



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2018-0623; FRL-10000-33]

### Propamocarb; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of propamocarb (also referred to as propamocarb hydrochloride (HCl) in this document) in or on guava, starfruit, the leafy greens subgroup 4-16A, the tuberous and corm vegetable subgroup 1C, and the fruiting vegetable group 8-10. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-2018-0623, 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](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 Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](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 FFDCFA 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-2018-0623 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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-2018-0623, 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 December 21, 2018 (83 FR 65660) (FRL-9985-67), 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 8E8692) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the propamocarb (propyl N-[3-(dimethylamino)propyl]carbamate in or on the following raw agricultural commodities: guava at 0.05 parts per million (ppm); starfruit at 0.05 ppm; leafy greens subgroup 4-16A at 150 ppm; vegetable, tuberous and corm, subgroup 1C at 0.30 ppm; and vegetable, fruiting, group 8-10 at 4.0 ppm. The petition also requested to amend 40 CFR 180.499 by removing the established tolerances for the residues of propamocarb in or on lettuce, head at 50 ppm; lettuce, leaf at 90 ppm; potato at 0.30 ppm; and vegetable, fruiting, group 8 at 2.0 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

EPA is establishing tolerances that vary slightly from what was requested to be consistent with Organization for Economic Cooperation and Development (OECD) Rounding Class Practice.

## **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 propamocarb including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with propamocarb 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.

Although propamocarb is a carbamate fungicide, it doesn't inhibit cholinesterase like many other carbamate pesticides, such as *N*-methyl carbamates. Neurotoxic effects include decreased motor activity following acute exposure and vacuolization of the choroid plexus (ventricles of the brain which produce cerebral spinal fluid) following subchronic and chronic durations. Other effects observed are indicative of toxicity to the digestive and gastro-intestinal

(GI) tracts in dogs (chronic erosive gastritis, vacuolization of the salivary gland and stomach), and the eye (hyporeflexivity of the fundus, retinal degeneration, and vacuolization of the retinal gland). In all species, decreased body weights, body-weight gains, and food consumption were observed following subchronic and chronic exposure.

Effects in the route-specific dermal and inhalation studies were primarily portal-of-entry effects. Dermal exposure caused dermal irritation in rats and rabbits at relatively high doses (greater than 500 mg/kg/day). Inhalation exposure caused labored breathing and the appearance of red material around the nose. Systemic effects were observed following inhalation exposure at similar doses that caused portal-of-entry effects; these included kidney cysts and changes in hematological parameters.

There was no evidence of increased quantitative pre- or postnatal susceptibility in the toxicity database for propamocarb-HCl in rats or rabbits. There was an increased qualitative susceptibility for propamocarb-HCl in rats. In the developmental rat studies, fetal effects included increased death, increased incidences of minor skeletal anomalies, increased incidences of small fetus, inter-atrial septal defects, and hemorrhage in the ears, upper GI tract, and nasopharynx/sinuses. Maternal effects consisted of decreased absolute body-weights, food consumption, post-implantation loss, and mortality. In rabbits there was an increased incidence of post-implantation loss in one of the two available studies, and no fetal effects in the second study. In the rat 2-generation reproduction studies, offspring effects consisted of decreased weights in both studies, as well as death, decreased viability and lactation indices and litter size at the limit dose (1,000 mg/kg/day) in one study. Parental effects were consistent with those previously described for adults. Reproductive effects consisted of increased vacuolization and decreased weight of the epididymides, decreased sperm counts and motility, and abnormal sperm

morphology.

The Agency has classified propamocarb-HCl as “not likely to be carcinogenic to humans” by all routes of exposure based upon lack of evidence of carcinogenicity in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by propamocarb 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 “Propamocarb Hydrochloride (HCl). Human Health Risk Assessment for Proposed Uses on Leafy Green Subgroup 4-16A, Guava, and Starfruit; and Crop Conversions for Fruiting Vegetable Group 8 to Crop Group 8-10, and Potato to Subgroup 1C (Tuberous and Corm Vegetables Subgroup)” on pages 28-33 in docket ID number EPA-HQ-OPP-2018-0623.

#### *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-pesticide>.

A summary of the toxicological endpoints for propamocarb used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of February 7, 2017 (82 FR 9519) (FRL-9957-68).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propamocarb, EPA considered exposure under the petitioned-for tolerances as well as all existing propamocarb tolerances in 40 CFR 180.499. EPA assessed dietary exposures from propamocarb 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.

Such effects were identified for propamocarb. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels

in food, EPA used tolerance-level residues and assumed 100 PCT for all commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that propamocarb 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 or PCT information in the dietary assessment for propamocarb. Tolerance level residues and 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 propamocarb in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of propamocarb. 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 Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of propamocarb for acute exposures are 4,860 parts per billion (ppb) for surface water and 73 ppb for ground water. The EDWCs of propamocarb for chronic exposures are 385 ppb for surface water and 70 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 4,860 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 385 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 nonoccupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Propamocarb is registered for use on golf course turf, which may result in dermal post-application exposures. No dermal hazard was identified in the toxicity database, so there is no need to conduct a quantitative residential exposure assessment.

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.”

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 as to propamocarb-HCl and any other substances and propamocarb-HCl does not appear to produce a toxic metabolite produced by other substances. Although a carbamate, propamocarb-HCl is not an *N*-methyl carbamate and does not cause cholinesterase inhibition. Thus, it was not included in the *N*-methyl carbamate cumulative risk assessment. For the purposes of this action, therefore, EPA has not assumed that propamocarb-HCl has a common mechanism of toxicity with other substances.

