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

■ 2. Section 180.572 is amended by:

i. In paragraph (a)(1), in the table, by removing the commodities ''peach'' and ''nectarine''; revising the tolerance levels for the commodities ''cattle, fat''; ''goat, fat''; ''hog, fat''; ''horse, fat''; and ''sheep, fat'' and by alphabetically adding commodities ''fruit, stone, group 12, except 12''; ''pea, garden, succulent''; ''pea, edible podded, succulent''; and ''vegetable, tuberous and corm''; and

ii. In paragraph (b), in the table, by removing the commodity tomato.

The amendments read as follows.

§ 180.572 Bifenazate; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* * * *	*
Cattle, fat	0.10
* * * *	*
Fruit, stone, group 12, except plum	2.5
Goat, fat	0.10
* * * *	*
Hog, fat	0.10
* * * *	*
Horse, fat	0.10
* * * *	*
Pea, garden, succulent	0.20
Pea, edible podded, succulent	4.0
* * * *	*
Plum	0.20
Sheep, fat	0.10
* * * *	*
Vegetable, tuberous and corm, subgroup 1C	0.10

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0292; FRL–8090–2]

S-metolachlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of S-metolachlor in or on pumpkin, and squash, winter. Interregional Research Project Number 4 (IR-4) requested these 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 August 30, 2006. Objections and requests for hearings must be received on or before October 30, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0292. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e–mail address: *brothers.shaja@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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e–CFR site 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*

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0292 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 30, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number

EPA–HQ–OPP–2006–0292, by one of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on–line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of April 21, 2006 71 FR 20663 FRL–8064–6, EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E7015) by IR–4, 681 Highway 1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.368(a)(3) be amended by establishing tolerances for combined residues 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, in or on pumpkin and squash, winter at 1.0 part per million (ppm), respectively. The tolerances were subsequently amended to 0.1 ppm for raw agricultural commodities previously mentioned. This notice included a summary of the petition prepared by Syngenta, 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 the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA–PEST/1997/November/Day–26/p30948.htm*.

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 tolerances for combined residues of S–metolachlor on pumpkin at 0.1 ppm, and squash, winter at 0.1 ppm. EPA's assessment of exposure and risk associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by metolachlor and S–metolachlor as well as the no–observed–adverse–effect–level (NOAEL) and the lowest–observed–adverse–effect–level (LOAEL) from the toxicity studies can be found at www.regulations.gov (Docket No. EPA–HQ–OPP– 2006–0292–0003; pages 53-64).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for metolachlor and S-metolachlor used for human risk assessment is discussed at www.regulations.gov (Docket No. EPA–HQ–OPP–2006–0292; pages 20-21).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.368) for the combined residues of S-metolachlor, in or on a variety of raw agricultural commodities. Meat, milk, poultry and egg tolerances have also been established. Risk assessments were conducted by EPA to assess dietary exposures from S-metolachlor in food as follows:

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. 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.

i. *Acute exposure*. Quantitative acute dietary exposure and 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.

In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), 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 acute exposure assessments: An acute dietary analysis for S-metolachlor was conducted using tolerance level residues and 100 % crop treated (CT) for all existing and proposed uses.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), 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 chronic dietary analysis for S-metolachlor was conducted using tolerance level residues and 100 %CT data for all existing and proposed uses.

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 of 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 chronic reference dose for metolachlor. EPA has concluded that the chronic dietary PAD is protective for cancer dietary risk. Therefore, a separate cancer aggregate risk assessment was not conducted.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for s-metolachlor drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of s-metolachor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

A drinking water assessment was conducted based on monitoring data from several sources, as well as on Tier 1 FIRST and SCI-GROW modeling results. This assessment is a worst-case scenario and demonstrates high end numbers. 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. Although it was determined by the EPA 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 crops with the highest maximum seasonal application rates are turf (S-metolachlor only) and corn (racemic metolachlor and S-metolachlor) with a maximum seasonal application rate of 4.0 lbs ai/A. Based on PRZM/EXAMS modeling the maximum peak and annual average concentrations of metolachlor/ S-metolachlor in surface water were 199 ug/l and 9.2 ug/l, respectively. Based on FIRST modeling results, the estimate of the drinking water concentration from surface water sources of metolachlor ESA, a major degradate of metolachlor, is not likely to exceed 31.9 ug/L for the annual peak concentration and 22.8 ug/L for the annual average exposure for use on turf/corn at a maximum annual application rate of 4.0 lbs ai/A. Based on FIRST modeling results, the estimate of the drinking water concentration from surface water sources of metolachlor OA, another major degradate of metolachlor, is not likely to exceed 91.4 ug/L for the annual peak concentration and 65.1 ug/L for the annual average exposure for use on turf/corn at a maximum annual application rate of 4.0 lbs ai/A (ground application with no spray drift).

