



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2016-0295; FRL-9967-73]**

**Nitrapyrin; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of nitrapyrin in or on almond hulls and the tree nut group 14-12. Dow AgroSciences 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-2016-0295, 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 Printing 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 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-2016-0295 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-2016-0295, 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 20, 2016 (81 FR 47150) (FRL-9948-45), 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 6F8470) by Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.350 be amended by establishing tolerances for residues of the herbicide, nitrapyrin [2-chloro-6-(trichloromethyl) pyridine] and its metabolite, 6-chloropicolinic acid (6-CPA), in or on nut, tree group 14-12 at 0.02 parts per million (ppm) and almond, hulls at 0.07 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the level at which the tolerance is being established for almond hulls. The reason for this change is 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 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 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.

The liver is the major target organ of nitrapyrin in both subchronic and chronic studies via the oral route; no toxicity was seen in the subchronic dermal study. Effects in the oral studies were generally consistent among the species tested (rat, mouse, rabbit, and dog), progressed with time, and typically included increased liver weights, enlarged livers, and/or hepatocellular hypertrophy. Only increased liver weights in the absence of other toxic effects in the liver were noted in the rabbit; however, by study design no other liver parameters were measured. Although some of the observed liver effects (i.e., increased liver weights and hypertrophy) suggest an adaptive response, pronounced decreases in body weight were evident in mice at higher doses and clear signs of hepatotoxicity (i.e., marked changes in clinical chemistry, indicative of liver toxicity and histopathology, leading to malignant tumor formation in mice) are seen only after prolonged exposure. In the chronic dog study, liver toxicity was indicated by marked changes in clinical chemistry parameters (alkaline phosphatase and cholesterol), increased liver weight, and hypertrophy. In rats, increased liver weights were also

associated with clinical chemistry changes and histopathology (vacuolation consistent with fatty changes). By contrast to the other species, liver toxicity in mice progressed from liver weight alterations (associated with histopathological findings of hypertrophy, mitotic figures and necrosis) to significantly increased liver adenomas and non-significantly increased liver carcinomas at  $\geq 250$  mg/kg/day.

Kidney effects (increased kidney weights accompanied by intratubular mineralization and multifocal necrosis of the intratubular epithelium) were observed in male rats only, in both the two generation reproduction study and the chronic toxicity study. These kidney effects are indicative of  $\alpha$ -2u-globulin accumulation with eventual progression to renal tumors. This finding of  $\alpha$ -2u-globulin was confirmed by immunoperoxidase stain in the rat chronic study. The response, which only occurs in male rats, is not relevant to humans.

Nitrapyrin did not show qualitative or quantitative susceptibility in the rabbit or rat developmental studies. In the developmental toxicity in the rabbit, an increased incidence of crooked hyoid bones was seen at the highest dose tested (HDT). This effect is considered to be treatment-related but not adverse because it does not affect the health of the animal. In the rat developmental study, delayed ossification and decreased fetal body weight occurred at the same dose as maternal toxicity (reduced body weight/weight gain and reduced food consumption) and are not considered more severe than the maternal effects. Toxic effects in the two generation reproduction study 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).

In the acute neurotoxicity study, following a single oral dose of 400 mg/kg nitrapyrin, male and female rats showed slight tremors; females also showed gait incoordination, palpebral

closure, and perineal fecal staining accompanied by decreased total motor activity ( $\approx 40\%$  M & F) and an effect on distribution of motor activity (i.e., characterized as a more rapid decline activity than control in both sexes) on Day 1 only. In the subchronic neurotoxicity study, increased landing foot splay in males and females, and increased motor activity in females (equivocal in males) were observed at the same Lowest Observed Adverse Effect Level (LOAEL) (120 mg/kg/day) as systemic effects (increased liver weights, pale livers and increased liver size) in rats. However, there was no evidence of gross pathology or neuropathology in these studies or in any other study throughout the database.

There is also no evidence of immunotoxicity or mutagenicity.

The available data on carcinogenicity of nitrapyrin includes reports of multiple tumor types that were reported (renal tumors in male rats, stomach, epididymis, or Harderian gland neoplasms in either male or female mice). Following five peer review meetings to evaluate the carcinogenic potential of nitrapyrin as a nitrification inhibitor, EPA concluded that the reported tumors were either not treatment-related or not relevant for the human risk assessment, with the exception of the mouse liver tumors. At that time, the Agency classified nitrapyrin as “suggestive evidence of carcinogenic potential”. Following this classification, mode of action (MOA) studies were submitted that suggest that nitrapyrin is a mitogen that induces the male mouse liver tumors through activation of the constitutive androstane receptor (CAR), a nuclear receptor. Since the MOA data were not considered complete (no MOA data on female mice), a final decision on the MOA has not been made. The weight of evidence remains as suggestive of carcinogenicity for the following reasons:

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 MOA.

