



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0095; FRL-9996-85]

Nitrapyrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of nitrapyrin in or on multiple commodities which are identified and discussed later in this document.

Interregional Research Project No. 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-2018-0095, 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 Publishing 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-2018-0095 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-2018-0095, 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 FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8645) by Interregional Research Project No. 4 (IR-4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.350 be amended by establishing tolerances for residues of the nitrification inhibitor nitrapyrin (2-chloro-6-(trichloromethyl) pyridine) and its metabolite, 6-chloropicolinic acid (6-CPA), calculated as the stoichiometric equivalent of nitrapyrin, in or on citrus, dried pulp at 0.094 parts per million (ppm); citrus, oil at 0.37 ppm; fruit, citrus, group 10-10 at 0.03 ppm; leaf petiole vegetable subgroup 22B at 0.4 ppm; Vegetable, *brassica*, head and stem, group 5-16 at 0.07 ppm; vegetable, bulb, group 3-07 at 0.3 ppm; and vegetable, leafy, group 4-16 at 0.3 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, 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 is establishing tolerances that vary from what the petitioner requested, as authorized under FFDCA section 408(d)(4)(A)(i). EPA's explanation for those variations is contained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for nitrapyrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with nitrapyrin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

In oral studies, the liver is the target organ for nitrapyrin, and liver effects are evident in all species tested. Clear signs of hepatotoxicity (*i.e.*, marked changes in clinical chemistry in dogs, indicative of liver toxicity and histopathology in rats and mice, leading to malignant tumor formation in mice) are seen after repeated exposure. Nitrapyrin does not show qualitative or quantitative susceptibility in the rat or rabbit developmental studies or in the 2-generation reproduction study. The observed adverse effects (e.g., delayed ossification and decreased fetal body weight in the developmental rat study and liver effects in pups in the rat reproduction study) occurred at the same doses as maternal toxicity. There is low concern for the altered motor activity seen after acute or subchronic exposure because: clear no-observed adverse effect levels (NOAELs) and lowest-observed adverse effect levels (LOAELs) have been established; no corroborating gross pathological or neuropathological effects were found in any other study in the database; and the selected endpoints are protective of the observed effects.

Nitrapyrin is not mutagenic or immunotoxic, and no effects were observed in the subchronic dermal toxicity study in rabbits up to the limit dose. Nitrapyrin is classified as having “suggestive” evidence of carcinogenicity, based on liver adenomas and carcinomas in mice. This classification is supported by the following factors: (1) Liver tumors were not seen in the 2-year carcinogenicity study in rats; (2) The response is

driven by benign adenomas; (3) Mutagenicity was ruled out as a mode of action; and (4) There are adequate data supporting the MOA of mitogenesis through activation CAR nuclear receptors in male mice but not in female mice. In addition, the chronic reference dose (0.03 mg/kg/day) is approximately 4000X lower than the dose at which tumors are seen in the female mouse. Therefore, quantification of cancer risk using a non-linear Reference Dose (RfD) approach adequately accounts for all chronic toxicity, including carcinogenicity that could result from exposure to nitrapyrin.

Specific information on the studies received and the nature of the adverse effects caused by nitrapyrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of November 30, 2017 (82 FR 56739) (FRL-9967-73).

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 nitrapyrin used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of November 30, 2017 (82 FR 56739) (FRL-9967-73).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to nitrapyrin, EPA considered exposure under the petitioned-for tolerances as well as all existing nitrapyrin tolerances in 40 CFR 180.350. EPA assessed dietary exposures from nitrapyrin 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 nitrapyrin. 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 assumed tolerance-level residues and 100 percent crop treated (PCT).

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 assumed tolerance-level residues and 100 PCT.

iii. *Cancer.* Based on the data cited in Unit III.A., EPA has concluded that quantification of cancer risk using a nonlinear RfD approach adequately accounts for all chronic toxicity, including carcinogenicity that could result from exposure to nitrapyrin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *Chronic exposure.*

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for nitrapyrin. 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 nitrapyrin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of nitrapyrin. 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 Tier II pesticide water calculator (PWC), which incorporates the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of nitrapyrin residues of concern for acute exposures are estimated to be 51 parts per billion (ppb) for surface water and 76 ppb for ground water,

and for chronic exposures for non-cancer assessments are estimated to be 15 ppb for surface water and 67 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 76 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 67 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).

Nitrapyrin 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 nitrapyrin to share a common mechanism of toxicity with any other substances, and nitrapyrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that nitrapyrin 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 FFDCFA 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 are adequate pre-and/or post-natal toxicity studies that do not show quantitative susceptibility in the rabbit or rat developmental studies or in the two-generation reproduction study. In the developmental toxicity in the rabbit, an increased incidence of crooked hyoid bones was seen at the highest dose tested. This effect is considered to be treatment-related but not adverse. In the rat developmental study, developmental toxicity (delayed ossification and decreased fetal body weight) occurred at the same dose as maternal toxicity (reduced body weight/weight gain and reduced food consumption). Toxic effects in the 2-generation reproduction study also occurred at the same dose in both parental animals and the offspring and included increased liver weights (parental M and F; both generations), enlarged livers in F2 pups (M and F), and hepatic vacuolation consistent with fatty changes in parental and offspring animals (both sexes and both generations). Similarly,

gross pathological or neuropathological findings in the neurotoxicity studies were negative.

