appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 28, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: August 14, 2019.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart D—Arizona

■ 2. Section 52.120 is amended in paragraph (c), Table 4, under the table headings ''Post-July 1988 Rule Codification'' and ''Regulation III—Control of Air Contaminants,'' by revising the entries for ''Rule 337'' and ''Rule 342'' to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

TABLE 4—EPA-APPROVED MARICOPA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Post-July 1988 Rule Codification				
*	*	*	*	*
Regulation III—Control of Air Contaminants				
*	*	*	*	*
Rule 337	Graphic Arts	August 17, 2011	August 27, 2019, [INSERT **Federal Register** CITATION].	Submitted on January 15, 2014.
*	*	*	*	*
Rule 342	Coating Wood Furniture and Fixtures.	November 2, 2016	August 27, 2019 [INSERT **Federal Register** CITATION].	Submitted on June 22, 2017.
*	*	*	*	*

* * * * *

[FR Doc. 2019–18336 Filed 8–26–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0526; FRL–9998–22]

Sedaxane; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sedaxane in or on legume vegetables (dried or succulent), crop group 6. Syngenta Crop Protection, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 27, 2019. Objections and requests for hearings must be received on or before October 28, 2019, and must

be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2018–0526, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0526 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 October 28, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2018–0526, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 6, 2019 (84 FR 2115) (FRL–9987–08), 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 8F8679) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greenboro, NC 27419. The petition requested that 40 CFR 180.665 be amended by establishing a tolerance for residues resulting from seed treatment uses of the fungicide sedaxane, in or on legume vegetables (dried or succulent), crop group 6 at 0.01 parts per million (ppm) and to remove the existing tolerances for soybean, seed at 0.01 ppm and pea and bean, dried shelled, except soybean, subgroup 6C at 0.01 ppm upon establishment of the group 6 tolerance. That document referenced a summary of the petition prepared by Syngenta, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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 sedaxane including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sedaxane 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 main target tissue for sedaxane is the liver. Sedaxane also caused thyroid hypertrophy/hyperplasia in male rats. In the acute neurotoxicity (ACN) and sub-chronic neurotoxicity (SCN) studies, sedaxane caused decreased activity, muscle tone, rearing and grip strength; however, no adverse histopathology was observed, and EPA has concluded that there is low concern for neurotoxicity.

In the rat, no adverse effects in fetuses were seen in developmental toxicity studies at maternally toxic doses. In the rabbit, fetal toxicity was observed at the same doses as the dams. Offspring effects in the rat reproduction study occurred at the same doses causing parental effects.

The available data show evidence of liver tumors (in male rats and mice), thyroid tumors (in male rats), and uterine tumors (in female rats) resulting from exposure to sedaxane. Based on a weight of evidence of the available data, a constitutive androstane receptor/pregnane-X receptor (CAR/PXR)-mediated mitogenic mode-of action (MOA) was established for liver tumors in male mice and rats and a liver-mediated altered thyroid hormone homeostasis MOA was established for thyroid tumors in male rats. At this time, a MOA for the uterine tumors has not been identified.

To quantitatively assess the carcinogenic potential of sedaxane, EPA has concluded that a non-linear approach (*i.e.,* reference dose (RfD)) is appropriate for the following reasons: (1) There is a clear understanding of the threshold (non-linear) doses associated with the key events in the established MOAs leading to liver and thyroid tumors in rodents, the key events occur only at doses that well exceed the chronic reference dose (0.11 mg/kg/day); (2) Sedaxane is not mutagenic or genotoxic; (3) The dose at which uterine tumors was observed is at 261 mg/kg/day, which greatly exceeds the chronic reference dose (0.11 mg/kg/day) being used to assess chronic exposure to sedaxane.

Sedaxane has low acute toxicity by the oral, dermal, and inhalation routes. It is not a dermal sensitizer, causes no skin irritation and only slight eye irritation.

Specific information on the studies received and the nature of the adverse effects caused by sedaxane 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 December 8, 2017 (82 FR 57867) (FRL–9970–04).

