ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0671; FRL–9987–25]

Mandipropamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mandipropamid in or on multiple commodities which are identified and 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 March 22, 2019. Objections and requests for hearings must be received on or before May 21, 2019, 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–2017–0671, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. 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–2017–0671 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 May 21, 2019. 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–2017–0671, 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 July 24, 2018 (83 FR 34968) (FRL–9980–31), 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 7E8629) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of mandipropamid, 4-chloro-*N*-[2-(3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-α-(2-propynyloxy)-benzeneacetamide], in or on the raw agricultural commodities: Asparagus bean, edible podded at 0.90 parts per million (ppm); Bean (Phaseolus spp.), edible podded at 0.90 ppm; Bean (Vigna spp.), edible podded at 0.90 ppm; *Brassica,* leafy greens, subgroup 4–16B at 25 ppm; Catjang bean, edible podded at 0.90 ppm; Celtuce at 20 ppm; Chinese longbean, edible podded at 0.90 ppm; Citrus, dried pulp at 0.14 ppm; Citrus, oil at 2.2 ppm; Cowpea, edible podded at 0.90 ppm; Florence fennel at 20 ppm; French bean, edible podded at 0.90 ppm; Fruit, citrus, group 10–10 at 0.5 ppm; Garden bean, edible podded at 0.90 ppm; Goa bean, edible podded at 0.90 ppm; Green bean, edible podded at 0.90 ppm; Guar bean, edible podded at 0.90 ppm; Jackbean, edible podded at 0.90 ppm; Kidney bean, edible podded at 0.90 ppm; Kohlrabi at 3 ppm; Lablab bean, edible podded at 0.90 ppm; Leaf petiole vegetable subgroup 22B at 20 ppm; Leafy greens subgroup 4–16A at 25 ppm; Moth bean, edible podded at 0.90 ppm; Mung bean, edible podded at 0.90 ppm; Navy bean, edible podded at 0.90 ppm; Rice bean, edible podded at 0.90 ppm; Scarlet runner bean, edible podded at 0.90 ppm; Snap bean, edible podded at 0.90 ppm; Sword bean, edible podded at 0.90 ppm; Urd bean, edible podded at 0.90 ppm; Vegetable soybean, edible podded at 0.90 ppm; Vegetable, *Brassica,* head and stem, group 5–16 at

3 ppm; Velvet bean, edible podded at 0.90 ppm; Wax bean, edible podded at 0.90 ppm; Winged pea, edible podded at 0.90 ppm; and Yardlong bean, edible podded at 0.90 ppm.

Additionally, the petition requested to amend 40 CFR 180.637 by removing the tolerances for residues of mandipropamid in or on the raw agricultural commodities Bean, snap at 0.90 ppm; *Brassica,* head and stem, subgroup 5A at 3 ppm; *Brassica,* leafy greens, subgroup 5B at 25 ppm; and Vegetable, leafy except *Brassica,* group 4 at 20 ppm.

That document referenced a summary of the petition prepared by Syngenta Crop Protection, 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 modified the levels at which some tolerances are being established as well as some of the commodities in which tolerances are being established. The reason 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 mandipropamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mandipropamid 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.

Subchronic and chronic studies indicate that the liver and kidney are the primary target organs for mandipropamid. Liver effects observed in subchronic studies with rats, mice and dogs included periportal hypertrophy (rats), increased eosinophilia (rats and mice), increased plasma albumin, total protein, cholesterol, and gamma-glutamyl transferase (rats), increased liver weights (rats, mice and dogs), increased liver enzymes (dogs), increased pigment in hepatocytes and Kupffer cells (dogs), and centrilobular hepatocyte vacuolation (dogs). In the chronic dog study, increases in microscopic pigment in the liver, and increased liver enzymes were observed. In the chronic rat and mouse studies, liver toxicity was not observed. Nephrotoxicity was observed in the chronic rat study; however, in the chronic mouse study, only decreased body weight and food utilization were observed. The findings of liver toxicity and nephrotoxicity are consistent with the results from metabolism studies, in which radioactivity levels in liver and kidney were typically higher than other tissues. There were no consistent sex-related differences in target organ toxicity, although male rats appeared to be more sensitive to body weight effects.

No evidence of neurotoxicity was observed in the database, including rat acute or subchronic neurotoxicity studies. No systemic or dermal toxicity was observed in the rat following dermal exposure for 28 days up to the limit dose.

No evidence of increased pre- or postnatal quantitative or qualitative susceptibility was observed. No fetal or maternal toxicity was observed in developmental toxicity studies in the rat and rabbit. Decreased pup weights were observed in the rat two-generation reproduction study in the presence of decreased parental body weight and food utilization.

