ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0640; FRL–9936–71]

Saflufenacil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of saflufenacil in or on pomegranate. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 25, 2015. Objections and requests for hearings must be received on or before January 25, 2016, 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–2014–0640, 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), 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: Susan Lewis, Director, 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:

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://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 number EPA–HQ–OPP–2014–0640 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 January 25, 2016. 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–2014–0640, 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

In the **Federal Register** of February 11, 2015, (80 FR 7559) (FRL–9921–94), 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) 4F8305 by BASF Corporation, 26 Davis Drive, 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, in or on pomegranate at 0.03 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, 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.

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 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.

The effects observed following repeated oral exposures to saflufenacil are consistent with the proposed mode of toxicity involving inhibition of protoporphyrinogen oxidase (PPO) in mammals, resulting in disruption of heme biosynthesis. Toxicological effects from subchronic and chronic toxicity studies in rats, mice and dogs consisted of decreased hematological parameters (RBC, Ht, MCV, MCH, and MCHC) at approximately the same dose level (13–39 mg/kg/day), except in the case of the dog, where the effects were seen at a slightly higher dose (50–100 mg/kg/day). In line with the absorption, distribution, metabolism, and excretion (ADME) findings suggesting that male rats achieve a greater systemic exposure than females, males were the most sensitive sex in mice and rats, with LOAELs approximately 3–4X lower than their female counterparts. The hematological effects resulting from oral exposures to saflufenacil occurred around the same dose level from short- through long-term exposures without increasing in severity. Toxic effects were also seen in the liver (increased organ weight, centrilobular fatty change, lymphoid infiltrate) in mice, the spleen (increased organ weight and extramedullary hematopoiesis) in rats, and in both of these organs (increased iron storage in the liver and extramedullary hematopoiesis in the spleen) in dogs. These effects also occurred around the same dose level from short- through long-term exposures without a progression in severity.

Evidence for increased pre- and/or postnatal susceptibility was noted from the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. Decreased fetal body weights and increased skeletal variations occurred at doses (20 mg/kg/day) that were not maternally toxic in the developmental study in rats. Similarly, in rabbits, increased liver porphyrins in fetuses were observed at doses (200 mg/kg/day) that were not maternally toxic. In the 2-generation reproductive toxicity study in rats, there was evidence of increased qualitative susceptibility based on an increased number of stillborn pups, decreased pup viability and lactation indices, decreased pre-weaning body-weight and/or body-weight gain, and changes in hematological parameters at the same dose level as less severe maternal effects consisting of decrements in food intake, body-weight, body-weight gain, and changes in organ weights and hematological parameters indicative of anemia.

In an acute neurotoxicity (ACN) study in rats, a decrease in motor activity was observed on the day of dosing at the limit dose (2,000 mg/kg/day) in males only. However, the finding was not accompanied by any neuropathological changes and was considered a reflection of a mild and transient general systemic toxicity and not a substance-specific neurotoxic effect. In the subchronic neurotoxicity (SCN) study, systemic toxicity (anemia) was seen at 1,000 ppm (66.2 mg/kg/day) and 1,350 ppm (101 mg/kg/day) in males and females, respectively. There was no evidence of neurotoxicity or neuropathology in either the acute or subchronic neurotoxicity study.

In a 28-day dermal toxicity study in rats, saflufenacil did not induce any type of dermal or systemic toxicity up to the limit dose of 1,000 mg/kg bw/day.

Based on the results of acute toxicity studies, saflufenacil was ranked low for acute toxicity via the oral, dermal, and inhalation route of exposure. It was not classified as a dermal irritant or dermal sensitizer.

In a 28-day immunotoxicity study in mice, saflufenacil failed to induce toxicity specific to the immune system at the highest dose tested (*i.e.,* 52 mg/kg bw/day).

Saflufenacil was weakly clastogenic in the *in vitro* chromosomal aberration assay in V79 cells in the presence of S9 activation; however, the response was not evident in the absence of S9 activation. It was neither mutagenic in bacterial cells nor clastogenic in rodents *in vivo.* Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumors at the tested doses. Saflufenacil is classified as ''not likely carcinogenic to humans.''

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 can be found at *http://www.regulations.gov* in document *Saflufenacil. ''Human Health Risk Assessment in Support of Tolerances for Residues in/on Pomegranate''* pgs. 26–30 in docket ID number EPA–HQ–OPP–2014–0640.