The SCI-GROW screening model was used to estimate groundwater concentrations. The estimated concentration of metolachlor/ S-metolachlor in drinking water from shallow groundwater sources is 5.5 ug/l for application on corn at a seasonal maximum rate of 4.0 lbs ai/A. This concentration is appropriate for both the peak and annual average exposures. The EEC for metolachlor degradate ESA based on metolachlor use on turf/corn is not expected to exceed 65.8 ug/l for peak and annual average exposures. The EEC for metolachlor OA from metolachlor use on turf/corn is not expected to exceed 31.7 ug/l for peak and annual average exposures.

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

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For acute dietary risk, since the surface water EDWCs are higher than the groundwater EDWC, the peak concentration of 322.3 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, since the ground water EDWCs are higher than the surface water EDWC the ground water concentration of 103.0 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

The formulated S-metolachlor end-use product is labeled under the trade name Pennant MAGNUM™ (EPA Reg. No. 100-950) to distinguish the new product from the original metolachlor formulation named Pennant™ (EPA Reg. No. 100-691). Pennant MAGNUM™ (7.62 lbs. active ingredient per gallon) is labeled for use on commercial (sod farm) and residential warm-season turfgrasses and other

noncrop land including golf courses, sports fields, and ornamental gardens. Although not labeled as a restricted-use pesticide, Pennant MAGNUM™, as currently marketed, is not intended for homeowner purchase or use (intended for use by professionals). On this basis, with regard to the requirements of FQPA, metolachlor and S-metolachlor are assessed only for post application exposure and risk. Pennant MAGNUM™ and Pennant™ are both emulsifiable concentrates (EC).

For this risk assessment, small children are the population group of concern. Although the type of site that S-metolachlor may be used on varies from golf courses to ornamental gardens, the scenario chosen for risk assessment (residential turf use) represents what the Agency considers the likely upper-end of possible exposure. Post application exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. Since toxicity was not observed in a dermal toxicity study, up to a dose level of 1,000 mg/kg/day, the only parameter of risk addressed in this assessment is the possible oral exposure of small children from treated turf, or soil.

The estimate for hand-to-mouth exposure on the day of treatment is 0.037 mg/kg/day (MOE = 1,400) for S-metolachlor and 0.06 mg/kg/day (MOE = 840) for metolachlor. (MOE estimates are based on the short-term NOAEL of 50 mg/kg/day).

The estimate for object-to-mouth exposure on the day of treatment is 0.0092 mg/kg/day (MOE = 5,400) for S-metolachlor and 0.015 mg/kg/day (MOE = 3,300) for metolachlor. (MOE estimates are based on the short-term NOAEL of 50 mg/kg/day).

The estimate for soil ingestion exposure on the day of treatment is 0.00012 mg/kg/day (MOE = 400,000) for S-metolachlor and 0.0002 mg/kg/day (MOE = 250,000) for metolachlor. (MOE estimates are based on the short-term NOAEL of 50 mg/kg/day).

The estimate for hand-to-mouth, object-to-mouth, and soil ingestion combined (on the day of treatment) is 0.046 mg/kg/day (MOE = 1,100) for S-metolachlor and 0.075 mg/kg/day (MOE = 670) for metolachlor. (MOE estimates are based on the short-term NOAEL of 50 mg/kg/day).

The MOE estimates are greater than 100 and indicate that the potential metolachlor/S-metolachlor exposure (to children) associated with residential use is not of concern. Although considered an upper-bound, the exposure estimate for the three scenarios, combined, is recommended for aggregate (residential, food, and drinking water) risk estimates.

4. *Cumulative effects from 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to S-metolachlor and any other substances and S-metolachlor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that S-metolachlor has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website 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 uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*—i. *Metolachlor*. The prenatal developmental studies in the rat and rabbit revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. In the rabbit prenatal developmental toxicity study, at 360 mg/kg/day, maternal animals had persistent anorexia and decreased body weight gain; the NOAEL was 120 mg/kg/day. In the rat prenatal developmental toxicity study, frank toxicity [death, clinical signs (clonic and/or tonic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive salivation) and decreased body weight gain] was observed at the limit dose of 1,000 mg/kg/day in maternal animals; the NOAEL was 300 mg/kg/day. The developmental effects at 1,000 mg/kg/day included 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.

