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Chlorsulfuron; Pesticide Tolerance

[Federal Register: August 14, 2002 (Volume 67, Number 157)]
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ENVIRONMENTAL PROTECTION AGENCY
 40 CFR Part 180
[\[OPP-2002-0181; FRL-7192-9\]](#)

Chlorsulfuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).
 ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of chlorsulfuron; (2-chloro-N-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide) in or on grass, forage and grass, hay. E.I. du Pont de Nemours and Company, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 14, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0181, must be received on or before October 15, 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-2002-0181 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-305-6224; e-mail address: miller.joanne@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:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this

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, EXIT Disclaimer 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-2002-0181. 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 March 8, 2002 ([67 FR pages 10722 - 10727](#)) (FRL-6825-8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170), announcing the filing of a pesticide petition (PP 6F4752) by E.I. du Pont de Nemours and Company, Inc., P.O. Box 30, Newark, Delaware 19714-0030. This notice included a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.405 be amended by establishing tolerances for residues of the herbicide chlorsulfuron; (2-chloro-N-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide), in or on grass, forage at 11.0 part per million (ppm) and grass, hay at 19.0 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical

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residue in or on a food) only if EPA determines that the tolerance is ``safe.`` Section 408(b)(2)(A)(ii) 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) 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 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), 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), for tolerances for residues of chlorsulfuron in or on grass, forage at 11.0 ppm and grass, hay at 19.0 ppm. 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 chlorsulfuron are discussed in the following Table 1 as well as the no observed adverse effect level and the lowest observed adverse effect level from the toxicity studies reviewed.

Table 1.--Subchronic, Chronic, and Other Toxicity

Guideline No.	Study Type	Results
870.3150	6 Month oral toxicity in nonrodents	NOAEL = 18.5 mg/kg/day LOAEL = 82.3 mg/kg/day based on decreased body weight and body-weight gain.
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 165 mg/kg/day LOAEL = 500 mg/kg/day based on clinical signs, vaginal discharge with associated alopecia. Developmental NOAEL = 500 mg/kg/day LOAEL = 1500 mg/kg/day based on decreased fetal body weight.
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 75 mg/kg/day LOAEL = 200 mg/kg/day based on decreased body weight gain. Developmental NOAEL = 200 mg/kg/day LOAEL = 400 mg/kg/day based on a slight increase in visceral malformations and decreased fetal body weight.
870.3800	3-Generation Reproduction in rodents	Parental NOAEL = 125 mg/kg/day LOAEL is greater than 125 mg/kg/day, no effects observed. Reproductive NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on decreased female fertility Offspring NOAEL = 125 mg/kg/day LOAEL = 125 mg/kg/day, no effects observed.
870.4100	Chronic toxicity dogs	NOAEL = 60.6 mg/kg/day LOAEL = 215 mg/kg/day based on decreased body-weight gain, erythrocyte counts and hemoglobin levels.
870.4200	Carcino-genicity mice	NOAEL = 108 mg/kg/day LOAEL = 750 mg/kg/day based on decreased body weight and body-weight gain. (no) evidence of carcinogenicity
870.4300	Carcinogenicity rats	NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on decreased body weight in males. (no) evidence of carcinogenicity
870.5385	Cytogenetics	No evidence of

870.7485	Metabolism and pharmacokinetics	Chlorsulfuron is rapidly absorbed, metabolized, and excreted following oral exposure. The major routes of elimination are the urine (58% - 72%) and feces (20% - 35%).
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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. The 3-generation reproductive toxicity study is classified unacceptable, and it is considered a datagap. Reproductive toxicity was observed but was of questionable significance in both litters of the F₃ generation, as evidenced by decreased female fertility. Offspring toxicity was not observed. This study had numerous deficiencies including but not limited to:

1. No assessment of estrous cyclicity, sperm parameters.
2. No assessment of male reproductive performance.
3. Parental animals not subjected to gross pathology or histopathology examinations.
4. No assessment of developmental landmarks.
5. Pup histopathology evaluations conducted only for the F_{3B} generation.

Although this reproduction study on chlorsulfuron conformed to the old guideline requirements, it is unacceptable under the current guideline requirement in light of the fact that most of the parameters used for FQPA assessment are not provided in the available study. The Agency applied a FQPA database uncertainty factor of 3X to account for the unacceptable reproduction study. Exposure estimates are upper bound and will not underestimate exposure to chlorsulfuron. The 3X FQPA database uncertainty factor applies to all dietary and non-dietary residential exposure scenarios and no Special FQPA safety factor is required.

