

relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 9, 2009.

**Steven Bradbury,**

*Acting Director, Office of Pesticides Program.*

■ 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 180.648 is added to subpart C to read as follows:

**§180.648 Meptyldinocap; tolerances for residues.**

(a) *General.* Tolerances are established for the combined residues of the fungicide meptyldinocap, 2-(1-methylheptyl)-4,6-dinitrophenyl (2E)-2-butenolate and 2,4-DNOP, 2,4-dinitro-6-(1-methylheptyl)phenol expressed as meptyldinocap in or on the following commodities:

Commodity	Parts Per Million
Grape	0.20

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

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

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

[FR Doc. E9-22523 Filed 9-22-09; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2009-0003; FRL-8436-7]**

**Halosulfuron-methyl; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of halosulfuron-methyl and its metabolites and degradates, in or on soybean, seed. Canyon Group, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0003. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available,

e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: [stanton.susan@epa.gov](mailto:stanton.susan@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 those engaged in the following activities:

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

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

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet

under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0003 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 as required by 40 CFR part 178 on or before November 23, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0003, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

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

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

## II. Petition for Tolerance

In the **Federal Register** of April 8, 2009 (74 FR 15971) (FRL–8407–4), EPA

issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7424) by Canyon Group, LLC, c/o Gowan Company, 370 South Main St., Yuma, AZ 85364. The petition requested that 40 CFR 180.479 be amended by establishing a tolerance for residues of the herbicide halosulfuron-methyl, methyl 3-chloro-5-(4,6-dimethoxyprimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylic acid, in or on soybean at 0.05 parts per million (ppm). That notice referenced a summary of the petition prepared by Canyon Group, LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

EPA has revised the proposed commodity term from “soybean” to “soybean, seed” to agree with the Agency’s Food and Feed Commodity Vocabulary. EPA has also revised the tolerance expressions for the existing plant and livestock commodity tolerances and the new tolerance on soybean, seed. The reasons for these changes are explained in Unit IV.C.

### III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for

tolerance for residues of halosulfuron-methyl and its metabolites and degradates on soybean, seed at 0.05 ppm. EPA’s assessment of exposures and risks associated with establishing tolerances follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Halosulfuron-methyl has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is non-irritating to the skin and eyes and is not a dermal sensitizer. With repeated dosing, the available data show that the dog is the most sensitive mammalian species. In the dog, decreased body weight was seen in the chronic oral toxicity study and decreased body weight gain was observed in females in the subchronic oral toxicity study. In the rat and mouse, there was a non-specific decrease in body weight gain at high dose levels in short-term and long-term oral and dermal studies. Halosulfuron-methyl is classified as “not likely to be carcinogenic to humans” based on a lack of evidence for carcinogenicity in mice and rats following long-term dietary administration. Halosulfuron-methyl is negative for mutagenicity in a battery of mutagenicity studies. There is no evidence of immunotoxicity or neurotoxicity in the available studies for halosulfuron-methyl.

There was no quantitative evidence for increased susceptibility of fetuses or offspring following prenatal and/or postnatal exposure to halosulfuron-methyl in the developmental and reproductive toxicity studies. However, there was qualitative evidence for increased susceptibility. In the rat developmental toxicity study, increased fetal and litter incidences of soft tissue (dilation of the lateral ventricles) and skeletal variations, and decreased mean fetal body weight and mean litter size were seen at a dose resulting in less severe maternal effects (increased incidence of clinical observations, reduced body weight gains, reduced food consumption and food efficiency). In the rabbit study, increases in resorptions and post-implantation losses and a decrease in mean litter size were seen in the presence of decreases in body weight and food consumption in maternal animals. Thus, in both species,

the developmental effect was considered to be qualitatively more severe than maternal effects. In the reproduction study in rats, parental effects (decreased body weights, body weight gains, and reduced food consumption during the pre-mating period in both sexes) were comparable in severity to offspring effects (decreased body weight in the F1 pups and marginal decreased body weight in F2 pups).

Specific information on the studies received and the nature of the adverse effects caused by halosulfuron-methyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document, *Halosulfuron-methyl: Human Health Risk Assessment for Proposed Uses on Soybean*, page 36 in docket ID number EPA-HQ-OPP-2009-0003.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus,

the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for halosulfuron-methyl used for human risk assessment can be found at <http://www.regulations.gov> in the document, *Halosulfuron-methyl: Human Health Risk Assessment for Proposed Uses on Soybean*, page 13 in docket ID number EPA-HQ-OPP-2009-0003.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to halosulfuron-methyl, EPA considered exposure under the petitioned-for tolerance as well as all existing halosulfuron-methyl tolerances in 40 CFR 180.479. EPA assessed dietary exposures from halosulfuron-methyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects (decreased mean litter size, increased number of resorptions and increased postimplantation loss, assumed to occur after a single exposure) were identified for the population subgroup females 13 to 49 years old. No such effects were identified for the general population, including infants and children.

