part 41)'' and adding in its place ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200''.

PART 59—GRANTS TO STATES FOR CONSTRUCTION OR ACQUISITION OF STATE HOMES

■ 19. The authority citation for part 59 continues to read as follows:

Authority: 38 U.S.C. 101, 501, 1710, 1742, 8105, 8131–8137.

§ 59.124 [Amended]

■ 20. Amend § 59.124(a) by removing ''Single Audit Act of 1984 (see part 41 of this chapter)'' and adding in its place ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200''.

PART 61—VA HOMELESS PROVIDERS GRANT AND PER DIEM PROGRAM

■ 21. The authority citation for part 61 continues to read as follows:

Authority: 38 U.S.C. 501, 2001, 2002, 2011, 2012, 2061, 2064.

Subpart B—Capital Grants

§ 61.16 [Amended]

■ 22. Amend § 61.16(a) by removing ''OMB Circular A–122 as codified at 2 CFR part 230.'' and adding in its place ''the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200.''.

Subpart E—Technical Assistance Grants

■ 23. Amend § 61.50 by revising paragraph (b)(3)(i) to read as follows:

§ 61.50 Technical assistance grants-general.

* * * * *

(b) * * *

(3) * * *

(i) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200;

* * * * *

Subpart F—Awards, Monitoring, and Enforcement of Agreements

§ 61.61 [Amended]

■ 24. Amend § 61.61(a) by removing ''VA common grant rules at 38 CFR parts 43 and 49 and the OMB Circulars, including those cited in § 61.66.'' and adding in its place ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200.''.

■ 25. Revise § 61.66 to read as follows:

§ 61.66 Financial management.

(a) All recipients must comply with applicable requirements of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200.

(b) All entities receiving assistance under this part must use a financial management system that follows generally accepted accounting principles and meets the requirements set forth under 2 CFR part 200. All recipients must implement the requirements of 2 CFR part 200 when determining costs reimbursable under all awards issued under this part.

(Authority: 38 U.S.C. 501)

§ 61.67 [Amended]

■ 26. Amend § 61.67:

■ a. In paragraph (c) by removing ''38 CFR 49.32'' and adding in its place ''2 CFR part 200''.

■ b. In paragraph (f) by removing ''38 CFR 49.34'' and adding in its place ''2 CFR part 200''.

PART 62—SUPPORTIVE SERVICES FOR VETERANS FAMILIES PROGRAM

■ 27. The authority citation for part 62 continues to read as follows:

Authority: 38 U.S.C. 501, 2044, and as noted in specific sections.

■ 28. Amend § 62.70:

■ a. By revising paragraph (a).

■ b. In paragraph (b) by removing ''OMB Circular A–110, Subpart C, Section 21 (codified at 2 CFR 215.21) and 38 CFR 49.21.'' and adding in its place ''2 CFR part 200.''.

■ c. In paragraph (c) by removing ''OMB Circular A–122, Cost Principles for Non-Profit Organizations, codified at 2 CFR part 235.'' and adding in its place ''2 CFR part 200.''.

The revision reads as follows:

§ 62.70 Financial management and administrative costs.

(a) Grantees must comply with applicable requirements of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200.

* * * * *

PART 64—GRANTS FOR THE RURAL VETERANS COORDINATION PILOT (RVCP)

■ 29. The authority citation for part 64 continues to read as follows:

Authority: 38 U.S.C. 501, 523 *note.*

■ 30. Amend § 64.14 by revising paragraph (b)(2) to read as follows:

§ 64.14 RVCP grant agreement.

* * * * *

(b) * * *

(2) Abide by the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards under 2 CFR part 200, and 2 CFR parts 25 and 170, if applicable.

* * * * *

[FR Doc. 2015–17416 Filed 7–21–15; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0354; FRL–9930–84]

Sedaxane; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sedaxane as a seed treatment for cotton, undelinted seed; cotton, gin byproducts; and beet, sugar. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 22, 2015. Objections and requests for hearings must be received on or before September 21, 2015, 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–2014–0354, 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: Susan Lewis, 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–2014–0354 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 September 21, 2015. 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–2014–0354, 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 August 1, 2014 (79 FR 44729) (FRL–9911–67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8263) by Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide sedaxane, *N*-[2-[1,1′-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide, as a seed treatment for cotton, undelinted seed at 0.01 parts per million (ppm); cotton, gin byproducts at 0.01 ppm; and beet, sugar at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, 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 has altered the commodity name from ''beet, sugar'' to ''beet, sugar, roots''. The reason for this change is explained 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 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 toxicological effects reported in the submitted animal studies such as mitochondrial disintegration and glycogen depletion in the liver are consistent with the pesticidal mode of action also being the mode of toxic action in mammals. The rat is the most sensitive species tested, and the main target tissue for sedaxane is the liver. Sedaxane also caused thyroid hypertrophy/hyperplasia. In the acute neurotoxicity (ACN) and sub-chronic neurotoxicity (SCN) studies, sedaxane caused decreased activity, decreased muscle tone, decreased rearing, and decreased grip strength. There are indications of reproductive toxicity in rats such as decreased follicle counts, but these effects did not result in reduced fertility. Offspring effects in the reproduction study occurred at the same doses causing parental effects, and do not indicate any quantitative or qualitative increase in sensitivity in rat pups. In the rat, no adverse effects in fetuses were seen in developmental toxicity studies at maternally toxic

