continue to attain the 1997 8-hour ozone NAAQS.

VI. Statutory and Executive Order Reviews

These actions make determinations of attainment based on air quality, result in the suspension of certain federal requirements, grant attainment date extensions, and/or would not impose additional requirements beyond those imposed by state law. For that reason, these actions:

- Are not ''significant regulatory actions'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Do not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, these actions do not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP obligations discussed herein do not apply to Indian Tribes and thus will not impose substantial direct costs on Tribal governments or preempt Tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 1, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 19, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.282 is amended by adding paragraph (e) to read as follows:

§ 52.282 Control Strategy and regulations: Ozone.

* * * * *

(e) *Determinations of Attainment:* Effective January 2, 2013.

(1) *Approval of applications for extensions of applicable attainment dates.* Under section 181(a)(5) of the Clean Air Act, EPA is approving the applications submitted by the California Air Resources Board dated March 23, 2010 and May 24, 2010 for extensions of the applicable attainment date for the Mariposa and Tuolumne Counties and Nevada County 8-hour ozone nonattainment areas, respectively, from June 15, 2010 to June 15, 2011.

(2) *Determinations of attainment by the applicable attainment dates.* EPA has determined that the Amador and Calaveras Counties, Chico, Kern County, Mariposa and Tuolumne Counties, Nevada County, and Sutter County 8-hour ozone nonattainment areas in California attained the 1997 8-hour ozone national ambient air quality standard (NAAQS) by their applicable attainment dates. The applicable attainment dates are as follows: Amador and Calaveras Counties (June 15, 2010), Chico (June 15, 2007), Kern County (June 15, 2010), Mariposa and Tuolumne Counties (June 15, 2011), Nevada County (June 15, 2011), and Sutter County (June 15, 2007).

(3) *Determinations of attainment.* EPA is determining that the Amador and Calaveras Counties, Chico, Kern County, Mariposa and Tuolumne Counties, Nevada County, Sutter County and Ventura County 8-hour ozone nonattainment areas have attained the 1997 8-hour ozone standard, based upon complete quality-assured data for 2009–2011. Under the provisions of EPA's ozone implementation rule (see 40 CFR 51.918), these determinations suspend the attainment demonstrations and associated reasonably available control measures, reasonable further progress plans, contingency measures, and other planning SIPs related to attainment for as long as the areas continue to attain the 1997 8-hour ozone standard. If EPA determines, after notice-and-comment rulemaking, that any of these areas no longer meets the 1997 ozone NAAQS, the corresponding determination of attainment for that area shall be withdrawn.

* * * * *

[FR Doc. 2012–29013 Filed 11–30–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0781; FRL–9370–6]

Halosulfuron-Methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of halosulfuron-methyl in or on multiple commodities which are identified and discussed later in this document. Canyon Group L.L.C., c/o Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 3, 2012. Objections and requests for hearings must be received on or before February 1, 2013, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0781, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Maggie Rudick, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0257; email address: *rudick.maggie@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2011–0781 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 1, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0781, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of December 8, 2011 (75 FR 76676) (FRL–9328–8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7916) by Canyon Group L.L.C., c/o Gowan Company, 370 South Main St., Yuma, AZ 85364. The petition requested that 40 CFR 180.479 be amended by establishing tolerances for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonylamino sulfonyl]-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, in or on millet, proso, forage at 7.0 parts per million (ppm); millet, proso, hay at 0.02 ppm; millet, proso, grain at 0.01 ppm; millet, proso, straw at 0.01 ppm; grass, forage, fodder, and hay, group 17, forage at 17 ppm; and grass, forage, fodder, and hay, group 17, hay at 0.90 ppm. That document referenced a summary of the petition prepared by Canyon Group, L.L.C., the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels, determined that established tolerances for certain livestock commodities should be increased and multiple new livestock commodity tolerances should be established. The reasons for these changes are explained in Unit IV.D.

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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 and to make a determination on aggregate exposure for halosulfuron-methyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with halosulfuron-methyl 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 a low acute toxicity via the oral, dermal, and inhalation routes of exposure. Halosulfuron-methyl is a non-irritant for skin and eyes and is not a dermal sensitizer.

With repeated dosing, halosulfuron-methyl produces non-specific effects, which are frequently characterized by reduced body weight/body weight gain in the test animals. 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 decrease in body weight gains at high dose levels in short- and long-term oral and dermal studies.

