

List of Subjects in 40 CFR Part 180

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

Dated: May 8, 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 § 180.641, in the table in
paragraph (a)(1):

■ i. Add alphabetically the entries:
“Beet, sugar, molasses”; “Beet, sugar,
roots”; “Carrot, roots”; “Fruit, stone,
group 12–12”; and “Nut, tree, group 14–
12”; and

■ ii. Remove entries for “Fruit, stone,
group 12” and “Nut, tree, group 14”.

The additions read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * *	*
Beet, sugar, molasses	0.30
Beet, sugar, roots	0.15
* * * *	*
Carrot, roots	0.15
* * * *	*
Fruit, stone, group 12–12	4.5
* * * *	*
Nut, tree, group 14–12	0.25
* * * *	*

[FR Doc. 2017–12348 Filed 6–13–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA–HQ–OPP–2016–0263; FRL–9961–80]

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 which are identified and discussed later in this document. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The regulation also removes the existing time-limited tolerances for residues on “bushberry subgroup 13–07B” and “caneberry subgroup 13–07A” because they are no longer needed as a result of this action.

DATES: This regulation is effective June 14, 2017. Objections and requests for hearings must be received on or before August 14, 2017, 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–2016–0263, 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 L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: RDfrNotices@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this action apply to me?**

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0263 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 August 14, 2017. 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–2016–0263, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about

dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 7, 2017 (82 FR 9555) (FRL-9956-86), 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 6F8457) by ISK Biosciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44077. The petition requested that 40 CFR 180.681 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 caneberry subgroup 13-07A at 3.0 parts per million (ppm); apple, wet pomace, at 2.0 ppm; bushberry, subgroup 13-07B at 6.0 ppm; cattle, fat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; cherry subgroup 12-12A at 5.0 ppm; fruit, pome, group 11-10 at 0.6 ppm; fruit, small vine climbing, except grape, subgroup 13-7E at 9.0 ppm; goat, fat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea and field pea at 0.05 ppm; pea and bean, succulent shelled, subgroup 6B, except cowpea at 0.04 ppm; peach subgroup 12-12B at 3.0 ppm; plum, prune, dried at 3.5 ppm; plum subgroup 12-12C at 0.8 ppm; sheep, fat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; and vegetable, legume, edible podded, subgroup 6A at 1.5 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 revised some of the proposed tolerances; determined that tolerances for residues in livestock commodities are not required; and corrected some of the commodity definitions. The reason for these changes are explained in Unit IV.D.

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 are can be found at <http://www.regulations.gov> in document *Isofetamid. Aggregate Human Health Risk Assessment for the Proposed New Agricultural Uses on Bushberry, Subgroup 13-07B; Caneberry, Subgroup 13-07A; Cherry, Subgroup 12-12A; Dried Shelled Pea and Bean, Except Soybean, Subgroup 6C; Edible-Podded Legume Vegetables, Subgroup 6A; Peach, Subgroup 12-12B; Plum, Subgroup 12-12C; Pome Fruit, Group 11-10; Small Vine Climbing Fruit, Except Grape, Subgroup 13-07E; Succulent Shelled Pea and Bean, Subgroup 6B; as well as Livestock Commodities; in Addition to Uses on Ornamental Plants (including Residential Use Sites)*, pages 12-18 in docket ID number EPA-HQ-OPP-2016-0263.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some

degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for isofetamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of July 30, 2015 (80 FR 45440) (FRL-9923-86).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isofetamid, EPA considered exposure under the petitioned-for tolerances as well as all existing isofetamid tolerances in 40 CFR 180.681. 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.* An unrefined chronic (food and drinking water) dietary assessment was conducted for all registered and proposed food uses of isofetamid using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The chronic dietary (food and drinking water) exposure assessment for isofetamid incorporated existing tolerance-level residues, Agency-recommended tolerance-level residues for proposed tolerances, DEEM default processing factors, and 100 PCT (percent crop treated). Some tolerance levels were adjusted to include residues of the metabolite, GPTC (a residue of concern for risk assessment). DEEM default processing factors were used for dried apples, apple juice, dried pear, cherry juice, dried apricot, dried peach, plum, prune juice, cranberry juice, and grape juice. The EDWC of 110

microgram/Liter ($\mu\text{g/L}$) was incorporated directly into the dietary assessment.

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 anticipated residue and/or PCT information in the dietary assessment for isofetamid. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

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 parts per billion (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 registered for the following uses that could result in residential exposures: Turfgrass including golf courses, residential lawns, and recreational turfgrass. It is currently under review for registering use on ornamental plants. The proposed ornamental use is not intended for homeowner use and therefore a quantitative residential handler assessment was not conducted. Additionally, post-application exposures for adults and children are expected to be negligible. However, the existing turf use may result in short- and

intermediate-term exposures.

