Coronado Beach bridge (SR 44), mile 845, shall open on signal, except that from 7 a.m. until 7 p.m., each day of the week, the draw need only open on the hour, twenty minutes past the hour and forty minutes past the hour.

* * * * *

Dated: March 21, 2003.

James S. Carmichael,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 03–7996 Filed 4–1–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0046; FRL–7299–8]

S-Metolachlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of *S*-metolachlor Acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)-, (*S*) 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 raw agricultural commodities grass forage, grass hay, spinach, sugar beet, sugar beet molasses, sugar beet tops, sunflower seed, sunflower meal, and tomato. The Interregional Research Project No. 4 (IR-4) and Syngenta Crop Protection requested theses tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 2, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0046, must be received on or before June 2, 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 VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Joanne Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (32532)

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–2003–0046. 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. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

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

In the **Federal Register** of January 29, 2003, (68 FR 4470–4475) (FRL–7281–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 6E4638, 8E5011, 6F6751, and 7F4897) by the Interregional Research Project No. 4 (IR-4), and Syngenta Crop Protection, New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903 and 410 Swing Road, Greensboro, NC 27419. That notice included a summary of the petition prepared by IR-4 and Syngenta, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.368(a) be amended by establishing a tolerance for combined residues of the herbicide *S*-metolachlor Acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)-, (*S*) 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 raw agricultural commodities grass forage at 12.0 parts per million (ppm), grass hay at 0.02 ppm, spinach at 0.5 ppm, sugar beet at 0.5 ppm, sugar beet dried pulp at 1.0 ppm, sugar beet molasses at 3.0 ppm, sugar beet tops at 15.0 ppm, sunflower at 0.5 ppm, sunflower meal at 1.0 ppm, and tomato at 0.1 ppm.

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....''

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).

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of Acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-methoxy-1-methylethyl)-, (*S*) 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 raw agricultural commodities; grass forage at 10.0 ppm; grass hay at 0.02 ppm; spinach at 0.5 ppm; sugar beet roots at 0.5 ppm; sugar beet molasses at 3.0 ppm; sugar beet tops at 15.0 ppm; sunflower seeds at 0.5 ppm; sunflower meal at 1.0 ppm; and tomato at 0.1 ppm. 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 for use in 1976. Racemic metolachlor consists of 50% each of the R-enantiomer (CGA 77101) and the *S*-enantiomer (CGA 77102, or alpha metolachlor). The *S*-enantiomer is the herbicidally active isomer. *S*-metolachlor is a racemic mixture comprised of 88% *S*-enantiomer and 12% *R*-enantiomer. Toxicity data has been submitted on both metolachlor and *S*-metolachlor. 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 metolachlor are discussed in Table 1a below as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1A.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY FOR METOLACHLOR (PC CODE 108801)

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 210 milligram/kilogram/day (mg/kg/day) for males LOAEL for males was not established NOAEL = 23.4 mg/kg/day for females LOAEL =259 mg/kg/day for females based on decreased body weight/body weight gain
870.3150	90-Day oral toxicity in nonrodents	NOAEL =8.77 mg/kg/day LOAEL = 29.42 mg/kg/day based on decreased body weight gain
870.3200	21-28 day dermal	Systemic NOAEL = 1,000 mg/kg/day Systemic LOAEL was not established dermal irritation NOAEL was not established dermal irritation LOAEL = 10 mg/kg/day based on very slight erythema, dry skin and fissuring (one animal)
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 300 mg/kg/day Maternal LOAEL = 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. Developmental NOAEL = 300 mg/kg/day Developmental LOAEL =1000 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
870.3700	Prenatal developmental in nonrodents	Maternal Toxicity NOAEL = 120 mg/kg/day Maternal Toxicity LOAEL = 360 mg/kg/day based on an increased incidence of clinical observations (persistent anorexia) and decreased body weight gain Developmental Toxicity NOAEL = 360 mg/kg/day Developmental Toxicity LOAEL was not established

