

effects of this rule elsewhere in this preamble.

### Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

### Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these

standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves establishment of a temporary security zone on a portion of the East River and Bronx Kill during the arrival and departure of the President of the United States to and from Randalls and Wards Islands. An environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

### List of Subjects in 33 CFR Part 165

Harbors, Marine security, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01-0092 to read as follows:

**§ 165.T01-0092 Security Zone, East River and Bronx Kill; Randalls and Wards Islands, NY**

(a) *Location.* The following area is a temporary security zone: All waters of

the East River between the Hell Gate Rail Road Bridge (mile 8.2), and a line drawn from a point at approximate position 40°47'27.12" N, 073°54'35.14" W (Lawrence Point, Queens) to a point at approximate position 40°47'52.55" N, 073°54'35.25" W (Port Morris Stacks), and all waters of the Bronx Kill southeast of the Bronx Kill Rail Road Bridge (mile 0.6).

(b) *Definitions.* For purposes of this section "Designated on-scene representative" is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on the COTP's behalf.

(c) *Effective period.* This section is effective from 4 p.m. until 11:30 p.m. on March 1, 2012.

(d) *Regulations.* (1) All persons are required to comply with the general regulations governing security zones found in 33 CFR 165.33.

(2) Entry, transit, or anchoring within the security zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or the COTP's designated representative. The designated on-scene representative may be on a Coast Guard vessel, or onboard a federal, state, or local agency vessel that is authorized to act in support of the Coast Guard.

(3) The COTP will provide notice of this security zone by appropriate means, which may include but are not limited to a Local Notice to Mariners or Broadcast Notice to Mariners.

(4) Vessel operators given permission to enter or operate in the security zone must comply with all directions given to them by the COTP or the designated on-scene representative. Those vessels may be required to anchor or moor up to a waterfront facility.

(5) Vessel operators desiring to enter or operate within the security zone shall telephone the COTP at 718-354-4356 or the designated on-scene representative via VHF channel 16 to obtain permission to do so.

Dated: February 14, 2012.

**G.P. Hitchen,**

*Captain, U.S. Coast Guard, Acting Captain of the Port New York.*

[FR Doc. 2012-4270 Filed 2-23-12; 8:45 am]

**BILLING CODE 9110-04-P**

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2010-0494; FRL-8883-1]

#### Flazasulfuron; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

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

**DATES:** This regulation is effective February 24, 2012. Objections and requests for hearings must be received on or before April 24, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0494. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; email address: [stanton.susan@epa.gov](mailto:stanton.susan@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0494 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 April 24, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0494, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

**II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of August 4, 2010 (75 FR 46926) (FRL-8834-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7666) by ISK Biosciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44077. The petition requested that 40 CFR part 180 be amended by adding a section for the herbicide flazasulfuron and establishing tolerances therein for residues of flazasulfuron, N-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]-3-(trifluoromethyl)-2-pyridinesulfonamide, in or on fruit, citrus, group 10 at 0.01 parts per million (ppm); grapes at 0.01 ppm; and sugarcane at 0.01 ppm. That notice 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.

EPA has made minor changes to the citrus and grape commodity terms. The reason for these changes is explained in Unit IV.C.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. \* \* \*”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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.

Flazasulfuron exhibits low acute toxicity via oral, dermal and inhalation routes of exposure. It is not irritating to the skin or eyes and is not a dermal sensitizer. Subchronic studies in animals indicated decreased body weight gain, slight anemia in rats, and liver abnormalities in dogs. Dermal or systemic toxicity was not seen in a subchronic dermal study in rabbits at dose levels up to the limit dose.

In the longer-term mammalian toxicity studies, the kidney and liver were the primary target organs of flazasulfuron toxicity. Observed effects included adverse changes in kidney function (chronic nephropathy) and

kidney physiology (enlargement, dark color of kidney), increases in liver weight and hepatocellular hypertrophy, increases in inflammatory cell infiltration, hepatocellular necrosis, hepatocellular swelling, and bile duct proliferation.

Developmental toxicity was observed in both rats and rabbits. Reduced fetal weights and delays in ossification were seen in a developmental toxicity study with Sprague-Dawley rats; an increased incidence of visceral malformations (intraventricular septal defect) was seen in a developmental study with Wistar rats. The developmental study in rabbits showed high incidences of abortion at the highest dose tested. Decreases in body weight and chronic nephropathy were observed in offspring in a 2-generation rat reproduction toxicity study. The effects on offspring in these studies occurred at dose levels which were also toxic to the parents.

A transient decrease in motor activity 5 hours post-dosing on Day 0 was observed at the mid-dose in an acute neurotoxicity study. This observation may be associated with a systemic effect and not with neurotoxicity. The effect was reversed by the next scheduled observation (Day 7), and neurohistopathologic evaluation of tissues from the central and peripheral nervous systems of high dose and control animals did not demonstrate any test material-related neurotoxic lesions.