Residential exposure may occur by the dermal and incidental oral routes of exposures following the application of isofetamid on residential turf. However, since dermal hazard has not been identified for isofetamid, the only exposure scenario quantitatively assessed is for post-application incidental oral (for children 1 to <2 years old). These exposures have been assessed with current policies, which include the Agency's 2012 Residential Standard Operating Procedures (<http://www.epa.gov/pesticides/science/residential-exposure-sop.html>) along with policy changes for body weight assumptions.

Even though a previous risk assessment identified residential handler risk estimates for use in aggregate assessment, based on current policy and that isofetamid products are intended for sale/use to/by professional applicators, residential handler exposure assessments for turf are no longer applicable to the isofetamid aggregate risk assessment. Therefore, the aggregate assessment for this action only includes a risk contribution from residential post-application incidental oral exposure for children 1 to <2 years old.

There is the potential for post-application exposure for individuals as a result of being in an environment that has been previously treated with isofetamid such as residential ornamental lawns. Since dermal hazard has not been identified for isofetamid, a quantitative assessment for dermal exposure is not necessary and the only exposure scenarios quantitatively assessed are for children 1 to <2 years old who may experience short-term incidental oral exposure to isofetamid from treated turf. Intermediate-term incidental oral post-application exposures are possible (i.e., from soil ingestion due to the persistence of isofetamid); however, the short-term incidental oral exposures are protective of the possible intermediate-term incidental oral exposures because the POD for both durations is the same. Post-application inhalation exposure is expected to be negligible for the proposed residential uses.

The post-application incidental oral MOE values were calculated based on the scenario of liquid application of isofetamid to turf. Post-application risk estimates for all incidental oral scenarios are not of concern (MOEs range from 5,900 to 4,000,000). The incidental oral scenarios (i.e., hand-to-mouth and object-to-mouth) should be considered inter-related and it is likely that they occur interspersed amongst

each other across time. However, combining these scenarios would be overly-conservative because of the conservative nature of each individual assessment. Incidental oral risk estimates are highly conservative because the short- and intermediate-term incidental oral POD is based on a 90-day exposure duration which represents daily exposure for 90 days. 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.”

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* 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 tolerance level 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 4.0% 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 an aggregate MOE of 1,600 for children (1–2 years old). Because EPA’s level of concern for isofetamid is a MOE of 100 or below, this MOE is 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 is available to enforce the tolerance expression. Multiresidue methods testing data have been submitted for isofetamid and GPTC. The data indicate that multiresidue methods are not suitable for analysis of isofetamid and GPTC, so the multiresidue methods cannot serve as enforcement methods. The multiresidue data have been forwarded to the Food and Drug Administration (FDA).

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 MRLs for isofetamid. There are no Canadian, Codex, or Mexican maximum residue limits (MRLs) for isofetamid in/on the commodities included in this petition.

C. Revisions to Petitioned-For Tolerances

All tolerance levels are based upon the Organization for Economic Co-operation and Development's (OECD) tolerance calculation procedures. Thus, the tolerance levels established in this notice for isofetamid in/on bushberry, subgroup 13-07B; cherry, subgroup 12-12A; plum, prune, dried; dried shelled pea and bean, except soybean, subgroup 6C; and succulent shelled pea and bean, subgroup 6B are lower than those requested by the petitioner. The tolerance levels established in this notice for caneberry, subgroup 13-07A and fruit, small vine climbing, except grape, subgroup 13-07E are higher than those requested by the petitioner based on the OECD calculation procedures.

Additionally, the Agency has determined that tolerances requested for residues in livestock commodities are not required. These tolerances fall under 40 CFR 180.6(a)(3) regarding secondary residues in livestock commodities, *i.e.*, it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

The following commodity definitions have been corrected: Bushberry subgroup 13-07B; fruit, small vine climbing, except grape, subgroup 13-07E; pea and bean, dried shelled, except soybean, subgroup 6C; and pea and bean, succulent shelled, subgroup 6B.

V. Conclusion

Therefore, tolerances are established for residues of isofetamid, in or on apple, wet pomace, at 2.0 parts per million (ppm); bushberry subgroup 13-07B at 5.0 ppm; caneberry subgroup 13-07A at 4.0 ppm; cherry subgroup 12-12A at 4.0 ppm; fruit, pome, group 11-10 at 0.60 ppm; fruit, small vine climbing, except grape, subgroup 13-07E at 10.0 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, at 0.040 ppm; pea and bean, succulent shelled, subgroup 6B, at 0.030 ppm; peach subgroup 12-12B at 3.0 ppm; plum, prune, dried at 1.50 ppm; plum subgroup 12-12C at 0.80 ppm; and vegetable, legume, edible podded, subgroup 6A at 1.50 ppm. Additionally, the existing time-limited tolerances are being removed for both Caneberry subgroup 13-07A at 4.0 ppm, and for Bushberry subgroup 13-07B at 5.0 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