In estimating acute dietary exposure of females 13 to 49 years old, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994-1996 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all existing and new uses of halosulfuron-methyl.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT for all existing and new uses of halosulfuron-methyl.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA classified halosulfuron-methyl as "not likely to be carcinogenic to humans." Therefore, an exposure

assessment to evaluate cancer risk is unnecessary for this chemical.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for halosulfuron-methyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for halosulfuron-methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of halosulfuron-methyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of halosulfuron-methyl for acute exposures are estimated to be 8.3 parts per billion (ppb) for surface water and 0.065 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 1.7 ppb for surface water and 0.065 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration value of 59.2 ppb was used to assess the contribution from drinking water. This value is substantially higher than the modeled EDWCs for acute and chronic exposures (8.3 ppb and 1.7 ppb, respectively) and was derived from preliminary modeling using a different model (a Tier one rice model). This model overestimates levels that would occur in drinking water, because it does not consider the degradation of the pesticide or the dilution of the pesticide as it is transported away from the rice field into the drinking water source. The Agency has concluded that the EDWCs derived using the FIRST model and based on the crop scenarios corn and sugarcane provide a more reasonable high end estimate of expected levels in surface water used for drinking water. However, since acute and chronic exposure estimates using the higher value are below EPA's LOC, EPA did not revise the dietary exposure assessment to incorporate the lower EDWCs.

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).

Halosulfuron-methyl is currently registered for the following uses that could result in residential exposures: Residential turfgrass and ornamentals. EPA assessed residential exposure using the following assumptions: Residential handlers may receive short-term dermal and inhalation exposure to halosulfuron-methyl when mixing, loading and applying halosulfuron-methyl products. Adults and children may be exposed to halosulfuron-methyl residues through dermal contact with turf during post-application activities. In addition, toddlers may receive short-term and intermediate-term oral exposure from incidental ingestion during post-application activities. EPA assessed short-term dermal and inhalation exposure of residential handlers and the following post-application exposure scenarios:

- i. Adult and toddler post-application dermal exposure
- ii. Toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer.
- iii. Toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass.
- iv. Toddlers' incidental ingestion of soil from pesticide-treated residential areas.
- v. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found halosulfuron-methyl to share a common mechanism of toxicity with any other substances, and halosulfuron-methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that halosulfuron-methyl does not have 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for halosulfuron-methyl includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A., there was qualitative evidence of increased susceptibility of fetuses in the rat and rabbit developmental studies. Fetal effects (increased incidences of soft tissue and skeletal variations, decreased mean fetal body weight and mean litter size in the rat study; increases in resorptions and post-implantation losses and a decrease in mean litter size in the rabbit study) occurred at doses resulting in less severe maternal toxicity (increased incidence of clinical observations, reduced body weight gains, reduced food consumption and food efficiency in the rat study; decreases in body weight and food consumption in the rabbit study). The degree of concern for these effects is low, and there are no residual uncertainties for prenatal toxicity in rats and rabbits for the following reasons. In both studies, there are clear NOAELs/LOAELs for developmental and maternal toxicities; developmental effects were seen in the presence of maternal toxicity; and effects were seen only at the high dose. Additionally, in rats, developmental effects were seen at a dose which is approaching the limit-dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for halosulfuron-methyl is adequate to assess prenatal and postnatal toxicity. In accordance with 40 CFR part 158 Toxicology Data requirements, an

immunotoxicity study (870.7800) is required for halosulfuron-methyl. In the absence of specific immunotoxicity studies, EPA has evaluated the available halosulfuron-methyl toxicity data to determine whether an additional uncertainty factor is needed to account for potential immunotoxicity. The toxicology database for halosulfuron-methyl does not show any evidence of biologically relevant effects on the immune system following exposure to this chemical. The overall weight-of-evidence suggests that this chemical does not directly target the immune system. Based on these considerations, EPA does not believe that conducting immunotoxicity testing will result in a point of departure lower than those already selected for halosulfuron-methyl risk assessment, and an additional database uncertainty factor is not needed to account for the lack of this study.

ii. There is no indication that halosulfuron-methyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is evidence of increased qualitative susceptibility in *in utero* rats and rabbits in the prenatal developmental studies, the degree of concern for developmental effects is low, and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of halosulfuron-methyl.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to halosulfuron-methyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by halosulfuron-methyl.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of

additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to halosulfuron-methyl will occupy <1% of the aPAD for females 13 to 49 years old, the only population group for which acute exposure is of toxicological concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to halosulfuron-methyl from food and water will utilize 1.6% of the cPAD for the general U.S. population and 4.6% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of halosulfuron-methyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Halosulfuron-methyl is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to halosulfuron-methyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs ranging from 2,800 (infants less than 1 year old) to 4,800 (females, 13 to 49 years old). The aggregate MOEs for adults include short-term dermal and inhalation exposures for residential handlers and post-application dermal exposures from activities on turfgrass previously treated with halosulfuron-methyl. The aggregate MOEs for children's subgroups include short-term post-application dermal and incidental oral exposures from activities on halosulfuron-methyl-treated turfgrass.

