Mariners and vehicle operators can better plan their transits according to the published schedule of operation. Vessels that can pass under the bridge without a bridge opening may do so at any time.

This deviation from the normal operating regulations is authorized under 33 CFR 117.43.

Dated: May 4, 1999.

**R.M. Larrabee,**

*Real Admiral, Coast Guard, Commander, First Coast Guard District.*

[FR Doc. 99–11926 Filed 5–11–99; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300854; FRL–6078–5]**

**RIN 2070–AB78**

## Halosulfuron; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of methyl-5-[((4,6-dimethoxy-2-pyrimidinyl) amino]carbonylaminosulfonyl-3-chloro-1–1*H*-pyrazole- 4-carboxylate in or on almond, hulls; corn, sweet, kernel + cob with husks removed; corn, sweet, forage; corn, sweet, fodder, corn, pop, grain; corn, pop, fodder; cotton, undelinted seed; cotton, gin by-products, pistachio, nutmeat; rice, grain; rice, straw; sugarcane, cane; and tree-nuts (crop group 14), nutmeat. This regulation also reduces tolerances for corn, field, grain; corn, field, forage; corn, field, fodder; sorghum, grain, grain; sorghum, grain, forage and sorghum, grain, fodder/stover. This regulation also deletes tolerances for soybean, seed soybean, forage; soybean, hay; wheat, grain; wheat, forage; and wheat, straw. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective May 12, 1999. Objections and requests for hearings must be received by EPA on or before July 12, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP–300854], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300854], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300854]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, Tompkins.Jim@epa.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 23, 1997 (62 FR 33864) (FRL–5722–8) and May 29, 1998 (63 FR 29401) (FRL–5791–2), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Monsanto Company, 700 14th St., Suite 1100, Washington, DC 20005. This notice included a summary of the petition prepared by Monsanto Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.479 be amended by establishing tolerances for residues of the herbicide methyl 5-[(4,6-dimethyloxy-2-pyrimidinyl)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate in or on sugarcane, cane at 0.05 parts per million (ppm) (PP 6F4620) (62 FR 33864); sweet corn, (kernel plus cobs with husks removed at 0.1 ppm); sweet corn, forage at 0.5 ppm; sweet corn, fodder/stover at 1.5 ppm; popcorn, grain at 0.1 ppm; popcorn, fodder/stover at 1.5 ppm (PP 6F4661) (62 FR 33864).

PP 8F4937 (63 FR 29401) proposed the establishment of tolerances for residues of methyl-5-[(4,6-dimethyloxy-2-pyrimidinyl) amino] carbonylaminosulfonyl-3-chloro-1-methyl- 1*H*-pyrazole-4- carboxylate in or on undelinted cotton seed and cotton gin by-products at 0.05 ppm, rice grain at 0.05 ppm, rice straw at 0.20 ppm, tree nut group (Group 14) nutmeat at 0.05 ppm and hulls at 0.20 ppm, pistachio, nutmeat at 0.05 ppm; and pistachio hulls at 0.2 ppm. The petition also proposed the establishment of tolerances for this chemical on corn, field, grain at 0.05 ppm; forage at 0.2; fodder at 0.8 ppm; sorghum, grain at 0.05 ppm, sorghum, forage at 0.05 ppm, sorghum, fodder/stover at 0.1 ppm. The petition also requested the removal of indirect or inadvertent tolerance (40 CFR 180.479(b)), in or on the following raw agricultural commodities when present therein as a result of the application of halosulfuron-methyl to growing crops, soybean, forage at 0.5 ppm, soybean, hay at 0.5 ppm, soybean, seed at 0.5 ppm, wheat, forage at 0.1 ppm, wheat, grain at 0.1 ppm and wheat, straw at 0.2 ppm.

During the course of the review the Agency determined that the commodity tree nut hulls should be revised to read almond, hulls and that a tolerance for pistachio, hulls was not necessary as this commodity is not a significant livestock feed item. EPA also determined that the residue crop field data supported the establishment of tolerances for halosulfuron-methyl on corn, sweet, kernel + cob with husks removed at 0.05 ppm; corn, sweet, forage at 0.2 ppm corn, sweet, fodder at 0.8 ppm; corn, pop, grain at 0.05 ppm; and corn, pop, fodder at 0.8 ppm. This regulation is amended to reflect these revisions.

### I. Background and Statutory Findings

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) 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) 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 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).

## II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), 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 halosulfuron-methyl and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl]-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate on sugarcane, cane at 0.05 ppm, sweet corn (kernel plus cobs with husks removed) at 0.05 ppm, sweet corn forage at 0.2 ppm, sweet corn fodder/stover at 0.8 ppm, popcorn grain at 0.05 ppm and popcorn fodder/stover at 0.8 ppm, undelinted cotton seed at 0.05 ppm, cotton gin by-products at 0.05 ppm, rice, grain at 0.05 ppm, rice, straw at 0.20 ppm, tree nut group (crop group 14), nutmeat at 0.05 ppm, almond, hulls at 0.20 ppm, and pistachio, nutmeat at 0.05 ppm. The assessment will include currently established tolerances for residues of halosulfuron in or on field corn, grain at 0.05 ppm, field corn, forage at 0.2 ppm and field corn, fodder at 0.8 ppm, sorghum, grain at 0.05 ppm, sorghum, forage at 0.05 ppm, sorghum, fodder/stover at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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. The nature of the toxic effects caused by halosulfuron-methyl are discussed in this unit.

1. Acute toxicology studies place the technical-grade halosulfuron-methyl in Toxicity Category III or IV for all routes of exposure. It is not a dermal sensitizer and essentially non-irritating to the skin.

2. A 90–day feeding study in rats fed dosages of 7.4, 28.8, 116, and 497 milligrams/kilograms/day (mg/kg/day) for males and 8.9, 37.3, 147, and 640 mg/kg/day for females and resulted in a lowest observed adverse effect level (LOAEL) of 497 mg/kg/day in males and 640 mg/kg/day in females based on findings of decreased body weight gain, slight changes in several clinical chemistry parameters, and an increase in vacuolated livers and kidney tubular pigmentation, and a no observable adverse effect level (NOAEL) of 116 mg/kg/day in males and 147 mg/kg/day in females.

3. A 21–day dermal toxicity study in rats fed dosages of 0, 10, 100, or 1,000 mg/kg/day resulted in a NOAEL of 100 mg/kg/day in males and 1,000 mg/kg/day in females. The only treatment-related effect was a decrease in body weight gain of the 1,000 mg/kg/day group in males.

4. A 1–year chronic oral study in dogs fed dosages of 0, 0.25, 1.0, 10.0, and 40.0 mg/kg/day resulted in a LOAEL of 40 mg/kg/day based on decreased weight gains and changes in hematological and blood chemistry parameters in females and a NOAEL of 10 mg/kg/day for systemic toxicity.

5. A 78–week carcinogenicity study was performed on mice fed dosages of 0, 4.0, 41.1, 410.0, and 971.9 mg/kg/day (males) and 0, 5.2, 51.0, 509.1, and 1,214.6 mg/kg/day (females). Males in the 971.6 mg/kg/day group had decreased body weight gains and an increased incidence of microconcretion/mineralization in the testis and epididymis. No treatment-related effects were noted in females. Based on these results, a LOAEL of 971.9 mg/kg/day was established in males and NOAELs of 410 mg/kg/day in males and 1,214.6 mg/kg/day in females were established. The study showed no evidence of carcinogenicity.

6. A combined chronic toxicity/carcinogenicity study in rats fed dosages of 0, 0.44, 4.4, 43.8, 108.3, and 225.2 mg/kg/day (males) and 0, 0.56, 5.6, 53.6, and 138.6 mg/kg/day (females) resulted in a LOAEL of 225.2 mg/kg/day in males and 138.6 mg/kg/day in females based on decreased body weight gains, and a NOAEL of 108.3 mg/kg/day in males and 56.3 mg/kg/day in females. The study showed no evidence of carcinogenicity.

7. A developmental toxicity study in rats fed dosages of 0, 75, 250, and 750 mg/kg/day resulted in a developmental LOAEL of 750 mg/kg/day based on decreases in mean litter size, increased number of resorptions, decreased mean fetal body weight, increases in fetal litter incidences of dilation of the lateral ventricles and other anaomalities in the developmental of the fetal nervous system, and skeletal variations such as anomalities or delays in ossificationin the thoracic vertebrae, sternebrae, and ribs, and a developmental NOAEL of 250 mg/kg/day. The maternal LOAEL was 750 mg/kg/day based on increased incidence of clinical observations, reduced body weight gains, and reduced food consumption and food efficiency. The maternal NOAEL was 250 mg/kg/day.

8. A developmental toxicity study in rabbits fed dosages of 0, 15, 50, and 150 mg/kg/day resulted in a developmental LOAEL of 150 mg/kg/day, based on decreased mean litter size and increases in resorptions, and post-implantation loss, and a developmental NOAEL of 50 mg/kg/day. The maternal LOAEL was 150 mg/kg/day based on reduced body weight gain, reduced food consumption and food efficiency. The maternal NOAEL was 50 mg/kg/day.

9. A dietary 2–generation reproduction study in rats fed dosages of 6.3, 50.4, and 223.2 (males) and 7.4, 58.7, and 261.4 mg/kg/day (females) through 1 breeding and 2 breedings of the offspring from the initial generation (7.4, 61.0, and 274,2 mg/kg/day for males and 8.9, 69.7, and 319.9 mg/kg/day resulted in parental toxicity at 223.2 mg/kg/day in males and 261.4 mg/kg/day in females in the form of decreased body weights, decreased body weight gains, and reduced food consumption during the premating period. Very slight effects were noted in body weights of the offspring at this dose. This effect was considered to be developmental toxicity (developmental delay) rather than a reproductive effect based on general parental systemic toxicity. No effects were noted on reproductive or other developmental toxicity

parameters. The systemic/developmental toxicity LOAEL was 223.2 mg/kg/day in males and 261.4 mg/kg/day in females; the systemic/developmental toxicity NOAEL was 50.4 mg/kg/day in males and 58.7 mg/kg/day in females. The reproductive LOAEL was greater than 223.2 mg/kg/day in males and 261.4 mg/kg/day in females; the reproductive NOAEL was equal to or greater than 223.2 mg/kg/day in males and 261.4 mg/kg/day in females.

10. Bacterial/mammalian microsomal mutagenicity assays were performed and found halosulfuron-methyl not to be mutagenic. Two mutagenicity studies were performed to test gene mutation and found to produce no chromosomal aberrations or gene mutations in cultured Chinese hamster ovary cells. An *in vivo* mouse micronucleus assay did not result in a significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow cells. A mutagenicity study was performed on rats and unscheduled DNA synthesis was not induced in primary rat hepatocytes.

11. In the rat metabolism study, parent compound absorption was rapid but incomplete. Excretion was relatively rapid at all doses tested with a majority of radioactivity eliminated in the urine and feces by 72 hours and appeared to be independent of dose and sex. Fecal elimination of parent was apparently the result of unabsorbed parent.

12. The toxicology studies listed below were conducted with the metabolite, 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid (3-CSA). Based on the toxicological data of the 3-CSA metabolite, EPA concluded that the metabolites have lower toxicity compared to the parent compound and that it should not be included in the tolerance expression. The residue of concern is the parent compound only.

i. A 90–day rat feeding study resulted in a LOAEL in males of >20,000 ppm and a NOAEL of 20,000 ppm (1,400 mg/kg/day). In females, the lowest effect level (LEL) is 10,000 ppm (772.8 mg/kg/day) based on decreased body weight gains and a NOAEL of 1,000 ppm (75.8 mg/kg/day).

ii. A developmental toxicity resulted in a lowest observed effect level (LOEL) for maternal toxicity of >1,000 mg/kg/day based on the absence of systemic toxicity, a NOAEL of 1,000 mg/kg/day. The developmental LOEL is >1,000 mg/kg/day and the NOAEL is 1,000 mg/kg/day.

iii. The microbial reverse gene mutation did not produce any mutagenic effect while the mammalian cell gene mutation/Chinese hamster ovary cells did not show a clear evidence of mutagenic effect in the Chinese hamster ovary cells.

iv. The mouse micronucleus assay did not show any clastogenic or aneugenic effect.

*B. Toxicological Endpoints*

1. *Acute toxicity*. The acute dietary Reference Dose (RfD) of 0.5 mg/kg/day is based on the rabbit developmental NOAEL of 50 mg/kg/day and should be used for assessing acute dietary risks for the sub-populations, Females 13+ as well as Infants and Children. Although, the endpoint is developmental toxicity occurring in utero, and thus may not be suitable for use in risk assessment for Infants and Children, EPA determined that it is appropriate to use for this subpopulation (Infants and Children) because there is evidence of alteration to the development of the fetal nervous system in the developmental toxicity study in rats. Oral administration resulted in dilation of the lateral ventricles, dilation of the third ventricle, spinal cord agenesis, and adrenal agenesis at 750 mg/kg/day; and malformed brain cortex at 250 mg/kg/day in rats only. Thus, EPA determined that potential effects on functional development mandate the use of this endpoint for females of child bearing age (Females 13+) as well as for infants and children.

This endpoint is not applicable for adult males. A dose and endpoint was not identified for this subpopulation since no toxicological effects applicable to adult males and attributable to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits.

2. *Short- and intermediate-term toxicity*. No short- or intermediate-term inhalation toxicity endpoints were identified. The Agency selected a short term dermal endpoint based on the rabbit oral developmental NOAEL of 50 mg/kg/day and a 75% dermal absorption factor instead of the 21–day dermal study because:

i. There is a consistent pattern in the fetal effects (decreased mean litter size, increased number of resorptions, and increased postimplantation loss) observed in 2 species (rats and rabbits) via the oral route.

ii. The developmental effects are considered acute effects and thus are appropriate for this exposure period of concern (i.e., 1–7 days).

iii. The reproductive/fetal parameters are not evaluated in the dermal toxicity study, and thus the consequences of these effects cannot be ascertained for the dermal route of exposure.

iv. This endpoint will provide adequate protection for the subpopulation Female 13+ (i.e., pregnant workers).

Since an oral NOAEL was selected, a dermal absorption factor of 75% should be used for this dermal risk assessment. The Agency estimated a dermal absorption rate of 75% (i.e. a dermal:oral toxicity ratio of 75%) based on the results of an oral developmental toxicity study and a 21–day dermal toxicity study in the same species (rats). In the oral developmental toxicity study, the maternal NOAEL was 250 mg/kg/day and the LOAEL was 750 mg/kg/day based on decreases in body weight gains and food consumption. In the 21–day dermal toxicity study, the systemic toxicity NOAEL was 100 mg/kg/day and the LOAEL was 1,000 mg/kg/day based on decreased body weight gain in males. A ratio of the LOAELs from the oral and dermal studies, indicated an approximate dermal absorption rate of 75% (oral LOAEL of 750 mg/kg/day ÷ dermal LOAEL of 1,000 mg/kg/day x 100 = 75%). This absorption factor may overestimate dermal absorption due to sensitivity differences in toxicity between the sexes (the developmental toxicity LOAEL is in females, and the 21–day dermal toxicity LOAEL is in males).

The Agency selected the intermediate-term endpoint based on the chronic dog NOAEL of 10 mg/kg/day based on decreased body weight gains and changes in hematology and clinical chemistry parameters in females at the LOAEL of 40 mg/kg/day. At 40 mg/kg/day, decreases in body weight gain were seen during study weeks 0–13 in both sexes with the decrease being more pronounced in males (21%) than females (7%). Overall weight gain for the entire study (weeks 0–52) was not significantly affected in male dogs, but was decreased by 16% in female dogs at this dose. EPA selected this dose and endpoint for an intermediate-term risk assessment because the body weight anomalies, observed in both sexes during various phases of the study, meet the exposure period of concern (i.e., 1-week to several months). Since an oral NOAEL was selected, a dermal absorption factor of 75% should be used for this dermal risk assessment.

3. *Chronic toxicity*. EPA has established the RfD for halosulfuron-methyl at 0.1 mg/kg/day. This RfD is based on the chronic dog NOAEL of 10 mg/kg/day with decreased body weight gains and changes in clinical chemistry parameters in females at the LOAEL of 40 mg/kg/day.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in the

mouse or rat. On September 23, 1993, EPA tentatively classified halosulfuron-methyl as a Group E chemical based on the lack of evidence of carcinogenicity in male and female mice and rats. On February 26, 1998, EPA classified halosulfuron-methyl as a Not Likely human carcinogen. There is an adequate mutagenicity data base that shows halosulfuron-methyl is not mutagenic.