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 nitrapyrin is complete.
- ii. An acceptable acute neurotoxicity study and an acceptable subchronic neurotoxicity study are available for nitrapyrin. Acutely, nitrapyrin induced tremors and other functional observation battery effects (i.e., slight gait incoordination, palpebral closure and perineal fecal staining) at the high dose (400 mg/kg) only. Decreased motor activity was seen in both sexes at 400 mg/kg and in females at 80 mg/kg. In contrast, increased motor activity was observed in the subchronic neurotoxicity study in female rats but only at high doses (≥ 500 mg/kg/day). However, concern is low since: (1) there are clear NOAELs/LOAELs; (2) there are no corroborating gross pathological or neuropathological findings; (3) there was no evidence of neurotoxicity in other studies in the database; and (4) the selected endpoints are protective of the observed effects.
- iii. There is no evidence that nitrapyrin 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. Effects on the offspring were either not treatment-related or occurred only at the same parental dose.
- 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 nitrapyrin in drinking water. These assessments will not underestimate the exposure and risks posed by nitrapyrin.

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 nitrapyrin will occupy 8.5% of the aPAD for all infants (less than 1-year old), 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 nitrapyrin from food and water will utilize 17% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for nitrapyrin.

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). However, nitrapyrin is not registered for, or proposed for, any residential uses. Therefore, because there is no short-term 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 nitrapyrin.

4. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., EPA considers the chronic aggregate risk assessment to be protective of any aggregate cancer risk. As there is no chronic risk of concern, EPA does not expect any cancer risk to the U.S. population from aggregate exposure to nitrapyrin.

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 nitrapyrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatograph/electron capture detector) is available to enforce the tolerance expression. Seven analytical methods are available in Volume II of the Pesticide Analytical Manual (PAM ii – Pesticide Reg. Sec. 180.350) for tolerance enforcement for nitrapyrin and/or for metabolite 6-CPA.

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

The Codex has not established a MRL for nitrapyrin.

C. Revisions to Petitioned-For Tolerances

EPA is establishing tolerances for residues of nitrapyrin at different levels than requested in the petition for most commodities. For fruit, citrus, group 10-10, dried pulp and fruit, citrus, group 10-10, oil, EPA established the tolerances based on the processing study and highest average field trial residue for the raw agricultural commodity lemon. This leads to higher tolerances (0.5 ppm for fruit, citrus, group 10-10, dried pulp and 2 ppm for fruit, citrus, group 10-10, oil) than those proposed by petitioner (0.094 ppm and 0.37 ppm, respectively). EPA also corrected the commodity names for these commodities.

Based on the residue chemistry data and the Organization for Economic Co-Operation and Development (OECD) tolerance-calculation procedure, EPA is establishing different tolerances for fruit, citrus, group 10-10; leaf petiole vegetable subgroup 22B; vegetable, *Brassica*, head and stem, group 5-16; and vegetable, leafy, group 4-16, because the tolerance values proposed by the petitioner do not include the combined residues of nitrapyrin and its metabolite 6-CPA.

In addition, EPA is revising the tolerance expression in §180.350(a) to correctly identify nitrapyrin as a nitrification inhibitor rather than the current identification as an

insecticide. The rest of the tolerance expression remains the same. The revised tolerance expression is:

(a) *General.* Tolerances are established for residues of the nitrification inhibitor nitrapyrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of nitrapyrin (2-chloro-6-(trichloromethyl) pyridine) and its 6-CPA metabolite (6-chloro-picolinic acid), calculated as the stoichiometric equivalent of nitrapyrin, in or on the commodity.

V. Conclusion

Therefore, tolerances are established for residues of nitrapyrin, by measuring only the sum of nitrapyrin (2-chloro-6-(trichloromethyl) pyridine) and its 6-CPA (6-chloropicolinic acid) metabolite, calculated as the stoichiometric equivalent of nitrapyrin, in or on fruit, citrus, group 10-10 at 0.06 ppm; fruit, citrus, group 10-10, dried pulp at 0.5 ppm; fruit, citrus, group 10-10, oil at 2 ppm; leaf petiole vegetable subgroup 22B at 0.5 ppm; vegetable, *Brassica*, head and stem, group 5-16 at 0.1 ppm; vegetable, bulb, group 3-07 at 0.3 ppm; and vegetable, leafy, group 4-16 at 0.4 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: August 8, 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 § 180.350, paragraph (a):

a. Revise the introductory text.

b. Add alphabetically the entries for “Fruit, citrus, group 10-10”; “Fruit, citrus, group 10-10, dried pulp”; “Fruit, citrus, group 10-10, oil”; “Leaf petiole vegetable subgroup 22B”; “Vegetable, *Brassica*, head and stem, group 5-16”; “Vegetable, bulb, group 3-07”; and “Vegetable, leafy, group 4-16” to the table.

The revision and additions read as follows:

§ 180.350 Nitrapyrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the nitrification inhibitor nitrapyrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of nitrapyrin (2-chloro-6-(trichloromethyl) pyridine) and its 6-CPA metabolite (6-chloro-picolinic acid), calculated as the stoichiometric equivalent of nitrapyrin, in or on the commodity:

Commodity	Parts per million
* * * * *	* *
Fruit, citrus, group 10-10	0.06
Fruit, citrus, group 10-10, dried pulp	0.5
Fruit, citrus, group 10-10, oil	2
Leaf petiole vegetable subgroup 22B	0.5
* * * * *	* *
Vegetable, <i>Brassica</i> , head and stem, group 5-16	0.1

Vegetable, bulb, group 3-07	0.3
Vegetable, leafy, group 4-16	0.4
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