In the prenatal developmental toxicity study in rats, increases in resorptions, soft tissue (dilation of the lateral ventricles) and skeletal variations, and decreases in body weights were seen in the fetuses compared to clinical signs and decreases in body weights and food consumption in the maternal animals at similar dose level.

In the rabbit developmental toxicity study, increases in resorptions and post-implantation losses and decrease in mean litter size was seen in the presence of decreases in body weight and food consumption in maternal animals were observed. However, a clear no-observed-adverse-effect-level (NOAEL) for these effects was established in both rat and rabbit developmental toxicity studies.

Halosulfuron-methyl did not produce reproductive effects. No neurotoxic effects were observed in the acute or subchronic neurotoxicity studies. Halosulfuron-methyl is classified as ''not likely to be carcinogenic to humans'' because in both rat and mouse carcinogenicity studies halosulfuron-methyl does not cause; compound-related increases in tumor incidence. It is negative for mutagenicity in a battery of genotoxicity studies. Specific information on the studies received and the nature of the adverse effects caused by halosulfuron-methyl as well as the 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 New Uses on Proso Millet and Crop Group 17 (Grass, Forage, Fodder, and Hay)'' at p. 19 in docket ID number EPA–HQ–OPP–2011–0781.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). 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 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 is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR HALOSULFURON-METHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	NOAEL = 50 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 0.5 mg/kg/day. aPAD = 0.5 mg/kg/day	Developmental Toxicity—Rabbit. LOAEL = 150 mg/kg/day based on decreased mean litter size, increased number of resorptions (total and per dam) and increased post-implantation loss (developmental toxicity).
Acute dietary (General population including infants and children).	N/A	N/A	No adverse effect attributable to a single dose was identified; therefore, no dose/endpoint was selected for this exposure scenario.
Chronic dietary (All populations)	NOAEL = 10 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.1 mg/kg/day. cPAD = 0.1 mg/kg/day.	Chronic Toxicity—Dog. LOAEL = 40 mg/kg/day based on decreased body weight gains in females.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR HALOSULFURON-METHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days).	NOAEL = 50 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Developmental Toxicity—Rabbit. LOAEL = 150 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency (maternal toxicity).
Incidental oral intermediate-term (1 to 6 months).	NOAEL = 10 mg/kg/day. UF_A= 10X UF_H= 10X FQPA SF = 1X	LOC for MOE = 100	13 Week Subchronic Toxicity—Dog. LOAEL = 40 mg/kg/day based on decreased body weight gains and food efficiency along with hematological and clinical chemistry changes.
Dermal short-term (1 to 30 days).	NOAEL = 100 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	21 Day Dermal Toxicity Study—Rats. LOAEL = 1,000 mg/kg/day based on decreased body weight gains in males.
Dermal intermediate-term (1 to 6 months).	NOAEL = 10 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	13 Week Subchronic Toxicity—Dog. LOAEL = 40 mg/kg/day based on decreased body weight gains and food efficiency along with hematological and clinical chemistry changes.
Inhalation short-term (1 to 30 days).	NOAEL = 50 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Developmental Toxicity—Rabbit. LOAEL = 150 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency (maternal toxicity).
Inhalation (1 to 6 months)	NOAEL = 10 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	13 Week Subchronic Toxicity—Dog. LOAEL = 40 mg/kg/day based on decreased body weight gains and food efficiency along with hematological and clinical chemistry changes.
Cancer (Oral, dermal, inhalation).	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.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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 tolerances 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 were identified for halosulfuron-methyl. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted an unrefined assessment that assumed 100 percent crop treated (PCT), dietary exposure evaluation model (DEEM™) 7.81 default concentration factors, and tolerance-level residues for all existing and proposed uses. There was no indication of an adverse effect attributable to a single dose for the general U.S. population. Therefore, an acute dietary assessment was not conducted for the general U.S. population.

