ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0331; FRL–7283–2]

S-metolachlor; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues (free and bound) of the herbicide s-metolachlor [(S)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], its R-enantiomer and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in or on sweet potatoes. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sweet potatoes. This regulation establishes a maximum permissible level for residues of s-metolachlor in this food commodity. The tolerance will expire and is revoked on December 31, 2004. Although the exemption was granted for the active ingredient s-metolachlor and the time-limited tolerance is being set for s-metolachlor, the Agency has determined that residues of concern for s-metolachlor are the same as those for metolachlor, and therefore, the tolerance is being included under 40 CFR 180.368 but under its own section in paragraph (b). Metabolites of metolachlor are assumed to be toxicologically equivalent to parent metolachlor. The Agency has determined that the residues of concern for plant and animal commodities are metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751.

DATES: This regulation is effective January 3, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0331, must be received on or before March 4, 2003.

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

FOR FURTHER INFORMATION CONTACT: Andrew Ertman,Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:(703)308–9367; e-mail address: sec-18-mailbox@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 a federal or state government agency involved in administration of environmental quality programs (i.e., Departments of Agriculture, Environment, etc). Potentially affected entities may include, but are not limited to:

• Federal or State Government Entity, (NAICS 9241), Departments of Agriculture, Environment, etc.

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

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0331. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the'' **Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml__00/Title__40/40cfr180_(_00.html, a beta site currently under development.

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for the combined residues (free and bound) of the herbicide s-metolachlor [(S)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], its R-enantiomer and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on sweet potatoes at 0.2 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2004. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for S-metolachlor on Sweet Potatoes and FFDCA Tolerances

The States of Louisiana and Mississippi requested the use of s-metolachlor on sweet potatoes to control sedges due to an increased pressure from these weed species and a lack of effective registered alternatives. EPA has authorized under FIFRA section 18 the use of s-metolachlor on sweet potatoes for control of sedges in Louisiana and Mississippi. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of s-metolachlor in or on sweet potatoes. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2004, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sweet potatoes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether s-metolachlor meets EPA's registration requirements for use on sweet potatoes or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of s-metolachlor by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Louisiana and Mississippi to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for s-metolachlor, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

The Agency has determined that the residues of concern for plant and animal commodities are metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751. Metabolites of metolachlor are assumed to be toxicologically equivalent to parent metolachlor. The residues of concern for s-metolachlor are the same as those for metolachlor.

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of s-metolachlor and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for the combined residues (free and bound) of the herbicide s-metolachlor [(S)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], its R-enantiomer and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in or on sweet potatoes at 0.2 ppm.

EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. 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 endpoint. 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 intra species differences.

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

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (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 $x10^{-6}$ 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.

S-metolachlor, [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], is a member of the chloroacetanilide class of herbicides. In this risk assessment the term s-metolachlor will refer to a metolachlor product which is enriched in the S-isomer. The term metolachlor will refer to a racemic mixture of the R and S isomers.

Toxicological endpoints have been selected for metolachlor and s-metolachlor for use in human health risk assessments. The Agency has determined that metolachlor and s-metolachlor are of comparable toxicity, and therefore, studies with both chemicals were used interchangeably for toxicology endpoint selection.

A summary of the toxicological endpoints for s-metolachlor used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR S-METOLACHLOR FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	NOAEL = 300 mg/kg/day UF = 100 Acute RfD = 3.0 mg/kg/day	FQPA SF = 1x aPAD = acute RfD/FQPA SF = 3.0 mg/kg/day	Prenatal developmental toxicity study in rats LOAEL = 1,000 mg/kg/day based on death, clinical signs of toxicity (clonic and/or tonic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive salivation) and decreased body weight gain
Acute Dietary (General population including infants and children)	NOAEL = 300 mg/kg/day UF = 100 Acute RfD = 3.0 mg/kg/day	FQPA SF = 1x aPAD = acute RfD/FQPA SF = 3.0 mg/kg/day	Prenatal developmental toxicity study in rats LOAEL = 1,000 mg/kg/day based on death, clinical signs of toxicity (clonic and/or tonic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive salivation) and decreased body weight gain
Chronic Dietary (All populations)	NOAEL = 9.7 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD/FQPA SF = 0.1 mg/kg/day	Chronic study in dogs LOAEL = 33.0 mg/kg/day based on decreased body weight gain in females
Short-Term Dermal (1 to 7 days) (Residential)	Hazard was not identified for quantification of risk. No systemic toxicity was seen at the limit dose (1,000 mg/kg/day) following dermal applications and there is no concern for developmental toxicity in rats or rabbits.		
Intermediate-Term Dermal (1 week to several months) (Residential)	Hazard was not identified for quantification of risk. No systemic toxicity was seen at the limit dose (1000 mg/kg/day) following dermal applications and there is no concern for developmental toxicity in rats or rabbits.		
Long-Term Dermal (several months to lifetime) (Residential)	dermal (or oral) study NOAEL= 9.7 mg/kg/day (dermal absorption rate = 58% when appropriate)	LOC for MOE = 100 (Residential)	Chronic toxicity study in dogs LOAEL = 33.0 mg/kg/day based on decreased body weight gain in females
Short-Term Inhalation (1 to 7 days) (Residential)	Inhalation (or oral) study NOAEL= 50 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Prenatal developmental toxicity study in rats LOAEL = 500 mg/kg/day based on increased incidence of clinical signs, decreased body weight/body weight gain, food consumption, and food efficiency
Intermediate-Term Inhalation (1 week to several months) (Residential)	Inhalation (or oral) study NOAEL = 8.8 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Subchronic (6 month) toxicity study in dogs LOAEL based on decreased body weight gain

