technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption 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.

XIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 23, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* *	*	* *
Lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9).	.....	Solvent
Lactic acid, 2-ethylhexyl ester, (2S)-(CAS Reg. No. 186817–80–1).	.....	Solvent
* *	*	* *

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* *	*	* *
Lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9).	.....	Solvent
Lactic acid, 2-ethylhexyl ester, (2S)-(CAS Reg. No. 186817–80–1).	.....	Solvent
* *	*	* *

[FR Doc. 05–17360 Filed 8–30–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0326; FRL–7716–1]

S-metolachlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues (free and bound) of S-metolachlor in or on certain commodities as set forth in Unit II. of the **SUPPLEMENTARY INFORMATION**. The Interregional Research Project Number 4 (IR–4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), on behalf of the registrant, Syngenta Crop Protection, Swing Road, Greensboro, NC 276419.

DATES: This regulation is effective August 31, 2005. Objections and

requests for hearings must be received on or before October 31, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2004–0326. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

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

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

II. Background and Statutory Findings

In the **Federal Register** of August 13, 2004 (69 FR 50196) (FRL–7371–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (3E6787) by IR-4 on behalf of Syngenta Crop Protection, Swing Road, Greensboro, NC 27419. The petition requested that 40 CFR 180.368 be amended by establishing tolerances for 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, S-metolachlor. It should be noted that the above chemical nomenclature for S-metolachlor differs slightly from that previously listed under 40 CFR 180.368(a)(2). The Agency is establishing these tolerances for residues of S-metolachlor under a new paragraph, 180.368 (a)(3), using this nomenclature because it is more technically accurate in terms of the nature of the residues and the components determined by the analytical method. The Agency has determined that the tolerance expression as listed in paragraph (a)(2) should be changed and will be proposing that change in an upcoming rule. Further chemical definition of S-metolachlor can be found in Unit III. A. of this document. In petition, PP 3E6787, IR-4 requested tolerances for S-metolachlor in or on the following raw agricultural commodities (RACs):

1. Brassica, head and stem, subgroup 5A at 0.5 parts per million (ppm).
2. Cattle, fat at 0.04 ppm; cattle, kidney at 0.20 ppm; cattle, meat at 0.04 ppm; cattle, meat byproducts, except kidney at 0.04 ppm.
3. Corn, field, grain at 0.10 ppm; corn, field, stover at 6.0 ppm; corn, field, forage at 6.0 ppm; corn, sweet, forage at 6.0 ppm; corn, sweet, stover at 6.0 ppm; corn, pop, stover at 6.0 ppm; corn, pop, grain at 6.0 ppm; corn, sweet, kernel plus cob with husk removed at 0.1 ppm.
4. Cotton, gin byproducts at 4.0 ppm; cotton, undelinted seed at 0.1 ppm.
5. Egg at 0.04 ppm.
6. Garlic, bulb at 0.1 ppm.
7. Goat, fat 0.04 ppm; goat, kidney at 0.20 ppm; goat, meat at 0.04 ppm; goat, meat byproducts, except kidney at 0.04 ppm.
8. Horse, fat 0.04 ppm; horse, kidney at 0.20 ppm; horse, meat at 0.04 ppm; horse, meat byproducts, except kidney at 0.04 ppm.
9. Leafy petioles subgroup 4B at 0.10 ppm.
10. Milk at 0.02 ppm.
11. Onion, dry bulb at 0.1 ppm; onion, green at 2.0 ppm.
12. Pea and bean, dried shelled, except soybean, subgroup 6C at 0.1 ppm.
13. Peanut 0.2 ppm; peanut, hay at 20 ppm; peanut, meal at 0.40 ppm.
14. Poultry, fat at 0.04 ppm; poultry, meat at 0.04 ppm; poultry, meat byproducts, except liver at 0.04 ppm.
15. Safflower, seed at 0.1 ppm.
16. Shallot at 0.1 ppm.
17. Sheep, fat at 0.04 ppm; sheep, kidney at 0.20 ppm; sheep, meat at 0.04 ppm; sheep, meat byproducts, except kidney at 0.04 ppm.
18. Sorghum grain, stover at 4.0 ppm; sorghum grain, forage at 1.0 ppm; sorghum grain, grain at 0.3 ppm.
19. Soybean, seed at 0.2 ppm; soybean, forage at 5.0 ppm; soybean, hay at 8.0 ppm.
20. Vegetable, foliage of legume, except soybean, subgroup 7A at 15 ppm.
21. Vegetable, fruiting, group 8 at 0.5 ppm.
22. Vegetable, legume, edible podded, subgroup 6A at 0.5 ppm.
23. Vegetable, root, except sugar beet, subgroup 1B at 0.3 ppm.
24. Vegetable, tuberous and corm, subgroup 1C at 0.2 ppm.

