

## LIBRARY OF CONGRESS

## Copyright Royalty Board

## 37 CFR Part 385

[Docket No. 2011–3 CRB Phonorecords II]

## Adjustment of Determination of Compulsory License Rates for Mechanical and Digital Phonorecords

**AGENCY:** Copyright Royalty Board, Library of Congress.**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Copyright Royalty Judges are making a technical amendment to the regulations regarding the rates and terms for the section 115 statutory license for the use of musical works in physical phonorecord deliveries, permanent digital downloads, ringtones, interactive streaming, limited downloads, limited offerings, mixed service bundles, music bundles, paid locker services, and purchased content locker services. The technical amendment corrects a clerical error regarding an accounting provision in the final rule.

**DATES:** *Effective:* January 1, 2014.**FOR FURTHER INFORMATION CONTACT:**

Richard Strasser, Senior Attorney, or Gina Giuffreda, Attorney Advisor. Telephone: (202) 707-7658 or email at [crb@loc.gov](mailto:crb@loc.gov).

**SUPPLEMENTARY INFORMATION:** On November 13, 2013, the Copyright Royalty Judges (Judges) published in the *Federal Register* final regulations setting the rates and terms for the section 115 statutory license for the use of musical works in physical phonorecord deliveries, permanent digital downloads, ringtones, interactive streaming, limited downloads, limited offerings, mixed service bundles, music bundles, paid locker services, and purchased content locker services. 78 FR 67938. In the preamble to the final rule, the Judges stated that they could not adopt an accounting provision proposed in § 385.12(e)<sup>1</sup> because of a

<sup>1</sup> The Judges proposed two accounting provisions—§ 385.12(e) and § 385.22(d)—each of which would have required the licensee's statement of account to "set forth each step of its calculations with sufficient information to allow the copyright owner to assess the accuracy and manner in which the licensee determined the payable royalty pool and per-play allocations (including information sufficient to demonstrate whether and how a minimum royalty or subscriber-based royalty floor pursuant to § 385.13 does or does not apply) and, for each offering reported, also indicate the type of licensed activity involved and the number of plays of each musical work (including an indication of any overtime adjustment applied) that is the basis of the per-work royalty allocation being paid." 77

finding by the Register of Copyrights (Register) that adoption by the Judges of such a provision "represent[ed] an encroachment on the Register's [exclusive] authority regarding statements of account" kept under the section 115 statutory license. *See Id.* at 67940, *citing* 78 FR 28772 (May 16, 2013). Due to an inadvertent oversight, however, no instruction reflecting the removal of § 385.12(e) appeared in the regulatory text.<sup>2</sup> The Judges now correct this error.

Section 803(c)(4) of the Copyright Act authorizes the Judges to issue "an amendment to a written determination to correct any technical or clerical errors in the determination" and directs that such amendment "be set forth in a written addendum to the determination that shall be distributed to the participants and shall be published in the *Federal Register*." 17 U.S.C. 803(c)(4).<sup>3</sup> The Judges make this correction by today's notice pursuant to their continuing jurisdiction under section 803(c)(4) of the Copyright Act.

**List of Subjects in 37 CFR Part 385**

Copyright, Phonorecords, Recordings.

**Final Regulations**

For the reasons set forth in the preamble, the Copyright Royalty Judges amend Part 385 of Chapter III of title 37 of the Code of Federal Regulations as follows:

**PART 385—RATES AND TERMS FOR USE OF MUSICAL WORKS UNDER COMPULSORY LICENSE FOR MAKING AND DISTRIBUTING OF PHYSICAL AND DIGITAL PHONORECORDS**

- 1. The authority citation for part 385 continues to read as follows:

**Authority:** 17 U.S.C. 115, 801(b)(1), 804(b)(4).

**§ 385.12 [Amended]**

- 2. Section 385.12 is amended by removing paragraph (e).

FR 29259, 29267 (May 17, 2012). The language of proposed § 385.22(d) mirrored that in § 385.12(e), except for non-substantive conforming language needed for its inclusion in proposed Subpart C.

