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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0112; FRL-9961-54]

Flazasulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2016-0112, 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., 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-2016-0112 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2016-0112, 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 April 25, 2016 (81 FR 24044) (FRL-9944-86), 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 6F8447) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A,

Concord, Ohio 44077. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide, flazasulfuron (N-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(trifluoromethyl)-2-pyridinesulfonamide), in or on olive at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 flazasulfuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flazasulfuron 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 risk assessment for flazasulfuron is based on a well-characterized and complete toxicology database. After oral administration to rats, more than 84% of the dose of flazasulfuron was excreted within 72 hours, mostly as parent compound. Urinary elimination accounted for about 80-90% of the dose and fecal elimination for about 10-20%. Females tended to eliminate more in the urine, and slightly more rapidly, than males. Tissue distribution was rapid but incomplete. While levels in tissue were generally low, the tissues with highest concentrations were the blood, liver, and muscle.

The liver was the main target organ of flazasulfuron in most species tested, with effects ranging from non-adverse liver hypertrophy to more severe histopathological findings like inflammatory cell infiltration, hepatocellular necrosis and swelling, and bile duct proliferation. Rats also showed kidney toxicity (nephropathy) after chronic exposure. No adverse effects were observed in most short and intermediate duration (≤ 90 days) studies; only reduced body weight gain and non-adverse liver effects (increased weight and hepatocellular hypertrophy) were observed in some of the subchronic toxicity studies.

Developmental toxicity was observed in rats and abortions in rabbits; however, findings in rats were not consistent across strains. A small increase in the incidence of intraventricular septal defect was observed in Wistar rats but not in Sprague-Dawley rats. Significant decreases in mean fetal body weight were observed in both rat strains at the limit dose. In these same studies in the rat, the maternal animals showed no adverse effects. A high incidence of abortion

and decreased food consumption, but no specific fetal effects, were observed in rabbits. While the developmental studies indicate there is offspring susceptibility in rats, both rat studies provide clear no-observed-adverse-effect levels (NOAELs) for the adverse fetal effects. Furthermore, the points of departure (PODs) used for risk assessment are lower than doses associated with fetal effects; therefore, the assessments are protective of the observed offspring effects.

No increase in tumor incidence was seen in rats or mice. Flazasulfuron is not genotoxic. There was no evidence of neurotoxicity in the database. The acute toxicity data indicate that flazasulfuron has low acute oral, dermal, and inhalation toxicity. It was not found to be a skin irritant, but was a moderate eye irritant. Flazasulfuron was not a dermal sensitizer. Flazasulfuron is classified as "not likely to be carcinogenic in humans" based on the lack of carcinogenic effects in the rat and mouse carcinogenicity studies, and lack of a mutagenicity concern.

Specific information on the studies received and the nature of the adverse effects caused by flazasulfuron as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document titled "Flazasulfuron. Aggregate Human Health Risk Assessment for the Proposed New Use on Olives" at page 23 in docket ID number EPA-HQ-OPP-2016-0112.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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 flazasulfuron used for human risk assessment is discussed in Unit II. B. of the final rule published in the **Federal Register** of September 5, 2014 (79 FR 52985) (FRL–9915–32).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to flazasulfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing flazasulfuron tolerances in 40 CFR 180.655. EPA assessed dietary exposures from flazasulfuron 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 flazasulfuron. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) under the Continuing Survey of Food Intake by Individuals (CSFII) and the CDC under the National Health and Nutrition Examination Survey/ What We Eat in America (NHANES/WEIA) 2003 – 2008. The acute dietary exposure analyses incorporate tolerance-level residues of the currently registered and proposed crops combined with 100% crop treated (%CT) to determine the exposure and risk estimates. Residues of flazasulfuron were all <Level of Quantification (LOQ) (<0.01 ppm) in/on olive fruit and olive oil; therefore, processing factors could not be calculated. An acceptable method was used for residue quantitation, and adequate data were submitted to support sample storage intervals and conditions. In the crop field trials, all residues of parent flazasulfuron in olive were nondetectable. Since all residues were <LOQ, residue decline could not be assessed. Acceptable metabolism studies on grapes, sugarcane, and tomatoes are available. Residues of flazasulfuron were not detected in the tomato study and were only detected as a trace or minor component in the grape and sugarcane studies. Therefore, the processing factors were set at 1 in the dietary exposure assessment.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WEIA 2003 – 2008. The chronic dietary exposure analyses incorporate tolerance-level residues of the currently registered and proposed crops combined with 100 %CT to determine the exposure and risk estimates. Processing factors were set at 1 in the dietary exposure assessment.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that flazasulfuron 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 flazasulfuron. 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 flazasulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flazasulfuron. 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 Pesticide Root Zone Model Ground Water (PRZM GW) for ground water and the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) for surface water, the estimated drinking water concentrations (EDWCs) of flazasulfuron for acute exposures are estimated to be 26.9 parts per billion (ppb) for surface water and 90.8 ppb for ground water.

For chronic exposures for non-cancer assessments EDWCs are estimated to be 4.67 ppb for surface water and 55.6 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 90.8 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 55.6 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).

