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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0278; FRL–7679–5]

Tribenuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of tribenuron methyl in or on canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed. E.I. DuPont De Nemours and Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, this regulatory action is part of the tolerance reassessment requirements of section 408(q) of the FFDCA 21 U.S.C. 346a(q), as amended by the FQPA of 1996. By law, EPA is required to reassess 100% of the tolerances in existence on August 2, 1996, by August 2006. This regulatory action will count for eight reassessments toward the August 2006 deadline.

DATES: This regulation is effective September 22, 2004. Objections and requests for hearings must be received on or before November 22, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0278. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: James 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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

B. How Can I Access Electronic Copies of This Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of July 7, 2004 (69 FR 40909) (FRL–7364–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F6135) by E.I. DuPont de Nemours and Company, DuPont Crop Protection, Barley Mill Plaza, Wilmington, DE 19880–0038. The petition requested that 40 CFR 180.451 be amended by establishing a tolerance for residues of the herbicide tribenuron methyl, [methyl 2-[[[[(4-methoxy -6-methyl-1, 3, 5-triazin-2-yl) methylamino] carbobyl]amino]sulfonyl]benzoate], in or on imazethapyr tolerant canola at 0.02 parts per million (ppm), cotton gin trash at 0.02 ppm, cotton seed at 0.02 ppm, and Crop Development Center (CDC) triffid flax at 0.02 ppm. That notice included a summary of the petition prepared by E. I. DuPont de Nemours and Company, the registrant. There were no comments received in response to the notice of filing.

During the course of the review the Agency decided to correct the Company address and correct the listings for the commodities canola, cotton and flax. The company address is changed to DuPont Crop Protection, Stine-Haskell Research Center, Newark, DE 19714. The listing of the commodities imazethapyr tolerant canola, cotton seed, cotton gin trash and Crop Development Center (CDC) triffid flax are corrected to read canola, seed; cotton, undelinted seed; cotton, gin byproducts and flax, seed; respectively.

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 a tolerance for residues of tribenuron methyl on canola, seed at 0.02 ppm, cotton, gin byproducts at 0.02 ppm, cotton, undelinted seed at 0.02 ppm, and flax, seed at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tribenuron methyl 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	NOAEL = 7 (males and 8 (females) milligrams/kilogram/day (mg/kg/day) LOAEL = 118 (males) and 135 (females) mg/kg/day based on decreased body weight gain, food consumption and food efficiency; decreased absolute heart, liver, and kidney weights; increase relative brain, heart, liver, kidney, testes, and spleen weights; decreased serum glucose and globulin; no histopathologic lesions; likely cachexia
870.3150	90–Day oral toxicity--non-rodents	NOAEL = > 73.3 (males) and > 78.0 (females) HDT mg/kg/day
870.3200	21/28-Day dermal toxicity	NOAEL = limit dose, 1,000 mg/kg/day, resulted in serious toxicity and death. No NOAEL or LOEAL defined. Toxicity included treatment site lesions, hypokinesia, decreased body weights and food consumption, and kidney pathology, but the cause of death could not be determined. Although this study is core supplementary, another study is not needed. Worker exposure is expected to be 4 to 5 orders of magnitude less than limit dose.
870.3700	Prenatal developmental--rodents	Maternal NOAEL = 20 mg/kg/day Maternal LOAEL = 125 mg/kg/day based on decreased maternal body weight gain and food consumption Developmental NOAEL = 20 mg/kg/day Developmental LOAEL = 125 mg/kg/day based on decreased body weight. At 500 mg/kg/day (HDT) there were increased resorption, fetal deaths, and incomplete ossifications
870.3700	Prenatal developmental--non-rodents	Maternal NOAEL = 20 mg/kg/day Maternal LOAEL = 80 (HDT) mg/kg/day based on 10% decreased food consumption, increased abortions Developmental NOAEL = 20 mg/kg/day Developmental LOAEL = 80 mg/kg/day based on HDT-10% decrease in body weight compared to controls-not statistically significant). Abortions were increased at 80 mg/kg/day. Teratology was not observed.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 2 mg/kg/day Parental/Systemic LOAEL = 21 mg/kg/day based on decreased body weight gain in F_{1a} adult females Reproductive NOAEL = 2.5 mg/kg/day Reproductive LOAEL = 25 mg/kg/day based on decreased body weight gain during lactation for F_{1b} and F_{2b} pups Offspring NOAEL = 2.5 mg/kg/day Offspring LOAEL = 25 mg/kg/day based on decreased absolute splenic weights
870.4100	Chronic toxicity--rodents	NOAEL = 0.95 (males)/1.2 (females) mg/kg/day LOAEL = 10 (males)/13 (females) mg/kg/day based on decreased body weight gain in both sexes. Statistically significant increase in mammary gland adenocarcinomas in female rats at 76 mg/kg/day highest dose tested (HDT)
870.4100	Chronic toxicity--dogs	NOAEL = 0.79 (males)/8.16 (females) mg/kg/day LOAEL = 8.18 (males)/52.02 (females) mg/kg/day based on elevated serum bilirubin, AST, and urinary volume, reduced body weight gain (20%) in females; increased serum creatinine, bilirubin, AST, and globulin, decreased body weight gain of 18.2% in males.