Several of the proposed tolerances were subsequently amended as follows:

Tolerances for vegetable, fruiting, group 8 (except tabasco pepper) at 0.1 ppm; tomato, paste at 0.3 ppm; a separate regional tolerance for pepper, tabasco at 0.5 ppm; brassica, head and stem increased from 0.5 to 0.6 ppm; corn, pop, grain decreased from 6.0 to 0.1 and barley straw from 0.1 to 0.5 ppm. Furthermore, the proposed tolerance of cattle, goat, horse and sheep meat byproducts, except kidney at 0.04 ppm was subsequently amended to establish tolerances for meat byproducts, except kidney and liver of cattle, goat, horse and sheep at 0.04 ppm and separate tolerances for liver of cattle, goat, horse and sheep at 0.1 ppm. The tolerance for poultry, meat byproducts, except liver at 0.04 ppm was also amended to poultry, meat byproducts at 0.04 ppm.

Additionally, IR–4 proposed to amend 40 CFR 180.368(a)(2) by removing tolerances 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], 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 the following RAC's: Carrot, roots at 0.20 ppm; Horseradish at 0.20 ppm; onion, green at 0.20; rhubarb at 0.10 ppm; swiss chard at 0.10 ppm; and tomato at 0.1 ppm. The Agency concurs with this proposal based on the fact that these uses are covered by crop group and/or crop subgroup tolerances promulgated under section (a)(3) of this ruling.

Additionally, IR–4 proposed to amend 40 CFR 180.368(d) by establishing tolerances for indirect or inadvertent 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, S-metolachlor in or on the following RAC's:

1. Animal feed, nongrass, group 18 at 1.0 ppm
2. Barley, grain at 0.1 ppm; barley straw at 0.1 ppm
3. Buckwheat, grain at 0.1 ppm
4. Oat, forage at 0.5 ppm; oat, grain at 0.1 ppm; oat straw at 0.5 ppm
5. Peanut, meal at 0.4 ppm
6. Rice, grain at 0.1 ppm; rice, straw at 0.5 ppm
7. Rye, forage at 0.5 ppm; rye, grain at 0.1 ppm; rye straw at 0.5 ppm
8. Wheat, forage at 0.5 ppm; wheat grain at 0.1 ppm; wheat straw at 0.5 ppm

These tolerances for the various grains (barley, buckwheat, oats, rice, rye, wheat) and nongrass animal feeds are being established to cover residues of S-metolachlor in these crops when planted as rotational crops following treatment of a primary crop. The Agency concludes that these tolerances should be assigned to § 180.368(d) for indirect and inadvertent residues, and that adequate data are available to set the rotational crop tolerance for the nongrass animal feeds at 1.0 ppm. In addition, the Agency has concluded that tolerances should be established on the hays of barley, oats, and wheat at 1.0 ppm in paragraph (d). The peanut meal tolerance will be established under paragraph (a)(3) and is not necessary as proposed in (d).

The notice proposing these tolerances included a summary of the petition prepared by Syngenta Crop Protection, Incorporated, the registrant. There were no comments received in response to the notice of filing.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues (free and bound) of S-metolachlor on commodities and at tolerance levels presented in Unit II. of this document. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

Metolachlor is a chloroacetanilide herbicide that was first registered as a pesticide in 1976. Metolachlor (known as racemic metolachlor) is a mixture consisting of 50% each of the R-enantiomer (CGA 77101) and the S-enantiomer (CGA 77102). The S-enantiomer is the herbicidally active isomer.S-metolachlor is also a racemic mixture comprised of 88% S-enantiomer and 12% R-enantiomer. The Agency has determined that S-metolachlor has either comparable or decreased toxicity as compared to racemic metolachlor.

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 S-metolachlor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in Unit III.A. of the **Federal Register** of April 2, 2003 (68 FR 15945) (FRL–7299–8).

B. Toxicological Endpoints

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

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer}= point of departure/ exposures) is calculated. A summary of the toxicological endpoints for S-metolachlor used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 2, 2003 (68 FR 15945) (FRL–7299–8). Should you desire additional information in this regard, please refer to that document.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.368(a)(2)) for the combined residues of S-metolachlor, in or on a variety of RAC's. S-metolachlor is a selective, chloroacetanilide herbicide that is applied as a preplant, preplant-incorporated (PPI), pre-emergence, or post-emergence application, primarily for the control of grass weeds. S-metolachlor is registered to Syngenta Crop Protection, Inc., for use on a wide variety of crops including: Corn, cotton, grasses grown for seed, legume vegetables, peanuts, potatoes, safflower, sorghum, sunflower, and tomatoes and complement the metolachlor (racemic mixture) product line with S-metolachlor products that contain a higher percentage of active pesticidal ingredient.

Permanent tolerances for the combined S-metolachlor residues have been established in/on plant commodities ranging from 0.1 ppm in/ on a variety of plant commodities to 15 ppm in/on sugar beet tops 40 CFR 180.368(a))(2). Permanent tolerances are also established for combined residues of racemic metolachlor in 180.368(a)(1) and (c) at levels of 0.02 to 30 ppm.

The Agency has recently reviewed plant metabolism data on S-metolachlor from field tests on soybeans and corn, *in vitro* tests on corn seedlings, and greenhouse tests on seedlings of corn, sorghum, soybeans and peanuts. These data support the petitioners assertion that the metabolism of S-metolachlor in plants is similar to the racemic mixture, metolachlor. The Agency has also recently reviewed animal metabolism data on S-metolachlor. Data from a goat metabolism study indicated that the residues of concern for S-metolachlor in animals are the same as for metolachlor. For both metolachlor and S-metolachlor the residues of concern in plants and animals include the parent compound and its metabolites, determined as the derivatives CGA-37913 and CGA-49751. In the case of S-metolachlor tolerances, the residues of the R-enantiomer should be included in the expression.

Risk assessments were conducted by EPA to assess dietary exposures from 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 1 day or single exposure. In conducting the acute dietary risk assessment EPA used the Lifeline™ Model, Version 2.0, which incorporates food consumption data as reported by respondents in the United State Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. A conservative Tier 1 acute dietary exposure assessment was conducted for all labeled metolachlor and all labeled and proposed S-metolachlor food uses using 100% crop treated (CT) and tolerance level residues.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the Lifeline™ Model, Version 2.0, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A conservative Tier 1 chronic dietary exposure assessment was conducted for all labeled metolachlor and all labeled and proposed S-metolachlor food uses using 100% CT and tolerance level residues.

Both the acute and chronic analyses assume tolerance-level residues on all crops with established, pending, or proposed tolerances for metolachlor and/or S-metolachlor (collectively referred to as metolachlor in this document). In cases where separate tolerance listings occur for both metolachlor and S-metolachlor on the same commodity, the higher value of the two is used in the analyses. The analyses also assume that 100% of the crops included in the assessment were treated with metolachlor. These assumptions result in overestimates of exposure and are, therefore, highly conservative with respect to dietary risk assessment.

iii. *Cancer*. Metolachlor has been classified as a Group C, possible human carcinogen based on liver tumors in rats at the highest dose tested (HDT). The

chronic NOAEL, 15 milligram/kilogram/day (mg/kg/day), that was established based on tumors in the rat seen at the HDT of 150 mg/kg/day) is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the chronic reference dose for metolachlor. The Agency concludes that the chronic dietary PAD is protective for cancer dietary risk. Therefore, a separate cancer dietary risk assessment was not conducted.

2. *Dietary exposure from drinking water.* The environmental fate database is complete for S-metolachlor. Parent metolachlor/S-metolachlor appear to be moderately persistent to persistent, and range from mobile to highly mobile in different soils. Metolachlor and S-metolachlor are expected to have similar degradation pathways and rates in soil and water environments.

Drinking water assessment was conducted based on monitoring data from several sources, as well as on Tier 1 First Index Reservoir Screening Tool (FIRST) and Screening Concentration In Groundwater (SCI-GROW) and Tier II modeling (PRZM/EXAMS) for selected vulnerable sites. This assessment is a worst-case scenario and demonstrates high end numbers. It is important to note that the analytical methods used to obtain the monitoring data are not able to distinguish between metolachlor and S-metolachlor; therefore, the estimated environmental concentrations (EECs) presented in this risk assessment are representative of both racemic metolachlor and S-metolachlor.

EECs for metolachlor and S-metolachlor were calculated for both the parent compound and the ethanesulfonic acid (ESA) and oxanilic acid (OA) degradates. The PRZM/EXAMS model was used to estimate the EECs for the surface water concentrations of the parent compound and the FIRST model was used to estimate the EECs for the surface water concentrations of the ESA and OA degradates. Groundwater concentrations were modeled using the SCI-GROW. 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 the risk assessment since they were found in greater abundance than the parent in water monitoring studies.

The EECs were estimated for the crops with the highest maximum seasonal application rates, turf (S-metolachlor only) and corn (racemic metolachlor and S-metolachlor) with a maximum seasonal application rate of 4.0 lbs ai per acre (lbs ai/acre).

i. *Surface water modeling of parent metolachlor/S-metolachlor.* Based on PRZM/EXAMS modeling the maximum peak and annual average concentrations of metolachlor/S-metolachlor in surface water were 199 µg/l and 9.2 µg/l, respectively. Based on an evaluation of U.S. Geological Survey (USGS) National Water Quality Assessment (NAWQA) surface water monitoring data, the estimate of the maximum drinking water concentration from surface water sources of parent metolachlor/S-metolachlor is 77.6 µg/l, and the EEC is 4.3 µg/l for the maximum annual time-weighted mean concentration for parent metolachlor/S-metolachlor. These data suggest that the PRZM/EXAMS estimates for metolachlor/S-metolachlor are slightly overestimating the potential impact of metolachlor/S-metolachlor use on surface water.

ii. *Surface water modeling of degradates.* Based on FIRST modeling results, the estimate of the drinking water concentration from surface water sources of metolachlor ESA (ground application with no spray drift) is not likely to exceed 31.9 µg/L for the annual peak concentration and 22.8 µg/L for the annual average exposure for use on turf/corn at a maximum annual application rate of 4.0 lbs ai per acre. Based on FIRST modeling results, the estimate of the drinking water concentration from surface water sources of metolachlor OA (ground application with no spray drift) is not likely to exceed 91.4 µg/L for the annual peak concentration and 65.1 µg/L for the annual average exposure for use on turf/corn at a maximum annual application rate of 4.0 lbs ai per acre.

iii. *Groundwater modeling of parent metolachlor/S-metolachlor.* Metolachlor/S-metolachlor appears to be mobile in different soil types. Metolachlor/S-metolachlor and its degradates have been detected in ground water demonstrating that it is likely to impact ground water resources. In order to augment existing monitoring data, the (SCI GROW) screening model was used to estimate ground water concentrations. The model estimates the upper bound ground water concentrations of pesticides likely to occur when the pesticide is used at the maximum allowable rate in areas with ground water vulnerable to contamination. The estimated concentration of metolachlor/S-metolachlor in drinking water from shallow ground water sources is 5.5 µg/l for application on corn at a seasonal maximum rate of 4.0 lbs ai. per acre. This concentration is appropriate for both the peak and annual average exposures.

From the available ground water monitoring data , the highest annual maximum concentration from the (NAWQA) ground water monitoring data for acute exposure to metolachlor/S-metolachlor is 32.8 µg/l. Data collected in Iowa as part of the NAWQA program indicate that metolachlor/S-metolachlor has been detected in ground water at concentrations as high as 15.4 µg/l. However, these data are not used quantitatively in the risk assessment because the next highest concentration detected is 1.7 µg/l suggesting that the maximum concentration may be an outlier. Additionally, recent data collected by the Suffolk County, New York Department of Health Services, Bureau of Groundwater Resources indicate that both metolachlor/S-metolachlor (analytical methods did not determine the enantiomeric ratio) and its degradates have been detected in ground water. In data collected between 1997 and 2001, metolachlor/S-metolachlor was detected in 60 well samples with a maximum concentration of 83 µg/l. No information was available on frequency of detection and since only summary statistics were provided, these data are not used quantitatively in this assessment. Nonetheless, even use of the 83 µg/l value as the exposure level in drinking water would not raise the aggregate risk estimate, as discussed in Unit III.E. of this document the level of concern.