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

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity

and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased quantitative pre- or postnatal susceptibility in the toxicity database for propamocarb-HCl in rats or rabbits. There was an increased qualitative susceptibility for propamocarb-HCl in rats. In the developmental rat studies, fetal effects included increased death, increased incidences of minor skeletal anomalies, increased incidences of small fetus, inter-atrial septal defects, and hemorrhage in the ears, upper GI tract, and nasopharynx/sinuses. Maternal effects consisted of decreased absolute body-weights, food consumption, post-implantation loss, and mortality. In rabbits there was an increased incidence of post-implantation loss in one of the two available studies, and no fetal effects in the second study. In the rat 2-generation reproduction studies, offspring effects consisted of decreased weights in both studies, as well as death, decreased viability and lactation indices and litter size at the limit dose (1,000 mg/kg/day) in one study. Parental effects were consistent with those previously described for adults. Reproductive effects consisted of increased vacuolization and decreased weight of the epididymides, decreased sperm counts and motility, and abnormal sperm morphology.

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 propamocarb is complete.

ii. There are two guidelines acute neurotoxicity (ACN) and two subchronic neurotoxicity (SCN) studies for propamocarb-HCl. There was evidence of neurotoxicity (decreased motor activity and vacuolization of the choroid plexus) in several studies following propamocarb-HCl exposure, including the ACN and SCN studies; however, concern is low since the effects are well-characterized with clear NOAEL/LOAEL values and the selected endpoints are protective of the observed effects.

iii. There is no evidence of increased quantitative pre- or post-natal susceptibility following exposure to propamocarb-HCl. There is evidence of increased qualitative susceptibility in one of the rat studies in the database; however, concern for these effects is low because: (1) the effects are well characterized, (2) clear NOAELs were established, (3) the endpoints selected are protective of these effects, and (4) the effects were seen in the presence of maternal/parental toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to propamocarb in drinking water. These assessments will not underestimate the exposure and risks posed by propamocarb.

#### *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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to propamocarb will occupy 42% of the aPAD for all infants, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to propamocarb from food and water will utilize 53% of the cPAD for females 13 to 49 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of propamocarb is not expected.

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).

A short- and intermediate-term oral adverse effect was identified; however, propamocarb is not registered for any use patterns that would result in either short- or intermediate-term oral 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 oral 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- or intermediate-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 propamocarb.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, propamocarb is not expected to

pose a cancer risk to humans.

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

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An adequate gas chromatography/nitrogen-phosphorus detection (GC/NPD) method is available for enforcing the proposed tolerances. The method has undergone a successful independent laboratory validation and petition method validation and is currently listed in the Pesticide Analytical Manual (PAM) Vol. II.

##### *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). 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex does not have maximum residue limits (MRLs) for guava and starfruit so harmonization is not an issue.

Codex does have MRLs for leaf and head lettuce at 100 ppm which is different than the U.S. tolerance being established on the leafy greens subgroup 4-16A. EPA is not harmonizing the U.S. tolerance with the Codex MRL because based on available residue data and using the OECD MRL calculation procedure, the tolerance value should be 150 ppm. EPA uses the OECD MRL calculation procedure in order to ensure that the tolerance value is not underestimated.

Codex has MRLs on eggplant at 0.3 ppm, bell pepper at 3 ppm and tomato at 2 ppm. The U.S. tolerance of 4 ppm on the fruiting vegetable group 8-10 is not harmonized with the Codex MRLs for the individual crops. Because EPA has data supporting the establishment of the crop groups and no data that indicate a need to establish separate individual commodities, the effect is that tolerances for individual commodities are not harmonized with Codex MRLs.

Codex has a potato MRL established 0.3 ppm and is harmonized with the U.S. tolerance of 0.3 ppm on the tuberous and corm vegetable subgroup 1C.

## **V. Conclusion**

Therefore, tolerances are established for residues of propamocarb (propyl N-[3-(dimethylamino)propyl]carbamate in or on guava at 0.05 ppm; leafy greens subgroup 4-16A at 150 ppm; starfruit at 0.05 ppm; vegetable, fruiting, group 8-10 at 4 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.3 ppm.

Additionally, the following tolerances are withdrawn from 40 CFR 180.499 as unnecessary due to the newly established tolerances: lettuce, head at 50 ppm; lettuce, leaf at 90 ppm; potato at 0.30 ppm; and vegetable, fruiting, group 8 at 2.0 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition

submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), 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: October 25, 2019.

**Daniel Rosenblatt,**

*Acting 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 § 180.499(a):

a. Remove “the following table” and “the following tolerance levels” and add “table 1 to this paragraph (a)” and “the tolerance levels in table 1 to this paragraph (a)” in their places, respectively; and

b. Revise the table.

The revision reads as follows:

**§ 180.499 Propamocarb; tolerances for residues.**

(a) \* \* \*

Table 1 to Paragraph (a)

Commodity	Parts per million
Guava	0.05
Leafy greens subgroup 4-16A	150
Starfruit	0.05
Tomato, paste	5.0
Vegetable, cucurbit, group 9	1.5
Vegetable, fruiting, group 8-10	4
Vegetable, tuberous and corm, subgroup 1C	0.3

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