TABLE 1A.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY FOR METOLACHLOR (PC CODE 108801)—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects	Parental Toxicity NOAEL = 75.8 mg/kg/day (F_0 males/females: 75.8/85.7 mg/kg/day; F_1 males/females: 76.6/84.5 mg/kg/day). Parental LOAEL was not established Reproductive toxicity NOAEL = 75.8 mg/kg/day (F_0 males/females: 75.8/85.7 mg/kg/day; F_1 males/females: 76.6/84.5 mg/kg/day). Reproductive toxicity LOAEL was not established Offspring NOAEL = 23.5 mg/kg/day (F_0 males/females: 23.5/ 26.0 mg/kg/day; F_1 males/females: 23.7/25.7 mg/kg/day) Offspring LOAEL = 75.8 mg/kg/day based on F_0 males/females: 75.8/85.7 mg/kg/day; F_1 males/females: 76.6/84.5 mg/kg/day) based on decreased body weight.
870.4100	Chronic toxicity dogs	NOAEL = 9.7 mg/kg/day for females LOAEL = 33mg/kg/day for females based on decreased body weight NOAEL =32.7 mg/kg/day for males. LOAEL for males was not established
870.4300	Chronic Toxicity/Carcinogenicity in Rodents	NOAEL = 15 mg/kg/day for females LOAEL = 150 mg/kg/day for females based on slightly decreased body weight gain and food consumption. The NOAEL =150 mg/kg/day for males. The LOAEL was not established for males. Administration of doses up to 3,000 ppm (150 mg/kg/day) was associated with statistically significant increases in liver adenomas and combined adenoma/carcinoma in female rats. In male rats, there was a statistically significant trend but not pair-wise significance for liver tumors.
870.4300	Carcinogenicity mice	NOAEL = 150 mg/kg/day LOAEL = 450 mg/kg/day based on possible treatment-related deaths in females and decreased body weight/body weight gain in males and females no evidence of carcinogenicity
870.5100	Gene mutation -bacterial reverse mutation	negative up to cytotoxic doses (1,000 μg/plate)
870.5300	Gene mutation - mouse lymphoma	no effect on the incidence of mutations in the presence or absence of metabolic activation
870.5395	Cytogenetics Micronucleus assey in Chinese hampsters	no effect of treatment on incidence of micronuclei induction
870.5450	Cytogenetics dominant lethal assey in mice	no effect on embryonic death, pre- and post-implantation or fertility rates in mated females
870.5550	Other Effects DNA Damage/Repair in rat hepatocytes	negative
870.5550	Other Effects DNA Damage/Repair in human fibroblasts	negative
870.5550	Other Effects Unscheduled DNA synthesis in rat hepatocytes	negative for induction of UDS; however, significant increases in percentage of cells in S-phase were observed in females dosed at 500 mg/kg (but not at 1,000 or 1,500 mg/kg) and sacrificed at 15 hours
870.7485	Metabolism and pharmacokinetics Unacceptable	The major metabolic pathway proposed from analysis of urinary as well as fecal metabolites is one of cleavage of the ether bond and subsequent oxidation to the carboxylic acid, as well as hydrolytic removal of the chlorine atom. Conjugation of CGA 24705 or metabolites with gluronic acid or sulfate does not appear to occur. Aqueous extractable urinary radioactivity contained 58% of the total urinary radioactivity and was composed of 5 different radioactive fractions, which were not identified. Current guideline recommendations as to dose levels and use of both sexes in metabolism studies were not followed. Thus, whether the metabolic pattern is altered with dose or repeated exposure cannot be evaluated from these data.

TABLE 1A.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY FOR METOLACHLOR (PC CODE 108801)—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics Unacceptable	Conclusions: Single low (1.5 mg/kg), single high (300 mg/kg) and repeated low (1.5 mg/kg/day for 15 days) oral doses of metolachlor were readily absorbed and eliminated by male and female rats. Urinary and fecal elimination of radioactivity associated with orally administered ^{14}C metolachlor was essentially complete within 48 to 72 hours after dosing. Low- and high-dose females eliminated ^{14}C more rapidly ($p<0.003$, half-lives of elimination, 16.6 and 15.6 hours, respectively) than low- and high-dose males and repeated-dose animals of both sexes (half-lives, 18.2 and 20.0 hours). Elimination by all animals followed first-order kinetics. Approximately one-half to two-thirds (48 to 64 percent) of the ^{14}C administered was recovered from the urine within 7 days; similar amounts were present in the feces. Low-dose males eliminated slightly more of the radioactive dose in the feces (55 percent) than the urine (48 percent). The opposite trend was seen in the low-dose females and repeated-dose rats of both sexes; these animals excreted approximately 58 to 64 percent of the ^{14}C dose in the urine and 42.5 to 46.5 percent in the feces within 7 days after dosing. High-dose animals excreted similar amounts (58 to 60 percent) of the radioactive dose in the urine and feces. Total recoveries of ^{14}C (urine, feces, and tissues) tended to be high and were between 105 and 122.5 percent.
870.7485	Metabolism and pharmacokinetics	In a rat metabolism study (MRID #431642–01),^{14}C-Metolachlor was administered orally in PEG–200 HWI 6117–208 or corn oil ABR–94001 to groups (5 sex/dose) of male and female Sprague-Dawley rats at a low oral dose (1.5 mg/kg), repeated low oral dose (1.5 mg/kg x 14 days), and a single high dose (300 mg/kg). Control animals (1/sex) received blank formulation. Comparison of oral and intravenous data showed that of the administered dose, between 69.6% and 93.2% was absorbed. Distribution data showed that the only significant sites of residual radioactivity at 7 days post-dose were residual carcass (0.9 – 2.2% of the administered dose) and red blood cells (0.95 – 1.53 μg equivalents/gram in blood cells for all low dose male and female rats). Dosing regimen did not result in any apparent accumulation of residual radioactivity. Excretion data showed that urine and feces were both significant routes for elimination of metolachlor derived radioactivity. In the low dose groups, the urine appeared more of a predominant route for excretion in female rats than in males, whereas fecal excretion was slightly higher in males. However, at the high oral dose, there were no apparent sex-related differences in the pattern of urinary excretion. Examination of urinary excretion data as presented in graphical format indicated that at the 300 mg/kg dose, excretion was delayed vs the low oral dose, suggesting saturation of elimination.

