fluoxastrobin, including its metabolites and degradates, in or on the commodities in the table below, when present therein as a result of the application of fluoxastrobin to the growing crops listed in paragraph (a)(1) of this section. Compliance with the tolerance levels specified below is to be determined by measuring only fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl] oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, calculated as the stoichiometric equivalent of fluoxastrobin.

Commodity	Parts per million
Alfalfa, forage	0.050
Alfalfa, hay	0.10
Cotton, gin byproducts	0.020
Grain, cereal, forage, fodder, and straw, group 16, except corn	0.10
Grass, forage	0.10
Grass, hay	0.50
Vegetable, foliage of legume, group 7	0.050

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0276; FRL–8800–8]

Prosulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prosulfuron and its metabolites and degradates in or on cereal grain commodities. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, 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–2008–0276. 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*.

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 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 cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select ''Test Methods & Guidelines'' on the left-side navigation menu.

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–2008–0276 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 February 16, 2010.

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–2008–0276, 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 August 13, 2008 (73 FR 47186) (FRL–8375–8), 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 5F4469) by Syngenta Crop Protection, Inc., PO Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.481 be amended by establishing tolerances for residues of the herbicide prosulfuron, 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea, in or on field and popcorn grain, fodder, and forage at 0.01 parts per million (ppm); cereal grains group (except rice and wild rice), fodder at 0.01 ppm; forage at 0.10 ppm; grain at 0.01 ppm; hay at 0.20 ppm; straw at 0.02 ppm; cattle, goat, hog, horse, sheep fat, kidney, liver, meat, and meat byproducts at 0.05 ppm; and milk at 0.01 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, 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.

Based upon review of the data supporting the petition, EPA has determined that corn and livestock commodity tolerances proposed in the petition are not required. EPA has also revised the cereal grain commodity terms and the tolerance expression for prosulfuron. 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 tolerances for residues of prosulfuron and its metabolites and degradates on grain, cereal, forage, fodder, and straw, group 16, except rice, fodder at 0.01 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice, forage at 0.10 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice, hay at 0.20 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice, straw at 0.02 ppm; and grain, cereal, group 15, except rice at 0.01 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.

Toxicology studies indicate that prosulfuron has minimal toxicity under acute exposure conditions and that it is not a skin or eye irritant or dermal sensitizer. In chronic and subchronic studies with prosulfuron, some treatment-related effects were observed, most commonly effects on body weight. Evidence of neurotoxicity was also observed in gavage studies. Effects consistent with neurotoxicity (primarily gait and sensorimotor effects) were observed in rabbits in the developmental toxicity range-finding study and in rats in the acute neurotoxicity screening study. However, neurotoxic effects were not observed following oral exposure to prosulfuron, and there was no evidence from the developmental and reproductive studies of increased susceptibility to these effects in rat or rabbit fetuses or offspring.

Previously, EPA classified prosulfuron as a Group D Chemical (''Not Classifiable as to Human Carcinogenicity''), a classification consistent with the cancer guidelines in effect at the time (1995). This classification was based on the lack of evidence of carcinogenicity in male or female mice at the limit dose and equivocal evidence of carcinogenicity in female rats. In female rats, there was suggestive evidence of a possible treatment-related increase in the incidence of adenocarcinomas of the mammary glands at the mid dose but not at the high dose. This lack of dose-response (i.e. the relatively limited response in the high dose group and a more pronounced response in the middle-dose group) along with the lack of evidence of carcinogenicity in mice and the lack of evidence for *in vivo* or *in vitro* mutagenicity lowered the concern for the carcinogenic potential of prosulfuron. EPA has reviewed this evidence under the current 2005 guidelines for Carcinogen Risk Assessment and concluded that Prosulfuron should be classified as ''Not Likely to Be Carcinogenic to Humans.''

Specific information on the studies received and the nature of the adverse effects caused by prosulfuron 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 titled ''Prosulfuron. Revised Human Health Risk Assessment for the Proposed Establishment of Permanent Tolerances for Uses in/on Cereal Grains (Crop Group 15), Except Rice'', page 33 in docket ID number EPA–HQ–OPP–2008–0276.

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 prosulfuron used for human risk assessment can be found at *http://www.regulations.gov* in the document titled ''Prosulfuron. Revised Human Health Risk Assessment for the Proposed Establishment of Permanent Tolerances for Uses in/on Cereal Grains (Crop Group 15), Except Rice'', page 17 in docket ID number EPA–HQ–OPP–2008–0276.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to prosulfuron, EPA considered exposure under the petitioned-for tolerances. There are no other tolerances currently in effect for prosulfuron. Temporary tolerances on cereal grains and livestock commodities expired on December 31, 1999. EPA is establishing permanent tolerances on cereal grain commodities in this action but has determined that livestock tolerances are unnecessary, since there is no expectation of finite residues in livestock commodities from prosulfuron's use on cereal grains. EPA assessed dietary exposures from prosulfuron 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.

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 assumed that residues are present in cereal grains at the tolerance level and that 100% of cereal grains are treated with prosulfuron.

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 that residues are present in cereal grains at the tolerance level and that 100% of cereal grains are treated with prosulfuron.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA does not expect prosulfuron to pose a cancer risk. Therefore, an exposure assessment to evaluate cancer risk is unnecessary for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for prosulfuron. Tolerance level residues and 100% CT 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 prosulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prosulfuron. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of prosulfuron for acute exposures are estimated to be 1.872 parts per billion (ppb) for surface water and 0.655 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 0.583 ppb for surface water and 0.655 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 1.872 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.655 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). Prosulfuron is not registered for any specific use patterns that would result in residential exposure.