*C. Exposures and Risks*

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.479) for the residues of methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4- carboxylate, and its metabolites determined as 3-chloro-1-methyl-5- sulfamoylpyrazole-4-carboxylic acid and expressed as the parent equivalents, in or on a variety of raw agricultural commodities. Tolerances are established on meat by products of cattle, goats, hogs, horses, and sheep at 0.1 ppm. Risk assessments were conducted by EPA to assess dietary exposures from halosulfuron methyl as follows:

i. *Acute exposure and risk.* 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.

The acute dietary RfD of 0.5 mg/kg/day is based on a developmental (rabbit) NOAEL of 50 mg/kg/day and an uncertainty factor of 100. The Agency has determined that a postnatal developmental neurotoxicity study in rats is required for halosulfuron-methyl based on the following weight-of-the-evidence considerations: In the developmental toxicity study in rats, there was evidence of alterations to the development of the fetal nervous system at 750 mg/kg/day (the highest dose tested), including dilation of the lateral ventricles (16 fetuses/5 litters), dilation of the third ventricle (1/1), spinal cord agenesis (1/1), and adrenal agenesis (1/1) at the high dose; and malformed brain cortex (1/1) at 250 mg/kg/day. There was no evaluation of perfused nervous system tissues, since acute and subchronic neurotoxicity studies in rats were not required. The primary concern is the lack of information available in the data base that would allow the determination of whether functional deficits would be observed at dose levels below those which result in frank malformations of the central nervous system. Thus, Agency criteria require that a developmental neurotoxicity study be submitted.

The 10x factor for protection of infants and children (as required by FQPA) should be removed for the following reasons: There was no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to halosulfuron-methyl. In the prenatal developmental toxicity studies in rats and rabbits and the 2–generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

The requirement of a developmental neurotoxicity study in rats did not warrant application of additional safety factors because: (a) The alterations observed in the fetal fetal nervous system occurred in only one species (in rats and not in rabbits); (b) the fetal effects which will be investigated in the required developmental neurotoxicity study were seen only at a dose of 750 mg/kg/day which is close to the limit-dose (1,000 mg/kg/day); (c) there was no evidence of clinical signs of neurotoxicity, brain weight changes, or neuropathology in the subchronic or chronic studies in rats; (d) the developmental neurotoxicity study is required only as confirmatory data to understand what the effect is at a high exposure (dose) level; and (e) exposure assessments do not indicate a concern for potential risk to infants and children based on the results of the field trial studies and the very low application rate (equivalent to 0.06 lbs. active ingredient per acre). Detectable residues are not expected in human foods.

A Dietary Exposure Evaluation Model (DEEM) analysis for halosulfuron-methyl was performed which incorporated proposed permanent tolerances for sweet corn, popcorn, tree nuts, pistachio, and rice; and the revised tolerances for field corn and grain sorghum. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–91 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of halosulfuron-methyl in the commodity supply. This Tier 1 analysis assumed tolerance-level residues for all commodities having halosulfuron-methyl tolerances and 100% of the associated crops received halosulfuron-methyl treatment. The Theoretical Maximum Residue Concentrations (TMRCs) resulting from these assumptions should be considered a very conservative estimate of the exposure. The acute dietary TMRC for the United States (U.S.) population is 0.000304 mg/kg/day or 0.06% of the RfD; 0.000754 or 0.15 non-nursing infants (less than 1 year old and 0.000250 or 0.05% of the RfD for females (13–19 not pregnant/not nursing (np/nn). Refinement of the estimates through the use of percent-of-crop-treated data and anticipated residues will result in lower exposure estimates. Even with these conservative assumptions, the risks from both acute dietary (food only) exposure to halosulfuron-methyl are less than 1% for all population subgroups listed in the DEEM analysis. Therefore, the risk from acute ''food only'' exposure is below the Agency's level of concern (i.e. ≤ 100% of the acute RfD in the absence of additional safety factors, as is the case for halosulfuron-methyl).

ii. *Chronic exposure and risk.* The chronic dietary RfD of 0.1 mg/kg/day is based on the chronic dog study with a NOAEL of 10 mg/kg/day and an uncertainty factor of 100. As discussed above the 10x FQPA safety factor was removed.

A DEEM analysis for halosulfuron-methyl was performed which incorporated proposed permanent tolerances for sweet corn, popcorn, tree nuts, pistachio, and rice; revised tolerances for field corn and grain sorghum; and revoked tolerances for wheat and soybean. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–91 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of halosulfuron-methyl in the commodity supply. This Tier 1 analysis assumed tolerance-level residues for all commodities having halosulfuron-methyl tolerances and 100% of the associated crops received halosulfuron-methyl treatment. The TMRCs resulting from these assumptions should be considered a very conservative estimate of the exposure. The chronic TMRC for the U.S. population is 0.000102 mg/kg/day or 0.1% of the RfD; 0.000158 mg/kg/day or 0.2 of the RfD for all infants (less than 1 year old); 0.000238 or 0.2% of the RfD for children (1–6); and 0.000100 mg/kg/day or 0.1% of the RfD for females (13–19 years not pregnant or nursing). Refinement of the estimates through the use of percent-of-crop-treated data and anticipated residues will result in lower exposure estimates. Even with these conservative assumptions, the risks from chronic dietary (food only) exposure to halosulfuron-methyl are less than 1% for all population subgroups listed in the DEEM analysis. Therefore, the risk from chronic ''food only'' exposure is below the Agency's level of concern (i.e.

≤ 100% of the chronic RfDs in the absence of additional safety factors, as is the case for halosulfuron-methyl).