<sup>2</sup> Today's amendment concerns only proposed § 385.12(e) because this section was adopted initially by the Judges in 2009. *See* 74 FR 4510 (Jan. 26, 2009). Proposed § 385.22(d) was part of a newly proposed Subpart C, *see* 77 FR 29259 (May 17, 2012), and was not adopted in the final rule published on November 13, 2013.

<sup>3</sup> The Judges provided a copy of this technical amendment to the participants of this proceeding prior to its submission to the *Federal Register* for publication.

Dated: November 18, 2013.

**Suzanne M. Barnett,***Chief Copyright Royalty Judge.*

Approved by:

**James H. Billington,***Librarian of Congress.*

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

[EPA–HQ–OPP–2012–0980; FRL–9903–57]

**Mandipropamid; Pesticide Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances in or on multiple commodities and removes several established tolerances for residues of mandipropamid, 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 December 20, 2013. Objections and requests for hearings must be received on or before February 18, 2014, 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–2012–0980, 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), EPA West 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:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: [RDfRNotices@epa.gov](mailto: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/textidx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/textidx?&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-2012-0980 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 February 18, 2014. 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-2012-0980, 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 27, 2013 (78 FR 13295) (FRL-9380-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8126) by IR-4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.637 be amended by establishing tolerances for residues of the fungicide mandipropamid, 4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-alpha-(2-propynyloxy)-benzeneacetamide, in or on basil, dried at 200 parts per million (ppm); basil, fresh at 30 ppm; bean, succulent at 0.90 ppm; cowpea, forage at 15 ppm; fruit, small, vine climbing, subgroup 13-07F, except fuzzy kiwifruit at 2.0 ppm; ginseng at 0.3 ppm; onion, bulb, subgroup 3-07A at 0.1 ppm; onion, green, subgroup 3-07B at 7.0 ppm; and vegetable, fruiting, group 8-10 at 1.0 ppm. The petition additionally requested to remove the established tolerances in or on grape at 1.4 ppm; onion, dry bulb at 0.05 ppm; onion, green at 4 ppm; okra at 1.0 ppm; and vegetable, fruiting, group 8 at 1.0 ppm, upon establishment of the associated proposed tolerances. That document referenced a summary of the petition prepared on behalf of IR-4 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 determined that the proposed tolerances should not be established on succulent bean or cowpea forage, and that a tolerance should be established on snap

bean. The Agency has also determined that the proposed tolerances in or on small vine climbing fruit subgroup 13-07F, bulb onion subgroup 3-07A and green onion subgroup 3-07B should be revised. EPA has also revised the commodity terminology for fresh and dried basil and determined that the tolerance expression should be revised for all commodities. Finally, EPA determined that the time-limited tolerance on fresh basil should be removed. The reasons for these changes are explained in Unit IV.C.

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

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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 is the primary target organ for mandipropamid. Liver effects were identified in subchronic studies with rats, mice, and dogs. Liver effects included increased plasma albumin, total protein, cholesterol, and gamma-glutamyl transferase, as well as periportal hypertrophy in rats; increased liver enzymes, increased pigment in hepatocytes and Kupffer cells, and centrilobular hepatocyte vacuolation in dogs; increased eosinophilia in rats and mice; and increased liver weights in rats, mice and dogs. In the chronic dog study, increases in microscopic pigment in the liver and increased liver enzymes were observed. No liver effects were observed in chronic rat and mouse studies up to the highest doses tested. Instead, nephrotoxicity was observed in the chronic rat study and decreased body weight and food utilization was observed in the chronic mouse study. The findings of liver toxicity and nephrotoxicity are consistent with the results from metabolism studies where the tissues with the highest levels of radioactivity were the liver followed by the kidney.

No evidence of neurotoxicity was observed in the acute or subchronic neurotoxicity screening battery. No systemic or dermal toxicity was observed following dermal exposure for 28 days, up to the limit dose. No immunotoxicity was observed up to the highest dose tested in the mouse immunotoxicity study.

No evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rats and rabbits or in a 2-generation reproduction study in rats. The only effects observed in fetuses or pups were in the 2-generation reproduction study, where decreased pup body weight was observed in the presence of maternal toxicity (decreased body weight, body weight gain, and food utilization). In addition, there was a delay in preputial separation in F1 males which was considered to be the result of lower body weights.