The nature of the toxic effects caused by *S*-metolachlor are discussed in Table 1b below as well as the NOAEL and the LOAEL from the toxicity studies reviewed.

TABLE 1B.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY FOR S-METOLACHLOR (PC CODE 108800)

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL = 15 milligram/kilogram/day (mg/kg/day) LOAEL = 150 mg/kg/day based on lower body weights/body weight gains, reduced food consumption and food efficiency and increased kidney weights in males
870.3100	90–Day oral toxicity rodents	NOAEL = 208 mg/kg/day in males and 236 mg/kg/day in females LOAEL was not defined.
870.3150	90–Day oral toxicity in nonrodents	NOAEL = 62 mg/kg/day in males and 74 mg/kg/day in females LOAEL = was not established
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 50 mg/kg/day LOAEL = 500 mg/kg/day based on increased clinical signs of toxicity, decreased body weights/body weight gains, food consumption and food efficiency. Developmental NOAEL = 1,000 mg/kg/day LOAEL was not established
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 20 mg/kg/day LOAEL =100 mg/kg/day based on clinical signs of toxicity Developmental NOAEL = 500 mg/kg/day LOAEL was not established

TABLE 1B.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY FOR S-METOLACHLOR (PC CODE 108800)—Continued

Guideline No.	Study Type	Results
870.5100	Gene Mutation Test	There was no indication that *S*-metolachlor technical induced a mutagenic effect in any tester strain either in the presence or the absence of S9 activation.
870.5395	Cytogenetics Micronucleus test	There was no evidence that *S*-metolachlor technical induced a clastogenic or aneugenic effect in either sex at any dose or sacrifice time.
870.5550	Other Effects Unscheduled DNA synthesis	*S*-metolachlor technical was negative for genotoxicity but positive for cellular proliferation when tested up to overtly toxic and cytotoxic doses in this *in vivo/in vitro* rat hepatocyte RDS/UDS assay.
870.7485	Metabolism and pharmacokinetics	*S*-metolachlor has a high affinity for and a long half-life in blood (especially RBC) which might contribute to the retarded depletion of tissue residues.
870.7485	Metabolism and pharmacokinetics Unacceptabler	The 72 hour mean recovery of radioactivity in urine, feces, and carcass following administration of 0.5 mg/kg of Phenyl-U-^{14}C CGA-24705 was 43.1%, 47.0%, and 7.4% in males and 54.0%, 39.4%, and 4.1% in females, respectively. In contrast, both sexes excreted more of the label in the feces (M:F 59.7%:53.4%) than in the urine (M:F 29.4%:39.8%) during the same period following administration of the same dose of Phenyl-U-^{14}C CGA–77102 (the *S*-enantiomer) (MRID 44491401).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) 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 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* approachassumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. EPA's Health Effects Division's Cancer Assessment Review Committee has classified metolachlor as a Group C carcinogen with risk quantitated using a non-linear approach. The NOAEL of 15 mg/kg/day from the rat combined chronic toxicity/carcinogenicity study is based on neoplastic nodules/hepatocellular carcinomas seen at the highest dose tested of 150 mg/kg/day. The Agency notes that the tumor NOAEL of 15 mg/kg/day 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 PAD is protective for cancer dietary risk. Therefore, a separate cancer aggregate risk assessment was not conducted, and cancer DWLOC values were not calculated. A summary of the toxicological endpoints for *S*-Metolachlor used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METOLACHLOR/*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 (all population subgroups)	NOAEL = 300 mg/kg/day UF = 100x	FQPA SF = 1X aPAD = 3.0 mg/kg/day	Prenatal developmental toxicity study in rats with metolachlor- 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 population subgroups)	NOAEL= 9.7 mg/kg/day UF = 100x	FQPA SF = 1x cPAD = 0.1 mg/kg/day	Chronic study in dogs with metolachlor- endpoint is decreased body weight in females
Incidental Oral, Short-term (one to 30 days)	NOAEL = 50	Target MOE = 100	Prenatal developmental toxicity study in rats with metolachlor- increased incidence of clinical signs, decreased body weight/body weight gain, food consumption, and food efficiency
Incidental Oral, Intermediate-term (one month to 180 days)	NOAEL = 8.8	Target MOE = 100	Subchronic (6 month) toxicity study in dogs with metolachlor-decreased body weight gain
Dermal, Short- and Intermediate-Term	No systemic toxicity was seen at the limit dose (1,000 mg/kg/day) following dermal applications	None	Hazard was not identified for quantification of risk.there is no concern for developmental toxicity in rats or rabbits.
Dermal, Long-Term[a] (greater than 180 days)	Oral NOAEL = 9.7	Target MOE = 100	chronic toxicity study in dogs with metolachlor-decreased body weight gain in females
Inhalation, Short-Term[b]	Oral NOAEL = 50	Target MOE = 100	Prenatal development toxicity study in rats with *S*-metolachlor-increased incidence of clinical signs, decreased body weight/body weight gain, food consumption, and food efficiency
Inhalation, Intermediate-Term[b]	Oral NOAEL = 8.8	Target MOE = 100	subchronic (6 month) toxicity study in dogs with metolachlor- decreased body weight gain
Inhalation, Long-Term[b]	Oral NOAEL = 9.7	Target MOE = 100	chronic toxicity study in dogs with metolachlor- decreased body weight gain in females
Cancer	Classification: Group C, possible human carcinogen with risk quantitated using a non-linear approach.		

