking water. The dietary exposure is based on sugar beets, because chicory was not reported as being consumed in the 1989–1992 CSFII. Therefore, inclusion of chicory in the dietary analysis would not alter the exposure or risk estimates from those obtained from sugar beets. The cRfD or 0.024 mg/kg/day was determined where the NOAEL of 2.44 mg/kg/day is based on decreased body weight gain, alterations in hematology (mainly in males) and increases in the incidence of interstitial hyperplasia in the testes at the LOAEL of 30.6 mg/kg/day. A 100–fold UF for interspecies extrapolation and intraspecies variability was applied.

iii. *Cancer*. Triflusulfuron methyl is classified as a Group C—possible human carcinogen chemical and for the purpose of risk characterization the RfD approach should be used for quantification of human risk. This decision was based on evidence of statistically significant, dose related increases in the incidence of interstitial cell adenomas of the testes at two doses, as well as statistically significant positive trend for these tumors in male rats. The testicular interstitial cell adenomas observed in the rat were benign. There was no reported increased tumor incidences of any type in the female rat and the dosing was adequate for assessing the carcinogenic potential of triflusulfuron methyl. Evidence of a hormonal mechanism for development of these benign tumors in rats does exist, however, the data were suggestive but not conclusive. Although there was some evidence of clastogenic activity for triflusulfuron methyl, positive results were only seen with activation in human lymphocytes/chromosomal aberration assay. Triflusulfuron methyl is a member of a class of chemicals known as sulfonylureas. Of the 12

analogs structurally related to triflusulfuron methyl, three sulfonylureas have been associated with carcinogenicity in rodents. Primisulfuron methyl and prosulfuron are classified as Group D carcinogens (not classifiable as to human carcinogenicity). Only tribenuron methyl is classified as a Group C carcinogen (possible human carcinogen), however, a Q* for cancer risk assessment is not required because there is no evidence of genotoxicity and the increased incidence of mammary gland tumors is observed at doses which exceed the maximum tolerated dose. Therefore the RfD approach is appropriate for quantification of human cancer risk.

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

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 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 LOCs.

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 triflusulfuron methyl they are further discussed in the aggregate risk sections in Unit III. E.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of triflusulfuron methyl for acute exposures are estimated to be 0.42 parts per billion (ppb) for surface water and 0.5 ppb for ground water. The EECs for chronic exposures are estimated to be 0.005 ppb for surface water and 0.5 ug/L (micrograms/Liter) 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).

Triflusulfuron methyl is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to 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 does not have, at this time, available data to determine whether triflusulfuron methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, triflusulfuron methyl 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 triflusulfuron methyl 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional 10–fold margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal 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. *Pre-natal and post-natal sensitivity*. There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental studies. No developmental toxicity was seen at the limit dose (1,000 mg/kg/day) in rats. In rabbits, developmental toxicity manifested as abortions in the presence of severe maternal toxicity (mortality, abortions, clinical signs, decreased body weight, and food efficiency). In the 2–generation reproductive toxicity study, the effects in the offspring (decreased pup body weight in F1 on days 14 and 21; late lactation) can be attributed to the decreases in body weights seen in the parental animals. In addition, this decrease was seen only in the F1 generation but not in the second generation. There is no indication for a developmental neurotoxicity study since no neuropathological or neurobehavioral effects in the acute or subchronic neurotoxicity studies were observed; no alteration of the fetal nervous system was observed; and no evidence of neurotoxicity was found in other studies in the data base.

3. *Conclusion*. The toxicity data base for triflusulfuron methyl is complete except for a 28–day inhalation (nose only) toxicity study. This study is of marginal value for the FFDCA determination because there are no residential uses of triflusulfuron methyl. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on these reasons, the FQPA Safety Factor for the protection of children has been removed (i.e. reduced to 1x.)

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. 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 EPA Office of Water are used to calculate DWLOCs: 2L/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*. Because there are no effects attributable to a single, oral dose of triflusulfuron methyl is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to triflusulfuron methyl from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for infants <1 year, and <1% of the cPAD for children aged 1–6 years and children aged 7–12 years. There are no residential uses for triflusulfuron methyl that result in chronic residential exposure to triflusulfuron methyl. 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 cPAD, as shown in Table 4 of this unit:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.000011	<1	0.005	0.50	840
Female (13–50 years)	0.000009	<1	0.005	0.50	720
All infants (<1 year)	0.000040	<1	0.005	0.50	240
Children (1–6 years)	0.000025	<1	0.005	0.50	240

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).

Triflusulfuron methyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

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).

Triflusulfuron methyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population*. Triflusulfuron methyl has been designated a Category C ''possible human carcinogen'' and does not require a separate cancer risk assessment. Because the RfD approach was determined appropriate for quanification of human cancer risk, the chronic aggregate risk assessment is sufficiently protective of human health.

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 triflusulfuron methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate tolerance enforcement method is available in PAM II. The method extracts residues of triflusulfuron methyl in a buffered acetonitrile solution, cleans the extract on a phenyl solid-phase extraction cartridge, and quantitates residues on a HPLC/UV system.

B. International Residue Limits

There are no Canadian or Codex MRLs established for triflusulfuron methyl.

C. Conditions

Submission of a 28–day inhalation (nose only) toxicity study is required as condition of registration.

V. Conclusion

Therefore, the tolerances are established for residues of triflusulfuron methyl, methyl 2-[[[[[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]-3-methylbenzoate, in or on chicory, roots at 0.05 ppm; and time-limited tolerances for sugar beet, root at 0.05 ppm and sugar beet, top at 0.05 ppm are converted to permanent tolerances and redefined as beet, sugar, roots and beet, sugar, tops.

VI. Objections and Hearing Requests

Under section 408(g) of 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old FFDCA sections 408 and 409. 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–2002–0082 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 August 12, 2002.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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.

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.

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.2. Mail your copies, identified by docket ID number OPP–2002–0082, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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. Submission to Congress and the Comptroller General

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: May 31, 2002.

Peter Caulkins,

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), 346(a) and 374.

2. Section 180.492 is revised to read as follows:

§ 180.492 Triflusulfuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, triflusulfuron methyl 2-[[[[[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]-3-methylbenzoate in or on the raw agricultural commodities:

Commodity	Parts per million
Beet, sugar, roots	0.05
Beet, sugar, tops	0.05
Chicory, roots	0.05

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

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

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

[FR Doc. 02–14501 Filed 6–11–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0099; FRL–7182–1]

RIN 2070–AB78

Spinosad; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues/combined residues of spinosad in or on stored grains (barley, corn, oats, rice, sorghum/milo, and wheat). Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. The tolerance will expire on May 31, 2004. This time-limited tolerance is to permit the marketing of stored grains in accordance with the Experimental Use Permit (EUP) 62719-EUP-50 which is being issued concurrently.

DATES: This regulation is effective June 12, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0099, must be received on or before August 12, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0099 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–8587; e-mail address: sproat.william@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide