Saflufenacil; Pesticide Tolerances

A Rule by the Environmental Protection Agency on 09/03/2014

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This regulation is effective September 3, 2014. Objections and requests for hearings must be received on or before November 3, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

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ACTION Final Rule.

SUMMARY This regulation establishes and revises tolerances for residues of saflufenacil in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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Document Number: 2014-20947

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RELATED TOPICS

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This regulation is effective September 3, 2014. Objections and requests for hearings must be received on or before November 3, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

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The dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2013-0622 and EPA-HQ-OPP-2014-0124, are 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), West William Jefferson Clinton 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:

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Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

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I. General Information

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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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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 numbers EPA-HQ-OPP-2013-0622 and EPA-HQ-OPP-2014-0124 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 November 3, 2014. 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-2013-0622 and EPA-HQ-OPP-2014-0124, 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 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.html*.

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

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In the **Federal Register** of October 25, 2013 (78 FR 63938) (FRL-9901-96), 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 3F8192) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.649 be amended by establishing tolerances for residues of the herbicide saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2 *H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites, *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2 *H*)-pyrimidinyl)-4-fluorobenzoyl]-*N′*-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil, in or on grass, forage at 15 parts per million (ppm); grass, hay at 20 ppm; grass, seed screenings at 0.9 ppm; and grass, straw at 1.5 ppm and revising the livestock commodity tolerances for (cattle, goat, horse, and sheep): Fat from 0.01 ppm to 0.05 ppm; liver from 2.5 ppm to 45 ppm; and meat byproducts, except liver from 0.05 ppm to 0.5 ppm; hog, fat from 0.01 ppm to 0.05 ppm; hog, liver from 0.80 ppm to 45 ppm; and hog, meat byproducts, except liver from 0.02 ppm to 0.5 ppm.

The same **Federal Register** document of October 25, 2013, also announced BASF Corporation's filing of a pesticide petition (PP 3F8185) that requested 40 CFR 180.649 be amended by revising tolerances for saflufenacil and its metabolites in or on barley, grain from 0.10 ppm to 1.0 ppm; barley, straw from 0.10 ppm to 15.0 ppm; barley, bran from 0.10 ppm to 1.53 ppm; wheat, grain from 0.10 ppm to 0.6 ppm; and wheat, straw from 0.10 ppm to 6.0 ppm, included under the existing tolerances for “Grain, cereal, group 15” and “Grain, cereal, forage, fodder and straw group 16.” In addition, BASF Corporation requested to amend the existing commodity definition, “Grain, cereal, forage, fodder and straw group 16” to “Grain, cereal, forage, fodder and straw, group 16, except barley, rice and wheat straw” as well as amend the commodity definition, “Grain, cereal, group 15” to “Grain, cereal, group 15, except barley and wheat.”

Finally, in the **Federal Register** of February 25, 2014 (79 FR 10458) (FRL-9906-77), 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 4F8229) by BASF Corporation. The petition requested that 40 CFR 180.649 be amended by establishing tolerances for residues of the herbicide saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2 *H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites, *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-

3,6-dihydro-1(2 *H*)-pyrimidinyl)-4-fluorobenzoyl]-*N′*-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil in or on olive at 0.03 ppm. These documents referenced summaries of the petitions prepared by BASF Corporation, the petitioner, which are available in the dockets, *http://www.regulations.gov*. There were no comments received in response to these notices of filings.

Based upon review of the supporting data, EPA has made modifications to the proposed tolerances which include:

1. Rounding the proposed tolerance for barley, bran.

2. Revising the commodity definition for crop group 16.

3. Decreasing the proposed tolerances for grass, seed screenings and grass, straw.

4. Increasing the existing tolerance for residues in or on grain, aspirated fractions.

5. Making several changes to the proposed livestock tolerances.

The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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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 chemicalresidue. . . ."

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 saflufenacil, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with saflufenacil 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. In the **Federal Register** of February 21, 2014 (79 FR 9861) (FRL-9905-87), EPA published a final rule establishing tolerances for residues of the herbicide saflufenacil and its metabolites in or on sugarcane, fish, and shellfish commodities based on EPA's conclusion that aggregate exposure to saflufenacil is safe for the general population, including infants and children. Since that rulemaking, there have been no additional tolerance actions for saflufenacil, nor has the toxicity profile for saflufenacil changed. Specific information on the studies received and the nature of the adverse effects caused by saflufenacil, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in that rulemaking which can be found in the docket under docket ID numbers EPA-HQ-OPP-2012-0775 and EPA-HQ-OPP-2013-0008.