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.
[a] Since an oral NOAEL was selected, a dermal absorption factor of 58% should be used in route-to-route extrapolation.
[b] Since an oral NOAEL was selected, an inhalation factor of 100% should be used in route-to-route extrapolation.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances for metolachlor currently cover residues of *S*-metolachlor on the same commodities for the same use pattern when the maximum labeled use rate of *S*-metolachlor is approximately 35 percent less than the historical use rate of metolachlor.

Tolerances have been established (40 CFR 180.368(a)) for the combined residues of metolachlor and *S*-metolachlor in or on a variety of raw agricultural commodities. Tolerances for residues of both metolachlor and s-metolachlor in or on raw agricultural commodities include the combined residues of (free and bound) metolachlor and its metabolites, determined as the derivatives, CGA–37913 and CGA–47951, each expressed as parent compound. Permanent tolerances for metolachlor/*S*-metolachlor residues have been established on various plant commodities ranging from 0.1 ppm in/on numerous commodities to 30.0 ppm in/on peanut forage and hay (40 CFR 180.368(a)). Time-limited tolerances associated with section 18 emergency exemptions have been established for metolachlor residues in/on grass forage and hay, spinach, and tomato commodities (40 CFR 180.368(b)). Tolerances associated with regional registrations have also been established for metolachlor residues in/on dry bulb onions, cabbage, and various peppers (chili, Cubanelle, and tabasco) (40 CFR 180.368(c)). 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 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: A conservative Tier I acute dietary exposure assessment was conducted for all labeled metolachlor and *S*-metolachlor food uses. Inputs for this assessment included tolerance-level residue values and an assumption that 100% of all labeled crops were treated with metolachlor/*S*-metolachlor. For all supported registered commodities, the acute dietary exposure estimates are

below the Agency's level of concern (<100% aPAD) at the 95th exposure percentile for the general U.S. population and all population subgroups. The acute dietary risk estimate for the highest exposed population subgroup, children 1–6 years of age, is <1% of the aPAD. Acute dietary risk estimates are not of concern. Results of the acute dietary risk assessment are presented in Table 3 below.

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 CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A conservative Tier I chronic dietary exposure assessment was conducted for all supported metolachlor and *S*-metolachlor food uses. For all supported registered commodities, the chronic dietary exposure estimates are below the Agency's level of concern (<100% cPAD) for the general U.S. population and all population subgroups. The chronic dietary risk estimate for the highest exposed population subgroup, children 1–6 years of age, is 4% of the cPAD. Chronic dietary risk estimates are not of concern. Results of the chronic dietary risk assessment are presented in Table 3 below.

TABLE 3.—SUMMARY OF DIETARY EXPOSURE ESTIMATES FOR METOLACHLOR AND S-METOLACHLOR

Population Subgroup	Acute Dietary		Chronic Dietary		Cancer Risk
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD	
General U.S. Population	0.004111	<1	0.001643	2	NA
All Infants (<1 year old)	0.006855	<1	0.002280	2	N/A
Children 1–2 years old	0.008224	<1	0.004025	4	NA
Children 3–5 years old	0.006965	<1	0.003510	4	NA
Children 6–12 years old	0.005003	<1	0.002412	2	NA
Youth 13–19 years old	0.003309	<1	0.001515	2	NA
Adults 20–49 years old	0.002815	<1	0.001263	1	NA
Females 13–49 years old	0.002965	<1	0.001349	1	NA
Adults 50+ years old	0.002839	<1	0.001226	1	NA

NA = not applicable

The Agency notes that the conservative Tier I dietary assessments for metolachlor and *S*-metolachlor could be refined for more realistic dietary exposure estimates by using available percent crop treated estimates, field trial and monitoring data, and processing factors; however, the estimated dietary risk to metolachlor and *S*-metolachlor is not of concern for all populations in both the acute and chronic assessments. Further refinements are not warranted at this time.

2. *Dietary exposure from drinking water.* A drinking water assessment for metolachlor and *S*-metolachlor involved the analysis of surface and ground water monitoring data, prospective ground water study data, and Tier I (FIRST and screening concentration in ground water (SCI-GROW)) and Tier II (pesticide root zone modeling/exposure analysis modeling system (PRZM/EXAMS)) modeling results. This assessment includes concentrations of parent metolachlor/*S*-metolachlor and the degradates metolachlor ethanesulfonic acid (ESA) and metolachlor oxanilic acid (OA). Although it was determined by the Metabolism Assessment Review Committee that the ESA and OA metabolites appear to be less toxic than parent metolachlor/*S*-metolachlor, they are included in this risk assessment since they were found in greater abundance than the parent in water monitoring studies.

The Agency notes that a key assumption of the drinking water assessment is that reported monitoring data represent both racemic metolachlor and *S*-metolachlor. The analytical methods for surface and ground water monitoring data used in this assessment were unable to distinguish between metolachlor and *S*-metolachlor at the time monitoring was conducted. However, the Agency believes that the fate properties of racemic metolachlor and *S*-metolachlor are similar. Therefore, the EECs used in this risk assessment are representative of both racemic metolachlor and *S*-metolachlor.