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

Guideline No.	Study Type	Results
870.4200	Carcinogenicity--rats	NOAEL = 0.95 (males)/1.2 (females) mg/kg/day LOAEL = 10 (males)/13 (females) mg/kg/day based on decreased body weight gain in both sexes. Statistically significant increase in mammary gland adenocarcinomas in female rats at 76 mg/kg/day (HDT)
870.4300	Supplement-Estrogenic Activity in Rats	Dose levels: 0 and 390 mg/kg/day for 90 days. Weak estrogenic activity was observed in female rats. The technical and seven metabolites may be agonists for the estrogen receptor.
870.4300	Carcinogenicity--mice	NOAEL = 3 (males) mg/kg/day LOAEL = 30 mg/kg/day based on bilateral seminiferous degenertion and oligospermia. Although frank toxicity was not observed in the females, HED peer review judged the dose levels to be adequate. No evidence of carcinogenicity
870.5100	Gene mutation Bacterial	negative in *Salmonella Typhimurium*
870.5300	Gene Mutation Mammalian	negative in Chinese hamster ovary cells in *in vitro*
870.5375	Cytogenetics	negative for structural chromosomal damage and when tested in a micronucleus test in mice
870.7485	Metabolism and pharmacokinetics	The major route of excretion in rats is the urine. Urine samples contained two to four times of the administered radioactivity than the feces. Tissue levels of tribenuron methyl and its metabolites increased with dose, but there was no concentration of radioactivity in any particular organ or tissue.

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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or 1 in 10 million (1×10^{-7}). 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 tribenuron methyl used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	NOAEL= 0.8 mg/kg/day UF = 100 ..... Chronic RfD = 0.008 mg/kg/day.	Special FQPA SF = 1 cPAD = chronic RfD ÷ Special FQPA SF = 0.008 mg/kg/day.	Chronic Dog LOAEL = 8.2 mg/kg/day based on elevated bilirubin, elevated serum liver enzymes, increased urinary volume, and 20% reduction in body weight gain.
Cancer (oral, dermal, inhalation)	Classified as Group C (possible human carcinogen) not mutagenic)	chronic risk assessment protective of any potential carcinogenic risk	NA

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.451) for the residues of tribenuron methyl, in or on a variety of raw agricultural commodities. Tolerances are established for barley, oats, wheat, and grass forage and hay group. No tolerances for meat products, eggs, or milk are established. Risk assessments were conducted by EPA to assess dietary exposures from tribenuron 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 studies that identify an acute hazard based on toxic effects observed following a single oral exposure (dose) of tribenuron methyl. The developmental toxicity rat study in which a 9% reduction in body weight occurred on the fourth day of dosing (day 9) was considered. However, this reduction in body weight gain was only slight and could not be attributed to a single dose since the reduction occurred on day 4 of dosing. Other effects observed in the developmental toxicity study such as decreased fetal wight (7.4%) and increased incidence of fetal resorptions (not statistically significant) were considered for an endpoint in reproductive females, but again, effects could not be attributed to a single dose. Since there was no litter loss or other acute effects, the aRfD is not appropriate for the assessment.

ii. *Chronic exposure*. Dietary exposure estimates were conducted using the Lifeline model (Version 2.0) which incorporates consumption data from the USDA Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-96 and 1998. The 1994-96, 1998 data are based on reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods ''as consumed'' are linked to EPA-defined food commodities using publicly available recipe translation files (developed jointly by USDA/ARS and EPA). Lifeline models individual dietary exposures over a season by selecting a new CSFII diary each day from a set of similar individuals, based on age and season attributes. The Lifeline chronic dietary exposure estimate is based on an average daily exposure from a profile of 1,000 individuals over a 1–year period. Further information regarding the Lifetime model can be found at the following we site:*www.Lifeline* ™*group.org*.