iv. *Groundwater modeling of degradates.* The EEC for metolachlor ESA from use on turf/corn is not expected to exceed 65.8 µg/l for peak and annual average exposures. The EEC for metolachlor OA from use on turf/corn is not expected to exceed 31.7 µg/l for peak and annual average exposures. These values exceed the maximum values detected in the Iowa NAWQA study (63.7 µg/l for metolachlor ESA and 4.4 µg/l for metolachlor OA and also exceed those detected in the two PGW studies (metolachlor ESA was detected at a maximum concentration of 24 µg/l, while metolachlor OA was detected at a maximum concentration of 15.6 µg/l).

Recent data collected by the Suffolk County, New York Department of Health Services, Bureau of Groundwater Resources indicate that both metolachlor/S-metolachlor (analytical methods did not determine the enantiomeric ratio) and its degradates have been detected in ground water. In data collected between 1997 and 2001, metolachlor ESA was detected in 296 wells with a maximum concentration of 39.7 µg/l, while metolachlor OA was detected in 228 wells with a maximum concentration of 49.6 µg/l. No information was available on frequency of detection and only summary statistics were provided on these data. Therefore,

these data are not used quantitatively in this assessment. However, these data suggest that the screening level SCI-GROW estimates for metolachlor ESA and OA are slightly overestimating the potential impact of metolachlor/S-metolachlor use on ground water.

A summary of metolachlor EEC's in surface water and ground water is presented in Table 1.

TABLE 1.—METOLACHLOR EEC'S

	Surface Water (peak)	Surface Water (average)	Ground Water
Parent	199	9.2	5.5
Metolachlor ESA	31.9	22.8	65.8
Metolachlor OA	91.4	65.1	31.7
Total EECs (ppb)	322.3	97.1	103.0

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).

S-metolachlor is registered (as an emulsifiable concentrate formulation) for use on lawn, turf (including sod farms), golf courses, sports fields, and ornamental gardens and marketed to commercial applicators. Current product labels include the statement, ''Not intended for homeowner purchase or use.'' Therefore, a residential handler assessment was not conducted.

Based on the use pattern of residential products, duration of post application exposure is expected to be short term. A short-term dermal endpoint was not selected, since no systemic toxicity was seen at the limit dose of 1,000 mg/kg/day; therefore, a dermal risk assessment was not conducted.

Post-application inhalation exposure is also expected to be minimal since S-metolachlor is only applied in an outdoor setting and the label specifies that residents should not re-enter treated areas until after sprays have dried. Based on these assumptions, a postapplication inhalation exposure was not calculated.

However, the following post-application incidental oral scenarios following application to lawns and turf have been identified:

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

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

iii. 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.

The exposure estimates for the three post-application scenarios (object-to-mouth, hand-to-mouth, and incidental soil ingestion) were combined to represent the possible (if not likely) high-end oral exposure resulting from lawn (or similar) use. Table 2 summarizes the results of the residential post-application assessment.

TABLE 2.—SUMMARY OF SHORT-TERM RESIDENTIAL POST-APPLICATION EXPOSURE

Exposure Scenario[a]	S-metolachlor[b]	Oral Dose (mg/kg/day)
Object-to-mouth	S-metolachlor	0.0092
Hand-to-mouth	S-metolachlor	0.037
Soil ingestion	S-metolachlor	0.00012
Combined exposure	S-metolachlor	0.046

[a]Exposure scenario represents oral exposure of children, with an assumed body weight of 15 kg.
[b]S-metolachlor application rate is 2.47 lb ai/acre.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has examined the common mechanism potential for S-metolachlor and has concluded that S-metolachlor should not be included with the chloroacetanilide pesticides designated as a ''Common Mechanism Group.'' The Agency's position is that only some chloroacetanailides, namely acetochlor, alachlor and butachlor should be considered as a ''Common Mechanism Group'' due to their ability to cause nasal turbinate tumors.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure in the available toxicity data.