The environmental fate data base is complete for metolachlor. Parent metolachlor/*S*-metolachlor appear to be moderately persistent to persistent, and range from mobile to highly mobile in different soils. Metolachlor/*S*-metolachlor have reportedly been detected as deep as the 36 to 48 inch soil layer (maximum sampled soil depth) in some studies. Degradation appears to be dependent on microbially mediated and abiotic processes. The frequency of detection of metolachlor/*S*-metolachlor from evaluated monitoring data suggest that contamination in drinking water sources may be widespread.

Environmental fate data comparing metolachlor and *S*-metolachlor indicate that both are expected to have similar degradation pathways and rates in soil and water environments, and both are expected to be mobile to highly mobile in soil and water environments.

i. *EECs for parent metolachlor/S-metolachlor.* No single surface or ground water monitoring study that was representative of the entire metolachlor/*S*-metolachlor use area was available for the drinking water assessment. As a result, the drinking water assessment for parent metolachlor/*S*-metolachlor is based primarily on monitoring data

from the following sources: the U.S. Geological Survey (USGS) National Water Quality Assessment (NAWQA) database, the US EPA STORET data base, the Acetochlor Registration Partnership (ARP) data base, and two USGS Reservoir Monitoring studies.

The acute estimated environmental concentration (EEC) of 77.6 parts per billion (ppb) was selected from the NAWQA database, and the chronic EEC of 4.3 ppb was selected from the maximum annual time weighted mean from the NAWQA data. These values are representative of the estimated concentration of parent metolachlor/*S*-metolachlor in monitored ambient surface water, and are supported by the metolachlor concentrations from the National Contaminant Occurrence Database representing analysis of treated drinking water, as well as from model predictions using PRZM/EXAMS.

Acute and chronic concentrations of parent metolachlor/*S*-metolachlor in ground water were modeled using SCI-GROW. SCI-GROW estimates the high-end 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. Estimates were based on two applications to corn/turf for a total of 4 lbs ai/acre (the maximum application rate). In comparison to the SCI-GROW estimate of 5.5 ppb in shallow ground water, the Iowa NAWQA data have a maximum concentration of 15.4 ppb. However, it should be noted that the second highest concentration of parent metolachlor/*S*-metolachlor in the Iowa NAWQA data is 1.7 ppb. Since the detections in the National NAWQA data (32.8 ppb) and in the Iowa NAWQA data (15.4 ppb) were single values outside the range of the rest of the data, EPA determined that use of SCI-GROW was more appropriate for the risk assessment.

Additionally, recent data collected by the Suffolk County, New York Department of Health Services, Bureau of Groundwater Resources indicate that both metolachlor and *S*-metolachlor, 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 ppb. No information was available on frequency of detection and only summary statistics were provided on these data; therefore, these data were not used quantitatively in the risk assessment. However, these data suggest that the SCI-GROW estimates for metolachlor/*S*-metolachlor are not overestimating the potential impact of metolachlor/*S*-metolachlor use on ground water. The SCI-GROW estimate of 5.5 ppb in ground water is appropriate for risk assessment purposes.

ii. *EECs for metolachlor ESA and OA degradates.* Only two small data sets were available on the ESA and OA degradates from the Iowa and Illinois NAWQA data. In the absence of more robust monitoring data for the degradates, upper-bound Tier I estimates for ESA and OA based on FIRST and SCI-GROW modeling were used to calculate EECs for the degradates. The modeling used conservative assumptions of selected fate parameters (aerobic soil metabolism rate constant and soil partitioning coefficient) as well as the maximum application rate of 4 lbs ai/acre on turf/corn.

Acute and chronic estimates of metolachlor ESA in surface water (based on FIRST modeling) are 31.9 ppb and 22.8 ppb, respectively. Acute and chronic estimates of metolachlor OA in surface water are 91.4 ppb and 65.1 ppb, respectively. The Agency notes that the application rate used for metolachlor ESA and OA in the model runs was estimated by converting maximum label rates for each use by the maximum percentage of degradate found in fate studies. In addition, each application rate was corrected for molecular weight differences of each degradate. However, a statistically significant relationship between parent metolachlor and degradates could not be established; therefore, the amount of degradate is an uncertainty in this assessment. This uncertainty was addressed in the screening level assessments using FIRST and SCI-GROW with conservative assumptions for model inputs. The model predictions for ESA and OA compare with the limited monitoring data available. The screening level predictions were higher than the available data suggesting that the predictions were likely upper bound and conservative. EPA determined that these upper bound predictions will not underestimate the potential exposures for infants and children from the use of metolachlor.