The following assumptions were made for the chronic exposure assessments: Tolerance level, 100% crop treated (CT), and default processing factors were used. Percent crop treated (PCT) or anticipated residues were not used.

iii. *Cancer*. Tribenuron methyl is classified as a Group C (Possible Human Carcinogen). The Agency also concluded that the carcinogenic response observed may be associated with a hormonal imbalance that may not occur at doses below a maximum tolerated dose (MTD). A quantitative carcinogenic risk assessment for tribenuron methyl is not considered appropriate because: (1) The increased incidence of mammary gland tumors was observed in female rats treated at the dose levels exceeding the (MTD; (2) there was no evidence of genetic toxicity shown in several studies; (3) structural analogs of tribenuron methyl were not associated with carcinogenic responses in rats and mice. In conclusion the Agency considers the chronic risk assessment, making use of the cPAD, to be protective of any potential carcinogenic 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 tribenuron 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 tribenuron methyl.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/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. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 tribenuron methyl they are further discussed in the aggregate risk Unit III.E.

Based on the FIRST, and SCI-GROW models, the EECs of tribenuron methyl for chronic exposures are estimated to be .413 ppb for surface water and 0.000006 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).

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

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to tribenuron methyl and any other substances and tribenuron 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 tribenuron 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 policy statements released by EPA's Office of Pesticide Programs (OPP) concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a maragin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Developmental and reproductive toxicity studies indicated no increased susceptibility of offspring to tribenuron methyl. However, increased number of resorptions (not statistically significant) and fetal deaths were observed at the highest dose tested when administered during the critical gestation period of pregnancy, in both the rat and the rabbit. The resorptions and fetal deaths indicate an effect due to maternal toxicity. In a two-generation reproduction study, reproductive effects of tribenuron methyl were limited to decreased body weight gain during lactation.

3. *Conclusion*. There is a complete toxicity database for tribenuron methyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The impact of tribenuron methyl on the nervous system has not been specifically evaluated in neurotoxicity studies. However, there was no evidence of neurotoxicity or neuropathology seen in either acute, subchronic, chronic, or reproductive studies, and there are no concerns for potential developmental neurotoxicity. Therefore, neurotoxicity data are not required for tribenuron methyl. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because of the completeness of the toxicity and exposure database and because the available data provided no indication of increased susceptibility (quantitative or qualitative) to rats or rabbits following *in utero* exposure to tribenuron methyl, or to prenatal and/or postnatal exposure in rat reproduction studies and there are no concerns for potential developmental neurotoxicity.

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 (drinking water level of concern) which are used as a point of comparison against 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 EPA's 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*. An acute risk assessment was not performed; there were no studies that identify an acute hazard based on toxic effects observed following a single oral exposure (dose) of tribenuron methyl.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tribenuron methyl from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants <1 year old, and <1% of the cPAD for children 3 to 5 years old. There are no residential uses for tribenuron methyl that result in chronic residential exposure to tribenuron methyl. In addition, there is potential for chronic dietary exposure to tribenuron methyl 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 cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRIBENURON METHYL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U. S. Population	0.008	<1	.413	.000006	300
All infants < 1 year old	0.008	<1	.413	.000006	100
Children 1–2 years old	0.008	<1	.413	.000006	100
Children 3–5 years old	0.008	<1	.413	.000006	100
Females 13–49 years old	0.008	<1	.413	.000006	200

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).

Tribenuron 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 level of concern.

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).

Tribenuron 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 level of concern.

5. *Aggregate cancer risk for U.S. population*. The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of any aggregate cancer risk. See Table 3, Unit III.E.2. Therefore, the aggregate risk is not expected to exceed the Agency's level of concern.

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 tribenuron methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methodology including liquid chromatography with a photoconductivity detector; high-performance liquid chromatography with UV detection (HPLC/UV); and gas chromatography using mass spectral detection (GC/MS) are available for enforcement of reassessed tolerances. These methods are published in PAM II.

Adequate enforcement methodology —liquid chromatography with detection via electospray mass spectroscopy is available to enforce the tolerance expression for canola, flax, and cotton. 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

The maximum residue level (MRL) in Canada for tribenuron methyl on canola is 0.1 ppm. Available residue data and use pattern support a U.S. tolerance of 0.02 ppm. No Mexican or Codex MRLs exist for tribenuron methyl on canola. There are no Canadian, Mexican, or Codex MRLs for tribenuron methyl on cotton or flax.