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 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 the LOAEL are identified. Uncertainty/safety factors (UFs) 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 saflufenacil used for human risk assessment is discussed in Unit III.B. of the February 21, 2014 **Federal Register** final rule.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating

dietary exposure to saflufenacil, EPA considered exposure under the petitioned-for tolerances as well as all existing saflufenacil tolerances in 40 CFR 180.649. EPA assessed dietary exposures from saflufenacil 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 saflufenacil. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture National Health and Nutrition Examination Survey, What We Eat in America, (USDA NHANES/WWEIA, 2003-2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors, and tolerance-level or higher (i.e., tolerance levels adjusted to take into account metabolite levels) residues for all foods.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA, 2003-2008. As to residue levels in food, EPA made the same assumptions (adjusted tolerance-level residues and 100 PCT) as in the acute dietary exposure assessment.

iii. *Cancer.* As indicated in the February 21, 2014 **Federal Register** final rule preamble for saflufenacil, EPA has concluded that saflufenacil 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 saflufenacil. Tolerance-level residues (or higher) 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 saflufenacil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of saflufenacil. 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 Tier II Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of saflufenacil for acute exposures are estimated to be 133 parts per billion (ppb) for surface water and 69.2 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 120 ppb for surface water and 51.5 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 133 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 120 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).

Saflufenacil 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 saflufenacil to share a common mechanism of toxicity with any other substances, and saflufenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that saflufenacil 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 Food Quality Protection Act Safety Factor (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*. Increased fetal susceptibility was observed in the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. Developmental effects (decreased fetal body weights and increased skeletal variations

in rats and increased liver porphyrins in rabbits) occurred at doses that were not maternally toxic in the developmental studies, indicating increased quantitative susceptibility. In the 2-generation reproductive toxicity study in rats, the reported offspring effects were more severe than the maternal effects at the same dose level, indicating evidence for increased qualitative susceptibility. An increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body-weight gain, and changes in hematological parameters occurred at the same dose level as maternal decrements in food intake, body weight, body-weight gain, and changes in hematological parameters and organ weights indicative of anemia.

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 saflufenacil is complete.

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

iii. The concern for increased susceptibility following prenatal or postnatal exposure is low because clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the 2-generation reproductive toxicity study. Further, the dose-response relationship for the effects of concern is also well characterized and being used for assessing risks. None of the effects in the developmental or reproduction studies were attributable to a single exposure and, therefore, are not of concern for acute risk assessment. The chronic point of departure used for risk assessment is protective of any developmental and offspring effects observed in these studies.

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 saflufenacil in drinking water. These assessments will not underestimate the exposure and risks posed by saflufenacil.

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 saflufenacil will occupy <1% of the aPAD for infants less than 1-year 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 saflufenacil from food and water will utilize 20% of the cPAD for infants less than 1-year old, the population group receiving the greatest exposure. There are no residential uses for saflufenacil.

3. *Short and intermediate-term risk*. Short and intermediate-term aggregate exposure takes into account short and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Because there is no short or 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 short-term risk), no further assessment of short or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for saflufenacil.

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

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 saflufenacil residues.

IV. Other Considerations

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A. Analytical Enforcement Methodology

Adequate enforcement methods “D0603/02” and “L0073/01” (liquid chromatography/mass spectroscopy/mass spectroscopy (LC-MS/MS)) are available to enforce the tolerance expression. These 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 MRLs established for residues of saflufenacil, measuring the levels of the parent only and not residues of the metabolites, as follows: 0.01 ppm in or on cereal grains, which includes barley, corn, and wheat; 0.05 ppm for maize fodder (dry), sorghum straw and fodder, dry; 0.05 ppm for barley straw and fodder, dry; 0.05 ppm for wheat straw and fodder, dry; 0.01 mammalian fats (except milk fats), which includes cattle, goat, hog, horse, and sheep; and 0.3 edible offal mammalian, which includes cattle, goat, hog, horse, and sheep.

Harmonization between the Codex MRLs for cereal grains and the U.S. tolerances for barley, grain and wheat, grain and between the Codex MRL for barley straw and fodder, dry and the U.S. tolerance for barley, straw and between the Codex MRL for wheat straw and fodder, dry and the U.S. tolerance for wheat, straw is not possible as the U.S. use pattern (harvest-aide/burndown application) results in significantly higher residues than the Codex use pattern (pre-emergence application). The higher residues translate into higher residues of saflufenacil in animal byproducts than are covered by the corresponding Codex MRLs for livestock commodities under the Codex use pattern; therefore, U.S. tolerances for livestock commodities cannot be harmonized with Codex MRLs for corresponding livestock commodities.