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR S-METOLACHLOR FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-Term Inhalation (several months to lifetime) (Residential)	Inhalation (or oral) study NOAEL= 9.7 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Chronic toxicity study in dogs LOAEL = 33.0 mg/kg/day based on decreased body weight gain in females
Cancer (oral, dermal, inhalation)	Metolachlor has been classified as a Group C, possible human carcinogen. This classification was based on the occurrence of liver tumors in rats at the highest dose level tested (150 mg/kg/day). The carcinogenic risks for metolachlor have been quantitated using a non-linear approach, with a NOAEL of 15 mg/kg/day. However, the NOAEL of 15 mg/kg/day that was established based on liver tumors in rats is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the chronic reference dose for metolachlor. It is assumed that the chronic dietary endpoint is protective for cancer dietary exposure. Therefore, a separate cancer aggregate risk assessment was not conducted, and cancer DWLOC values were not calculated.		

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

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* S-metolachlor, [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], is a member of the chloroacetanilide class of herbicides. In this risk assessment the term s-metolachlor will refer to a metolachlor product which is enriched in the S-isomer. The term metolachlor will refer to a racemic mixture of the R and S isomers. Currently, there are permanent tolerances for metolachlor (40 CFR 180.368) on a variety of crops and animal commodities. These tolerances range from 0.02 ppm to 30 ppm. There are also time-limited tolerances (in conjunction with section 18 uses) on grass, spinach, and tomatoes. Risk assessments were conducted by EPA to assess dietary exposures from metolachlor and s-metolachlor 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. 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 acute exposure assessments: The analyses assumed tolerance-level residues (with the exception of those with DEEM default processing factors) and 100% crop treated for all commodities.

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: The analyses assumed tolerance-level residues (with the exception of those with DEEM default processing factors) and 100% crop treated for all commodities.

iii. *Cancer*. Metolachlor has been classified as a Group C, possible human carcinogen. This classification was based on the occurrence of liver tumors in rats at the highest dose level tested (150 mg/kg/day). The carcinogenic risks for metolachlor have been quantitated using a non-linear approach, with a NOAEL of 15 mg/kg/day. However, the NOAEL of 15 mg/kg/day that was established based on liver tumors in rats is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the chronic reference dose for metolachlor. It is assumed that the chronic dietary endpoint is protective for cancer dietary exposure. Therefore, a separate cancer aggregate risk assessment was not conducted, and cancer DWLOC values were not calculated.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for s-metolachlor in drinking water. Because the Agency does not have comprehensive monitoring data for both parent and the degradates of concern in drinking water, exposure from drinking water is being addressed through modeled estimated environmental concentrations (EECs) and the use of drinking water levels of comparison (DWLOCs). This assessment includes concentrations of parent metolachlor and the degradates metolachlor ethanesulfonic acid (ESA) and metolachlor oxanilic acid (OA). Although it was determined by the Agency that the ESA and OA metabolites appear to be less toxic than parent metolachlor, they are included in this risk assessment because they were found in greater abundance than the parent in water monitoring studies.

The surface water EECs were derived from the National Water Quality Assessment Database (parent) and the FIRST Model (ESA and OA metabolites). The SCI-GROW Model was used to generate all ground-water EECs For a screening-level assessment for surface water EPA will generally 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 metolachlor and s-metolachlor they are further discussed in the aggregate risk sections below.