Acute and chronic estimates of metolachlor ESA in ground water (based on SCI-GROW modeling, turf/corn scenario) are not expected to exceed 65.8 ppb. This value is considered representative of both peak and long-term average concentrations because of the inherent transport nature of ground water (generally slow movement from the source of contamination both laterally and horizontally). Acute and chronic estimates of metolachlor OA in ground water (also based on the turf /corn scenario) are not expected to exceed 31.7 ppb. The Agency notes that these values exceed those detected in the Iowa NAWQA study (63.7 ppb for metolachlor ESA and 4.4 ppb for metolachlor OA), and also exceed those values detected in two PGW studies (metolachlor ESA was detected at a maximum concentration of 24 ppb while metolachlor OA was detected at a maximum concentration of 15.6 ppb). In addition, recent data collected by the Suffolk County, New York Department of Health Services, Bureau of Groundwater Resources indicate that both metolachlor and *S*-metolachlor, and its degradates, have been detected in ground water. In data collected between 1997 and 2001, metolachlor ESA was detected in 296 well samples with a maximum concentration of 39.7 ppb, while metolachlor OA was detected in 228 wells with a maximum concentration of 49.6 ppb. No information was available on frequency of detection and only summary statistics were provided on these data; therefore, these data were not used quantitatively in the risk assessment.

iii. *Drinking water levels of comparison (DWLOCs).* In the absence of chemical-specific monitoring data, the Agency uses drinking water levels of comparison to calculate aggregate risk. A drinking water level of comparison, or a DWLOC, is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. In other words, the DWLOC value represents the maximum theoretical exposure a person may have to pesticide residues through drinking water, after their exposure to the pesticide's residues through food and residential exposure have been taken into consideration. The Office of Pesticide Programs uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water; however, they do have an indirect regulatory impact through aggregate exposure and risk assessments.

DWLOCs are calculated for each type of risk assessment as appropriate (acute, short-term, intermediate-term, chronic, and cancer) and compared to the appropriate estimated concentration of a pesticide in surface and ground water. If the DWLOC is greater than the estimated surface and ground water concentration, (i.e., if the DWLOC > EEC), the Agency concludes with

reasonable certainty there is no drinking water risk of concern.

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 currently registered for use on the following residential non-dietary sites: lawn, turf (including sod farms), golf courses, sports fields, and ornamental gardens. Although not labeled as a restricted-use pesticide, the label indicates that it is not intended for use by homeowners but only for use by professional lawn care applicators. On this basis, a residential handler is not expected to be exposed to residues of *S*-metolachlor. Therefore, a residential handler assessment was not conducted.

There is potential for postapplication exposure to adults and children resulting from the use of *S*-metolachlor on residential lawns. Although the use sites for *S*-metolachlor vary from golf courses to ornamental gardens, the residential lawn scenario represents what the Agency considers 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 (1 to 30 days of exposure) only, based on a label specification of a 6–week interval before the re-application of *S*-metolachlor.

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 and dermal exposures are assumed to be minimal. Postapplication inhalation exposure is also expected to be minimal since *S*-metolachlor is 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 following application to lawns and turf have been identified: (1) Short-term oral exposure to toddlers and children following hand-to-mouth exposure; (2) short-term oral exposure to toddlers and children following object-to-mouth exposure; and (3) 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.

Since 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.

The exposure and risk estimates for the three residential exposure scenarios are assessed for the day of application (day ''0'') since children will likely contact the lawn immediately following application.

The following estimates/assumptions were used in the risk assessment: (1) A single application at the maximum label rate of 2.47 lb ai/acre for *S*-metolachlor, (2) exposure duration for children is assumed to be 2 hours per day, (3) the exposed child's weight is 15 kg (33 pounds), and (4) turf transferable residue (TTR) value of 5%, and object-to-mouth residue value of 20% of the application rate assumed.

The exposure estimates for the three postapplication 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). Combined post-application oral risk estimates for *S*-metolachlor are not of concern. The following Table 4 summarizes the results of the residential postapplication assessment:

TABLE 4.—SUMMARY OF RESIDENTIAL POSTAPPLICATION MOE VALUES

Exposure Scenario[a]	*S*-Metolachlor[b]	Oral Dose (mg/kg/day)	Oral Short-term MOE[c]
Object-to-mouth	*S*-metolachlor	0.0092	5,400
Hand-to-mouth	*S*-metolachlor	0.037	1,400
Soil ingestion	*S*-metolachlor	0.00012	400,000
Combined exposure	*S*-metolachlor	0.046	1,100

[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.
[c] Short-term oral MOE = NOAEL/Dose, where short-term oral NOAEL = 50 mg/kg/day.

S-metolachlor may be used on sports and recreational fields, as well as golf courses. However, the Agency believes that children's exposure to residues of *S*-metolachlor remaining on residential lawns after treatment represents the likely upper-end of exposure. Furthermore, since dermal and inhalation risks are not of concern, and oral exposures from sports and recreational fields, as well as golf courses, are expected to be minimal, risks for these other non-occupational settings are expected to be insignificant.

The Agency has conducted a direct exposure assessment for the use of *S*-metolachlor on lawns, and determined that there is no risk of concern from this use. No additional risk from *S*-metolachlor is expected from spray drift.

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.''

The chloroacetanilide pesticides represent a class of food use pesticides that have been given high priority by the Agency for the reassessment of tolerances in accordance with the mandates of FQPA. The group of chloroacetanilide pesticides covered by this review consists of acetochlor, alachlor, butachlor, metolachlor and propachlor. Various members of this group of chloroacetanilide pesticides have been shown to result in several different types of tumor responses in laboratory animals (e.g., nasal, thyroid, liver, and stomach tumors). Therefore, as part of the reassessment, EPA

scientists considered several different potential common mechanism of toxicity groupings for these chemicals.