C. Conditions

Based on the tolerance reassessment for barley, oats, and wheat, residue data are required for barley, hay; oat forage and hay; and wheat forage and hay. Submission of this data and proposal of appropriate tolerances will be required. There are no conditions of registration for the establishment of tolerances on canola, cotton, or flax.

V. Conclusion

Therefore, the tolerance is established for residues of tibenuron methyl, methyl 2-[[[[(4-methoxy-6-methyl-1, 3, 5-triazin-2-yl) methylamino]carbobyl]amino] sulfonyl]benzoate, in or on canola, seed at 0.02 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm, and flax, seed at 0.02 ppm. This action results in the reassessment of 8 tolerances as follows: barley, grain at 0.05 ppm; barley, straw at 0.10 ppm; oat, grain at 0.05 ppm; oat, straw at 0.1 ppm; wheat, grain at 0.05 ppm; wheat, straw at 0.10 ppm; and tolerances with regional registration for grass, forage, fodder, and hay group (except bermudagrass); forage at 0.10 ppm; and grass, forage, fodder, and hay group (except bermudagrass); hay at 0.10 ppm listed in 40 CFR 180.451. Also, even though many of the tolerancs for the current commodities listed in § 180.451 have not been changed and only tolerances for canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed are being added, EPA is printing § 180.451 in its entirety to restructure the section so that it matched the other sections in subpart C.

VI. Objections and Hearing Requests

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

tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0278. 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 22, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0278, 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 **ADDRESSES**. 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 FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the

relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 10, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—AMENDED

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

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

■ 2. Section 180.451 is revised to read as follows:

§ 180.451 Tribenuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for the residues of the herbicide tribenuron methyl (methyl-2-[[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, straw	0.10
Canola, seed	0.02
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
Flax, seed	0.02
Oat, grain	0.05
Oat, straw	0.10
Wheat, grain	0.05
Wheat, straw	0.10

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

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) are established for residues of the herbicide tribenuron methyl (methyl-2-[[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass, forage, fodder and hay, group (except Bermudagrass); forage	0.10
Grass, forage, fodder and hay, group (except Bermudagrass); hay	0.10

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

[FR Doc. 04–20982 Filed 9–21–04; 8:45 am]

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CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Parts 2552 and 2553

Senior Corps

AGENCY: Corporation for National and Community Service.

ACTION: Final rule; correction.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation'') hereby amends its regulations for the Senior Corps. These amendments make technical corrections to the final rules issued on April 14, 2004, for the Foster Grandparent Program and on April 19, 2004, for the Retired and Senior Volunteer Program. Two amendments herein provide technical corrections to the Foster Grandparent Program and Retired and Senior Volunteer Program regulations to ensure consistency concerning the allowability of volunteer expenses among the Foster Grandparent, Retired and Senior Volunteer, and Senior Companion Programs and bring them in line with the corresponding provision for the Senior Companion Program, as it was amended on April 19, 2004. The third amendment deletes one sentence in the Retired and Senior Volunteer Program regulations so as to ensure consistency throughout the entire section.

DATES: These changes are effective as of September 22, 2004.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Boynton at (202) 606–5000, ext. 499 or by e-mail: *pboynton@cns.gov.*

List of Subjects

45 CFR Part 2552

Aged, Grant programs—social programs, Volunteers.

45 CFR Part 2553

Aged, Grant programs—social programs, Volunteers.

■ For the reasons discussed in the Summary, the Corporation for National and Community Service amends 45 CFR parts 2552 and 2553 as follows:

PART 2552—FOSTER GRANDPARENT PROGRAM

■ 1. The authority citation for part 2552 continues to read as follows:

Authority: 42 U.S.C. 4950 *et seq.*

■ 2. In § 2552.45, revise paragraph (f) to read as follows:

§ 2552.45 What cost reimbursements are provided to Foster Grandparents?

* * * * *

(f) *Other volunteer expenses.* Foster Grandparents may be reimbursed for expenses incurred while performing their volunteer assignments, provided these expenses are described in the Memorandum of Understanding negotiated with the volunteer station to which the volunteer is assigned and there are sufficient funds available to cover these expenses and meet all other requirements identified in the notice of grant award.

PART 2553—RETIRED AND SENIOR VOLUNTEER PROGRAM

■ 3. The authority citation for part 2553 continues to read as follows:

Authority: 42 U.S.C. 4950 *et seq.*

■ 4. In § 2553.43, remove the last sentence of paragraph (a) and revise paragraph (e) to read as follows:

§ 2553.43 What cost reimbursements are provided to RSVP volunteers?

* * * * *

(e) *Other volunteer expenses.* RSVP volunteers may be reimbursed for