3. *Conclusion*. There is a sufficient toxicity data base and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor for the protection of infants and children has been reduced to 1X because:

i. The toxicology data base is complete for the FQPA assessment.

ii. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to metolachlor in the available toxicity data.

iii. A developmental neurotoxicity study is not required for S-metolachlor.

iv. The dietary (food and drinking water) and non-dietary exposure (residential) assessments will not underestimate the potential exposures for infants and children from the use of S-metolachlor.

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

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

When EECs for surface water and ground water are less than the calculated DWLOCs, 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*. The acute aggregate risk assessment addresses potential exposure from combined residues of metolachlor/S-metolachlor on food and total residues of metolachlor/S-metolachlor plus ESA and OA degradates in drinking water (surface water and ground water). Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to metolachlor/S-metolachlor will occupy <1% of the aPAD for the U.S. population and all population subgroups. In addition, there is potential for acute dietary exposure to metolachlor/S-metolachlor and the ESA and OA degradates in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO METOLACHLOR/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	322	103	105,000
Infants (<1year)	3.0	<1	322	103	30,000
Children (1–2 years)	3.0	<1	322	103	30,000
Females (13–49 years)	3.0	<1	322	103	90,000

2. *Chronic risk*. The chronic aggregate risk assessment addresses potential exposure from combined residues of metolachlor/S-metolachlor on food and total residues of metolachlor/S-metolachlor plus ESA and OA degradates in drinking water (surface water and ground water). There are no residential uses that result in chronic residential exposure to S-metolachlor. EPA has concluded that chronic exposure to metolachlor/S-metolachlor from food will utilize 1% of the cPAD for the U.S. population, 4% of the cPAD for children 1 to 2 years, the subpopulations at greatest exposure and 1% of the cPAD for females 13 to 49 years. In addition, there is potential for chronic dietary exposure to metolachlor/S-metolachlor and ESA and OA degradates in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.–AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO METOLACHLOR/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	1	97	103	3,500
Infants (<1 year)	0.1	2	97	103	1,000
Children (1 to 2 years)	0.1	4	97	103	1,000
Females (13 to 49 years)	0.1	1	97	103	3,000

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).

S-metolachlor 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 residential exposures for metolachlor/S-metolachlor.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in an aggregate MOE of 1,000 for children 1 to 2 years. This aggregate MOE does 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 metolachlor/S-metolachlor and ESA and OA degradates in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water 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 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO METOLACHLOR/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 (1–2 years)	1,000	100	97	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/S-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 was not performed.

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. However, the NOAEL (15 mg/kg/day), that was established based on tumors in the rat (seen at the HDT of 150 mg/kg/day) is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the cRfD dose for metolachlor. Therefore, the chronic risk assessment is protective for cancer as well as other chronic risks.

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 metolachlor/S-metolachlor residues.

IV. 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. Residue data from the most recent field trials and processing studies were obtained using an adequate GC/NPD method (AG–612), which is a modification of Method I. Adequate data are available on the recovery of metolachlor through Multi-residue Method Testing Protocols. The FDA PESTDATA database indicates that metolachlor is completely recovered through Method 302, PAM Vol. I (3rd ed., revised 10/97).

B. International Residue Limits

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

V. Conclusion

Therefore, the tolerances are established at 180.368 for 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 S-metolachlor, in or on vegetable brassica, head and stem, subgroup 5A at 0.6 ppm; cattle, fat at 0.04 ppm; cattle, kidney at 0.20 ppm; cattle liver at 0.1 ppm; cattle, meat at 0.04 ppm; cattle, meat byproducts, except kidney and liver at 0.04 ppm; corn, field, grain at 0.10 ppm; corn, field, stover at 6.0 ppm; corn, field, forage at 6.0 ppm; corn, sweet, forage at 6.0 ppm; corn, sweet, stover at 6.0 ppm; corn, pop, stover at 6.0 ppm; corn, pop, grain at 0.1 ppm; corn, sweet, kernel plus cob with husk removed at 0.1 ppm; cotton, gin byproducts at 4.0 ppm; cotton, undelinted seed at 0.1 ppm; egg at 0.04 ppm; garlic, bulb at 0.1 ppm;

