

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0385; FRL-10027-01-OCSPP]

Isometamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isofetamid in or on multiple commodities discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 29, 2022. Objections and requests for hearings must be received on or before September 27, 2022, 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-2021-0385, is available at <https://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 and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; 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 Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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-2021-0385 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 27, 2022. 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-2021-0385, by one of the following methods:

- **Federal eRulemaking Portal:** <https://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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 21, 2021 (86 FR 58239) (FRL-8792-04-OCSPP), 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 1E8913) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to amend 40 CFR part 180.681 to establish tolerances for residues of the fungicide isofetamid, N-[1,1-dimethyl-2-[2-methyl-4-(1-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide including its metabolites and degradates, in or on the raw agricultural commodities ginseng at 3 ppm; individual commodities of Proposed Crop Subgroup 6-XXA: Edible podded bean legume vegetable subgroup at 0.6 ppm; individual commodities of Proposed Crop Subgroup 6-XXB: Edible podded pea legume vegetable subgroup at 1.5 ppm; individual commodities of Proposed Crop Subgroup 6-XXC: Succulent shelled bean subgroup at 0.04 ppm; individual commodities of Proposed Crop Subgroup 6-XXD: Succulent shelled pea subgroup at 0.04 ppm; individual commodities of Proposed Crop Subgroup 6-XXE: Dried shelled bean (except soybean), subgroup at 0.04 ppm; and individual commodities of Proposed Crop Subgroup 6-XXF: Dried shelled pea subgroup at 0.04 ppm. See the October 21, 2021, **Federal Register** notice for the specific commodities. Additionally, the petition requested to remove the established tolerances in or on the raw agricultural commodities: Pea and bean, dried shelled, except soybean, subgroup 6C at 0.040 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.030 ppm; and vegetable, legume, edible podded, subgroup 6A at 1.50 ppm. That document referenced a summary of the petition, which is available in the docket, <https://www.regulations.gov>.

There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the crop group definitions to be consistent with Agency terminology and removing the existing tolerances for Vegetable, legume, edible podded, subgroup 6A; Pea and bean, succulent shelled, subgroup 6B; and Pea and bean, dried shelled, except soybean, subgroup 6C.

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 therein, 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.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings in 2015 and 2017 in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to isofetamid and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from the 2015 and 2017 rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of isofetamid, see Unit III.A. of the isofetamid tolerance rulemaking published in the **Federal Register** of July 30, 2015 (80 FR 45438) (FRL–9923–86).

Toxicological points of departure/ Levels of concern. For a summary of the Toxicological Points of Departure/ Levels of Concern for isofetamid used for human risk assessment, please reference Unit III.B. of the July 30, 2015, rulemaking.

Exposure assessment. EPA’s dietary exposure assessments have been updated to include the additional exposure from the new use of isofetamid on ginseng and the crop group expansions to all the individual bean and pea commodities in proposed crop group 6–XX, which is not yet finalized. An acute dietary exposure assessment was not performed as there are no appropriate toxicological effects attributable to a single exposure (dose). An unrefined chronic aggregate dietary (food and drinking water) exposure and risk assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses 2005–2010 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 unrefined chronic dietary exposure assessment used tolerance-level residues and assumed 100 percent crop treated (PCT) for all registered and proposed commodities. Default processing factors were used for all other proposed and registered processed commodities. Exposure to drinking water was incorporated directly into the dietary assessment. A cancer dietary assessment was not conducted because isofetamid is classified as “not likely to be carcinogenic to humans.”

Drinking water and non-occupational exposures. The previously recommended estimated drinking water concentrations (EDWCs) remain current and are considered protective potential

drinking water residue levels anticipated from the proposed tolerance updates. As stated in the July 30, 2015, rulemaking, the chronic dietary exposure and risk assessment incorporate the highest total estimated drinking water concentrations (EDWC) of 110 parts per billion directly into this dietary assessment. The residential exposure assessment has not changed since the June 14, 2017, rulemaking (82 FR 27149) (FRL–9961–80) because there are no proposed new residential uses. For a summary of the residential exposure analysis for isofetamid used for the human risk assessment, please reference Unit III.C.3. of the June 14, 2017, rulemaking.

Cumulative exposure. 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.” Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for isofetamid and 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 not assumed that isofetamid has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the July 30, 2015, rulemaking for a discussion of the Agency’s rationale for that determination.