In reviewing this issue, EPA scientists were guided by several relevant Agency science policies, including Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity. Additionally, on March 19, 1997, the Agency presented to the FIFRA Scientific Advisory Panel (SAP) a draft case study illustrating the application of the Common Mechanism Guidance to the grouping of chloroacetanilide pesticides based on a common mechanism of toxicity. The SAP agreed with the Agency's conclusion that there is sufficient evidence to support the grouping of certain chloroacetanilides that cause nasal turbinate tumors by a common mechanism of toxicity.

Upon consideration of the SAP comments, EPA's own reviews and the data underlying these reviews, as well as additional information received by the Agency from registrants or presented in the open literature since the 1997 draft document, EPA has revised its science document discussing the potential grouping of chloroacetanilide pesticides, or a subgroup of them, based on a common mechanism of toxicity.

In the revised document entitled ''The Grouping of a Series of Chloroacetanilide Pesticides Based on a Common Mechanism of Toxicity,'' EPA has concluded that only some of the pesticides that comprise the class of chloroacetanilides should be designated as a ''Common Mechanism Group'' based on the development of nasal turbinate tumors by metabolism to a highly, tissue reactive moiety, i.e., quinoneimine. Thus, only acetochlor, alachlor, and butachlor should be grouped based on a common mechanism of toxicity for nasal turbinate tumors. Although metolachlor does distribute to the nasal turbinates, and might produce a quinoneimine, it is not apparent from currently available data that it shares the same target site in the nasal tissue as acetochlor, alachlor and butachlor. Although propachlor does produce a precursor of a quinoneimine, the available data do not support its tumorigenicity to the nasal turbinates.

In conclusion, it is the Agency's position, that only some chloroacetanilides, namely acetochlor, alachlor, and butachlor should be considered as a ''Common Mechanism Group'' due to their ability to cause nasal turbinate tumors. For purposes of a cumulative risk assessment as a part of the tolerance reassessment process for acetochlor, alachlor, and butachlor, these three pesticides will be considered as a Common Mechanism Group. Following the initiation of a cumulative risk assessment, further analyses of new or existing data may occur which could impact the Agency's evaluation of specific members of this group or the group as a whole.

D. 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. *Prenatal and postnatal sensitivity.* Prenatal developmental studies in the rat and rabbit revealed no evidence of a qualitative or quantitative susceptibility in fetal animals.

3. *Conclusion.* There is a complete toxicity data base for *S*-metolchlor and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA Safety Factor Committee met on November 5, 2001 to evaluate the hazard and exposure data for metolachlor and *S*-metolachlor, and recommended that the FQPA Safety Factor for the protection of infants and children be reduced to 1x for the following reasons: (1) The toxicology database is complete for the FQPA assessment; (2) 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; (3) a developmental neurotoxicity study is not required for metolachlor; and (4) 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 metolachlor.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* An acute aggregate risk assessment addresses potential exposure from combined residues of metolachlor/*S*-metolachlor on food and in drinking water (both surface and ground water). Potential residential exposures are not incorporated into an acute aggregate risk assessment. As shown in Table 5 below, the EECs are below the Agency's back-calculated DWLOC values for the parent compound, the ESA degradate, and the OA degradate. The combined value of the parent plus the degradates is also below the acute DWLOC value. The Agency concludes that acute aggregate risk estimates are not of concern for any population subgroup.

TABLE 5.—ACUTE DWLOC CALCULATIONS FOR 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	200.9	103	1.0×10^5
Females 13–50	3.0	1	200.9	103	9.0×10^4
Children 1–6	3.0	1	200.9	103	3.0×10^4
Males 13–19	3.0	1	200.9	103	9.0×10^4

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

2. *Chronic risk.* A chronic aggregate risk assessment considers chronic exposure from food, drinking water, and non-occupational (residential) pathways of exposure. For metolachlor and *S*-metolachlor, there are no chronic

(greater than 180 days of exposure) non-occupational exposure scenarios. Therefore, the chronic aggregate risk assessment will consider exposure from food and drinking water only. The EECs for ground water residues of the parent compound (5.5), the ESA degradate (65.8), and the OA degradate (31.7) are below the Agency's chronic DWLOC values for all population subgroups. The combined value of the parent plus degradates (103) is also below the chronic DWLOC value. The EECs for surface water residues of the parent compound (4.3), the ESA degradate (22.8), and the OA degradate (65.1) are below the Agency's chronic DWLOC values for all population subgroups. The combined value of the parent plus degradates (92.2) is also below the chronic DWLOC value. The Agency concludes that chronic aggregate risks are not of concern.