Short- and intermediate-term exposure and risk. Margins of exposures (MOEs) can be calculated for food as well as residential exposures. The short-term NOAEL for females 13+ and infants and children is 50 mg/kg/day. Comparing the NOAEL of 50 mg/kg/day with the chronic food exposure from the DEEM analysis of 0.00025 mg/kg /day for females 13+ np/nn and 0.00075 mg/kg/day for infants/children results in food MOEs of 200,000 for females 13+ and 67,000 for infant/children.

The intermediate-term NOAEL is based on the chronic dietary NOAEL of 10 mg/kg/day. Comparison of the NOAEL of 10 mg/kg/day with the chronic food exposures from DEEM of 0.00010 for adult males and females 13+ np/nn and 0.00024 mg/kg/day for infants/children result in food MOEs of 100,000 for adult males and females 13+ and 42,000 for infants/children.

2. *From drinking water.* There are no established Maximum Contaminant Levels (MCL) for residues of halosulfuron-methyl in drinking water. It is not listed for MCL development or drinking water monitoring under the Safe Drinking Water Act nor is it a target of EPA's National Survey of Wells for Pesticides. No health advisory levels for halosulfuron-methyl in drinking water have been established. There are no information of any halosulfuron-methyl detections in any wells, ponds, lakes or streams resulting from its use in the United States. No monitoring data on residues of halosulfuron-methyl in surface and ground water are readily available. EPA used the SCI-GROW (Screening Concentration In Ground Water) to estimate residues of halosulfuron-methyl in ground water and the PRZM/EXAMS II to estimate the surface water concentrations. The SCI-GROW model is derived from a maximum 90–day average concentrations from monitoring studies conducted at sites believed to be vulnerable to, and under conditions likely to result in ground water contamination. Since variations in ground water concentrations are generally relatively minor over time periods of interest, the concentrations can be considered both acute and chronic values.

The estimated drinking water environmental concentrations (DWEC) for halosulfuron-methyl in ground water (acute and chronic) is 0.008 µgram/Liter (µg/L). The estimated acute and chronic DWECs for surface water are 4.3 µg/L and 1.1 µg/L, respectively. These estimates are based on a maximum application rate of 0.063 lbs. active ingredient/acre (ai/A) which may be applied twice per use season. Drinking water levels of comparisons (DWLOCs) for acute, short-term, intermediate-term, and chronic exposure were calculated and compared with DWECs. The Agency's default body weights and consumption values used to calculate DWLOCs are 70 kg/2L for adult males; 60 kg/2L for adult females; and 10 kg/1L for children.

i. *Acute exposure and risk.* EPA has calculated a DWLOC for acute exposure to halosulfuron-methyl in drinking water for the relevant population subgroups, females 13+ years of age and infants and children. The acute DWLOC is 15,000 µg/L for females (13+ years old) and 5,000 µg/L for infants and children, which is substantially higher than the DWECs for surface water (4.3 µg/L) and ground water (0.008 µg/L). Acute exposure to halosulfuron-methyl in drinking water is below the calculated drinking water level of concern.

ii. *Chronic exposure and risk.* EPA has calculated the DWLOCs for chronic exposure to halosulfuron-methyl in drinking water. For chronic exposure to halosulfuron-methyl in surface and ground water, the DWLOCs are 3,500 µg/L for the U.S. population (48 states), 3,000 µg/L for females 13+ years and 1,000 µg/L for infants/children, which are substantially higher than the chronic surface water DWEC of 1.1 µg/L and the ground water DWEC of 0.008 µg/L. Chronic exposure to halosulfuron-methyl in drinking water is below the calculated drinking water level of concern.

iii. *Short-term and intermediate-term exposure and risk.* The short-term DWLOCs calculated for drinking water are 10,000 µg/L for females 13+ and 3,700 µg/L for infants and children. The intermediate term DWLOCs calculated for drinking water are 590 µg/L for adult males; 57 µg/L for females (13+ np/nn) and 160 µg/L for infants and children. Intermediate-term DWLOCs are substantially higher than the DWEC for chronic surface water (1.1 µg/L). Short-term DWLOCs substantially higher than the DWEC for acute surface water (4.3 µg/L. Short- and intermediate- term exposures are below the calculated drinking water levels of concern.

3. *From non-dietary exposure.* Halosulfuron-methyl is currently registered for use on the following residential non-food sites: commercial and residential turf and on other non-crop sites including airports, cemeteries, fallow areas, golf courses, landscaped areas, public recreation areas, residential property, road sides, school grounds, sod or turf seed farms, sports fields, landscaped areas, with established woody ornamentals and other similar use sites. For residential handlers and postapplication activities, short- to intermediate-term exposures may occur. Chronic exposures (6 or more months of continuous exposure) are not expected.

i. *Acute exposure and risk.* There is a potential for exposure to halosulfuron-methyl by homeowner mixer/loaders. However, since endpoints for acute dermal or inhalation were not identified, the use on residential non-food sites is not expected to pose an unacceptable acute risk.

ii. *Chronic exposure and risk.* Chronic exposures for residential use are not expected. A chronic non-dietary endpoint was not identified, therefore the use on residential non-food sites is not expected to pose an unacceptable chronic risk.

iii. *Short- and intermediate-term exposure and risk.* There is a potential for short-term and intermediate-term dermal exposure to residential handlers. Chemical specific or site specific data are not available to assess residential exposure to residues of halosulfuron-methyl on turf, therefore, the DRAFT Standard Operating Procedures (SOP) for Residential Exposure Assessments were employed to assess the following postapplication exposure scenarios: (a) dermal exposure from pesticide residues on turf; (b) children's incidental nondietary ingestion of pesticide residues on residential lawn from hand-to-mouth transfer; and (c) children's ingestion of pesticide-treated turfgrass.