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 population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not performed as there were no appropriate toxicological effects

attributable to a single exposure (dose) observed in available oral toxicity studies, including maternal toxicity in the developmental toxicity studies. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 4.0% of the cPAD for children 1 to 2 years old, the group with the highest exposure. The combined short-term food, water, and residential exposures result in an aggregate MOE of 670 for children 1 to 2 years old. This MOE is greater than the level of concern of 100 and is therefore not of concern. Isofetamid is classified as "Not Likely to Be Carcinogenic to Humans"; therefore, EPA does not expect isofetamid exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes 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. More detailed information on this action can be found in the document titled "Isofetamid. Human Health Risk Assessment for the Petition to Establish Permanent Tolerances and Associated Section 3 Registration for Residues Resulting from Proposed Use on Ginseng and for Crop Group Conversions and Expansions." in docket ID EPA-HQ-OPP-2021-0385.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 30, 2015, rulemaking.

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 FFDC section 408(b)(4).

There are no Codex MRLs for isofetamid in or on ginseng. Presently, there are Codex MRLs established for residues of isofetamid on edible podded beans and peas at 0.6 ppm and on dry beans and peas at 0.09 ppm. The U.S. tolerances of 0.6 ppm for the commodities in the proposed edible podded bean legume subgroup are harmonized with the Codex MRL for edible podded beans. The U.S. tolerances for the edible podded pea commodities at 1.5 ppm are not harmonized with the lower Codex MRL

of 0.6 ppm. Harmonization with Codex is not possible for the commodities in the proposed edible podded pea legume vegetable subgroup because decreasing the U.S. tolerance could cause U.S. growers to have violative residues despite legal use of isofetamid according to the label. EPA considered harmonizing the tolerances for dried bean and dried pea commodities with the Codex MRL, but rather elected to be consistent with the Canadian MRL.

V. Conclusion

Therefore, tolerances are established for residues of isofetamid in or on Bean, adzuki, dry seed at 0.04 ppm; Bean, American potato, dry seed at 0.04 ppm; Bean, asparagus, dry seed at 0.04 ppm; Bean, asparagus, edible podded at 0.6 ppm; Bean, black, dry seed at 0.04 ppm; Bean, broad, dry seed at 0.04 ppm; Bean, broad, succulent shelled at 0.04 ppm; Bean, catjang, dry seed at 0.04 ppm; Bean, catjang, edible podded at 0.6 ppm; Bean, catjang, succulent shelled at 0.04 ppm; Bean, cranberry, dry seed at 0.04 ppm; Bean, dry, dry seed at 0.04 ppm; Bean, field, dry seed at 0.04 ppm; Bean, French, dry seed at 0.04 ppm; Bean, French, edible podded at 0.6 ppm; Bean, garden, dry seed at 0.04 ppm; Bean, garden, edible podded at 0.6 ppm; Bean, goa, dry seed at 0.04 ppm; Bean, goa, edible podded at 0.6 ppm; Bean, goa, succulent shelled at 0.04 ppm; Bean, great northern, dry seed at 0.04 ppm; Bean, green, dry seed at 0.04 ppm; Bean, green, edible podded at 0.6 ppm; Bean, guar, dry seed at 0.04 ppm; Bean, guar, edible podded at 0.6 ppm; Bean, kidney, dry seed at 0.04 ppm; Bean, kidney, edible podded at 0.6 ppm; Bean, lablab, dry seed at 0.04 ppm; Bean, lablab, edible podded at 0.6 ppm; Bean, lablab, succulent shelled at 0.04 ppm; Bean, lima, dry seed at 0.04 ppm; Bean, lima, succulent shelled at 0.04 ppm; Bean, morama, dry seed at 0.04 ppm; Bean, moth, dry seed at 0.04 ppm; Bean, moth, edible podded at 0.6 ppm; Bean, moth, succulent shelled at 0.04 ppm; Bean, mung, dry seed at 0.04 ppm; Bean, mung, edible podded at 0.6 ppm; Bean, navy, dry seed at 0.04 ppm; Bean, navy, edible podded at 0.6 ppm; Bean, pink, dry seed at 0.04 ppm; Bean, pinto, dry seed at 0.04 ppm; Bean, red, dry seed at 0.04 ppm; Bean, rice, dry seed at 0.04 ppm; Bean, rice, edible podded at 0.6 ppm; Bean, scarlet runner, dry seed at 0.04 ppm; Bean, scarlet runner, edible podded at 0.6 ppm; Bean, scarlet runner, succulent shelled at 0.04 ppm; Bean, snap, edible podded at 0.6 ppm; Bean, sword, dry seed at 0.04 ppm; Bean, sword, edible podded at 0.6 ppm; Bean, tepary, dry seed at 0.04 ppm; Bean, urd, dry seed at 0.04 ppm; Bean,