goat, fat 0.04 ppm; goat, kidney at 0.20 ppm; goat, liver at 0.1 ppm; goat, meat at 0.04 ppm; goat, meat byproducts, except kidney and liver at 0.04 ppm; horse, fat 0.04 ppm; horse, kidney at 0.20 ppm; horse liver at 0.1 ppm; horse, meat at 0.04 ppm; horse, meat by-products, except kidney and liver at 0.04 ppm; vegetable leaf petioles subgroup 4B at 0.10 ppm; milk at 0.02 ppm; onion, dry bulb at 0.1 ppm; onion, green at 2.0 ppm; vegetable legumes, pea and bean, dried shelled, except soybean, subgroup 6C at 0.1 ppm; peanut at 0.2 ppm; peanut, hay at 20 ppm; peanut, meal at 0.40 ppm; poultry, fat at 0.04 ppm; poultry, meat a 0.04 ppm; poultry, meat by-products, at 0.04 ppm; safflower, seed at 0.1 ppm; shallot, bulb at 0.1 ppm; sheep, fat at 0.04 ppm; sheep, kidney at 0.20 ppm; sheep, liver at 0.1 ppm; sheep, meat at 0.04 ppm; sheep, meat by-products, except kidney and liver at 0.04 ppm; sorghum grain, stover at 4.0 ppm; sorghum grain, forage at 1.0 ppm; sorghum grain, grain at 0.3 ppm; soybean, seed at 0.2 ppm; soybean, forage at 5.0 ppm; soybean, hay at 8.0 ppm; tomato, paste at 0.3 ppm; vegetable, foliage of legume, except soybean, subgroup 7A at 15 ppm; vegetable, fruiting, group 8, except tabasco pepper, at 0.1 ppm; vegetable, legume, edible podded, subgroup 6A at 0.5 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.3 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.2 ppm; pepper tabasco at 0.5 ppm; nongrass, animal feed (forage, fodder, straw, hay), group 18 at 1.0 ppm; barley, grain at 0.1 ppm; barley straw at 0.5 ppm; barley hay at 1.0 ppm; buckwheat, grain at 0.1 ppm; oat, forage at 0.5 ppm; oat, grain at 0.1 ppm; oat, straw at 0.5 ppm; rice, grain at 0.1 ppm; rice, straw at 0.5 ppm; rye, forage at 0.5 ppm; rye, grain at 0.1 ppm; rye, straw at 0.5 ppm; wheat, forage at 0.5 ppm; wheat, grain at 0.1 ppm; wheat, straw at 0.5 ppm and wheat, hay at 1.0 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0326 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 31, 2005.

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

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

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0326, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income*

Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 23, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.368 is amended:

i. In paragraph (a)(2), in the table, by removing the commodities carrot, roots; horseradish; onion, green; rhubarb; swiss chard; and tomato;

ii. By adding paragraph (a)(3);

iii. By adding paragraph (c)(2); and

iv. In paragraph (d) by adding text.

The amendments read as follows:

§ 180.368 Metolachlor; tolerances for residues.

(a) * * *

(3) 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 or on the following raw agricultural commodities:

Commodity	Parts per million
* * *	* *
Cattle, fat	0.04
Cattle, kidney	0.2
Cattle, liver	0.1
Cattle, meat	0.04
Cattle, meat by-products, except kidney and liver	0.04
Corn, field, stover	6.0
Corn, pop, stover	6.0
Corn, sweet, stover	6.0
Corn, field, forage	6.0
Corn, sweet, forage	6.0
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, field, grain	0.1
Corn, pop, grain	0.1
Cotton, gin byproducts	4.0
Cotton, undelinted seed	0.1
Egg	0.04
Garlic, bulb	0.1
Goat, fat	0.04
Goat, kidney	0.2
Goat, liver	0.1
Goat, meat	0.04
Goat, meat byproducts, except kidney and liver	0.04
* * *	* *
Horse, fat	0.04
Horse, kidney	0.2
Horse, liver	0.1
Horse, meat	0.04
Horse, meat by-products, except, kidney and liver	0.04
* * *	* *
Milk	0.02
Onion, dry bulb	0.1
Onion, green	2.0
Peanut	0.2
Peanut, hay	20.0
Peanut, meal	0.4
Poultry, fat	0.04
Poultry, meat	0.04
Poultry, meat by-products	0.04
* * *	* *
Safflower, seed	0.1
Shallot, bulb	0.1
Sheep, fat	0.04

