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: September 10, 2003.

James Jones,

Director, 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 180.592 is added to read as follows:

§ 180.592 Butafenacil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide butafenacil, (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cotton, gin byproducts	10
Cotton, undelinted seed	0.50

(2) Tolerances are established for residues of the herbicide butafenacil, (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) and its metabolite CGA-293731 (1-carboxy-1-methylethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate), in or on the following livestock commodities:

Commodity	Parts per million
Cattle, kidney	0.05
Cattle, liver	0.50
Goats, kidney	0.05
Goats, liver	0.50
Hog, kidney	0.05
Hog, liver	0.50
Horse, kidney	0.05
Horse, liver	0.50
Sheep, kidney	0.05
Sheep, liver	0.50

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertant residues.* [Reserved]

[FR Doc. 03–23853 Filed 9–18–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0300; FRL–7324–9]

S-Metolachlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of the herbicide S-metolachlor and its metabolites in or on asparagus; carrot, roots; horseradish; onion, green; rhubarb; and swiss chard. The 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 (FQPA) of 1996.

DATES: This regulation is effective September 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0300, must be received on or before November 18, 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: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address:jamerson.hoyt@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)
- Animal production (NAICS 112)
- Food manufacturer (NAICS 311)
- Pesticide manufacturer (NAICS 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–2003–0300. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http//www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/ 40cfr180_00.html*, a beta site currently under development.

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

II. Background and Statutory Findings

In the **Federal Register** of August 13, 2003 (68 FR 48373) (FRL–7320–9), 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 (4E4420, 7E4916, 8E5029, 8E5030, 9E6055, and 2E6374) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Syngenta Crop Protection, Swing Road, Greensboro, NC 27641, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.368 be amended by establishing tolerances 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 (CGA-37913) and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone (CGA-49751), each expressed as the parent compound, in or on asparagus at 0.1 part per million (ppm) (9E6055); carrot, roots at 0.1 ppm (7E4916); horseradish at 0.1 ppm (7E4916); onion, green at 0.2 ppm (2E6374); pepper, bell at 0.50 ppm (4E4420); pepper, nonbell at 0.50 ppm (4E4420); rhubarb at 0.1 ppm (8E5029); and swiss chard at 0.1 ppm (8E5030). IR-4 subsequently revised 7E4916 to propose tolerances for carrot, roots at 0.20 ppm and horse radish at 0.20 ppm. IR-4 also withdrew 4E4420 for pepper. IR-4 plans to submit a pesticide petition proposing a tolerance for fruiting vegetable group, which includes bell and nonbell pepper, later in 2003.

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, November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of 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 tolerances for combined residues of S-metolachlor and its metabolites on asparagus at 0.10 ppm; carrot, roots at 0.20 ppm; horseradish at 0.20 ppm; onion, green at 0.20 ppm; rhubarb at 0.10 ppm; and swiss chard at 0.10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

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

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by S-metolachlor as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in Unit III.A. of the **Federal Register** of April 2, 2003 (68 FR 15945) (FRL–7299–8).

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is

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

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 factors (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 Percent 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* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure.'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for S-metolachlor used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 2, 2003 (68 FR 15945) (FRL–7299–8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances established for metolachlor (40 CFR 180.368(a)(1) and (c)) 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% less than the historical use rate of metolachlor. Tolerances have also been established (40 CFR 180.368(a)(2)) for the combined residues of S-metolachlor, in or on a variety of raw agricultural commodities. Time-limited tolerances are established for metolachlor and S-metolachlor (40 CFR 180.368(b)) in support of section 18 emergency exemptions. Risk assessments were conducted by EPA to assess combined dietary exposures from metolachlor and S-metolachlor in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. In conducting this acute dietary risk assessment, EPA used the Dietary Exposure Evaluation Model (DEEM) software with the Food Commodity Intake Database (FCID) which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. A conservative Tier 1 acute dietary exposure assessment was conducted for all labeled metolachlor and all labeled and proposed S-metolachlor food uses using 100% crop treated (CT) and tolerance level residues.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, EPA used the DEEM software with the FCID which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. A conservative Tier 1 combined, chronic dietary exposure assessment was conducted for all labeled metolachlor and all labeled and proposed S-metolachlor food uses using 100% CT and tolerance level residues.