For residential handlers the default assumptions for area treated and exposure duration time were selected from the DRAFT SOP for Residential Exposure Assessments (December 18, 1997). The SOP does not list a mixer/loader/applicator scenario for dry flowable (water-dispersible granule). Therefore, the unit exposure for ''garden hose end sprayer/liquid/open pour (MLAP)'' was selected as a default value. Based on Pesticide Handlers Exposure Data (PHED), a liquid formulation is believed to have a higher dermal exposure potential than a dry flowable. Default assumptions were used with the maximum application rate on the label to estimate residential handler exposure to halosulfuron-methyl. According to Table A–1 of the SOPs for Residential Exposure Assessments, the method used for estimating residential applicator exposure is believed to produce a central tendency to high-end estimate of exposure.

The short-term dermal MOE for residential handlers (60 kg adult) is 4,200. This MOE is greater than 100 and therefore does not exceed EPAs level of concern.

For adult and children postapplication scenarios the default assumptions, such as dermal transfer coefficient, exposure time, hand surface area, ingestion frequency, residue dissipation, and ingestion rates, were selected from the DRAFT SOPs for Residential Exposure Assessments (December 18, 1997). The dislodgeable foliar residue value used for intermediate exposure estimates was based on the average of the first 10–days (20% for fraction of ai retained on the foliage and 10% for fraction of residue that dissipates daily). Default assumptions were used with the maximum application rate on the label to estimate postapplication exposure to children and adults from treated lawns. According to Table A–1 of the SOP's for Residential Exposure Assessments, the method used for estimating postapplication exposure is believed to produce a high-end estimate of exposure.

The short-term dermal exposure and risk from treated lawn MOEs for adult females, adult males, and children are 330, 390, and 420, respectively. The intermediate-term dermal MOEs for adult females, adult males, and children are 100, 120, and 130, respectively. Both short and intermediate-term dermal MOEs are 100 or greater, and therefore do not exceed EPA's level of concern.

The short- and intermediate-term oral exposure and risk for hand to mouth transfer MOEs for children are 4,900 and 1,500, respectively. Both short and intermediate-term oral MOEs are greater than 100, and therefore do not exceed EPA's level of concern.

The short- and intermediate-term oral exposure and risk incidental ingestion MOEs for children are 210,000 and 66,000, respectively. Both short and intermediate MOEs are greater than 100, and therefore do not exceed EPAs level of concern.

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

EPA does not have, at this time, available data to determine whether halosulfuron-methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, halosulfuron-methyl 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 halosulfuron-methyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

*D. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute risk.* Acute aggregate risk includes exposure form food + water. The risk from acute ''food only'' exposure is less than 1% of the RfD for all population subgroups which is less than the Agency's level of concern (100% of the RfD). The lowest DWLOC calculated was 5,000 µg/L for infants/children. The DWLOC calculated for females (13+ np/nn) was 15,000 µg/L. Both of these levels are higher than the DWLOC for acute surface water (4.3 µg/L) and ground water (0.008 µg/L). Therefore, the risk from aggregate exposure to halosulfuron-methyl does not exceed EPAs level of concern.

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to halosulfuron-methyl from food will utilize 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1–6) which utilizes 0.2% of the RfD as discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to halosulfuron-methyl in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to halosulfuron-methyl residues.

3. *Short- and intermediate-term exposure and risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short-term and intermediate-term residential exposure. For halosulfuron-methyl, EPA has determined that it is appropriate to aggregate exposure via the oral route (from food and water) with those via oral and dermal routes from residential uses. The MOEs can be calculated for dietary as well as residential exposures. However, there are no drinking water estimates (only estimates of surface water). Assuming a minimum Aggregate MOE of 100, short-term DWLOC was calculated. MOEs for ''food only'' and residential exposures are 200,000 and 310 for females 13+. The short-term DWLOC for females 13+ years is 10,000 µg/L. Short-term aggregate DWLOCs are substantially higher than the DWEC for acute surface water (4.3 µg/L). The food and residential (oral and dermal) MOEs are well above the acceptable short-term aggregate MOE of 100. Therefore, short-term aggregate risk does not exceed EPA's level of concern. These estimates of food and residential exposure are considered to be somewhat conservative.

Intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus intermediate-term residential uses. The MOEs for ''food only'' and residential exposures are 100,000 and 120 for adult males, 100,000 and 102 for females 13+. The intermediate-term DWLOCs are 590 µg/L and 57 µg/L, respectively for adult males and females 13+ years. Intermediate-term DWLOCs are substantially higher than the DWEC for chronic surface water (1.1 µg/L). The MOEs for food only and residential exposure (dermal) are higher than 100. Therefore, intermediate-term aggregate risk does not exceed EPA's level of concern.

4. *Aggregate cancer risk for U.S. population.* EPA has classified halosulfuron-methyl as a ''not likely'' carcinogen (no evidence of carcinogenicity to humans) based on the lack of evidence of carcinogenicity in mice and rats and therefore has a reasonable certainty that no harm will result from exposure to residues of halosulfuron-methyl.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to halosulfuron-methyl residues.

*E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of halosulfuron-methyl, EPA considered

data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base 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. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Pre- and postnatal sensitivity*. Based on the developmental and reproductive toxicity studies, there is no indication of increased sensitivity of rats or rabbits to in utero and/or postnatal exposure to halosulfuron-methyl. In these studies, the effects in the fetuses/offspring was observed only at or above treatment levels which resulted in evidence of parental toxicity.

