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: July 22, 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 § 180.418, revise the entries for ''corn, field, forage,'' ''corn, field, stover,'' and ''corn, pop, stover'' in the table in paragraph (a)(2) to read as follows:

§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Corn, field, forage	9.0
* * * * *	
Corn, field, stover	30
* * * * *	
Corn, pop, stover	30
* * * * *	

* * * * *

[FR Doc. 2015–18737 Filed 7–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0138; FRL–9923–86]

Isofetamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isofetamid in or on multiple commodities that are identified and discussed later in this document. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 30, 2015. Objections and requests for hearings must be received on or before September 28, 2015, 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–2013–0138, 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, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; 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–2013–0138 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 September 28, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0138, 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 June 5, 2013 (78 FR 33785) (FRL–9386–2), 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 3F8142) 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 fungicide isofetamid, *N*-[1,1-dimethyl-2-[2-methyl-4-(1-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide in or on almond at 0.02 parts per million (ppm); almond, hulls at 0.2 ppm; lettuce, head at 6.0 ppm; lettuce, leaf at 7.0 ppm; low growing berry crop subgroup 13–07G at 4.0 ppm; rapeseed, crop subgroup 20A at 0.04 ppm; and small fruit vine climbing crop subgroup 13–07F at 3.0 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.

Based upon review of the data supporting the petition, EPA has determined that additional tolerances are necessary; revised some of the proposed tolerances; and corrected some commodity definitions for the tolerances. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with 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 isofetamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isofetamid 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 toxicology database is complete for isofetamid. In repeated dose studies, the liver was the primary target organ in the rat, mouse, and dog, as indicated by increased liver weights, changes in the clinical chemistry values, and liver hypertrophy. A second target organ was the thyroid in the rat and dog, as indicated by changes in thyroid weights and histopathology. Adrenal weight changes were observed in the subchronic rat and dog studies. In the rat and dog, the dose levels where toxicity was observed were similar or higher in the chronic studies compared with the respective subchronic studies, showing an absence of progression of liver toxicity with time. There was no evidence of carcinogenicity in the rat or mouse cancer studies; the mutagenicity battery was negative. There are no genotoxicity, neurotoxicity, or immunotoxicity concerns observed in the available toxicity studies. Developmental toxicity was not observed in the rat or rabbit, and offspring effects such as decreased body weight were seen only in the presence of parental toxicity in the multi-generation rat study. Isofetamid is classified as ''Not Likely to be Carcinogenic to Humans'' based on the absence of increased tumor incidence in acceptable/guideline carcinogenicity studies in rats and mice. Isofetamid is not acutely toxic; it is classified as Toxicity Category III for acute oral and dermal exposure, and Toxicity Category IV for inhalation exposure. Furthermore, it is not irritating to the eye or skin, and it is not a dermal sensitizer. Specific information on the studies received and the nature of the adverse effects caused by isofetamid 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 *Isofetamid. Aggregate Human Health Risk Assessment for the Proposed New Uses of the New Active Fungicide,*

including Agricultural Uses on Almonds, Lettuce, Small Vine Climbing Fruits (Crop Subgroup 13–07F), Low Growing Berries (Crop Subgroup 13–07G), and Rapeseed (Crop Subgroup 20A); and Uses on Turfgrass (including Golf Courses, Sod Farms, Seed Farms, Recreational Fields, and Commercial/Residential Lawns) at pages 12–18 in docket ID number EPA–HQ–OPP–2013–0138.

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://www.epa.gov/pesticides/factsheets/riskassess.htm*.