2. *Dietary exposure from drinking water.* The environmental fate data base is complete for S-metolachlor. Parent metolachlor/S-metolachlor appear to be moderately persistent to persistent, and range from mobile to highly mobile in different soils. Metolachlor and S-metolachlor are expected to have similar degradation pathways and rates in soil and water environments. This assessment includes concentrations of parent metolachlor/S-metolachlor and the degradates metolachlor ethane sulfonic acid (ESA) and metolachlor oxanilic acid (OA). Although it was determined 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. No surface or ground water monitoring studies that specifically target metolachlor/S-metolachlor were 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) data base, the U.S. EPA STORET data base, the Acetochlor Registration Partnership (ARP) data base, and two USGS reservoir monitoring studies.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and include a PC area factor as an adjustment to account for the maximum PC coverage within a watershed ordrainage basin.

The acute estimated environmental concentration (EEC) of 77.6 parts per billion (ppb) was selected from the NAWQA data base, and the chronic EEC of 4.3 ppb was selected from the maximum annual time weighted mean from the NAWQA data. These values represent the estimated concentration of parent metolachlor/S-metolachlor in surface water, and are supported by the metolachlor concentrations from the National Contaminant Occurrence Data base representing analysis of treated drinking water, as well as from model predictions using PRZM/EXAMS. When the monitoring data and modeling data are considered together, there is a general agreement between the various

sources of information used in the assessment.

Acute and chronic concentrations of parent metolachlor/S-metolachlor are not expected to exceed 5.5 ppb in ground water (based on SCI-GROW modeling). SCI-GROW estimates the upper bound ground water concentrations of pesticides likely to occur when the pesticide is used at the maximum allowable rate in areas with ground water vulnerable to contamination. Estimates were based on two applications to corn/turf for a total of 4 lbs. active ingredient/acre (the maximum application rate).

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 application rate used for metolachlor ESA and OA in the model 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. 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. Monitoring data suggest that the SCI-GROW estimates for metolachlor ESA and OA are slightly over estimating the potential impact of metolachlor/S-metolachlor use on ground water.

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

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

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). There is the potential for post-application exposure to adults and children resulting from the use of S-metolachlor on residential lawns. Post-application exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. Post-application exposure is considered to be short-term (1– days of exposure), based on label directions limiting application to one time per season.

A short-term dermal risk assessment was not conducted since no systemic toxicity was observed at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day) following dermal application and there is no concern for developmental toxicity in rats and rabbits. Post-application inhalation exposure is also expected to be minimal since S-metolachlor is only applied outdoors, the vapor pressure is low and the label specifies that residents should not reenter treated areas until after the spray has dried.

The following post-application 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; (3) short-term oral exposure to toddlers and children following soil ingestion. The Health Effect Division Standard Operating Procedures for Residential Exposure Assessments (Draft, December 18, 1997) were used as a guideline for the residential post-application assessment. Also, standard values for turf transferable residues, turf transfer coefficients, and hand-to-mouth activities were used as amended by Exposure Policy 12 (Science Advisory Panel on Exposure, February 22, 2001). 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 active ingredient/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.

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.'' EPA has examined the common mechanism potential for S-metolachlor and has concluded that S-metolachlor should not be included with the chloroacetanilide pesticides designated as a ''Common Mechanism Group.'' The Agency's position is that only some chloroacetanailides, namely acetochlor, alachlor and butachlor should be considered as a ''Common Mechanism Group'' due to their ability to cause nasal turbinate tumors. Although metolachlor does distribute to the nasal turbinates, and might produce a quinonimine, it is not apparent from the available data that metolachlor shares the same target site in the nasal tissue as acetochlor, alachlor, and butachlor.