The EPA determined that a postnatal developmental neurotoxicity study in rats is required based on the following weight-of-evidence considerations: (a) In the developmental toxicity study in rats, there was evidence of alterations to the development of the fetal nervous system at 750 mg/kg/day (highest dose tested) including dilation of the lateral ventricles (16 fetuses/5 litters), dilation of the third ventricle (1/1), spinal cord agenesis (1/1) and adrenal agenesis (1/1) at the high dose; and malformed brain cortex (1/1) at 250 mg/kg/day; (b) There was no evaluation of perfused nervous system tissues, since acute and subchronic neurotoxicity studies in rats were not required. The primary concern is the lack of information in the data base that would allow the determination of whether functional deficits would be observed at dose levels below those which result in frank malformations of the central nervous system.

iii. *Conclusion*. Except for the pending requirements for a developmental neurotoxicity study, the toxicity data base is complete for halosulfuron-methyl and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. EPA concludes, based on reliable data, that use of the standard margin of safety will be safe for infants and children without the addition of another tenfold factor. The requirement of a developmental neurotoxicity study in rats did not warrant application of additional safety factor because: (a) the alterations observed in the fetal nervous system occurred in only one species (in rats and not in rabbits); (b) the fetal effects which will be investigated in the required developmental neurotoxicity study were seen only at a dose of 750 mg/kg/day which is close to the limit-dose (1,000 mg/kg/day); (c) there was no evidence of clinical signs of neurotoxicity, brain weight changes, or neuropathology in the subchronic or chronic studies in rats; (d) the developmental neurotoxicity study is required only as confirmatory data to understand what the effect is at a high exposure (dose) level; and (e) exposure assessments do not indicate a concern for potential risk to infants and children based on the results of the field trial studies and the very low application rat (0.06 lbs ai/A). Detectable residues are not expected in human foods.

2. *Acute risk*. The acute dietary RfD was determined to be 0.5 mg/kg/day based on the NOAEL from the developmental rabbit study (50 mg/kg/day) and a safety factor of 100. Based on the high-end exposures, the percent of the RfD occupied for the U.S. population was 0.06%, 0.15% for non-nursing infants (<1 year old) and 0.05% females 13+ years old. The subgroup with the highest exposure was the non-nursing infants (<1 year old). The drinking water level of comparison (DWLOC) for acute exposure to halosulfuron-methyl residues for infants/children is 5,000 µg/L. The maximum concentration of halosulfuron-methyl in drinking water (4.3 µg/L) is less than EPA's level of comparison for halosulfuron-methyl in drinking water as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that the potential risk from aggregate acute exposure (food and water) would not exceed the Agency's level of concern.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to halosulfuron-methyl from food will utilize 0.2% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to halosulfuron-methyl in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. An aggregate exposure estimate and risk assessment was calculated for postapplication exposure to halosulfuron from treated lawns. Short-term MOEs for food, residential oral, and residential dermal are 67,000, 5,000, and 420 respectively, for infants and children. The intermediate-term MOEs for food, residential oral, and residential dermal are 42,000, 1,500, and 130, respectively for infants and children. The short and intermediate-term DWLOCs for infants and children were 3,700 and 160 mg/L, respectively. The short and intermediate DWLOCs are substantially higher than the DWECs for acute surface water (4.3 µg/L) and chronic surface water (1.1 µg/L). The food and residential MOEs are above the acceptable aggregate MOE of 100. Therefore, short-and intermediate-term aggregate risk does not exceed EPAs level of concerns for infants and children.

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

## III. Other Considerations

### *A. Metabolism In Plants and Animals*

Plant metabolism studies have been submitted and reviewed for corn, sugarcane, and soybean. These studies show that the primary residue resulting from preemergence applications is 3-chlorosulfonamide acid. With postemergence application, the major residue is parent halosulfuron-methyl, except in corn, in which 3-chlorosulfonamide acid predominates. Inadvertent residues in rotational crops are also primarily 3-chlorosulfonamide acid. However, 3-chlorosulfonamide acid is not of toxicological concern and the residue to be regulated in plants is halosulfuron-methyl per se, as

determined by the HED Metabolism Committee.

Goat and hen metabolism studies on halosulfuron-methyl have been accepted by EPA. As with plants, the residue of concern in animals is halosulfuron-methyl per se. The current Agency-approved method for enforcement of tolerances for halosulfuron-methyl in animal commodities is based on analysis of the chlorosulfonamide half of the halosulfuron-methyl molecule; thus, it quantitates residues of parent halosulfuron-methyl as well as those metabolites containing the chlorosulfonamide acid moiety (i.e., it is not specific to halosulfuron-methyl per se.) The requested uses are not expected to increase the residues in animal commodities above those already regulated by 40 CFR 180.479. Animal tolerances will still be expressed as halosulfuron-methyl and its metabolites determined as 3-chlorsulfonic acid, expressed as parent equivalent.

*B. Analytical Enforcement Methodology*

Adequate analytical methodology (gas chromatography with electron capture detection) is available for enforcement of tolerances for halosulfuron-methyl in animal commodities. Adequate analytical methology (gas chromatography/thermionic specific is available for enforcement of tolerances for halosulfuron in plant commodities.

Adequate enforcement methodology (gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

*C. Magnitude of Residues*

The available crop field trial data support the establishment of tolerances for residues of the herbicide halosulfuron-methyl, [methyl 5-[( 4,6-dimethoxy-2-pyrimidinyl) amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate] in or on the raw agricultural commodities almond, hull at 0.2 part per million (ppm); corn, field, fodder at 0.8 ppm; corn, field, forage at 0.2 ppm; corn, field, grain at 0.05 ppm; corn, pop, fodder at 0.8 ppm; corn, pop, grain at 0.05 ppm; corn, sweet, fodder, at 0.8 ppm; corn, sweet forage at 0.2 ppm; corn, sweet, kernel + cob with husks removed at 0.05 ppm; cotton, gin by products at 0.05 ppm; cotton, undelinted seed at 0.05 ppm; pistachio, nutmeat at 0.05 ppm rice, grain at 0.05 ppm, rice, straw at 0.2 ppm; sorghum, grain, fodder/stover at 0.1 ppm sorghum, grain, forage at 0.05 ppm, sorghum, grain, grain at 0.05 ppm; sugarcane, cane at 0.05 ppm; and tree nuts (crop group 14), nutmeat at 0.05 ppm.