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

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ISOFETAMID 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 (All Populations)	A toxicity endpoint was not identified. Toxicological effects attributable to a single exposure (dose) were not observed in oral toxicity studies.		
Chronic dietary (All populations)	NOAEL = 76.6 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.77 mg/kg/day cPAD = 0.77 mg/kg/day	Reproduction and fertility effects (rat) LOAEL = 679/775 mg/kg/day based on hepatocellular hypertrophy in the liver and follicular cell hypertrophy in the thyroid in both sexes and generations, decreased spleen weights and cytoplasmic eosinophilic inclusion bodies in the liver of F1 males, and decreased pup body weight in both sexes and generations.
Incidental oral short-term (1 to 30 days) and Incidental oral intermediate-term (1 to 6 months)	NOAEL = 76.6 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Residential LOC for MOE = 100.	Reproduction and fertility effects (rat) LOAEL = 679/775 mg/kg/day based on hepatocellular hypertrophy in the liver and follicular cell hypertrophy in the thyroid in both sexes and generations, decreased spleen weights and cytoplasmic eosinophilic inclusion bodies in the liver of F1 males, and decreased pup body weight in both sexes and generations
Dermal Short-Term (1–30 days)	A toxicity endpoint was not identified. Systemic toxicity was not seen in 28-day dermal toxicity in rats up to the limit dose (1,000 mg/kg/day). There are no concerns for developmental or reproductive toxicity or neurotoxicity in rat and rabbit studies.		
Inhalation short-term (1 to 30 days)	NOAEL = 76.6 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Residential LOC for MOE = 100	Reproduction and fertility effects (rat) LOAEL = 679/775 mg/kg/day based on hepatocellular hypertrophy in the liver and follicular cell hypertrophy in the thyroid in both sexes and generations, decreased spleen weights and cytoplasmic eosinophilic inclusion bodies in the liver of F1 males, and decreased pup body weight in both sexes and generations.
Cancer (Oral, dermal, inhalation)	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. 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_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* EPA assessed dietary exposures from isofetamid 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. No such effects were identified in the toxicological studies for isofetamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the 2003–2008 food consumption data from the USDA's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). A partially refined chronic (food and drinking water) dietary assessment was conducted assuming mean field trial residues of the combined residues of parent and GPTC for all proposed crops and 100% CT. Empirical and default processing factors were used as available.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that isofetamid 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 PCT information in the dietary assessment for isofetamid. Mean field trial residues of the combined residues of parent and GPTC were used.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for isofetamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of isofetamid. 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 Flooded Application Model and the Pesticide Root Zone Model Ground Water (PRZM GW) the estimated drinking water concentrations (EDWCs) of isofetamid for chronic exposures for non-cancer assessments are estimated to be 110 ppb for surface water and 43 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 110 ppb was used to assess the contribution from 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).

Isofetamid is currently under review for registering the following uses that could result in residential exposures: Foliar and systemic fungicide for control in turfgrass including golf courses, residential lawns, and recreational turfgrass. Since there may be residential use sites, residential handler exposure and risk estimates were calculated for all possible residential exposure scenarios. Including all possible residential exposure scenarios provides a conservative and health protective assessment for the potential for homeowners to use the professionally labeled products on residential use sites. Since there is no dermal toxicity endpoint, the residential handler assessment only includes the inhalation route of exposure. Residential handler exposure is expected to be short-term in duration as a maximum of eight applications are allowed per year. Thus, intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Unit exposure values and estimates for area treated or amount handled were taken from the Agency's 2012 Residential SOPs [1] (Lawns/Turf). The algorithms used to estimate exposure and dose for residential handlers can be found in the 2012 Residential SOPs [2] (Lawns/Turf). Risk estimates of all possible scenarios are not of concern. Short-term inhalation MOEs range from 850,000 to 18,000,000. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 isofetamid to share a common mechanism of toxicity with any other substances, and isofetamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isofetamid 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.*

[1] Available: *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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.* There is no evidence of developmental toxicity or reproductive susceptibility, and there are no residual uncertainties concerning pre- or post-natal toxicity or exposure.

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 isofetamid is complete.

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

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

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and average (mean) field trial residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to isofetamid in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by isofetamid.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, isofetamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isofetamid from food and water will utilize <1% of the cPAD for children (1–2 years 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 isofetamid 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). Isofetamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to isofetamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 24,000 and 3,900 for adults and children (1–2 years old) respectively. Because EPA's level of concern for isofetamid is a MOE of 100 or below, these MOEs are not of concern.

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, isofetamid 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 isofetamid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, isofetamid 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 isofetamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography with tandem mass spectrometry (LC–MS/MS) method (Document Number JSM0119; MRID 49011967) is available to enforce the tolerance expression.

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 any MRLs for isofetamid. Canada is concurrently establishing tolerances for all of the same commodities identified in this document except almond hulls because Canada does not set tolerances on livestock feed commodities. Canada's recommended tolerance levels for these commodities are the same as the U.S. established tolerance levels. The tolerance expression for the U.S. and Canada is the same, with isofetamid as the residue of concern for primary crops.