There was no evidence of a treatment-related increase in tumor incidence in the mouse carcinogenicity study or the rat chronic/carcinogenicity study. There was no evidence of genotoxicity in bacterial reverse gene mutation, mammalian in vitro forward gene mutation, mammalian in vivo clastogenicity, or unscheduled DNA synthesis assays. Therefore, mandipropamid is classified as ''not likely to be carcinogenic to humans.''

Specific information on the studies received and the nature of the adverse effects caused by mandipropamid 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 the document titled ''Mandipropamid. Aggregate Human Health Risk Assessment Supporting Section 3 Registration of Proposed New Uses on Citrus Fruits Group 10–10 and Succulent Beans, Along with Various Crop Group and Subgroup Conversions'' on pages 35–39 in docket ID number EPA–HQ–OPP–2017–0671.

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 mandipropamid used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MANDIPROPAMID 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, including infants and children, and females 13–49).	No appropriate endpoint for a single exposure was identified in the database.		
Chronic dietary (All populations)	NOAEL= 5 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	Chronic toxicity study—dog. LOAEL = 40 mg/kg/day, based on increased incidence and severity of microscopic pigment in the liver, and increased alkaline phosphatase activity in both sexes, as well as increased alanine aminotransferase activity in males.
Cancer (Oral, dermal, inhalation)	Classified as not likely to be carcinogenic to humans.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. 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_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to mandipropamid, EPA considered exposure under the petitioned-for tolerances as well as all existing mandipropamid tolerances in 40 CFR 180.637. EPA assessed dietary exposures from mandipropamid 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 mandipropamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16, which uses 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) from 2003 through 2008. As to residue levels in food, the chronic dietary risk assessment assumed tolerance-level residues in all commodities with existing tolerances except tuberous and corm vegetable subgroup 1C. For the chronic dietary risk assessment, this subgroup was assessed at 0.115 ppm, which assumes tolerance-level residues of parent mandipropamid (0.09 ppm), and includes metabolite SYN 500003 in parent-equivalents (at 0.025 ppm). Tolerance-level residues associated with the proposed new uses and crop group conversions were also used in the assessment. The Agency's 2018 Default Processing Factors were used for all processed commodities for which they were available. The empirical processing factor from the grape processing study was used for grape wine/sherry (1.5X). A processing factor was not used for grape raisin because a tolerance is currently established in raisin. Similarly, processing factors were not used for citrus oil and dried pulp because the Agency is establishing separate tolerances in these commodities.

iii. *Cancer.* Based on the lack of evidence of carcinogenicity or genotoxicity, the Agency has classified mandipropamid as ''not likely to be a human carcinogen'' and therefore, there is no concern for cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for mandipropamid. Tolerance level residues and 100 PCT were assumed for all food commodities except as noted in section III.C.ii.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for mandipropamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of mandipropamid. 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 FQPA Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of mandipropamid for chronic exposures are estimated to be 9.0 ppb for surface water and 79 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration value of 79 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Mandipropamid is not registered for any specific use patterns that would result in residential exposure.

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

assumed that mandipropamid 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 website 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 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.* No evidence of increased pre- or postnatal quantitative or qualitative susceptibility was observed. No fetal or maternal toxicity was observed in developmental toxicity studies in the rat and rabbit. Decreased pup weights were observed in the rat two-generation reproduction study in the presence of decreased parental body weight and food utilization.

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 mandipropamid is complete.

ii. There is no indication that mandipropamid 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 mandipropamid 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 except as noted in section III.C.ii. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to mandipropamid in drinking water. These assessments will not underestimate the exposure and risks posed by mandipropamid.

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, mandipropamid 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 mandipropamid from food and water will utilize 49% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for mandipropamid.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, mandipropamid is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or 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 short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for mandipropamid.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

There is an adequate enforcement method available for the quantitation of mandipropamid in plant commodities. Method RAM 415/01, using high performance liquid chromatography with tandem mass spectrometric detection (LC/MS/MS), has been adequately validated by an independent laboratory. It has a validated limit of quantitation (LOQ) of 0.01 ppm. An acceptable confirmatory method is also available.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

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.

There are no harmonization issues with Codex regarding the new use on citrus fruits because Codex has not established MRLs for mandipropamid in citrus commodities. Additionally, Codex has not established an MRL in

snap beans, so this is not a harmonization issue. Regarding the updated crop group/subgroup conversions, the tolerance in leafy vegetable group 4–16 is harmonized with the corresponding Codex MRLs. The tolerance in Brassica head and stem vegetable group 5–16, and the individual tolerance in kohlrabi, is harmonized with the Codex MRLs in cabbage and Chinese napa cabbage, but not the Codex MRL in broccoli. There are no Codex MRLs in Brussels sprouts, cauliflower or kohlrabi. The EPA is not harmonizing with the Codex MRL in broccoli because it is lower than the U.S. tolerance in *Brassica* head and stem vegetable group 5–16; setting a lower tolerance in broccoli could result in violative residues for U.S. growers. The tolerance in leaf petiole subgroup 22B, with individual tolerances in celtuce and Florence fennel, is harmonized with the Codex MRL in celery.