TABLE 6.—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	2	92.2	103	3442.50
Females 13–50	0.1	1	92.2	103	2962.11
Children 1–6	0.1	4	92.2	103	959.75
Males 13–19	0.1	2	92.2	103	2954.55

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

3. *Short-term risk.* A short-term aggregate risk assessment considers potential exposure from food, drinking water, and short-term, non-occupational (residential) pathways of exposure. For *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 (*S*-metolachlor use only) 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 *S*-metolachlor only, since Syngenta no longer holds any racemic metolachlor residential end-use products. EECs for the parent compound, the ESA degradate, and the OA degradate are below the short-term *S*-metolachlor DWLOC value for the population children (1 to 6 years old). The combined value of the parent plus the degradates is also below the short-term *S*-metolachlor DWLOC value. The Agency concludes that short-term aggregate risks from *S*-metolachlor are not of concern. The target MOE is 100, based on the 100x uncertainty factor, and the 1x FQPA safety factor. This MOE is not exceeded by the MOE for food which is 1.6×10^4 (short-term oral NOAEL (50 mg/kg/day)/chronic dietary exposure of children (0.003171 mg/kg/day); MOE for oral which is 1,100 (short-term oral NOAEL (50 mg/kg/day)/combined hand-to-mouth, object-to-mouth, and soil ingestion oral exposure (0.046 mg/kg/day *S*-metolachlor)); aggregate MOE for food and residential which is 1,000 (1 ÷ (1 ÷ MOE food) + (1 ÷ MOE oral)); or allowable water exposure which is 0.45 mg/kg/day (1 ÷ (1 ÷ Target Aggregate MOE) - (1 ÷ Aggregate MOE (food and residential)). The DWLOC is 4,000 ppb. The EEC for ground water is 103.3 ppb (parent 5.5, ESA metabolite 65.8 ppb and OA metabolite 32 ppb). The EEC for surface water is 92.2 ppb (parent 4.3, ESA metabolite 22.8 ppb and OA metabolite 65.1 ppb).

For informational purposes, it is noted that the EEC values for the parent compound, ESA degradate, and the OA degradate are below the metolachlor short-term DWLOC value for children. The combined value of the parent plus the degradates is also below the metolachlor short-term DWLOC value.

TABLE 7.—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 to 6	1,000	100	92.2	103.3	4,000

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 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. However, as noted under Unit III.B., Toxicological Endpoints, the NOAEL that was established based on tumors in the rat (15 mg/kg/day, seen at the highest dose tested 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. 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 metolachlor/*S*-metolachlor residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The Pesticide Analytical Manual (PAM) Vol. II, lists a gas chromatography/nitrogen phosphorous detection (GC/NPD) method (Method I) for determining residues in/on plants and a gas chromatography/mass spectrometry detection (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 (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.

C. Conditions

The need for a 28–day inhalation study has been identified for both metolachlor and *S*-metolachlor. Submission of this study would allow the Agency to improve characterization regarding the concern for toxicity via the inhalation route of exposure following application of metolachlor/*S*-metolachlor on multiple days in a commercial setting.

V. Conclusion

Therefore, the tolerance is established for combined residues or residues of *S*-metolachlor Acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)-, (*S*) 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 raw agricultural commodities each expressed as the parent compound in or on the raw agricultural commodities grass forage at 10.0 ppm, grass hay at 0.02 ppm, spinach at 0.5 ppm, sugar beet at 0.5 ppm, sugar beet molasses at 3.0 ppm, sugar beet tops at 15.0 ppm, sunflower at 0.5 ppm, sunflower meal at 1.0 ppm, and tomato at 0.1 ppm.

VI. 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 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–2003–0046 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 June 2, 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 VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0046, 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).

VII. Regulatory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 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.

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: March 25, 2003.

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 in paragraph (a) by designating the text following the paragraph heading ''General,'' as paragraph (a)(1) and by adding new paragraph (a)(2) to read as follows:

§ 180.368 Metholachlor; tolerances for residues.

(a) *General.* (1) * * *

(2) Tolerances are established for combined residues of the herbicide *S*-metolachlor acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)-, (*S*) 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 raw agricultural commodities:

Commodity	Parts per million
Beet, sugar, molasses	2.0
Beet, sugar, roots	0.5
Beet, sugar, tops	15.0
Grass, forage	10.0
Grass, hay	0.2
Spinach	0.5
Sunflower, seed	0.5
Sunflower, meal	1.0
Tomato	0.1

* * * * *

[FR Doc. 03–7800 Filed 4–1–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0328; FRL–7286–9]

Bacillus pumilus GB 34; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus pumilus* GB 34 when used as a seed treatment in or on soybeans and soybeans after harvest. Gustafson LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus pumilus* GB 34.

DATES: This regulation is effective April 2, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0328, must be received on or before June 2, 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 IX. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Anne Ball, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8717; e-mail address: *ball.anne@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:

- Industry (NAICS 111), *e.g.*, crop production
- Industry (NAICS 112), *e.g.*, animal production
- Industry (NAICS 311), *e.g.*, food manufacturing
- Industry (NAICS 32532, *e.g.*, pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in 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–2002–0328. 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.

To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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. Once in the system, select ''search'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of December 31, 2001 (66 FR 67522) (FRL–6813–8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 1F6344) by Gustafson LLC, 1400 Preston Road, Suite 400, Plano, TX 75093. This notice included a summary of the petition prepared by the petitioner Gustafson LLC. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *B. Pumilus* GB 34.

III. Risk Assessment

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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....'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information''