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 prosulfuron to share a common mechanism of toxicity with any other substances, and prosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that prosulfuron 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 prosulfuron includes a developmental toxicity study in the rat, two developmental toxicity studies and a range-finding developmental study in the rabbit, and a 2–generation reproduction toxicity study in the rat. There was no evidence of increased susceptibility of fetuses or offspring in any of these studies.

There were no maternal or fetal effects observed at any dose in the first of two rabbit developmental toxicity studies. In the second rabbit study and in the rat developmental toxicity study, a dose-related increase in small fetuses and skeletal effects was observed, but only in the presence of maternal toxicity (decreased body weight gain in the rat study; and increases in abortions, decreases in food consumption and decreased mean body weight gain in the rabbit study).

In the developmental range-finding study in rabbits, maternal effects consistent with neurotoxicity (hypoactivity, muscle weakness and

incoordination of limbs/ataxia) were observed at all doses tested. Sciatic nerve degeneration and white matter degeneration of the spinal cord were also observed at higher dose levels. There was no evidence of neurotoxicity to fetuses or offspring observed in any of the developmental or reproduction toxicity studies.

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 prosulfuron is adequate to assess prenatal and postnatal toxicity. In accordance with part 158 Toxicology Data requirements, an immunotoxicity study (870.7800) is required for prosulfuron. In the absence of specific immunotoxicity studies, EPA has examined the available prosulfuron toxicity data for evidence of immunotoxic effects. No evidence of immunotoxicity was found. Due to the lack of evidence of immunotoxicity for prosulfuron in available studies, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the chronic NOAEL of 5.3 milligrams/kilograms (mg/kg) bodyweight/day (bw/day) already established for prosulfuron, and an additional database uncertainty factor is not needed to account for the lack of this study.

ii. Although there was evidence of neurotoxicity following gavage exposure to prosulfuron in the rat (ataxia, decreased motor activity, decreased body temperature, impaired gait and righting reflex) and in the pregnant rabbit (ataxia, hypoactivity, neuropathology), there is low concern for these effects. The findings were observed only at high doses (at or above 250 mg/kg/day) following gavage dosing and were not observed following dietary exposure to levels up to 628 mg/kg/day. For example, the acute neurotoxicity study in rats involved gavage dosing and showed neurotoxic effects at 250 mg/kg/day but the subchronic neurotoxicity study in rats which did not involve gavage dosing did not show neurotoxic effects at the highest dose tested (628/313 male/female (M/F) mg/kg/day). The neurotoxicity findings in the pregnant rabbit were observed at a dose causing death, abortions and systemic toxicity, and the neuropathology did not show a dose-response. Furthermore, there was no evidence for neurotoxicity in offspring in the developmental studies or in the rat reproduction study, and increased prenatal and/or postnatal susceptibility was not observed. Based on these considerations, EPA has concluded that a developmental neurotoxicity (DNT) study is not required for prosulfuron and an additional uncertainty factor is not needed to account for potential neurotoxicity.

iii. There is no evidence that prosulfuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to prosulfuron in drinking water. Prosulfuron is not registered for residential uses. These assessments will not underestimate the exposure and risks posed by prosulfuron.

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 prosulfuron will occupy less than 1% of the aPAD for the general population and all population subgroups, including infants and children's subgroups.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to prosulfuron from food and water will utilize less than 1% of the aPAD for the general population and all population subgroups, including infants and children's subgroups. There are no residential uses for prosulfuron.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure take into account short-term or intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Prosulfuron is not registered for any use patterns that would result in residential exposure. Therefore, the short-term or intermediate-term aggregate risk is the sum of the risk from exposure to prosulfuron through food and water and will not be greater than the chronic aggregate risk.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)) is available to enforce the tolerance expression. 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*.

B. International Residue Limits

No CODEX maximum residue limits have been established for prosulfuron.

C. Revisions to Petitioned-For Tolerances

EPA has determined that the corn and livestock commodity tolerances proposed in the petition are not required. Field corn and popcorn are members of the Crop Group 15 (cereal grains); therefore, residues on corn commodities will be covered by the cereal grains (group 15) tolerances. Tolerances are not required for livestock commodities because there is no expectation of finite residues in livestock commodities from the use of prosulfuron on cereal grains. EPA has also revised the cereal grain commodity terms to agree with the Agency's Food and Feed Commodity Vocabulary.

Finally, EPA has revised the prosulfuron tolerance expression 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 makes clear that the

tolerances cover residues of prosulfuron and its metabolites and degradates, but that compliance with the tolerance levels will be determined by measuring only prosulfuron, 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea, in or on the commodities.

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

V. Conclusion

Therefore, tolerances are established for residues of prosulfuron and its metabolites and degradates in or on grain, cereal, forage, fodder, and straw, group 16, except rice, fodder at 0.01 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice, forage at 0.10 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice, hay at 0.20 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice, straw at 0.02 ppm; and grain, cereal, group 15, except rice at 0.01 ppm. Compliance with these tolerances will be determined by measuring only prosulfuron, 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea, in or on the commodities.

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: December 8, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.481 is revised to read as follows:

§ 180.481 Prosulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide prosulfuron and its metabolites and degradates in or on the commodities in the table below. Compliance with the tolerance levels specified in the table below is to be determined by measuring only prosulfuron, 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea, in or on the commodity.

Commodity	Parts per million
Grain, cereal, forage, fodder, and straw, group 16, except rice, fodder	0.01
Grain, cereal, forage, fodder, and straw, group 16, except rice, forage	0.10
Grain, cereal, forage, fodder, and straw, group 16, except rice, hay	0.20
Grain, cereal, forage, fodder, and straw, group 16, except rice, straw	0.02
Grain, cereal, group 15, except rice	0.01

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

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

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

[FR Doc. E9–30194 Filed 12–17–09; 8:45 am]

BILLING CODE 6560–50–S