urd, edible podded at 0.6 ppm; Bean, wax, edible podded at 0.6 ppm; Bean, wax, succulent shelled at 0.04 ppm; Bean, yardlong, dry seed at 0.04 ppm; Bean, yardlong, edible podded at 0.6 ppm; Bean, yellow, dry seed at 0.04 ppm; Chickpea, dry seed at 0.04 ppm; Chickpea, edible podded at 1.5 ppm; Chickpea, succulent shelled at 0.04 ppm; Cowpea, dry seed at 0.04 ppm; Cowpea, edible podded at 0.6 ppm; Cowpea, succulent shelled at 0.04 ppm; Edible podded pea, edible podded at 1.5 ppm; Ginseng at 3 ppm; Gram, horse, dry seed at 0.04 ppm; Grass pea, dry seed at 0.04 ppm; Grass pea, edible podded at 1.5 ppm; Jackbean, dry seed at 0.04 ppm; Jackbean, edible podded at 0.6 ppm; Jackbean, succulent shelled at 0.04 ppm; Lentil, dry seed at 0.04 ppm; Lentil, edible podded at 1.5 ppm; Lentil, succulent shelled at 0.04 ppm; Longbean, Chinese, dry seed at 0.04 ppm; Longbean, Chinese, edible podded at 0.6 ppm; Lupin, Andean, dry seed at 0.04 ppm; Lupin, Andean, succulent shelled at 0.04 ppm; Lupin, blue, dry seed at 0.04 ppm; Lupin, blue, succulent shelled at 0.04 ppm; Lupin, grain, dry seed at 0.04 ppm; Lupin, grain, succulent shelled at 0.04 ppm; Lupin, sweet white, dry seed at 0.04 ppm; Lupin, sweet white, succulent shelled at 0.04 ppm; Lupin, sweet, dry seed at 0.04 ppm; Lupin, sweet, succulent shelled at 0.04 ppm; Lupin, white, dry seed at 0.04 ppm; Lupin, white, succulent shelled at 0.04 ppm; Lupin, yellow, dry seed at 0.04 ppm; Lupin, yellow, succulent shelled at 0.04 ppm; Pea, blackeyed, succulent shelled at 0.04 ppm; Pea, crowder, dry seed at 0.04 ppm; Pea, crowder, succulent shelled at 0.04 ppm; Pea, dry, dry seed at 0.04 ppm; Pea, dwarf, edible podded at 1.5 ppm; Pea, English, succulent shelled at 0.04 ppm; Pea, field, dry seed at 0.04 ppm; Pea, garden, dry seed at 0.04 ppm; Pea, garden, succulent shelled at 0.04 ppm; Pea, green, dry seed at 0.04 ppm; Pea, green, edible podded at 1.5 ppm; Pea, green, succulent shelled at 0.04 ppm; Pea, pigeon, dry seed at 0.04 ppm; Pea, pigeon, edible podded at 1.5 ppm; Pea, pigeon, succulent shelled at 0.04 ppm; Pea, snap, edible podded at 1.5 ppm; Pea, snow, edible podded at 1.5 ppm; Pea, southern, succulent shelled at 0.04 ppm; Pea, sugar snap, edible podded at 1.5 ppm; Pea, winged, dry seed at 0.04 ppm; Pea, winged, edible podded at 0.6 ppm; Soybean, vegetable, dry seed at 0.04 ppm; Soybean, vegetable, edible podded at 0.6 ppm; Soybean, vegetable, succulent shelled at 0.04 ppm; Velvetbean, dry seed at 0.04 ppm; Velvetbean, edible podded at 0.6 ppm; Velvetbean, succulent shelled at 0.04

ppm; and Yam bean, African, dry seed at 0.04 ppm.