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

Halosulfuron-methyl is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure to halosulfuron-methyl through food and water with intermediate-term exposures for halosulfuron-methyl.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs ranging from 500 (U.S. population, females 13 to 49 years old, and adults 50 years and older) to 700 (infants less than 1 year old). The aggregate MOEs for adults include intermediate-term dermal and inhalation exposures for residential handlers and post-application dermal exposures from activities on turfgrass previously treated with halosulfuron-methyl. The inclusion of intermediate-term residential handler exposures in the aggregate MOE is conservative (protective), since intermediate-term exposure of handlers is unlikely. The aggregate MOEs for children's subgroups, including infants, include intermediate-term post-application dermal and incidental oral exposures from activities on halosulfuron-methyl-treated turfgrass.

5. *Aggregate cancer risk for U.S. population.* Based on a lack of evidence for carcinogenicity in mice and rats following long-term dietary administration, halosulfuron-methyl is not expected to pose a cancer risk.

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, or to infants and children from aggregate exposure to halosulfuron-methyl residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography, Monsanto Analytical Method RES-109-97-4) is available to enforce the tolerance. 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: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residues limits (MRLs) for halosulfuron-methyl.

##### C. Revisions to Petitioned-For Tolerance

EPA has revised the proposed commodity term from "soybean" to "soybean, seed" to agree with the Agency's Food and Feed Commodity Vocabulary. EPA is also revising the tolerance expression for soybean, seed and the existing plant and livestock commodities to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression for plants makes clear that the tolerances cover "residues of halosulfuron-methyl and its metabolites and degradates" and that compliance with the tolerance levels will be determined by measuring only halosulfuron-methyl. The revised tolerance expression for livestock commodities makes clear that the tolerances cover residues of halosulfuron-methyl and its metabolites and degradates and that compliance with the tolerance levels will be determined by measuring only those halosulfuron-methyl residues convertible to 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as the stoichiometric equivalent of halosulfuron-methyl. EPA is also revising the chemical name for halosulfuron-methyl to conform to the nomenclature recommendations of the Chemical Abstracts Service (CAS): methyl 3-chloro-5-[[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl] amino] sulfonyl]-1-methyl-1H-pyrazole-4-carboxylate.

EPA has determined that it is reasonable to make these changes in the tolerance expression final without prior proposal and opportunity for comment, because public comment is not necessary, in that the changes have no substantive effect on the tolerance, but rather are merely intended to clarify the existing tolerance expression.

#### V. Conclusion

Therefore, a tolerance is established for residues of halosulfuron-methyl and its metabolites and degradates on soybean, seed at 0.05 ppm. Compliance with the tolerance level will be determined by measuring only halosulfuron-methyl, methyl 3-chloro-5-[[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl] amino] sulfonyl]-1-methyl-1H-pyrazole-4-carboxylate, in or on the commodity.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and

Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCa, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCa. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian

tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 15, 2009.

**Rachel C. Holloman,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.479 is amended by revising the introductory text of paragraphs (a)(1) and (a)(2) and alphabetically adding an entry for “soybean, seed” to the table in paragraph (a)(2) to read as follows:

**§ 180.479 Halosulfuron-methyl; tolerances for residues.**

(a)\* \* \* (1) Tolerances are established for residues of the herbicide halosulfuron-methyl, methyl 3-chloro-5-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl] amino] sulfonyl]-1-methyl-1*H*-pyrazole-4-carboxylate, and its metabolites and degradates in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only those halosulfuron-methyl residues convertible to 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, expressed as the stoichiometric equivalent of halosulfuron-methyl, in or on the commodity.

\* \* \* \* \*

(2) Tolerances are established for residues of the herbicide halosulfuron-methyl and its metabolites and degradates in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only halosulfuron-methyl, methyl 3-chloro-5-[[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl] amino] sulfonyl]-1-methyl-1*H*-pyrazole-4-carboxylate, in or on the commodity.

Commodity	Parts per million
Soybean, seed .....	0.05

\* \* \* \* \*

[FR Doc. E9-22915 Filed 9-22-09; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2008-0810; FRL-8434-2]

**Spinosad; Pesticide Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of spinosad in or on date and pomegranate, and additionally increases established tolerances in or on almond hulls; tree nut, group 14; and pistachio. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0810. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(703) 305-7390; e-mail address: [nollen.laura@epa.gov](mailto:nollen.laura@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 those engaged in the following activities:

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

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

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-

OPP-2008-0810 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 as required by 40 CFR part 178 on or before November 23, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0810, by one of the following methods:

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

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

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

**II. Petition for Tolerance**

In the **Federal Register** of December 3, 2008 (73 FR 73648) (FRL-8391-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7445) by IR-4, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.495 be amended by establishing tolerances for residues of the insecticide, spinosad, a fermentation product of *Saccharopolyspora spinosa*, consisting of two related active ingredients: Spinosyn A (Factor A; CAS#131929-60-7) or 2-[[6-deoxy-2,3,4-tri-*O*-methyl- $\alpha$ -*L*-manno-pyranosyl]oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indacen[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS#131929-63-0) or 2-[[6-deoxy-2,3,4-tri-*O*-methyl- $\alpha$ -*L*-manno-pyranosyl]oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-