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 conducted a chronic dietary assessment that utilized the same food residue assumptions as in the acute dietary exposure assessment discussed in Unit III.C.1.i.

iii. *Cancer.* In both rat and mouse carcinogenicity studies, halosulfuron-methyl does not produce compound related increases in tumor incidence; EPA has concluded that halosulfuron-methyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for halosulfuron-methyl. Tolerance level residues and/or 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 Tier 1 Rice Model and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of halosulfuron-methyl for acute and chronic exposures are estimated to be 59.2 parts per billion (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 both acute and chronic dietary risk assessments, the water concentration value of 59.2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Halosulfuron-methyl is currently registered for the following uses that could result in residential exposures: Residential turf. EPA assessed residential exposure using the default assumptions of the 2012 Residential Standard Operating Procedures (SOPs). Residential handler short-term (1–30 days) dermal and inhalation exposures, and residential post-application short-term dermal and incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposures are expected from activities associated with the existing uses. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *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 Web site 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 Safety Factor (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 pre-natal 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 e.g., 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 e.g., 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 complete except for an immunotoxicity study. In accordance with 40 CFR part 158, Toxicology Data Requirements, an immunotoxicity study 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 POD 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 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 13–49 years old, the population group receiving the greatest exposure.

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 6% of the cPAD for all infants, 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 of 1,800 for adults and 840 for children. For adults, potential pathways of exposure include oral (background) and dermal (post-application primary) routes, while for children, potential pathways of exposure include oral (background) and incidental oral and dermal (primary) routes. Because EPA's level of concern for halosulfuron-methyl is a MOE of 100 or below, these MOEs are not of concern.

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). An intermediate-term adverse effect was identified; however, halosulfuron-methyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for halosulfuron-methyl.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, halosulfuron-methyl is not expected to pose a cancer risk to humans.

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 methodologies are available to enforce the tolerance expression: A gas chromatography with nitrogen phosphorus detection; GC/NPD method for crop commodities and a gas chromotagraphy with electron capture detection (GC/ECD) method for livestock commodities. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. There are no Maximum Residue Limits (MRLs) established by Codex, Canada, or Mexico for any crop or livestock commodities for halosulfuron-methyl.

C. Response to Comments

An anonymous citizen objected to the presence of any pesticide residues on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the FFDCA contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-for Tolerances

EPA has revised the requested tolerances by increasing the tolerance values for millet, proso, forage and grass, forage, fodder, and hay, group 17, forage and reducing the tolerance values for millet, proso, hay and grass, forage, fodder, and hay, group 17, hay. Differences in proposed and recommended tolerances may be attributed to the petitioner having used the North American Free Trade Agreement (NAFTA) tolerance calculation procedures for determining the tolerance and EPA's use of the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. Recently, EPA has adopted use of the OECD tolerance calculation procedures to increase international harmonization of tolerance levels. For grass hay, the petitioner used values below the level of quantitation (LOQ) in the tolerance calculation whereas EPA used LOQ values. In addition, already established tolerances for cattle, goat, horse, and sheep meat byproducts are being increased and multiple new livestock commodity tolerances are being established. Livestock tolerances are derived from reevaluation of the dairy/beef cattle diet with new feed items (millet and grass).

V. Conclusion

Therefore, tolerances are established for residues of halosulfuron-methyl, including its metabolites and degradates, as set forth in the regulatory text.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) 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 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.

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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 action 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: November 21, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.479 revise the table in paragraph (a)(1) and add alphabetically the following new entries to the table in paragraph (a)(2).

The revised and added text read as follows:

§ 180.479 Halosulfuron-methyl; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	1.0
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	1.0
Hog, meat byproducts	0.1
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	1.0
Milk	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	1.0

(2) * * *

Commodity	Parts per million
* * * * *	
Grass, forage, fodder, and hay, group 17, forage	20
Grass, forage, fodder, and hay, group 17, hay	0.5
* * * * *	
Millet, proso, forage	10
Millet, proso, grain	0.01
Millet, proso, hay	0.01
Millet, proso, straw	0.01
* * * * *	

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[FR Doc. 2012–29105 Filed 11–30–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA–HQ–OPPT–2011–0363; FRL–9355–9]

RIN 2070–AJ89

Health and Safety Data Reporting; Addition of Certain Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule requires manufacturers (including importers) of cadmium or cadmium compounds, including as part of an article, that have been, or are reasonably likely to be, incorporated into consumer products to report certain unpublished health and safety studies to EPA. The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA) to recommend chemicals and chemical mixtures to EPA for priority testing consideration, amends the TSCA section 4(e) *Priority Testing List* through periodic reports submitted to EPA. The ITC added cadmium and cadmium compounds to the *Priority Testing List* through its 69th ITC Report.

DATES: This final rule is effective January 2, 2013. For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time on December 17, 2012. (See 40 CFR 23.5.)

A request to withdraw a chemical from this final rule pursuant to § 716.105(c) must be received on or