Based on the National Water Quality Assessment Database (parent) and the FIRST Model (ESA and OA metabolites) and SCI-GROW models the estimated environmental concentrations (EECs) of parent metolachlor and its degradates for acute exposures are estimated to be 201 parts per billion (ppb) (parent: 77.6 ppb, ESA: 31.9 ppb, and OA: 91.4 ppb) for surface water and 103 ppb (parent: 5.5 ppb, ESA: 65.8 ppb, and OA: 31.7 ppb) for ground water. The EECs for chronic exposures are estimated to be 92 ppb (parent: 4.3 ppb, ESA: 22.8 ppb, and OA: 65.1 ppb) for surface water and 103 ppb (parent: 5.5 ppb, ESA: 65.8 ppb, and OA: 31.7 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).

i. *Handlers*. Metolachlor and s-metolachlor are registered (as an emulsifiable concentrate formulation) for use on lawn, turf (including sod farms), golf courses, sports fields, and ornamental gardens. Although metolachlor is not labeled as a restricted-use pesticide, it is not intended for homeowner purchase or use. On this basis, a residential handler is not expected to be exposed to residues of metolachlor and s-metolachlor. Therefore, a residential handler assessment was not conducted.

ii. *Postapplication*. There is potential for postapplication exposure to adults and children resulting from the use of metolachlor/s-metolachlor on residential lawns. Although the use sites for metolachlor and s-metolachlor vary from golf courses to ornamental gardens, the residential lawn scenario represents what the Agency considers to be the likely upper-end of possible exposure. Postapplication exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings.

Postapplication exposure is considered to be short-term (one to 30 days of exposure) only, based on a label specification of a six week interval before the re-application of metolachlor/s-metolachlor. The registrant has also indicated a label revision to limit application to one time per season.

A short-term dermal endpoint was not selected because no systemic toxicity was seen at the limit dose of 1,000 mg/kg/day. As a result, a dermal risk assessment was not conducted and dermal risks are assumed to be minimal. Postapplication inhalation exposure is expected to be minimal since metolachlor and s-metolachlor are only applied in an outdoor setting, the vapor pressure is low (2.8×10^{-5} mm Hg at 25°C), and the label specifies that residents should not re-enter treated areas until after sprays have dried.

The following postapplication incidental oral scenarios which result from application to lawns and turf have been identified:

a. Short-term oral exposure to toddlers and children following hand-to-mouth exposure;

b. Short-term oral exposure to toddlers and children following object-to-mouth exposure; and

c. Short-term oral exposure to toddlers and children following soil ingestion. The term ''incidental'' is used to distinguish the inadvertent oral exposure of small children from exposure that may be expected from treated foods or residues in drinking water.

As the FQPA safety factor for the protection of children and infants was reduced to 1x, a target MOE value of 100 has been identified for residential assessments. MOE values greater than 100 are not considered to be of concern to the Agency. MOE estimates are based on the dose level of 50 mg/kg/day established for short-term oral risk assessment.

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

EPA does not have, at this time, available data to determine whether s-metolachlor 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, s-metolachlor 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 s-metolachlor 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).

C. Safety Factor for Infants and Children

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

2. *Developmental toxicity studies*—i. *Prenatal developmental toxicity study—Metolachlor—Rat*. The maternal toxicity LOAEL was 1,000 mg/kg/day based on an increased incidence of death, clinical signs of toxicity (clonic and/or toxic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive lacrimation) and decreased body weight gain. The NOAEL was 300 mg/kg/day.

The developmental toxicity LOAEL was conservatively established at 1,000 mg/kg/day based on slightly decreased number of implantations per dam, decreased number of live fetuses/dam, increased number of resorptions/dam and significant decrease in mean fetal body weight. The NOAEL was 300 mg/kg/day.

ii. *Prenatal developmental toxicity study—S-metolachlor—Rat*. The maternal toxicity NOAEL was 50 mg/kg/day with a LOAEL of 500 mg/kg/day based on increased clinical signs of toxicity, decreased body weights and body weight gains and reduced food consumption and reduced food efficiency.

No significant treatment related developmental toxicity was noted at the dose levels tested. The developmental toxicity NOAEL was equal to or greater

than 1,000 mg/kg/day, the highest dose tested (HDT); a LOAEL was not reached.

iii. *Prenatal developmental toxicity study—Metolachlor—Rabbit*. The maternal toxicity LOAEL was 360 mg/kg/day based on an increased incidence of clinical observations (persistent anorexia) and decreased body weight gain. The NOAEL was 120 mg/kg/day. The developmental toxicity LOAEL was not established. The NOAEL was 360 mg/kg/day.

iv. *Prenatal developmental toxicity study—S-metolachlor—Rabbit*. The maternal toxicity NOAEL was 20 mg/kg/day with a LOAEL of 100 mg/kg/day based on clinical signs of toxicity.