The available crop residue data also support the deletion of the current established tolerances for soybean, forage at 0.5 ppm; soybean, hay at 0.5 ppm; soybean, seed at 0.5 ppm wheat, forage at 0.1 ppm; wheat, grain at 0.1 ppm; and wheat, straw at 0.2 ppm.

*D. International Residue Limits*

There are no CODEX, Canadian, or Mexican maximum residue limits (MRLs ) established for halosulfuron-methyl, therefore harmonization is not an issue.

*E. Rotational Crop Restrictions*

Tolerances were previously established for inadvertent residues in rotational crops. These tolerances were based on residues of 3-chlorosulfonamide acid which is not of toxicological concern and is no longer being regulated by EPA in plant commodities. Therefore, rotational crop tolerances are not necessary and are being deleted by this rule.

## IV. Conclusion

Therefore, tolerances are established for residues of methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate in almond, hulls at 0.2 ppm; corn, field, fodder at 0.8 ppm; corn, field, forage at 0.2 ppm; corn, field, grain at 0.05 ppm; corn, pop, fodder at 0.8 ppm, corn, pop, grain at 0.05 ppm; corn, sweet, fodder/stover at 0.8 ppm; corn, sweet, forage at 0.2 ppm; corn, sweet, kernel + cob with husks removed at 0.05 ppm; cotton, gin by-products at 0.05 ppm; cotton, undelinted seed at 0.05 ppm; pistachio, nutmeat at 0.05 ppm; rice, grain at 0.05 ppm; rice, straw at 0.2 ppm; sorghum, grain, fodder/stover at 0.1 ppm; sorghum; grain, forage at 0.05 ppm sorghum, grain, grain at 0.05 ppm; sugarcane, cane at 0.05 and tree nuts (crop group 14), nutmeat at 0.05 ppm.

These entries for corn, field, fodder, corn, field, forage; corn, field, grain; sorghum, grain, fodder/stover; sorghum, grain, forage; and sorghum, grain, grain will replace current entries for these commodities.

Established tolerances for indirect or inadvertent residues of the herbicide halosulfuron-methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole- 4-carboxylate, and its metabolites determined as the 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid and expressed as parent equivalents in on the following raw agricultural commodities when present to growing crops: soybean, forage at 0.05 ppm; soybean, hay at 0.5 ppm; soybean, seed at 0.5 ppm; wheat, forage at 0.1 ppm wheat, grain at 0.1 ppm, and wheat, straw at 0.1 ppm are being deleted.

## V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 12, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the **ADDRESSES** section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollies, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

## VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300854] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

## VII. Regulatory Assessment Requirements

### *A. Certain Acts and Executive Orders*

This final rule establishes, modifies, and revokes 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 determined that tolerance actions, in general, are ''not significant'' unless the action involves the revocation of a tolerance that may result in a substatial adverse and material affect on the economy. This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (P.A.), 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) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established, modified or revoked on the basis of a petition under FFDCA section 408(d), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

### *B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

### *C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of

Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

### VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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 the rule in the **Federal Register**. This 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: April 29, 1999.

**James Jones,**

*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 180.479, is revised to read as follows:

#### § 180.479 Halosulfuron; tolerances for residues.

(a) General. (1) Tolerances are established for residues of the herbicide halosulfuron, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino] carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid and expressed as parent equivalents, in or on the raw agricultural commodities listed below.

| Commodity | Parts per million |
|---|---|
| Cattle, mybp | 0.1 |
| Goats, mbyp | 0.1 |
| Hogs, mbyp | 0.1 |
| Horses, mbyp | 0.1 |
| Sheep, mbyp | 0.1 |

(2) Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonylaminosulfonyl-3-chloro-1-methyl-1*H*-pyrazole- 4-carboxylate, in or on the raw agricultural commodities listed below.

| Commodity | Parts per million |
|---|---|
| Almond, hulls | 0.2 |
| Corn, field, fodder | 0.8 |
| Corn, field, forage | 0.2 |
| Corn, field, grain | 0.05 |
| Corn, pop, fodder | 0.8 |
| Corn, pop, grain | 0.05 |
| Corn, sweet, fodder/stover | 0.8 |
| Corn, sweet, forage | 0.2 |
| Corn, sweet, kernel + cob with husks removed | 0.05 |
| Cotton, gin by-products | 0.05 |
| Cotton, undelinted seed | 0.05 |
| Pistachio, nutmeat | 0.05 |
| Rice, grain | 0.05 |
| Rice, straw | 0.2 |
| Sorghum, grain, fodder/stover | 0.1 |
| Sorghum, grain, forage | 0.05 |
| Sorghum, grain, grain | 0.05 |
| Sugarcane, cane | 0.05 |
| Tree nuts (crop group 14), nutmeat | 0.05 |

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

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

(d) *Indirect or inadvertent residues.* [Reserved]

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300840; FRL–6074–2]**

**RIN 2070–AB78**

## Azoxystrobin; Extension of Tolerance for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation extends a time-limited tolerance for combined residues of the fungicide azoxystrobin and its metabolites in or on watercress at 1.0 part per million (ppm) for an additional 18–month period. This tolerance will expire and is revoked on October 30, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on watercress. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

**DATES:** This regulation becomes effective May 12, 1999. Objections and requests for hearings must be received by EPA, on or before July 12, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300840], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300840], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.