There was no evidence of tumors in the carcinogenicity study in mice or in the chronic/carcinogenicity study in rats and there was no evidence that mandipropamid was mutagenic or clastogenic. 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 document, “Mandipropamid: Human Health Risk Assessment For New Uses On Basil, Ginseng and Snap Beans, as Well as Crop Group Expansions for Fruiting Vegetable; Small Fruit, Vine Climbing, Except Fuzzy Kiwifruit; and Bulb Onion and Green Onion Subgroups.” at pages 33–38 in docket ID number EPA–HQ–OPP–2012–0980.

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

A summary of the toxicological endpoints for 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 (General population including infants and children and females 13–49 years old). | No endpoint attributable to a single exposure was identified.                            |                                                        |                                                                                                                                                                                                                                                            |
| Chronic dietary (All populations) .....                                                        | NOAEL=5 mg/kg/day ....<br>UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 1x | Chronic RfD = 0.05 mg/kg/day.<br>cPAD = 0.05 mg/kg/day | Chronic Toxicity Study, Dogs 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. LOC = level of concern. Mg/kg/day = milligrams/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### 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, EPA used tolerance-level residues with the exception of subgroups 13-07F, 3-07A, and 3-07B, for which EPA used residue levels higher than the tolerance levels being established here; and tuberous and corm vegetable subgroup 1C, which was assessed at 0.026 ppm, in order to account for the SYN 500003 metabolite for this commodity. EPA assessed tolerances for subgroups 13-07F, 3-07A, and 3-07B using levels that were proposed by the petitioner and that were harmonized with Codex maximum residue levels. However, for reasons discussed in Unit IV.B., EPA is harmonizing these tolerance levels with the lower Canadian maximum residue levels (MRLs). The Agency also assumed 100 percent crop treated (PCT) estimates for all commodities and utilized default DEEM-FCID™ (ver. 7.81) processing factors, with the exception of chemical-specific processing factors for grape wine and sherry.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that mandipropamid 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 PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for mandipropamid. 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 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://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First 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 for non-cancer assessments are estimated to be 9.0 parts per billion (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 chronic dietary risk assessment, the water concentration value of 79 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). 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 Web site at <http://www.epa.gov/pesticides/cumulative>.

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

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants

and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There were no treatment-related effects observed in dams or fetuses in the developmental toxicity studies in rats or rabbits up to the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day). In the rat 2-generation reproductive study, decreased pup weight occurred only in the presence of comparable maternal toxicity (decreased body weight, body weight gain, and food utilization). Therefore, there is no increased quantitative or qualitative susceptibility to rat or rabbit offspring exposed *in utero* and/or postnatally to mandipropamid, and there are no residual uncertainties with respect to prenatal or postnatal 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 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 assessment was performed based on 100 PCT and tolerance-level residues for all commodities, with the exception of tuberous and corm vegetable subgroup 1C, which was assessed for the tolerance level plus the metabolite. 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 46% 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 short- or intermediate-term residential exposures. 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- and 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

Adequate enforcement methodology, a high performance liquid chromatography with tandem mass spectrometric detection (LC/MS/MS), is available to enforce the tolerance expression.

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

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international 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 established MRLs for mandipropamid in or on bell and nonbell pepper at 1 ppm, bulb onion at 0.1 ppm, grape at 2 ppm, and spring onions at 7.0 ppm. The tolerances are harmonized with the U.S. tolerances established in or on fruiting vegetable group 8–10 (including pepper) at 1.0 ppm. However, the tolerances in or on small vine climbing fruit except fuzzy kiwifruit subgroup 13–07F (including grape) at 1.4 ppm, bulb onion subgroup 3–07A at 0.05 ppm, and green onion subgroup 3–07B at 4 ppm are not harmonized with associated Codex MRLs on these commodities because it has been determined that the major export market for these commodities is Canada. Therefore, in order to maintain harmonization of U.S. tolerances and Canadian MRLs for these commodities, EPA is establishing these subgroup tolerances at the levels that align with the Canadian MRLs. There are no Codex MRLs on the other commodities associated with this action.