No significant treatment related developmental toxicity was noted at the dose levels tested. The developmental toxicity NOAEL was equal to or greater than 500 mg/kg/day, HDT; a LOAEL was not reached.

3. *Reproductive toxicity study*. No reproduction studies with s-metolachlor are available, however, in the two-generation reproduction study with metolachlor in rats, there was no evidence of parental or reproductive toxicity at approximately 80 mg/kg/day, HDT. At this dose, there was a minor decrease in fetal body weight beginning at lactation day 4; the NOAEL was approximately 25 mg/kg/day. Since a similar body weight decrease was not seen on lactation day 0, the cause of the effect on later lactation days was most likely due to exposure of the pups to metolachlor in the diet and/or milk and therefore is not evidence of an increased quantitative susceptibility in post-natal animals.

The parental toxicity LOAEL was not established. The NOAEL was 1000 ppm (F0 males/females: 75.8/85.7 mg/kg/day; F1males/females: 76.6/84.5 mg/kg/day).

The reproductive toxicity LOAEL was not established. The NOAEL was 1000 ppm (F0 males/females: 75.8/85.7 mg/kg/day; F1males/females: 76.6/84.5 mg/kg/day).

The offspring LOAEL was conservatively established at 1000 ppm (F0 males/females: 75.8/85.7 mg/kg/day; F1males/females: 76.6/84.5 mg/kg/day) based on decreased body weight in F1 and F2 litters. The NOAEL is 300 ppm (F0 males/females: 23.5/ 26.0 mg/kg/day; F1males/females: 23.7/25.7 mg/kg/day).

4. *Prenatal and postnatal sensitivity*. The data bases for prenatal developmental toxicity for metolachlor and s-metolachlor are considered complete. The prenatal developmental studies in the rat and rabbit with both metolachlor and s-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. No significant developmental toxicity was observed in most studies even at the HDT.

The data base for reproductive toxicity of metolachlor is considered complete. No reproduction studies with s-metolachlor are available. In the two-generation reproduction study with metolachlor in rats, there was no evidence of parental or reproductive toxicity at approximately 80 mg/kg/day, HDT. At this dose, there was a minor decrease in fetal body weight beginning at lactation day 4; the NOAEL was approximately 25 mg/kg/day. Since a similar body weight decrease was not seen on lactation day 0, the cause of the effect on later lactation days was most likely due to exposure of the pups to metolachlor in the diet and/or milk and therefore is not evidence of an increased quantitative susceptibility in post-natal animals.

5. *Conclusion*. There is a complete toxicity data base for s-metolachlor when bridged with the database for metolachlor and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because:

i. The toxicological database is complete for FQPA assessment;

ii. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to in utero and/or postnatal exposure;

iii. A developmental neurotoxicity study is not required; and

iv. The dietary (food and drinking water) and residential exposure assessments will not underestimate the potential exposures for infants and children.

D. 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 + chronic non-dietary, non-occupational 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 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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to s-metolachlor 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 s-metolachlor on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to s-metolachlor will occupy <1 % of the aPAD for the U.S. population, <1 % of the aPAD for females 13 years and older, <1 % of the aPAD for all infant and children subpopulations. In addition, despite the potential for acute dietary exposure to s-metolachlor in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of s-metolachlor in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

TABLE 2.— AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO S-METOLACHLOR

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)*	Ground Water EEC (ppb)*	Acute DWLOC (ppb)
U.S. Population	3.0	< 1	201	103	1.0 x 105
All Infants (< 1 year old)	3.0	<1	201	103	3.0 x 104
Children (1-6 years old)	3.0	<1	201	103	3.0 x 104
Children (7-12 years old)	3.0	<1	201	103	3.0 x 104
Females (13-50 years old)	3.0	<1	201	103	9.0 x 104
Males (13-19 years old)	3.0	<1	201	103	1.0 x 105
Males (20+ years old)	3.0	<1	201	103	1.0 x 105
Seniors (55+ years old)	3.0	<1	201	103	1.0 x 105

* Represents the combined value of parent plus the ESA and OA degradates.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to s-metolachlor from food will utilize 2 % of the cPAD for the U.S. population, 2 % of the cPAD for all infants < 1 year old and 3 % of the cPAD for children 1-6 years old. Based the use pattern, chronic residential exposure to residues of s-metolachlor is not expected. In addition, despite the potential for chronic dietary exposure to s-metolachlor in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of s-metolachlor in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.1	2	92	103	3400
All Infants (< 1 year old)	0.1	2	92	103	980
Children (1-6 years old)	0.1	3	92	103	970
Children (7-12 years old)	0.1	2	92	103	980
Females (13-50 years old)	0.1	1	92	103	3000
Males (13-19 years old)	0.1	2	92	103	3400
Males (20+ years old)	0.1	1	92	103	3500
Seniors (55+ years old)	0.1	1	92	103	3500

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).