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 NOAEL and 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 RfD—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for sedaxane used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of December 8, 2017 (82 FR 57867) (FRL–9970–04).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sedaxane, EPA considered exposure under the petitioned-for tolerances as well as all existing sedaxane tolerances in 40 CFR 180.665. EPA assessed dietary exposures from sedaxane 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 sedaxane. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) under the Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and the CDC under the National Health and Nutrition Examination Survey What We Eat in America (NHANES/WWEIA) 2003–2008. As to residue levels in food, EPA assumed tolerance-level residues for all commodities and 100% crop treated. Default processing factors were used with the exception of peanut butter which uses empirical processing data.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WEIA 2003–2008. As to residue levels in food, EPA assumed tolerance-level residues for all commodities and 100% crop treated (CT). Default processing factors were used with the exception of peanut butter which uses empirical processing data.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to sedaxane. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for sedaxane. Tolerance-level residues and/or 100% CT 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 sedaxane in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sedaxane. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of sedaxane for acute exposures are estimated to be 4.1 parts per billion (ppb) for surface water and 15.1 ppb for ground and for chronic exposures for non-cancer assessments are estimated to be 1.2 ppb for surface water and 13.0 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 15.1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 13.0 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). Sedaxane 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.''

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 sedaxane and any other substances, and sedaxane does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sedaxane 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 *https://www.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.* There is no evidence for increased susceptibility following prenatal or post-natal exposures to sedaxane based on effects seen in developmental toxicity studies in rabbits or rats. In range-finding and definitive developmental toxicity studies in rats, neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to sedaxane was observed. In these studies, there were no single-dose effects. There was no evidence of increased susceptibility in a 2-generation reproduction study in rats following prenatal or post-natal exposure to sedaxane. Clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the 2-generation reproduction study. The dose-response relationship for the effects of concern is well characterized.

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 sedaxane is complete.

ii. Given the available information, there is low concern that sedaxane is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. In the rat, no adverse effects in fetuses were seen in developmental toxicity studies at maternally toxic doses. In the rabbit, fetal toxicity was observed at the same doses as the dam (increased unossified sternebrae and 13th rudimentary ribs, a decrease in fetal weights of 9% and increased abortions). In the dam, at the same doses, the effects were decreased body weight, reduced food consumption, and decreased defecation. In reproduction studies, offspring effects occurred at the same doses causing parental effects; thus, there was no quantitative or qualitative increase in sensitivity in rat pups. The LOAELs and NOAELs for the developmental and reproduction studies were clearly defined. The NOAEL used for the acute dietary risk assessment (30 mg/kg/day), based on effects observed in the ACN study, is protective of the developmental and offspring effects seen in rabbits and rats with the NOAELs of 100–200 mg/kg/day. Based on these considerations, there are no residual uncertainties for pre-and/or post-natal susceptibility.

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

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 sedaxane will occupy <1% of the aPAD for all infants (<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 sedaxane from food and water will utilize <1% of the cPAD for all population subgroups the population group receiving the greatest exposure. There are no residential uses for sedaxane.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no proposed or registered residential uses of sedaxane a short-term risk assessment was not performed. The chronic risk assessment is protective for any short-term exposures from food and drinking water.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no proposed or registered residential uses of sedaxane, an intermediate-term risk assessment was not performed. The chronic assessment is protective for any intermediate-term exposures from food and drinking water.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA has concluded that using the nonlinear approach based on the chronic RfD will be protective of potential carcinogenicity. Because the chronic risk is below the Agency's level of concern, EPA concludes there is no aggregate cancer risk from exposure to sedaxane.

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 sedaxane residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method is available to enforce the proposed tolerances for sedaxane in plant commodities. A modification of the Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method was developed for the determination of residues of sedaxane (as its isomers SYN508210 and SYN508211) in/on various crops. The sedaxane isomers (SYN508210 and SYN508211) are quantitatively determined by LC/MS/MS. The validated limit of quantitation (LOQ) reported in the method is 0.005 ppm for each sedaxane isomer.

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for sedaxane in or on the legume vegetables crop grouping.

V. Conclusion

Therefore, tolerances are established for residues of sedaxane in or on vegetable, legume, group 6 at 0.01 ppm. In addition, the Agency is removing the existing tolerances for pea and bean, dried shelled, except soybean, subgroup 6C, and soybean seed as they are unnecessary upon the establishment of the group 6 tolerance.

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 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 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 16, 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 § 180.665, amend the table in paragraph (a) as follows:

■ i. Remove the entry for ''Pea and bean, dried shelled, except soybean, subgroup 6C''; and

■ ii. Add alphabetically the entry ''Vegetable, legume, group 6''.

The addition reads as follows:

§ 180.665 Sedaxane; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Vegetable, legume, group 6	0.01

* * * * *

[FR Doc. 2019–18366 Filed 8–26–19; 8:45 am]

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 August 27, 2019. Objections and requests for hearings must be received on or before October 28, 2019, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–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 October 28, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–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 FFDCA 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