There was no evidence of carcinogenicity in the mouse oncogenicity study or the combined chronic toxicity/carcinogenicity study in the rat and no evidence of genotoxic potential in *in vitro* and *in vivo* mutagenicity studies. Based on the results of these studies, EPA has classified flazasulfuron as “No evidence of carcinogenicity to humans.”

Specific information on the studies received and the nature of the adverse effects caused by flazasulfuron 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 “Flazasulfuron: Human Health Risk Assessment for Proposed Uses on Citrus, Grapes, Sugarcane, Christmas Trees, and Industrial Vegetation,” at p. 36 in docket ID number EPA-HQ-OPP-2010-0494.

**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-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

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

**TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLAZASULFURON 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 females, 13–49 years old, infants and children).	NOAEL = 50 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day ..... aPAD = 0.5 mg/kg/day	Acute neurotoxicity study in rats. LOAEL = 1,000 mg/kg/day based on transient decrease in motor activity at Day 0 (5 hours post-dosing).
Chronic dietary (All populations) ....	NOAEL= 1.3 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.013 mg/kg/day ... cPAD = 0.013 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity in rats. LOAEL = 13.3 mg/kg/day based on adverse change in kidney function (chronic nephropathy).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLAZASULFURON FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Cancer (Oral, dermal, inhalation) ..	Classification: "No evidence of carcinogenicity to humans" based on lack of carcinogenic effects in the rat and mouse carcinogenicity studies and lack of a mutagenicity concern.		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

### 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. No other tolerances have been established for flazasulfuron. 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) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that 100% of citrus fruit, grape, and sugarcane commodities are treated with flazasulfuron and that residues on these commodities are present at the tolerance levels.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA made the same assumptions (tolerance-level residues and 100 percent crop treated (PCT)) as in the acute 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.

2. *Dietary exposure from drinking water.* The residues of concern in drinking water include flazasulfuron and its identified degradates DTPU (N-(4,6-dimethoxy-2-pyrimidinyl)-N-[3-(trifluoromethyl)-2-pyridinyl]urea), DTPP (4,6-dimethoxy-N-[3-(trifluoromethyl)-2-pyridinyl]-2-pyrimidinamine), TPSA (3-(trifluoromethyl)-2-

pyridinesulfonamide), ADMP (2-amino-4,6-dimethoxypyrimidine), HTPP (6-methoxy-2-[[3-(trifluoromethyl)-2-pyridinyl]amino]-4-pyrimidinol), and 2,3-GTP (3-trifluoromethyl-2-pyridylguanidine). The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flazasulfuron and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flazasulfuron and its degradates. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flazasulfuron and its degradates for acute exposures are estimated to be 26.9 parts per billion (ppb) for surface water and 102 ppb for ground water. EDWCs of flazasulfuron and its degradates for chronic exposures for non-cancer assessments are estimated to be 4.67 ppb for surface water and 102 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration value of 102 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 non-residential turf, including recreation areas (golf courses and professionally managed sports fields). There is a potential for post-application short-term dermal exposure of adults and children entering recreation areas which have been treated with flazasulfuron. However, since no hazard associated with dermal exposure was

identified in the toxicity database for flazasulfuron, flazasulfuron is not expected to pose a risk from post-application dermal exposure.

In accordance with current policy, EPA did not conduct a quantitative assessment of post-application inhalation exposure to flazasulfuron; however, volatilization of pesticides may be a source of post-application inhalation exposure of individuals nearby pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 <http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>. EPA is currently in the process of evaluating the SAP report and may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate post-application inhalation exposure into the Agency's risk assessments. In the case of flazasulfuron, although EPA has not conducted a quantitative assessment of post-application inhalation exposure, the Agency's concern for such exposures is low due to flazasulfuron's low vapor pressure ( $<1 \times 10^{-7}$  torr) and low acute toxicity.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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 flazasulfuron to share a common mechanism of toxicity with any other substances, and flazasulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flazasulfuron does not have a common mechanism of toxicity with other substances. For information regarding

EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicity database for flazasulfuron includes developmental toxicity studies in rats (Sprague-Dawley and Wistar) and rabbits and a 2-generation reproduction toxicity study in rats.