doses. In the rabbit, fetal toxicity (increased unossified sternebrae and 13th rudimentary ribs, decrease in fetal weights, increased numbers of abortions) was observed at the same doses that produced toxicity in the dams (abortions, decreased body weight gain/body weight loss, reduced food consumption, defecation), and therefore does not indicate any increased susceptibility. Sedaxane is tumorigenic in the liver in the rat and mouse, and led to tumors in the thyroid and uterus in the rat and was classified as ''likely to be carcinogenic to humans.'' Sedaxane was negative in the mutagenicity studies. The 28-day dermal study did not show systemic toxicity at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day). 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 can be found at *http://www.regulations.gov* in document ''Sedaxane. Human Health Risk Assessment to Support New Seed Treatment Uses on Cotton and Sugar Beet'' on pages 13–20 in docket ID number EPA–HQ–OPP–2014–0354.

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

A summary of the toxicological endpoints for sedaxane used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SEDAXANE 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 (All populations, including children and women 13–49 years of age).	NOAEL = 30 mg/kg/day. UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	Acute RfD = 0.30 mg/kg/day. aPAD = 0.30 mg/kg/day.	Rat ACN Study. LOAEL = 250 mg/kg based on reduced activity, decreased rearing, initial inactivity, piloerection, ruffled fur and recumbency, decreased BW, decreased BWG and food consumption (males). In females, weakened condition, swaying gait, and decreased activity, reduced muscle tone, decreased locomotor activity and rearing. The weakened condition, swaying gait and decreased activity were observed on days 2–7, while the other effects were on day 1.
Chronic dietary (All populations)	NOAEL= 11 mg/kg/day. UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	Chronic RfD = 0.11 mg/kg/day. cPAD = 0.11 mg/kg/day.	Chronic Rat Study. NOAEL= 11/14 mg/kg bw/day (male/female). LOAEL = 67/86 mg/kg bw/day (male/female) based on decreased hind limb grip strength increased liver weight, increased incidences of hepatocyte hypertrophy and eosinophilic foci, and thyroid follicular cell hypertrophy, basophilic colloid, epithelial desquamation and increased phosphate levels (males). In females it was based on decreased body weight and body weight gain, increased liver weight and the same histopathology noted above for males.
Cancer (Oral, dermal, inhalation).	''Likely to be Carcinogenic to Humans'' based on significant tumor increases in two adequate rodent carcinogenicity studies. $Q_1^* = 4.64 \times 10 - 3$ (mg/kg/day)$^{-1}$ (linear low-dose extrapolation model).		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). Q_1^* = Linear cancer slope factor

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) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in

food, EPA conducted a highly conservative acute dietary assessment using tolerance-level residues and 100% crop treated assumptions for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA conducted from 2003–2008. As to residue levels in food, EPA conducted a partially refined chronic dietary assessment using anticipated residue levels for all commodities and percent crop treated data.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that sedaxane should be classified as ''Likely to be Carcinogenic to Humans'' and a linear approach has been used to quantify cancer risk. Cancer risk was quantified using the same estimates as discussed in Unit III.C.1.ii., C*hronic exposure.* A linear low-dose extrapolation model (Q_1*) = 4.64×10^{-3} (mg/kg/day)$^{-1}$ was used to estimate cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) information.*

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT. The Agency estimated the PCT for existing uses as follows: For chronic and cancer dietary exposure assessment, 100 PCT was assumed for all commodities except for soybeans (51%), wheat (32%) and potato (67%), which incorporated average PCT estimates.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which sedaxane may be applied in a particular area.