C. Revisions to Petitioned-For Tolerances

EPA's tolerance levels are expressed to provide sufficient precision for enforcement purposes, and this may include the addition of trailing zeros (0.50 ppm rather than the proposed 0.5 ppm). The Agency does this in order to avoid the situation where rounding of an observed violative residue to the level of precision of the tolerance expression would result in a residue being considered non-violative (such as 0.54 ppm being rounded to 0.5 ppm). EPA made this revision for Fruit, citrus, group 10–10, Kohlrabi, and Vegetable, *Brassica,* head and stem, group 5–16.

Because the petitioner proposed separate tolerances in both subgroups 4–16A and 4–16B at 25 ppm, the Agency is establishing a single tolerance in leafy vegetable group 4–16 at 25 ppm rather than separate tolerances in the two subgroups. In addition, the Agency revised the commodity terminology to use the correct commodity definition for Florence fennel, which is Fennel, Florence, fresh leaves and stalk.

The proposed tolerance in citrus dried pulp (0.14 ppm) was incorrectly based on the dried pulp processing factor (2.9X) multiplied by the lowest average field trial value (LAFT) of 0.049 ppm from the orange field trials. However, per Office of Chemical Safety and Pollution Prevention (OCSPP) Residue Chemistry Test Guideline 860.1520, EPA based the tolerance on the processing factor (2.9X) multiplied by the highest average field trial value (HAFT) of 0.231 ppm from the lemon field trials (which had the highest HAFT of the three representative commodities), yielding a result of 0.67 ppm. Per the rounding protocol in the Organization for Economic Cooperation and Development (OECD) MRL Calculator User Guide, this result was increased to 0.70 ppm.

Similarly, the proposed tolerance in citrus oil (2.2 ppm) was incorrectly based on the oil processing factor (45X) multiplied by the LAFT of 0.049 ppm from the orange field trials. As for dried pulp, EPA based the tolerance in citrus oil on the processing factor (45X) multiplied by the HAFT of 0.231 ppm from the lemon field trials, yielding a result of 10.4 ppm. Per the rounding protocol in the OECD's MRL Calculator User Guide this result was increased to 15 ppm.

V. Conclusion

Therefore, tolerances are established for residues of mandipropamid in or on Asparagus bean, edible podded at 0.90 ppm; Bean (Phaseolus spp.), edible podded at 0.90 ppm; Bean (Vigna spp.), edible podded at 0.90 ppm; Catjang bean, edible podded at 0.90 ppm; Celtuce at 20 ppm; Chinese longbean, edible podded at 0.90 ppm; Citrus, dried pulp at 0.70 ppm; Citrus, oil at 15 ppm; Cowpea, edible podded at 0.90 ppm; Fennel, Florence, fresh leaves and stalk at 20 ppm; French bean, edible podded at 0.90 ppm; Fruit, citrus, group 10–10 at 0.50 ppm; Garden bean, edible podded at 0.90 ppm; Goa bean, edible podded at 0.90 ppm; Green bean, edible podded at 0.90 ppm; Guar bean, edible podded at 0.90 ppm; Jackbean, edible podded at 0.90 ppm; Kidney bean, edible podded at 0.90 ppm; Kohlrabi at 3.0 ppm; Lablab bean, edible podded at 0.90 ppm; Leaf petiole vegetable subgroup 22B at 20 ppm; Moth bean, edible podded at 0.90 ppm; Mung bean, edible podded at 0.90 ppm; Navy bean, edible podded at 0.90 ppm; Rice bean, edible podded at 0.90 ppm; Scarlet runner bean, edible podded at 0.90 ppm; Snap bean, edible podded at 0.90 ppm; Sword bean, edible podded at 0.90 ppm; Urd bean, edible podded at 0.90 ppm; Vegetable, *Brassica,* head and stem, group 5–16 at 3.0 ppm; Vegetable, leafy, group 4–16 at 25 ppm; Vegetable soybean, edible podded at 0.90 ppm; Velvet bean, edible podded at 0.90 ppm; Wax bean, edible podded at 0.90 ppm; Winged pea, edible podded at 0.90 ppm; and Yardlong bean, edible podded at 0.90 ppm.