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

Based on the data supporting the petition, EPA has revised basil, fresh to basil, fresh leaves and basil, dried to basil, dried leaves in order to correct the commodity terminology. EPA also determined that the following proposed tolerances should be amended in order to harmonize with Canadian MRLs on associated commodities: Small vine climbing fruit except fuzzy kiwifruit subgroup 13–07F from 2.0 ppm to 1.4 ppm; bulb onion subgroup 3–07A from 0.1 ppm to 0.05 ppm; and green onion subgroup 3–07B from 7.0 ppm to 4.0 ppm. Additionally, while EPA was petitioned for a tolerance on succulent bean, no field trial data were conducted on a succulent shelled bean cultivar in order to support the tolerance. Instead, the petitioner submitted snap bean data, which EPA determined is sufficient to support a tolerance of mandipropamid in or on bean, snap at 0.90 ppm. Snap beans are a subset of the larger succulent shelled bean definition, as defined in 40 CFR 180.1(g). Additionally, the Agency determined that the proposed tolerance in or on cowpea, forage cannot be established at this time because the use lacks a validated livestock analytical enforcement method for residues of mandipropamid. EPA also determined that the time-limited tolerance in or on fresh basil at 20 ppm should be removed, as it will be superseded by a permanent tolerance on fresh basil leaves at 30 ppm. Finally, the Agency has revised the tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of mandipropamid not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only mandipropamid.

#### V. Conclusion

Therefore, tolerances are established for residues of mandipropamid, 4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]- $\alpha$ -(2-propynyloxy)benzeneacetamide, in or on basil, dried leaves at 200 ppm; basil, fresh leaves at 30 ppm; bean, snap at 0.90 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 1.4 ppm; ginseng at 0.30 ppm; onion, bulb, subgroup 3–07A at 0.05 ppm; onion, green, subgroup 3–07B at 4.0 ppm; and vegetable, fruiting, group 8–10 at 1.0 ppm. This regulation additionally removes the established tolerances in or on grape at 1.4 ppm; onion, dry bulb at 0.05 ppm; onion, green at 4 ppm; okra

at 1.0 ppm; and vegetable, fruiting, group 8 at 1.0 ppm. Finally, this regulation removes the time-limited tolerance in or on basil, fresh at 20 ppm.

## VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under 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 final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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: December 16, 2013.

**Lois Rossi,**

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:

■ a. Revise the introductory text in paragraph (a).

■ b. Remove "Grape", "Okra", "Onion, dry bulb", "Onion green", and "Vegetable, fruiting, group 8" from the table in paragraph (a).

■ c. Add "Basil, dried leaves", "Basil, fresh leaves", "Bean, snap", "Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F", "Ginseng", "Onion, bulb, subgroup 3-07A", "Onion, green, subgroup 3-07B", and "Vegetable, fruiting, group 8-10" to the table in paragraph (a).

■ d. Revise the introductory text in paragraph (b).

■ e. Remove "Basil, fresh" from the table in paragraph (b).

The amendments read as follows:

### § 180.637 Mandipropamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of mandipropamid, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only mandipropamid (4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-α-(2-propynyloxy)benzeneacetamide) in or on the commodity.

| Commodity                                                                 | Parts per million |
|---------------------------------------------------------------------------|-------------------|
| Basil, dried leaves .....                                                 | 200               |
| Basil, fresh leaves .....                                                 | 30                |
| Bean, snap .....                                                          | 0.90              |
| * * * * *                                                                 |                   |
| Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F ..... | 1.4               |
| Ginseng .....                                                             | 0.30              |
| * * * * *                                                                 |                   |
| Onion, bulb, subgroup 3-07A                                               | 0.05              |
| Onion, green, subgroup 3-07B .....                                        | 4.0               |
| * * * * *                                                                 |                   |
| Vegetable, fruiting, group 8-10 .....                                     | 1.0               |
| * * * * *                                                                 |                   |

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of mandipropamid, including its metabolites and degradates, in or on the commodities listed in the table below resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified below is to be determined by measuring only mandipropamid (4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-α-(2-propynyloxy)benzeneacetamide) in or on the commodity. The tolerances expire on the date specified in the table.

\* \* \* \* \*

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