4. There are adequate data supporting the MOA of mitogenesis through activation CAR nuclear receptors in male mice.

Based on the available information and the fact that 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, the Agency concludes that quantification of cancer risk using a non-linear Reference Dose (RfD) approach will be protective of all chronic toxicity.

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 can be found at <http://www.regulations.gov> in the document titled "Nitrapyrin. Human Health Risk Assessment for Registration Review and New Use on Tree Nuts (Crop Group 14-12)" in docket ID number EPA-HQ-OPP-2016-0295.

*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 shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Nitrapyrin 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)	NOAEL = 16 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 0.16 mg/kg/day aPAD = 0.16 mg/kg/day	Acute neurotoxicity rat study LOAEL = 80 mg/kg, based on decreased total motor activity on Day 1 in females.
Chronic dietary (All populations)	NOAEL = 3 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.03 mg/kg/day cPAD = 0.03 mg/kg/day	1-year chronic dog study LOAEL = 15 mg/kg/day, based on increased absolute and relative liver weights, increased clinical chemistry (alkaline phosphatase & cholesterol) and liver hypertrophy in both sexes.
Cancer (Oral, dermal, inhalation)	Nitrapyrin is classified as “suggestive evidence of carcinogenic potential”. EPA has determined that using the chronic RfD to assess carcinogenic potential will be protective of any potential cancer risk.		

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

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 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 summarized in Unit III.A., EPA has concluded that 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.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for nitrapyrin. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used 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), 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 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 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.* Neither quantitative nor qualitative susceptibility was seen in either 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 (HDT). This effect is considered to be treatment-

related but not adverse. In the rat developmental study, delayed ossification and decreased fetal body weight occurred at the same dose as maternal toxicity. Toxic effects in the two 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. This decision is based on the following findings:

- i. The toxicity database for nitrapyrin is complete.
- ii. In an acute neurotoxicity study, 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 ( $\geq 500$  mg/kg/day). Because (1) there are clear NOAELs/LOAELs in the available studies for these effects and the selected endpoints are protective of the observed effects; (2) there is no corroborating gross pathological or neuropathological findings; and (3) there was no evidence of neurotoxicity in other studies in the database, the Agency's concern for potential neurotoxicity is low. Accordingly, and due to the lack of concerns for increased susceptibility in infants and children, there is no need to require a developmental neurotoxicity to further assess the potential for neurotoxicity in infants and children.

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 not adverse 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 to assess exposure to nitrapyrin in drinking water. The EPA believes that 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, drinking 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 utilize 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 drinking water will utilize 15% of the cPAD for children 1-2 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- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD, no further assessment of short- or intermediate-term risk is necessary 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*

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

The Codex has not established any MRLs for nitrapyrin.

### *C. Revisions to Petitioned-For Tolerances*

The tolerance being established for almond hulls is different than that proposed by the registrant. This difference is due to EPA using the Organization for Economic Cooperation and Development (OECD) Maximum Residue Limits (MRL) calculation procedures to determine appropriate tolerance levels. The results from the spreadsheet calculator supports a tolerance of 0.06 ppm for almond hulls, rather than 0.07 ppm as proposed.

Also, EPA has revised the tolerance expression to clarify (1) that as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of nitrapyrin not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

## **V. Conclusion**

Therefore, tolerances are established for residues of nitrapyrin, including its metabolites and degradates, in or on almond, hulls at 0.06 ppm and the nut, tree, group 14-12 at 0.02 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). 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 FFDC section 408(d), such as the tolerance 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 FFDC 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 27, 2017.

Daniel Kenny,  
*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 § 180.350, paragraph (a):

a. Revise the introductory text.

b. Add alphabetically entries to the table for “Almond, hulls”; and “Nut, tree, group 14-12”.

The revision and additions read as follows:

**§ 180.350 Nitrapyrin; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the insecticide nitrapyrin, including its metabolites and degradates, in or on the commodities 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 (6-chloropicolinic acid) metabolite, calculated as the stoichiometric equivalent of nitrapyrin, in or on the commodity:

Commodity	Parts per million
Almond, hulls	0.06
* * *	* * *
Nut, tree, group 14-12	0.02
* * *	* * *

\* \* \* \* \*