There was no evidence of increased quantitative susceptibility of fetuses or offspring to flazasulfuron in any of the developmental or reproductive toxicity studies, since the effects on offspring occurred at dose levels which were also toxic to the parents. There is a potential concern for increased qualitative susceptibility of offspring based on the intraventricular septal defect seen in offspring at minimally toxic maternal dose levels in the Wistar rat developmental toxicity study; however, the concern for the increased susceptibility is low, and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors (UFs) to be used in the risk assessment for flazasulfuron. There was a clear NOAEL and LOAEL in the Wistar rat study, and thus the dose response for the observed effect is well defined. In addition, since the Agency is using PODs for risk assessment that are lower than the NOAEL in the Wistar rat study, the PODs are protective of the adverse developmental effect.

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, except for an immunotoxicity study (OPPTS Guideline 870.7800) and a subchronic neurotoxicity study (OPPTS Guideline 870.6200b). These studies are now requirements under 40 CFR 158.500 for pesticide registration. In the absence of specific immunotoxicity and subchronic neurotoxicity studies, EPA has evaluated the available flazasulfuron toxicity database to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity or neurotoxicity.

With the exception of a transient decrease in motor activity at a high dose level (1,000 mg/kg/day) in the acute neurotoxicity study, which may be associated with a systemic effect, there is no evidence of neurotoxicity in the flazasulfuron toxicity database. There is no evidence of immunotoxicity in the database, as indicated by hematology, lymphoid organ weights and histopathology in standard studies. Consequently, EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment and for evaluation of the requirements under FQPA, and an additional database uncertainty factor is not needed to account for the lack of these studies.

ii. Although there was evidence of potential increased qualitative susceptibility of fetuses in the developmental toxicity study in Wistar rats, EPA's concern for increased qualitative susceptibility is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for flazasulfuron.

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

#### 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 aPAD and 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 4% 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 54% 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-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). Although there is potential for short-term residential dermal and inhalation post-application exposure to flazasulfuron, no short-term dermal hazard was identified for flazasulfuron and inhalation exposure is expected to be negligible; therefore, EPA relies on the chronic dietary risk assessment for evaluating short-term aggregate exposure to flazasulfuron.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, flazasulfuron is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for flazasulfuron.

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

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

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography/tandem mass spectrometry with multiple reaction monitoring (HPLC/MS-MS/MRM)) 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](mailto: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 U.N. 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.

##### C. Revisions to Petitioned-For Tolerances

EPA has revised the citrus fruit crop group and grape commodity terms. "Grapes" has been changed to "grape" to agree with the Agency's Food and Feed Vocabulary. ISK Biosciences Corporation petitioned for a tolerance on the crop group "fruit, citrus, group 10." In the **Federal Register** of December 8, 2010 (75 FR 76284) (FRL-8853-8), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised the citrus fruit crop group. Changes to crop group 10 included adding Australian desert lime, Australian finger lime, Australian round

lime, Brown River finger lime, Japanese summer grapefruit, Mediterranean mandarin, Mount White lime, New Guinea wild lime, Russell River lime, sweet lime, Tachibana orange, Tahiti lime, tangelo, tangor, trifoliolate orange, and unqi fruit; creating subgroups; revising the representative commodities; and naming the new crop group citrus fruit group 10-10. EPA indicated in the December 8, 2010 final rule as well as the earlier January 6, 2010 proposed rule (75 FR 807) (FRL-8801-2) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. That is possible here because, despite the revisions to the representative commodities for the crop group, the petitioner's residue data submission pertaining to the representative commodities for the earlier version of the crop group meets the residue data requirements for the revised representative commodities. Additionally, EPA assessed the risk taking into account the additional crops included in the revised crop group. Therefore, consistent with this December 8, 2010 rule, EPA is establishing a tolerance on the revised subgroup "fruit, citrus, group 10-10."

#### V. Conclusion

Therefore, tolerances are established for residues of flazasulfuron, N-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]-3-(trifluoromethyl)-2-pyridinesulfonamide, including its metabolites and degradates, as set forth in the regulatory text.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special

considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination With Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not

a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 9, 2012.

**Steven Bradbury,**

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.655 is added to read as follows:

**§ 180.655 Flazasulfuron; tolerances for residues.**

(a) *General.* Tolerances are established for residues of flazasulfuron, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flazasulfuron [N-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]-3-(trifluoromethyl)-2-pyridinesulfonamide].

Commodity	Parts per million
Fruit, citrus, group 10–10 .....	0.01
Grape .....	0.01
Sugarcane .....	0.01

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

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

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

[FR Doc. 2012–4332 Filed 2–23–12; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA–HQ–OPP–2009–0364; FRL–9336–9]**

**Fluopyram; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fluopyram in or on multiple commodities which are

identified and discussed later in this document. Bayer Crop Science requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 24, 2012. Objections and requests for hearings must be received on or before April 24, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0364. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Lisa Jones, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9424; email address: [jones.lisa@epa.gov](mailto:jones.lisa@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide

for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0364 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 April 24, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0364, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200