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 x 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 chlorsulfuron used for human risk assessment is shown in the following Table 2:

Table 2.--Summary of Toxicological Dose and Endpoints for Chlorsulfuron for Use in Human Risk Assessment

Exposure Scenario	Dose Used in Risk	FQPA SF* and Level of Concern for Risk	Study and Toxicological
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	Assessment, UF	Assessment	Effects
Acute Dietary females 13-50 years of age		no appropriate endpoint for this exposure scenario was identified	
Acute Dietary general population including infants and children		no appropriate endpoint for this exposure scenario was identified	
Chronic Dietary all populations	NOAEL = 5 mg/kg/day UF = 300..... Chronic RfD = 0.02 mg/kg/day.	FQPA SF = 1 cPAD = chronic RfD FQPA SF = 25 mg/kg/day based on 0.02 mg/kg/day.	rat chronic toxicity/carcinogenicity LOAEL on decreased body weight in males
Incidental Oral, Short-Term Residential Only	NOAEL = 75 mg/kg/day UF=300.....	FQPA SF = 1 LOC for MOE = 300.....	developmental toxicity study in rabbits LOAEL=200 mg/kg/day based on decreased body-weight gain
Incidental Oral, Intermediate-Term Residential Only	NOAEL = 75 mg/kg/day UF=300.....	FQPA SF = 1 LOC for MOE = 300.....	developmental toxicity study in rabbits LOAEL=200 mg/kg/day based on decreased body-weight gain
Short-Term Dermal (1 to 7 days) (Residential)	NOAEL = 75 mg/kg/day UF = 300.....	FQPA SF = 1 LOC for MOE = 300 (Residential).	developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body-weight gain

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Intermediate-Term Dermal (1 week to several months) (Residential)	NOAEL = 75 mg/kg/day UF = 300.....	FQPA SF = 1 LOC for MOE = 300 (Residential).	developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body-weight gain
Long-Term Dermal (several months to lifetime) (Residential)	NOAEL = 5 mg/kg/day UF = 300 when appropriate).	FQPA SF = 1 LOC for MOE = 300 (Residential).	chronic toxicity/carcinogenicity study in rats LOAEL = 25 mg/kg/day based on decreased body weight in males
Short-Term Inhalation (1 to 7 days) (Residential)	NOAEL = 75 mg/kg/day UF = 300.....	FQPA SF = 1 LOC for MOE = 300 (Residential).	developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body-weight gain
Intermediate-Term Inhalation (1 week to several months) (Residential)	NOAEL = 75 mg/kg/day UF = 300).....	FQPA SF = 1 LOC for MOE = 300 (Residential).	developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased body weight gain
Long-Term Inhalation (several months to lifetime) (Residential)	NOAEL = 5 mg/kg/day UF = 300).....	FQPA SF = 1 LOC for MOE = 300 (Residential).	chronic toxicity/carcinogenicity study in rats LOAEL = 25 mg/kg/day based on decreased body weight in males

* 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 180.405) for the residues of chlorsulfuron, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from chlorsulfuron 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 one day or single exposure. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies. No appropriate studies available show any acute dietary effects of concern.

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 USDA 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: Residue levels are at the recommended tolerances and 100% crop treated with chlorsulfuron. Results of dietary analyses showed exposure to chlorsulfuron consumed no more than 19.3% of the cPAD.

iii. Cancer. Chlorsulfuron was classified as having "no evidence of carcinogenicity" based upon lack of evidence of carcinogenicity in rats and mice. Therefore, a cancer dietary exposure analysis was not performed.

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

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

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

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

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Based on the FIRST and SCI-GROW models the EECs of total chlorsulfuron residues (both parent and degradation products) for acute exposures are estimated to be 59.7 parts per billion (ppb) and for chronic exposures are estimated to be 41.3 ppb in surface water. The EECs for acute and chronic exposures of chlorsulfuron (parent only) are estimated to be 3.5 ppb in 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).

Chlorsulfuron is currently registered for use on the following residential non-dietary sites: Lawns. The risk assessment was conducted using the following residential exposure assumptions: Adult handlers and adult and toddler postapplication exposure to treated turf. Residential exposure risk was assessed using the Residential Exposure Assessment Standard Operating Procedures (ResSOPs) standard values and assumptions. Adult handler exposure risk was not of concern with MOEs ranging between 8,800 and 190,000. Postapplication exposure risks for adults and toddlers also exceeded target MOEs, ranging between 770 and 400,000. Since the ResSOPs ranged between median and high end assessments, and the use assessed was for spot treatment, not the entire lawn, the residential postapplication exposure risk assessment was conservative.

4. Cumulative exposure to substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) 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 chlorsulfuron 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, chlorsulfuron 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 chlorsulfuron 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, FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. Prenatal and postnatal sensitivity. The toxicology database for chlorsulfuron contains acceptable guideline developmental studies which show no quantitative or qualitative evidence of increased susceptibility following in utero exposure. Susceptibility cannot be assessed in the 3-generation reproduction study in rats. The Agency determined that a 2-generation reproduction study is required for chlorsulfuron.