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 no adverse effects are observed (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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for saflufenacil used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SAFLUFENACIL 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 (General population including infants and children).	NOAEL = 500 mg/kg bw ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 5 mg/kg ..... aPAD = 5 mg/kg	Acute Neurotoxicity Study (rat). LOAEL = 2,000 mg/kg bw based on decreased motor activity representing mild and transient systemic toxicity in males.
Chronic dietary (All populations).	NOAEL = 4.6 mg/kg/day ..... UF_A =10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.046mg/kg/day ..... cPAD = 0.046 mg/kg/day	Chronic/Carcinogenicity (mouse). LOAEL = 13.8 mg/kg bw/day based on decreased red blood cells, hemoglobin, hematocrit, and porphyria observed in the satellite group.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. 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 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 (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA used an unrefined approach by assuming that 100% of the crop is treated and that residues are present at the tolerance-level or at tolerance-levels adjusted to account for the residues of concern for risk assessment for all foods. EPA also used default processing factors using the Dietary Exposure Evaluation Model (DEEM) 7.8.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the same conservative assumptions that were used for the acute dietary assessment noted above.

iii. *Cancer.* Based on the data summarized in Unit III.A., 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 percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for saflufenacil. Tolerance-level residues and/or 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 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Tier 1 Rice Model and 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.

The EDWCs for 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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.* As discussed in III.A., there is evidence of increased pre- and/or postnatal susceptibility in the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. 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 are also well characterized and being used for assessing risks. The point of departure for risk assessments would be protective of the developmental and offspring effects.

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 was no evidence of neurotoxicity or neuropathology in the acute and subchronic neurotoxicity study. The decrease in motor activity observed in the acute neurotoxicity study on the day of dosing at the limit dose (2,000 mg/kg/day) in males is considered a reflection of a mild and transient general systemic toxicity and not a substance-specific neurotoxic effect. No neurotoxic effects were seen in the sub-chronic neurotoxicity study.

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 are also well characterized and being used for assessing risks. The POD for risk assessments would be protective of the developmental and offspring effects.

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 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 less than 1% of the aPAD for all infants (<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 all infants (<1-year old) the population group receiving the greatest exposure. There are no residential uses for saflufenacil.

3. *Short-term and intermediate-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). Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water. Since there are no registered or proposed residential uses for saflufenacil that would result in short or intermediate-term residential exposures, 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 and intermediate-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

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectroscopy/mass spectroscopy (LC/MS/MS) Method D0603/02) 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; 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. The Codex has not established a MRL for saflufenacil on pomegranate. Therefore, harmonization of MRLs and U.S. tolerances is not an issue at this time.

C. Response to Comments

EPA received two comments to the docket, EPA–HQ–OPP–2014–0640; however, only one of these public submissions was in response to the Notice of Filing for PP# 4F8305, while the remaining comment pertained to an unrelated petition in the **Federal Register** notice. For PP# 4F8305, the commenter stated that they are in support of actions to set tolerance levels for pesticides on the food we eat and that we are taking a step in the right direction by making it safer for human consumption by placing more regulations on pesticide chemicals.

EPA agrees with the commenter and will continue to regulate pesticides

under the legal framework provided by the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) and Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), which allows EPA to assess the risk of pesticides and set tolerance levels for those pesticides on food commodities as deemed necessary to protect human health while still providing tools for growers so that they can meet the ever-growing food demands of this country and others.

V. Conclusion

Therefore, tolerances are established for residues of saflufenacil, (2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)-pyrimidinyl]-4-fluoro-N-[[methyl(1-methylethyl)amino]sulfonyl]benzamide) and its metabolites, in or on pomegranate at 0.03 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (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 17, 2015.

Susan Lewis,

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 § 180.649, add alphabetically the entry to the table in paragraph (a)(1) to read as follows:

§ 180.649 Saflufenacil; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
* * * * *	
Pomegranate	0.03
* * * * *	

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[FR Doc. 2015–29889 Filed 11–24–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 80

[Docket No. CDC–2015–0062; NIOSH–286]

RIN 0920–AA55

Occupational Safety and Health Research and Related Activities: Removal of Regulations Regarding Administrative Functions, Practices, and Procedures

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: With this action, the Department of Health and Human Services (HHS) removes its regulations pertaining to fees for direct training in occupational safety and health conducted by the National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control and Prevention (CDC). As a part of the retrospective review conducted by all Federal agencies, HHS has determined that these regulations are no longer in use by NIOSH and should be removed.

DATES: This rule is effective on November 25, 2015.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Ave., MS: C–46, Cincinnati, OH 45226; telephone (855)818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

In a notice of proposed rulemaking published on August 13, 2015 (80 FR 48473), HHS invited interested persons or organizations to submit written views, recommendations, and data regarding the removal of part 80. We received no comments on this rule.