Flazasulfuron is currently registered for use on turf that could result in residential exposures. Residential exposure may occur by the dermal, oral, and inhalation routes of exposures. Flazasulfuron does not pose a dermal hazard; therefore, only inhalation (handler exposure for adults) and oral (post-application incidental oral for children) were assessed. Non-occupational exposures to flazasulfuron are expected to be for short-term durations only. The recommended residential exposure for use in the adult aggregate assessment reflects inhalation exposure from applications to turf via backpack or manually pressurized handwand. The recommended residential exposure for use in the children 1 to <2 years old aggregate assessment reflects hand-to-mouth exposures from post-application exposure to turf treatments. A turf transferable residues (TTR) study is not required for flazasulfuron at this time since there was no dermal hazard identified and the hand-to-mouth MOE is greater than 1,000 based on default values for the fraction of application rate available for transfer after a turf application. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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."

In 2016, EPA's Office of Pesticide Programs released a guidance document entitled, "Pesticide Cumulative Risk Assessment: Framework for Screening Analysis" *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework*. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRA). The Agency has utilized this framework for flazasulfuron and determined that although flazasulfuron shares some chemical and/or toxicological characteristics (e.g., chemical structure or apical endpoint) with other pesticides, the toxicological database does not support a testable hypothesis for a common mechanism of action. No further data is required to determine that no common mechanism of toxicity exists for flazasulfuron and other pesticides and no further cumulative evaluation is necessary for flazasulfuron.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. The available data indicate that flazasulfuron produced developmental effects in the rabbit (increased abortions), and reproductive effects in the rat (decreased pup body weight), only at maternally/parentally toxic dose levels, and these developmental/offspring effects were not more severe than maternal/parental effects (increased abortions the rabbit, increased nephropathy and decreased pup body weight in the rat). While developmental effects (increased incidence of interventricular septal defect and reduced fetal weights) were seen in rats in the absence of maternal toxicity, an indication of quantitative and qualitative susceptibility, clear NOAELs and LOAELs have been established for these adverse fetal effects. Furthermore, the PODs used for risk assessment are lower than doses associated with these developmental effects. Therefore, the assessments are protective of the observed offspring effects, and the Agency has no concerns for quantitative or qualitative susceptibility.

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 flazasulfuron is complete.

ii. An acute neurotoxicity study was conducted with flazasulfuron at dose levels up to 2,000 mg/kg. Mean motor activity measurements at dose levels of 1,000 and 2,000 mg/kg for males and females were statistically significantly decreased from the respective control groups five hours post-dosing. Animals were less active with more resting time than controls. The effect was reversed by the next scheduled observation (Day 7). Neurohistopathologic evaluation did not demonstrate any test material related neurotoxic lesions following the examination of tissues from the central and peripheral nervous systems of high dose and control animals. The NOAEL was 50 mg/kg. A subchronic neurotoxicity study was conducted with

flazasulfuron at up to 732 mg/kg bw/day in the diet for 90 days. No biologically relevant neurotoxic effects were observed at the dose levels tested. The available neurotoxicity battery, therefore, did not raise concern for neurotoxicity. Similarly, the subchronic and chronic data in the database did not show any adverse effects that could be considered as neurotoxicity.

iii. While there is evidence of increased qualitative and quantitative susceptibility in the young based on rat malformations and decreased fetal weight in two rat developmental toxicity studies, the FQPA Safety Factor is reduced to 1X and is protective of the observed offspring susceptibility because there are clear NOAELs for the developmental effects in the two rat studies developmental toxicity studies and the PODs selected for risk assessment are protective of those effects.

iv. There are no residual uncertainties identified in the exposure databases. The exposure databases are complete or are estimated based on data that reasonably account for potential exposures. The acute and chronic dietary food exposure assessment were conservatively based on tolerance-level residues on the currently registered and proposed crops, 100% CT assumptions, and conservative ground water drinking water modeling estimates. The Agency does not believe that the non-dietary residential exposures are underestimated because they are also based on conservative assumptions. All of the exposure estimates are based on conservative assumptions and are not likely to result in underestimated risk.

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 flazasulfuron will occupy 3.1% of the aPAD for infants less than one-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 flazasulfuron from food and water will utilize 23% of the cPAD for infants less than one-year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flazasulfuron is not expected.

3. *Short- and intermediate-term aggregate risk*. There is potential short-term aggregate exposure to flazasulfuron via the dietary pathway (which is considered background exposure) and the residential pathway (which is considered the primary pathway). Since intermediate-term residential exposures are not likely to occur, intermediate-term aggregate risks were not assessed. Since there is no dermal endpoint, the short-term aggregate exposure assessment for adults includes dietary (food and drinking water) and inhalation handler exposures and results in an aggregate MOE of 1,600. The short-term aggregate exposure assessment for children 1-2 years old includes dietary (food and drinking water) and post-application hand-to-mouth exposure from treated turf and results in an aggregate MOE of 810. Because EPA's level of concern for flazasulfuron is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population*. A cancer aggregate risk assessment was not conducted because there was no evidence of carcinogenicity to humans based on lack of carcinogenic effects in the rat and mouse carcinogenicity studies.

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 flazasulfuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement method is available. The method uses high performance liquid chromatography/tandem mass spectrometry with multiple reaction monitoring (HPLC/MS-MS/MRM). The LOQ is 0.01 ppm.

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 flazasulfuron.

V. Conclusion

Therefore, tolerances are established for residues of flazasulfuron, herbicide, in or on olive at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action 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 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: April 26, 2017.

Michael Goodis,
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 § 180.655, add alphabetically the entry “Olive” to the table in paragraph (a) to read as follows:

§ 180.655 Flazasulfuron; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Olive	0.01
* * * * * * *	

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[FR Doc. 2017-10763 Filed: 5/24/2017 8:45 am; Publication Date: 5/25/2017]