3. Conclusion. The existing toxicological database for chlorsulfuron, while not complete, supports the establishment of permanent tolerances for chlorsulfuron per se and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. For dietary exposure estimates, a FQPA safety factor of 3 was used. Due to data deficiencies in the toxicology database, the Agency determined that an additional 3X database UF is needed for the protection of infants and children. An UF of 3X (as opposed to a 10X) is adequate because the chronic RfD is based on the NOAEL of 5 mg/kg/day established in the Combined Chronic/Carcinogenicity Study in Rats. This dose (5 mg/kg/day) is 25X lower than the highest dose tested (125 mg/kg/day) in the existing 3-generation Reproduction Study in which the effects noted were considered of questionable toxicological significance.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA 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 groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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 appropriate endpoint attributable to a single dose was not identified, therefore, no acute risk is expected.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to chlorsulfuron from food will utilize no more than 6.6% of the cPAD for the U.S. population, 7.3% of the cPAD for all infants and 19.3% of the cPAD for children 1-6 years old. Based on the use pattern, chronic

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residential exposure to residues of chlorsulfuron is not expected. Since no chronic residential scenarios have been identified, chronic DWLOCs for chlorsulfuron were calculated based on residues in food alone. 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 Chlorsulfuron

Population Subgroup	cPADmg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.02	6.6	41.3	3.5	654
Females 13-50 years old	0.02	4.3	41.3	3.5	574
Children 1-6 years old	0.02	19.3	41.3	3.5	161
All Infants	0.02	7.3	41.3	3.5	185

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).

Chlorsulfuron is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for chlorsulfuron.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,265 for adult males, 1,274 for adult females and 722 for toddlers. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of chlorsulfuron in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

Table 4.--Aggregate Risk Assessment for Short-Term Exposure to Chlorsulfuron

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Adult Male	1,265	300	41.3	3.5	6,674
Adult Female	1,274	300	41.3	3.5	5,734
Toddler	722	300	41.3	3.5	1,461

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). The intermediate-term aggregate risk is the same as the short-term aggregate risk (Table 4) since the toxicity end points are the same for both exposures.

5. Aggregate cancer risk for U.S. population. The carcinogenic potential of chlorsulfuron was classified as no evidence of carcinogenicity. Therefore, no cancer risk is expected.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Methods are available for the enforcement of tolerances for chlorsulfuron residues in/on plant and animal commodities. PAM Vol. II lists Methods I and II, High performance liquid chromatography methods with photoconductivity detection, for the determination of chlorsulfuron residues in plants and livestock commodities and milk.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits, therefore, issues of compatibility do not exist.

C. Conditions

The following data gaps must be fulfilled; a 21-day repeat dermal toxicity study, a subchronic inhalation study, and a 2-generation reproduction study.

V. Conclusion

Therefore, tolerances are established for residues of chlorsulfuron

in or on grass, forage at 11.0 ppm and grass, hay at 19.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCFA, 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 FFDCFA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made.

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The new section 408(g) 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), as was provided in the old FFDCFA 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-2002-0181 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 October 15, 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-2002-0181, 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

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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: July 30, 2002.
Donald R. Stubbs,
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 371.

2. Section 180.405 is revised to read as follows:

Sec. 180.405 Chlorsulfuron; tolerances for residues.

(a) General. (1) Tolerances are established for the combined residues of chlorsulfuron (2-chloro-N-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide) and its metabolite, 2-chloro-5-hydroxy-N-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain.....	0.1
Barley, straw.....	0.5
Oat, forage.....	20.0
Oat, grain.....	0.1
Oat, straw.....	0.5
Wheat, forage.....	20.0
Wheat, grain.....	0.1
Wheat, straw.....	0.5

(2) Tolerances are established for residues of chlorsulfuron (2-chloro-N-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)aminocarbonyl]benzenesulfonamide) in or on the following raw agricultural commodities.

Commodity	Parts per million
Cattle, fat.....	0.3
Cattle, meat.....	0.3
Cattle, meat byproducts.....	0.3
Goat, fat.....	0.3
Goat, meat.....	0.3
Goat, meat byproducts.....	0.3
Grass, forage.....	11.0
Grass, hay.....	19.0
Hog, fat.....	0.3
Hog, meat.....	0.3
Hog, meat byproducts.....	0.3
Horse, fat.....	0.3
Horse, meat.....	0.3
Horse, meat byproducts.....	0.3
Milk.....	0.1
Sheep, fat.....	0.3
Sheep, meat.....	0.3
Sheep, meat byproducts.....	0.3

- (b) Section 18 emergency exemptions. [Reserved].
- (c) Tolerances with regional registrations. [Reserved]
- (d) Indirect or inadvertent residues. [Reserved]

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