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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0615; FRL-9345-8]

Sedaxane; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sedaxane in or on multiple food commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc. 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-2010-0615, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Heather Garvie, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0034; email address: garvie.heather@*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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/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-2010-0615 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0615, by one of the following methods:

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2010-0615 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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.htm*.

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 11, 2010 (75 FR 48667) (FRL-8840-6), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP # 0F7721) by Syngenta Crop Protection, Inc., Regulatory Affairs, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide sedaxane, in or on barley, grain, seed at 0.01 parts per million (ppm); barley, hay, seed at 0.05 ppm; barley, straw, seed at 0.01 ppm; canola, seed at 0.01 ppm; oat,

grain, seed at 0.01 ppm; rye, seed at 0.01 ppm; soybean, forage, seed at 0.06 ppm; soybean, hay, seed at 0.4 ppm; soybean, seed at 0.01 ppm; triticale, seed at 0.01 ppm; wheat, forage, seed at 0.02 ppm; wheat, grain, seed at 0.01 ppm; wheat, hay, seed at 0.07 ppm; and wheat, straw, seed at 0.01 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., 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 tolerances to correct commodity definitions and to recommend tolerances other than the proposed tolerances. The reasons for these changes are 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 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, but these effects did not result in reduced fertility. In the rat, no adverse effects in fetuses were seen in developmental toxicity studies at maternally toxic doses. However, in the rabbit, fetal toxicity was observed at the same doses as the dams. Offspring effects in the

reproduction study occurred at the same doses causing parental effects, thus there was no qualitative increase in sensitivity in rat pups. 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 Canola, Cereal Grains (Barley, Oat, Rye, Triticale, and Wheat), and Soybean", dated February 16, 2012**,** pages 37-77 in docket ID number EPA-HQ-OPP-2010-0615.

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 the NOAEL and the LOAEL of concern are identified. Uncertainty/safety factors (USFs)

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 following Table.

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 (general populations, including infants and children)	NOAEL = 30 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.30 mg/kg/day aPAD = 0.30	Rat ACN Study NOAEL=30 mg/kg LOAEL=250 mg/kg based on reduced activity, decreased rearing, initial inactivity, piloerection,

		mg/kg/day	ruffled fur and recumbency, decreased BW, decreased BWG and food consumption (males). In females, weakened condition, swaying gait, decreased activity, reduced muscle tone, and 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 in males 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 (male). In females, it was based on decreased body weight and body weight gain, increased liver weight and the same thyroid histopathology noted above for males.
Cancer (Oral, dermal, inhalation)	Classification: "Likely to be Carcinogenic to Humans" based on significant tumor increases in two adequate rodent carcinogenicity studies. Q_1*= $4.64x10^{-3}$ $(mg/kg/day)^{-1}$		

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. = 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_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among

members of the human population (intraspecies). BW=Body weight. BWG=Body weight gain.

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. 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 U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted a highly conservative acute dietary risk assessment which used tolerance level residues and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA conducted a highly conservative chronic dietary risk assessment which used tolerance level residues and assumed 100 PCT for all commodities.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is

appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. 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. This finding is based on significant tumor increases in two adequate rodent carcinogenicity studies. EPA assessed exposure for the purpose of estimating cancer risk assuming tolerance level residues and 100 PCT for all commodities.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for sedaxane. 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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 FQPA Index Reservoir Screening Tool (FIRST) and Tier II pesticide root zone model (PRZM) (grab working-level sampling, ground water (GW) (Prerelease Version), the estimated drinking water concentrations (EDWCs) of sedaxane for acute

exposures are estimated to be 1.4 parts per billion (ppb) for surface water and 8.3 ppb for ground water. The water exposures for the chronic dietary and cancer assessments are estimated to be 0.9 ppb for surface water and 6.5 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 8.3 ppb was used to assess the contribution to drinking water. For chronic and cancer dietary risk assessment, the water concentration value of 6.5 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. 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 *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 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*. The toxicological database for sedaxane is complete with regard to prenatal and postnatal toxicity, and there are no residual uncertainties. 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. There was no evidence of increased susceptibility in a 2-generation reproduction study in rats following prenatal or postnatal exposure to sedaxane. There is no evidence of neuropathology or abnormalities in the development of the fetal nervous system from the available toxicity studies conducted with 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).