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

3. *Conclusion*. There is a complete toxicity data base and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor for the protection of infants and children has been reduced to 1X because: (1) The toxicology data base 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. (4) the dietary (food and drinking water) and non-dietary exposure (residential) assessments will not under estimate the potential exposures for infants and children from the use of metolachlor.

E. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

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

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO METOLACHLOR/S-METOLACHLOR

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S.population	3.0	<1	200.9	103	104856.1
Infants <1 year	3.0	<1	200.9	103	29931.45
Children 1 to 2 years old	3.0	<1	200.9	103	29917.76
Females 13 to 49 years old	3.0	<1	200.9	103	89915.55

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

TABLE 2.—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
Infants <**1** year	0.1	2	92.2	103	977.20
Children 1 to 2 years	0.1	4	92.2	103	959.75
Females 13 to 49 years	0.1	1	92.2	103	2962.11

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in an aggregate MOE of 1,000 for children 1 to 2 years. This aggregate MOE does not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of metolachlor/S-metolachlor and ESA and OA degradates in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 3:

TABLE 3.—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 2 years old	1,000	100	92.2	103.3	4,000

5. *Aggregate cancer risk for U.S. population*. The NOAEL that was established based on tumors in rats (15 mg/kg/day) is comparable to the NOAEL of 9.7 mg/kg/day selected for cRfD. Therefore, the chronic dietary end point is protective for cancer dietary exposure.

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 (GC)/NPD method (Method I) for determining residues in/on plants and a GC/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. Field trial data were obtained using adequate GC/NPD methods (AG-338 or AG-612), which are modifications of Method I. Adequate data are available on the recovery of metolachlor through Multi-residue Method Testing Protocols. The FDA PEST DATA data base indicates that metolachlor is completely recovered through Method 302, PAM Vol. I (3rd ed., revised 10/97).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residue methods@epa.gov.*

B. International Residue Limits

No maximum residue limits for either metolachlor or S-metolachlor have been established or proposed by Codex, Canada, or Mexico for any agricultural commodity; therefore, there are no compatibility issues with this action.

V. Conclusion

Therefore, tolerances are established 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 (CGA-37913) and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone (CGA-49751), each expressed as the parent compound, in or on asparagus at 0.10 ppm; carrot, roots at 0.20 ppm; horseradish at 0.20 ppm; onion, green at 0.20 ppm; rhubarb at 0.10 ppm; swiss chard at 0.10 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–2003–0300 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 November 18, 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–2003–0300, 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. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exemptedthese 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 notcontain 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 tolerances in this final rule, do not require the issuance of aproposed 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: September 12, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180— [AMENDED]

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

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

■ 2. Section 180.368 is amended by alphabetically adding commodities to the table in paragraph (a)(2) to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
Asparagus	0.10
* * * * *	
Carrot, roots	0.20
* * * * *	
Horseradish	0.20
Onion, green	0.20
* * * * *	
Rhubarb	0.10
* * * * *	
Swiss chard	0.10
* * * * *	

* * * * *

[FR Doc. 03–24014 Filed 9–16–03; 4:08 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0166; FRL–7325–4]

Flufenpyr-Ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of flufenpyr-ethyl; acetic acid, [2-chloro-4-fluoro-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-ethyl ester], in or on field corn, soybeans, and sugarcane, and the combined residues of flufenpyr-ethyl and its metabolite, S-3153 acid-4-OH; [2-chloro-4-hydroxy-5-[5-methyl-6-oxo-4-(trifluoromethyl)-1-(6H)-pyridazinyl]-phenoxy]-acetic acid, free and conjugated, in or on field corn forage and field corn stover. Valent USA Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0166, must be received on or before November 18, 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 I. 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 pest manufacturer. Potentially affected