Additionally, the existing tolerances on Vegetable, legume, edible podded, subgroup 6A; Pea and bean, succulent shelled, subgroup 6B; and Pea and bean, dried shelled, except soybean, subgroup 6C are removed as unnecessary since they are covered by the new tolerances established in this rulemaking.

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 to 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 tolerances 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, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. Amend § 180.681 by revising the table in paragraph (a) to read as follows:

§ 180.681 Isofetamid; tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond	0.01
Almond, hulls	0.01

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Apple, wet pomace	2.0
Bean, adzuki, dry seed	0.04
Bean, American potato, dry seed	0.04
Bean, asparagus, dry seed ..	0.04
Bean, asparagus, edible podded	0.6
Bean, black, dry seed	0.04
Bean, broad, dry seed	0.04
Bean, broad, succulent shelled	0.04
Bean, catjang, dry seed	0.04
Bean, catjang, edible podded ..	0.6
Bean, catjang, succulent shelled	0.04
Bean, cranberry, dry seed	0.04
Bean, dry, dry seed	0.04
Bean, field, dry seed	0.04
Bean, French, dry seed	0.04
Bean, French, edible podded ..	0.6
Bean, garden, dry seed	0.04
Bean, garden, edible podded ..	0.6
Bean, goa, dry seed	0.04
Bean, goa, edible podded	0.6
Bean, goa, succulent shelled ..	0.04
Bean, great northern, dry seed	0.04
Bean, green, dry seed	0.04
Bean, green, edible podded ..	0.6
Bean, guar, dry seed	0.04
Bean, guar, edible podded ...	0.6
Bean, kidney, dry seed	0.04
Bean, kidney, edible podded ..	0.6
Bean, lablab, dry seed	0.04
Bean, lablab, edible podded ..	0.6
Bean, lablab, succulent shelled	0.04
Bean, lima, dry seed	0.04
Bean, lima, succulent shelled ..	0.04
Bean, morama, dry seed	0.04
Bean, moth, dry seed	0.04
Bean, moth, edible podded ..	0.6
Bean, moth, succulent shelled	0.04
Bean, mung, dry seed	0.04
Bean, mung, edible podded ..	0.6
Bean, navy, dry seed	0.04
Bean, navy, edible podded ...	0.6
Bean, pink, dry seed	0.04
Bean, pinto, dry seed	0.04
Bean, red, dry seed	0.04
Bean, rice, dry seed	0.04
Bean, rice, edible podded	0.6
Bean, scarlet runner, dry seed	0.04
Bean, scarlet runner, edible podded	0.6
Bean, scarlet runner, succulent shelled	0.04
Bean, snap, edible podded ..	0.6
Bean, sword, dry seed	0.04
Bean, sword, edible podded ..	0.6
Bean, tepary, dry seed	0.04
Bean, urd, dry seed	0.04
Bean, urd, edible podded	0.6
Bean, wax, edible podded	0.6
Bean, wax, succulent shelled ..	0.04
Bean, yardlong, dry seed	0.04
Bean, yardlong, edible podded	0.6

TABLE 1 TO PARAGRAPH (a)—
Continued

Commodity	Parts per million
Bean, yellow, dry seed	0.04
Berry, low growing, subgroup 13–07G	4.0
Bushberry subgroup 13–07B	5.0
Caneberry subgroup 13–07A	4.0
Canola, refined oil	0.03
Cherry subgroup 12–12A	4.0
Chickpea, dry seed	0.04
Chickpea, edible podded	1.5
Chickpea, succulent shelled	0.04
Cowpea, dry seed	0.04
Cowpea, edible podded	0.6
Cowpea, succulent shelled	0.04
Edible podded pea, edible podded	1.5
Flax, seed, oil	0.03
Fruit, pome, group 11–10	0.60
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	3.0
Fruit, small vine climbing, except grape, subgroup 13–07E	10.0
Ginseng	3
Gram, horse, dry seed	0.04
Grape, raisin	5.0
Grass pea, dry seed	0.04
Grass pea, edible podded	1.5
Jackbean, dry seed	0.04
Jackbean, edible podded	0.6
Jackbean, succulent shelled	0.04
Lentil, dry seed	0.04
Lentil, edible podded	1.5
Lentil, succulent shelled	0.04
Lettuce, head	5.0
Lettuce, leaf	7.0
Longbean, Chinese, dry seed	0.04
Longbean, Chinese, edible podded	0.6
Lupin, Andean, dry seed	0.04
Lupin, Andean, succulent shelled	0.04
Lupin, blue, dry seed	0.04
Lupin, blue, succulent shelled	0.04
Lupin, grain, dry seed	0.04
Lupin, grain, succulent shelled	0.04
Lupin, sweet white, dry seed	0.04
Lupin, sweet white, succulent shelled	0.04
Lupin, sweet, dry seed	0.04
Lupin, sweet, succulent shelled	0.04
Lupin, white, dry seed	0.04
Lupin, white, succulent shelled	0.04
Lupin, yellow, dry seed	0.04
Lupin, yellow, succulent shelled	0.04
Mustard, seed, oil	0.03
Pea, blackeyed, succulent shelled	0.04
Pea, crowder, dry seed	0.04
Pea, crowder, succulent shelled	0.04
Pea, dry, dry seed	0.04
Pea, dwarf, edible podded	1.5