The U.S. tolerances for crop groups 15 and 16 are not harmonized with the Codex MRLs for cereal grains and straw and fodder because the compliance with the Codex MRLs involve measurement of residues of the parent only and not the metabolites, whereas the U.S. tolerance requires measurement of both, in order to be harmonized with Canadian tolerances.

C. Revisions to Petitioned-for Tolerances

EPA is making several revisions to the petitioned-for tolerances. These include the following. First, the petitioned value for barley bran is being rounded from 1.53 ppm to 1.5 ppm to be consistent with the current Organization for Economic Cooperation and Development (OECD) tolerance-

calculation procedure. Second, the commodity definition "Grain, cereal, forage, fodder, and straw group 16 (except barley, wheat and rice straw)" is being revised to "Grain, cereal, forage, fodder and straw group 16 (except barley and wheat straw)" as the new use pattern (harvest aid/desiccant) was not proposed for rice. Third, the petitioner requested tolerance values for grass straw and seed screenings were based on data from trials in which the samples were harvested at a significantly shorter preharvest interval (PHI) than that listed on the label. Additional residue data reflecting the actual PHI listed on the label showed lower residue levels; therefore, the tolerance values for grass straw and seed screenings are being decreased. Fourth, the existing tolerance of 10 ppm for residues in or on grain, aspirated fractions is being increased to 50 ppm as a result of the new tolerances for cereal grains and based on available residues data. Finally, EPA is making several revisions to the proposed livestock tolerances which include:

1. Decreasing the proposed tolerances for cattle, goat, sheep, hog and horse fat from 0.05 ppm to 0.04 ppm and meat byproducts (except liver) from 0.05 ppm to 0.03 ppm.

2. Increasing the tolerances proposed for cattle, goat, sheep and horse liver from 45 ppm to 50 ppm.

3. Decreasing the tolerance proposed for hog liver from 45 ppm to 2.0 ppm.

4. Establishing tolerances for cattle, goat, sheep and horse meat at 0.02 ppm.

5. Retaining the currently established tolerances for hog, fat or hog, meat byproducts (except liver), instead of increasing them as requested.

The tolerances being set for residues in livestock differ from the petitioned-for tolerances due to differences in calculation methods of the maximum reasonably balanced diets (MRBDs) with the results of the ruminant feeding study. It also appears that the petitioner over-estimated residues in hog commodities as a result of using the cattle MRDB.

V. Conclusion

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Therefore, tolerances are established for residues of saflufenacil, including its metabolites and degradates, as set forth in the regulatory text. Compliance with the plant tolerances is to be determined by measuring the sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2 *H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2 *H*)-pyrimidinyl)-4-fluorobenzoyl]-*N'*-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil.

Compliance with the livestock tolerances is to be determined by measuring only saflufenacil, 2-chloro-5-[3,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)-4-fluoro-N-[[methyl(1-methylethyl)amino]sulfonyl]benzamide.

VI. Statutory and Executive Order Reviews

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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

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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

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- Administrative practice and procedure
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- Reporting and recordkeeping requirements

Dated: August 25, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

begin regulatory text

PART 180—[AMENDED]

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

Authority:

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

2. In § 180.649:

a. Remove the commodities "Grain, aspirated fractions," "Grain, cereal, forage, fodder and straw group 16," and "Grain, cereal, group 15" in the table in paragraph (a)(1).

b. Add alphabetically the following commodities to the table in paragraph (a)(1).

c. Revise the following commodities in the table in paragraph (a)(2).

The amendments read as follows:

§ 180.649 Saflufenacil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
*****	
Barley, bran	1.5
Barley, grain	1.0
Barley, straw	15
*****	
Grain, aspirated grain fractions	50
Grain, cereal, forage, fodder and straw group 16 (except barley and wheat straw)	0.10
Grain, cereal, group 15 (except barley and wheat grain)	0.03
*****	
Grass, forage	15
Grass, hay	20
Grass, seed screenings	0.15
Grass, straw	0.15

* * * * *

(2) * * *

Commodity	Parts per million
Cattle, fat	0.04
Cattle, liver	50
Cattle, meat	0.02
Cattle, meat byproducts, except liver	0.30
*****	
Goat, fat	0.04
Goat, liver	50
Goat, meat	0.02
Goat, meat byproducts, except liver	0.30
*****	
Hog, liver	2.0
*****	
Horse, fat	0.04

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