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

ii. *S-metolachlor*. There was no evidence of increased quantitative or qualitative fetal susceptibility in the prenatal developmental studies in rats and rabbits. In the rat, maternal toxicity [increased clinical signs of toxicity (pushing head through bedding) and decreased body weights/body weight gains, food consumption and food efficiency was observed at 500 mg/kg/day; the NOAEL was 50 mg/kg/day. There were no developmental effects at 1,000 mg/kg/day, the HDT. In the rabbit, clinical signs of toxicity (little/none/soft stool) were observed at 100 mg/kg/day; the NOAEL was 20 mg/kg/day. No developmental effects were observed at 500 mg/kg/day, the HDT.

3. *Conclusion*. There is a complete toxicity data base for S-metolachlor 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 reduced to 1X for the following reasons:

i. The toxicology database 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 or S-metolachlor in the available toxicity data.

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

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to S-metolachlor will occupy <1% of the aPAD for the US population and other population subgroups, and 2% of the aPAD for all infants <1 year old. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to S-metolachlor from food and water will utilize 4% of the cPAD for the U.S. population, 10% of the cPAD for all infants < 1 year old, and 8% of the cPAD for children 1-2 years old. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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). A short-term aggregate risk assessment considers potential exposure from food, drinking water, and short-term, non-occupational (residential) pathways of exposure for a duration of 1 to 30 days.

Potential short-term, non-occupational risk scenarios for S-metolachlor consist of oral exposure of children to treated lawns only. In this aggregate short-term risk assessment, exposure from food, drinking water, and residential lawns has been considered. The exposure to food and water has already been considered in the chronic dietary risk assessment. Since only children have the potential for non-occupational, short-term risk, they are the only population subgroup for which an aggregate short-term risk assessment was conducted. Toddlers' S-metolachlor incidental oral exposure is assumed to include hand-to-mouth exposure, object-to-mouth exposure and exposure through incidental ingestion of soil.

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

Population	Short-Term Scenario				
	NOAEL mg/kg/day	LOC[1]	Average Food and Water Exposure mg/kg/day	Residential Exposure mg/kg/day[2]	Aggregate MOE (food, water and residential)[3]
All infants <1 yr old	50	100	0.010003	0.046	890

[1] The level of concern (LOC) MOE is 100, based on inter- and intra-species safety factors totaling 100.
[2] Residential Exposure = [Incidental Oral exposure from all possible sources-combined hand-to-mouth, object-to-mouth, and soil ingestion oral exposure]. No residential oral exposure is expected for adults
[3] Aggregate MOE = [NOAEL ÷ (Avg Food and Water Exposure + Residential Exposure)]

4. *Aggregate cancer risk for U.S. population*. S-metolachlor is classified as classified as a Group C, possible human carcinogen. EPA has concluded that the chronic dietary PAD is protective for cancer dietary risk and, as noted above, chronic exposure is below the chronic dietary PAD.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methodology is available for enforcing the current and proposed tolerances. The Pesticide Analytical Manual (PAM, Vol. II) lists a GC/NPD method (Methods 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 S-metolachlor and its metabolites as either CGA-37913 or CGA-49751 following acid hydrolysis. A modified version of this method (Syngenta Method No. 1848-01) which uses liquid chromotography/mass spectrometry/mass spectrometry (LC/MS/MS) has also been used. Adequate data are available on the recovery of metolachlor through Multi-residue Method Testing Protocols. The FDA PESTDATA database indicates that S-metolachlor is completely recovered through Method 302, PAM Vol. I.

B. International Residue Limits

There are currently no Codex, Canadian or Mexican MRLs for S-metolachlor; therefore there are no international harmonization issues for these actions.

V. Conclusion

Therefore, the tolerances are established for combined residues of 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, in or on pumpkin and squash, winter at 0.1 ppm.

VI. 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.

VII. 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, 2006.

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 in paragraph (a)(3) by adding commodities to the table to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

(a)* * *

(3) * * *

Commodity	Parts per million
* * *	* *
Pumpkin	0.1
* * *	* *
Squash, winter	0.1
* * *	* *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0537; FRL–8086–2]

Ethofumesate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of the herbicide, ethofumesate in or on carrot, roots (with regional restrictions for use in the States of Washington and Oregon), beet, garden, tops and beet, garden, roots; onion, bulb; garlic, bulb; shallot, bulb; and shallot, fresh leaves. The Interregional Research Project #4 (IR-4), 681 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).

DATES: This regulation is effective August 30, 2006. Objections and requests for hearings must be received on or before October 30, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0537. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., 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