TABLE 1 TO PARAGRAPH (a)—
Continued

Commodity	Parts per million
Pea, English, succulent shelled	0.04
Pea, field, dry seed	0.04
Pea, garden, dry seed	0.04
Pea, garden, succulent shelled	0.04
Pea, green, dry seed	0.04
Pea, green, edible podded	1.5
Pea, green, succulent shelled	0.04
Pea, pigeon, dry seed	0.04
Pea, pigeon, edible podded	1.5
Pea, pigeon, succulent shelled	0.04
Pea, snap, edible podded	1.5
Pea, snow, edible podded	1.5
Pea, southern, succulent shelled	0.04
Pea, sugar snap, edible podded	1.5
Pea, winged, dry seed	0.04
Pea, winged, edible podded	0.6
Peach subgroup 12–12B	3.0
Plum subgroup 12–12C	0.80
Plum, Prune, Dried	1.50
Rapeseed subgroup 20A	0.015
Sesame, oil	0.03
Soybean, vegetable, dry seed	0.04
Soybean, vegetable, edible podded	0.6
Soybean, vegetable, succulent shelled	0.04
Velvetbean, dry seed	0.04
Velvetbean, edible podded	0.6
Velvetbean, succulent shelled	0.04
Yam bean, African, dry seed	0.04

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1773–F]

RIN 0938–AU83

Medicare Program; FY 2023 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This rule updates the hospice wage index, payment rates, and aggregate cap amount for Fiscal Year

(FY) 2023. This final rule establishes a permanent mitigation policy to smooth the impact of year-to-year changes in hospice payments related to changes in the hospice wage index. In addition, this rule updates the Hospice Quality Reporting Program (HQRP) and discusses further development of the Hospice Outcomes and Patient Evaluation (HOPE) assessment instrument; updates the Quality Measures (QMs) that will be in effect in FY 2023 for the HQRP and future QMs; updates the Consumer Assessment of Healthcare Providers and Systems, Hospice Survey Mode Experiment, discusses a request for information on health equity, and updates the hospice survey and enforcement procedures.

DATES: These regulations are effective on October 1, 2022.

FOR FURTHER INFORMATION CONTACT:

For general questions about hospice payment policy, send your inquiry via email to: hospicepolicy@cms.hhs.gov.

For questions regarding the CAHPS® Hospice Survey, contact Lori Teichman at (410) 786–6684 and Lauren Fuentes at (410) 786–2290.

For questions regarding the hospice quality reporting program, contact Cindy Massuda at (410) 786–0652.

For information regarding the hospice special focus program, send your inquiry via email to QSOG_hospice@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This final rule updates the hospice wage index, hospice payment rates, and aggregate cap amount for FY 2023, as required under section 1814(i) of the Social Security Act (the Act). This rule also finalizes the permanent mitigation policy to smooth the impact of year-to-year changes in hospice payments related to changes in the hospice wage index. In addition, in this final rule, CMS discusses updates to the Hospice Quality Reporting Program (HQRP) that include the Hospice Outcomes and Patient Evaluation (HOPE) with national beta testing; the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Hospice Survey with Star Ratings; developing a web-based survey; Public Reporting; a request for information that builds from last year’s discussion on health equity, updates on advancing a health information exchange, and updates on hospice survey and enforcement procedures.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that