Additionally, the existing tolerances in/on Bean, snap at 0.90 ppm; *Brassica,* head and stem, subgroup 5A at 3 ppm; *Brassica,* leafy greens, subgroup 5B at 25 ppm; and Vegetable, leafy except *Brassica,* group 4 at 20 ppm are removed as unnecessary since they are covered by the new tolerances.

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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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: March 14, 2019.

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 § 180.637, in the table to paragraph (a):
■ a. Add alphabetically the entry ''Asparagus bean, edible podded'';
■ b. Remove the entry for ''Bean, snap'';
■ c. Add alphabetically the entries ''Bean (Phaseolus spp.), edible podded'' and ''Bean (Vigna spp.), edible podded'';
■ d. Remove the entries for ''Brassica, head and stem, subgroup 5A'' and ''Brassica, leafy greens, subgroup 5B''; and
■ e. Add alphabetically the entries ''Catjang bean, edible podded''; ''Celtuce''; ''Chinese longbean, edible podded''; ''Citrus, dried pulp''; ''Citrus, oil''; ''Cowpea, edible podded''; ''Fennel, Florence, fresh leaves and stalk''; ''French bean, edible podded''; ''Fruit, citrus, group 10–10''; ''Garden bean, edible podded''; ''Goa bean, edible podded''; ''Green bean, edible podded''; ''Guar bean, edible podded''; ''Jackbean, edible podded''; ''Kidney bean, edible podded''; ''Kohlrabi''; ''Lablab bean, edible podded''; ''Leaf petiole vegetable subgroup 22B''; ''Moth bean, edible podded''; ''Mung bean, edible podded''; ''Navy bean, edible podded''; ''Rice bean, edible podded''; ''Scarlet runner bean, edible podded''; ''Snap bean, edible podded''; ''Sword bean, edible podded''; ''Urd bean, edible podded''; ''Vegetable, *Brassica,* head and stem, group 5–16''; and ''Vegetable, leafy, group 4–16'';
■ f. Remove the entry for ''Vegetable, leafy except Brassica, group 4''; and
■ g. Add alphabetically the entries ''Vegetable soybean, edible podded''; ''Velvet bean, edible podded''; ''Wax bean, edible podded''; ''Winged pea, edible podded''; and ''Yardlong bean, edible podded''.

The additions read as follows:

§ 180.637 Mandipropamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
Asparagus bean, edible podded	0.90
* * * * *	
Bean (Phaseolus spp.), edible podded	0.90
Bean (Vigna spp.), edible podded	0.90
Catjang bean, edible podded	0.90
Celtuce	20
Chinese longbean, edible podded	0.90
Citrus, dried pulp	0.70
Citrus, oil	15
Cowpea, edible podded	0.90
Fennel, Florence, fresh leaves and stalk	20
French bean, edible podded	0.90
Fruit, citrus, group 10–10	0.50
* * * * *	
Garden bean, edible podded	0.90
* * * * *	
Goa bean, edible podded	0.90
* * * * *	
Green bean, edible podded	0.90
Guar bean, edible podded	0.90
* * * * *	
Jackbean, edible podded	0.90
Kidney bean, edible podded	0.90
Kohlrabi	3.0
Lablab bean, edible podded	0.90
Leaf petiole vegetable subgroup 22B	20
Moth bean, edible podded	0.90
Mung bean, edible podded	0.90
Navy bean, edible podded	0.90
* * * * *	
Rice bean, edible podded	0.90
Scarlet runner bean, edible podded	0.90
Snap bean, edible podded	0.90
Sword bean, edible podded	0.90
Urd bean, edible podded	0.90
Vegetable, *Brassica,* head and stem, group 5–16	3.0
* * * * *	
Vegetable, leafy, group 4–16	25
Vegetable soybean, edible podded	0.90
* * * * *	
Velvet bean, edible podded	0.90
Wax bean, edible podded	0.90
Winged pea, edible podded	0.90
Yardlong bean, edible podded	0.90

* * * * *

[FR Doc. 2019–05406 Filed 3–21–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 455

Office of Inspector General

42 CFR Part 1007

RIN 0936–AA07

Medicaid; Revisions to State Medicaid Fraud Control Unit Rules

AGENCIES: Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule amends the regulation governing State Medicaid Fraud Control Units (MFCUs or Units). The rule incorporates statutory changes affecting the Units as well as policy and practice changes that have occurred since the regulation was initially issued in 1978. These changes include a recognition of OIG's delegated authority; Unit authority, functions, and responsibilities; disallowances; and issues related to organization, prosecutorial authority, staffing, recertification, and the Units' relationship with Medicaid agencies. The rule is designed to assist the MFCUs in understanding their authorities and responsibilities under the grant program, clarify the flexibilities the MFCUs have to operate their programs, and reduce administrative burden, where