For metolachlor and s-metolachlor, potential short-term, non-occupational risk scenarios include oral exposure of children to treated lawns. In this aggregate short-term risk assessment, exposure from food, drinking water, and residential lawns has been considered. Since only children have the potential for non-occupational, short-term risk, they are the only population subgroup included below. Short-term DWLOC values have been calculated for both metolachlor and s-metolachlor, with the only difference in the calculations being different oral exposure values for metolachlor vs. s-metolachlor (based on different application rates).

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 640 for metolachlor and 1000 for s-metolachlor for children 1-6 years old (the only population sub-group of concern. 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 s-metolachlor in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO METOLACHLOR AND S-METOLACHLOR

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Children (1-6); Metolachlor	640	100	92	103	4,200
Children (1-6); S-Metolachlor	1,100	100	92	103	4,500

4. *Intermediate-term risk.* An intermediate-term aggregate risk assessment considers potential exposure from food, drinking water, and non-occupational (residential) pathways of exposure. However, for metolachlor, no intermediate-term non-occupational exposure scenarios (greater than 30 days exposure) are expected to occur. Therefore, intermediate-term DWLOC values were not calculated, and an intermediate-term aggregate risk assessment is not required.

5. *Aggregate cancer risk for U.S. population.* An aggregate cancer risk assessment considers potential carcinogenic exposure from food, drinking water, and non-occupational (residential) pathways of exposure. Metolachlor has been classified as a Group C, possible human carcinogen. This classification was based on the occurrence of liver tumors in rats at the highest dose level tested (150 mg/kg/day). The HED Cancer Assessment Review Committee has recommended that carcinogenic risks for metolachlor be quantitated using a non-linear approach, with a NOAEL of 15 mg/kg/day. However, the NOAEL of 15 mg/kg/day that was established based on liver tumors in rats is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the chronic reference dose for metolachlor. It is assumed that the chronic dietary endpoint is protective for cancer dietary exposure. Therefore, a separate cancer aggregate risk assessment was not conducted, and cancer DWLOC values were not calculated.

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 s-metolachlor residues.

V. Other Considerations

A. Analytical Enforcement Methodology

The Pesticide Analytical Manual (PAM) Vol. II, lists a GC/NPD method (Method I) for determining residues in/on plants and a GC/MSD method (Method II) for determining residues in livestock commodities. These methods determine residues of metolachlor and its metabolites as either CGA-37913 or CGA-49751 following acid hydrolysis.

B. International Residue Limits

No maximum residue limits (MRLs) for either metolachlor or S-metolachlor have been established or proposed by Codex, Canada, or Mexico for any agricultural commodity; therefore, no compatibility questions exist with respect to U.S. tolerances.

VI. Conclusion

Therefore, the tolerance is established for the combined residues (free and bound) of the herbicide s-metolachlor [(S)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on sweet potatoes at 0.2 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0331 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 March 4, 2003.

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

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

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box

360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP–2002–0331, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. 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 FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. 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: December 20, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. Section 180.368 is amended by designating the existing paragraph (b) as paragraph (b)(1) and adding a new paragraph (b)(2) to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.*

(1) * * *

(2) Time-limited tolerances are established for the combined residues (free and bound) of the herbicide s-metolachlor [(S)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], its R-enantiomer and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Sweet potato	0.2	12/31/04

* * * * *

[FR Doc. 03–5 Filed 1–2–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0335; FRL–7285–2]

Lambda-cyhalothrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of the pyrethroid lambda-cyhalothrin, 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3- phenoxybenzyl-(Z)-(1S,3S) -3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3- phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate in or on wild rice, grass forage, and grass hay. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on wild rice and pasture grass. This regulation establishes maximum permissible levels for residues of lambda-cyhalothrin and its epimer in these food commodities. The tolerances will expire and are revoked on December 31, 2005.

DATES: This regulation is effective January 3, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0335, must be received on or before March 4, 2003.

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

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703)308–9367; e-mail address: sec-18-mailbox@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 a Federal or State government agency involved in administration of environmental quality programs (i.e., Departments of Agriculture, Environment, etc). Potentially affected entities may include, but are not limited to:

• Federal or State Government Entity, (NAICS 9241), i.e., Departments of Agriculture, Environment, etc.

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

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0335. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the'' **Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml__00/Title__40/40cfr180_(_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's