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. Drinking water accounted for 95% of the total dietary exposure to 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 FQPA 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 22.0 ppb for ground water, for chronic exposures and cancer assessments are estimated to be 1.2 ppb for surface water and 19.3 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 22.0 ppb was used to assess the contribution to drinking water. For chronic and cancer dietary risk assessment, the water concentration of value 19.3 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.'' EPA has not found sedaxane to share a common mechanism of toxicity with 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 Web site at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA 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 and/or postnatal 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 postnatal 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. 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 (NOAELs of 100–200 mg/kg/day). In addition, there is no evidence of neuropathology or abnormalities in the development of the fetal nervous system from the available toxicity studies conducted with sedaxane.

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. There is no indication that sedaxane is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Although sedaxane caused changes in apical endpoints such as decreased activity, decreased muscle tone, decreased rearing and decreased grip strength in the ACN and SCN studies, EPA believes these effects do not support a finding that sedaxane is a neurotoxicant. The observed effects in the ACN and SCN studies were likely secondary to inhibition of mitochondrial energy production caused by sedaxane. Furthermore, there was no corroborative neuro-histopathology demonstrated in any study, even at the highest doses tested (*i.e.,* 2,000 mg/kg/day). Therefore, based on its chemical structure, its pesticidal mode of action, and lack of evidence of neuro-histopathology in any acute and repeated-dose toxicity study, sedaxane does not demonstrate potential for neurotoxicity. Since sedaxane did not demonstrate increased susceptibility to the young or specific neurotoxicity, a developmental neurotoxicity (DNT) study is not required.

iii. As discussed in Unit III.D.2., there is no evidence that sedaxane results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments are highly conservative (acute) or only partially refined (chronic), resulting in high-end estimates of dietary food exposure. 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 1.3% 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 infants (<1 year old), the population group receiving the greatest exposure. There are no residential uses for sedaxane.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short- and intermediate-term adverse effect was identified; however, sedaxane is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for sedaxane.

4. *Aggregate cancer risk for U.S. population.* The Agency has classified sedaxane as ''Likely to be Carcinogenic to Humans'' based on significant tumor increases in two adequate rodent carcinogenicity studies. A cancer dietary risk assessment was conducted using a linear low-dose extrapolation model (Q_1^*) = 4.64×10^{-3} (mg/kg/day)$^{-1}$ which indicated a risk estimate to the U.S. population as 2×10^{-6}. EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision that can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above in this unit, cancer risk should generally not be assumed to exceed the

benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Based on this approach, EPA considers the risks of cancer from exposure to sedaxane to be negligible.

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 sedaxane residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/tandem mass spectrometry (LC/MS/MS)) is available to enforce the tolerance expression. 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 both sedaxane isomers. A successful independent laboratory validation (ILV) study was also conducted on the modified QuEChERS method using samples of wheat green forage and wheat straw fortified with SYN508210 and SYN508211 at 0.005 and 0.05 ppm. The analytical standard for sedaxane, with an expiration date of February 28, 2018, is currently available in the EPA National Pesticide Standards Repository.

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 MRLs for sedaxane.

C. Revisions to Petitioned-For Tolerances

Although the petitioner sought a tolerance for the commodity name ''beet, sugar'', EPA is establishing a tolerance for ''beet, sugar, roots'' to be consistent with the general food and feed commodity vocabulary EPA uses for tolerances and exemptions.

V. Conclusion

Therefore, tolerances are established for residues of sedaxane, *N*-[2-[1,1′-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide, as a seed treatment for cotton, undelinted seed at 0.01 ppm; cotton, gin byproducts at 0.01 ppm; and beet, sugar, roots at 0.01 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 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: July 16, 2015.

G. Jeffrey Herndon,

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, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.665 Sedaxane; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Beet, sugar, roots	0.01
* * * * *	
Cotton, undelinted seed	0.01
Cotton, gin byproducts	0.01
* * * * *	

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[FR Doc. 2015–17999 Filed 7–21–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0232; FRL–9929–57]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of novaluron in or on multiple commodities and removes several existing tolerances which are identified and discussed later in this document. This regulation additionally revises existing tolerances in or on vegetable, cucurbit, group 9; and plum, prune, dried. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 22, 2015. Objections and requests for hearings must be received on or before September 21, 2015, 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–2014–0232, 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: Susan Lewis, 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–2014–0232 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 September 21, 2015. 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–2014–0232, by one of the following methods:

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL–9918–90), 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 4E8241) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide novaluron, (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy] phenyl]amino]carbonyl]-2,6-difluoro benzamide), in or on avocado at 0.60 parts per million (ppm); carrot at 0.05 ppm; bean at 0.60 ppm; vegetable, fruiting, group 8–10 at 1.0 ppm; fruit, pome, group 11–10 at 2.0 ppm; cherry subgroup 12–12A at 8.0 ppm; peach