Commodity	Parts per million
Sheep, kidney	0.2
Sheep, liver	0.1
Sheep, meat	0.04
Sheep, meat by-products, except kidney and liver	0.04
Sorghum, grain, forage	1.0
Sorghum, grain, stover	4.0
Sorghum, grain, grain	0.3
Soybean, forage	5.0
Soybean, hay	8.0
Soybean, seed	0.2
* * * * *	
Tomato, paste	0.3
Vegetable, brassica, head and stem, subgroup 5A	0.6
Vegetable, foliage of legume, except soybean, subgroup 7A	15.0
Vegetable, fruiting group 8, (except tabasco pepper)	0.1
Vegetable, leaf petioles, subgroup 4B	0.1
Vegetable, legume, edible podded, subgroup 6A	0.5
Vegetable, legume, pea and bean, dried shelled, (except soybean) subgroup 6C	0.1
Vegetable, root, (except sugar beet) subgroup 1B	0.3
Vegetables, tuberous and corm, subgroup 1C	0.2

* * * * *

(c) * * *

(2) Tolerances with regional registration as defined in § 180.1(n) 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 or on the following raw agricultural commodities:

Commodity	Parts per million
Pepper, tabasco	0.5

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent 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 the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, hay	1.0
Barley, straw	0.5
Buckwheat, grain	0.1
Nongrass, animal feed (forage, fodder, straw, hay) group 18	1.0
Oat, forage	0.5
Oat, grain	0.1
Oat, hay	1.0
Oat, straw	0.5
Rice, grain	0.1
Rice, straw	0.5
Rye, forage	0.5
Rye, grain	0.1
Rye, straw	0.5
Wheat, forage	0.5
Wheat, grain	0.1
Wheat, hay	1.0
Wheat, straw	0.5

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL–7961–3]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Amendment

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA, also the Agency or we in this preamble) today is granting a petition to modify an exclusion (or delisting) from the lists of hazardous waste previously granted to BMW Manufacturing Co., LLC (BMW) in Greer, South Carolina. This action responds to a petition for amendment submitted by BMW to eliminate the total concentration limits in its wastewater treatment sludge covered by its current conditional exclusion.

EPA received public comments on the November 26, 2004, Proposed Rule (69 FR 68851) and took into account all public comments before granting this final rule. The Agency re-evaluated the specific information initially provided by the petitioner in its original request and delistings granted to other automobile manufactures for their F019 waste. This final decision eliminates the total concentration limits for barium, cadmium, chromium, lead, nickel, and cyanide from its conditionally excluded wastewater treatment sludge from the requirements of the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA). The waste will still be subject to local, State, and Federal regulations for nonhazardous solid wastes.

DATES: Effective August 31, 2005.

ADDRESSES: The RCRA regulatory docket for this final rule is located at the EPA Library, U.S. Environmental Protection Agency, Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303, and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. The public may copy material from any regulatory docket at no cost for the first 100 pages, and at a cost of $0.15 per page for additional copies. For copying at the South Carolina Department of Health and Environmental Control, please see below.

FOR FURTHER INFORMATION CONTACT: For general and technical information concerning this final rule, please contact Kris Lippert, RCRA Enforcement and Compliance Branch (Mail Code 4WD–RCRA), U.S. Environmental Protection Agency, Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562-8605, or call, toll free (800) 241–1754, and leave a message, with your name and phone number, for Ms. Lippert to return your call. Questions may also be e-mailed to Ms. Lippert at *lippert.kristin@epa.gov.* You may also contact Cindy Carter, Appalachia III District, South Carolina Department of Health and Environmental Control (SCDHEC), 975C North Church Street, Spartanburg, South Carolina. If you wish to copy documents at SCDHEC, please contact Ms. Carter for copying procedures and costs.

SUPPLEMENTARY INFORMATION: The information in this section is organized as follows:

I. Overview Information
A. What Action Is EPA Finalizing?
B. Why Is EPA Approving This Petition for Amendment?
C. What Are the Terms of This Exclusion?
D. When Is the Final Amendment Effective?
E. How Does This Action Affect States?