C. Revisions to Petitioned-For Tolerances

The Agency has made revisions to some of the petitioned-for tolerance levels based on the following reasons:

1. Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures;

2. The parent only is the residue of concern for primary crop tolerances rather than parent and the metabolite GPTC; and

3. The concentration of residues in two processed commodities.

Since all residues of isofetamid (parent) were nondetectable (<0.01 ppm) in almond nutmeat and hulls, the proposed tolerances of 0.02 ppm for almond (nutmeat) and 0.2 ppm for almond hulls will both be reduced to 0.01 ppm, the limit of quantitation of the analytical method.

Based on the OECD tolerance calculation procedures, the proposed tolerance for head lettuce of 6.0 ppm will be reduced to 5.0 ppm. Based on the OECD tolerance calculation procedures, the proposed tolerance for the rapeseed subgroup 20A of 0.04 ppm will be reduced to 0.015 ppm.

The petitioner did not propose tolerances for the processed commodities, canola oil and raisins. Since residues concentrate significantly in canola oil and raisins, tolerances will be established at 0.03 ppm for *canola, refined oil,* and 5.0 ppm for *grape, raisin.* These Agency recommendations are based on the highest average field trial (HAFT) residues for canola seed and grape and the processing factors for canola oil and raisins. The petitioner did not propose tolerances for flaxseed oil, mustard seed oil, or sesame oil. However, flaxseed, mustard seed, and sesame are members of the rapeseed subgroup 20A, with canola as the representative crop, and treated commodities could be processed to produce sesame oil, mustard seed oil and flaxseed oil. Therefore, the Agency is also establishing tolerances for residues in flaxseed oil, mustard seed oil, and sesame oil. Tolerances are being established at 0.03 ppm, the same level as for refined canola oil.

Additionally, some of the requested tolerances have been corrected. Almond has been revised from 0.02 ppm to 0.01 ppm; almond, hulls from 0.2 ppm to 0.01 ppm; lettuce, head from 6.0 ppm to 5.0 ppm; and rapeseed, subgroup 20A from 0.04 ppm to 0.015 ppm. The Agency is setting tolerances on some processed commodities that were not

proposed by the petitioner including canola, refined oil at 0.03 ppm; flax, seed, oil at 0.03 ppm; grape, raisin at 5.0 ppm; mustard, seed, oil at 0.03 ppm and sesame, oil at 0.03 ppm.

V. Conclusion

Therefore, tolerances are established for residues of isofetamid, in or on almond at 0.01 ppm; almond, hulls at 0.01 ppm; canola, refined oil at 0.03 ppm; flax, seed, oil at 0.03 ppm; grape, raisin at 5.0 ppm; lettuce, head at 5.0 ppm; lettuce, leaf at 7.0 ppm; berry, low growing, subgroup 13–07G at 4.0 ppm; mustard, seed, oil at 0.03 ppm; rapeseed subgroup 20A at 0.015 ppm; sesame, oil at 0.03 ppm; and fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 3.0 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: July 21, 2015.

Jack Housenger,

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. Add § 180.681 to subpart C to read as follows:

§ 180.681 Isofetamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide isofetamid, 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 isofetamid, *N*-[1,1-dimethyl-2-[2-methyl-4-(1-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide, in or on the following commodities:

Commodity	Parts per million
Almond	0.01
Almond, hulls	0.01
Berry, low growing, subgroup 13–07G	4.0
Canola, refined oil	0.03
Flax, seed, oil	0.03
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	3.0
Grape, raisin	5.0
Lettuce, head	5.0
Lettuce, leaf	7.0
Mustard, seed, oil	0.03
Rapeseed subgroup 20A	0.015
Sesame, oil	0.03

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

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

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

[FR Doc. 2015–18738 Filed 7–29–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0714; FRL–9927–63]

Benalaxyl-M; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benalaxyl-M in or on grape and tomato. Since there are currently no U.S. registrations of benalaxyl-M for use on grape and tomato, this tolerance will allow the import of grape and tomato containing residues of benalaxyl-M. Technology Sciences Group, on behalf of Isagro S.p.A, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 30, 2015. Objections and requests for hearings must be received on or before September 28, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).