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 and includes the immunotoxicity study and neurotoxicity screening battery.

ii. The sedaxane toxicology database did not demonstrate evidence of neurotoxicity. There are no specific concerns for neurotoxicity as the observed effects in the ACN and SCN studies were likely secondary to inhibition of mitochondrial energy production caused by sedaxane. 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. There was no corroborative neuro-histopathology demonstrated in any study, even at the highest doses tested (i.e., 2,000 mg/kg/day). 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 susceptibility to the young or specific neurotoxicity, a developmental neurotoxicity (DNT) study is not required.

iii. 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 were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 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 population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, 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.

Sedaxane is a member of the pyrazole carboxamide fungicides. Metabolic processes involving cleavage of the linkage between the pyrazole and phenyl rings of these compounds have the potential to produce common pyrazole-metabolites. Indeed, confined rotational crops studies for sedaxane and isopyrazam demonstrate that low levels of three common metabolites form. However, due to the low levels of these compounds in rotational crops (≤0.01 ppm), and low concerns about their potential toxicity relative to parent molecules, any risks from aggregation of exposures to common metabolites across chemicals will be insignificant.

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 populations.

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 populations. 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). A short-term adverse effect was identified; however, sedaxane is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-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-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for sedaxane**.**

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). An intermediate-term adverse effect was identified; however**,** sedaxane is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for sedaxane**.**

5. *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. Accordingly, a cancer dietary risk assessment was conducted, indicating a risk estimate of 7×10^{-7} for the US population. This assessment assumed tolerance level residues, 100 PCT for all commodities, and included modeled drinking water estimates.

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

Adequate enforcement methodology 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. 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 April 2012, 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

The tolerance levels for feedstuffs for soybean, forage; wheat, forage; wheat, hay; and barley, hay being established by EPA differ from those proposed in the tolerance petition submitted by Syngenta. The Agency used the Organization for Economic Cooperation and Development tolerance calculation procedures to determine that the following tolerance levels are needed: 0.05 for soybean, forage; 0.015 for wheat, forage; 0.06 for wheat, hay; and 0.04 for barley, hay. The petitioner did not propose separate tolerances for feedstuffs derived from oat and rye, however, the Agency is establishing

them as follows: oat, forage at 0.015; oat, hay at 0.06; oat, straw at 0.01; rye, forage at 0.015; and rye, straw at 0.01. The wheat trials depict low but finite residues in forage, straw, and hay. Syngenta proposed, and EPA agrees, that tolerances are needed on these wheat feedstuffs. Because EPA is relying on magnitude of the residue data from wheat and barley to establish oat and rye tolerances, due to the crop similarities and identical use patterns, tolerances on oat and rye feedstuffs are needed as well. A separate tolerance for triticale is not required as wheat tolerances cover triticale by definition 40 CFR 180.1(g).

V. Conclusion

Therefore, the following tolerances are established for residues of sedaxane, in or on wheat, grain at 0.01 ppm; barley, grain at 0.01 ppm; soybean, seed at 0.01 ppm; canola, seed at 0.01 ppm; oat, grain at 0.01 ppm; rye, grain at 0.01 ppm; soybean, forage at 0.05 ppm; soybean, hay at 0.04 ppm; wheat, forage at 0.015 ppm; wheat, hay at 0.06 ppm; wheat, straw at 0.01 ppm; barley, hay at 0.04 ppm; barley, straw at 0.01 ppm; oat, forage at 0.015 ppm; oat, hay at 0.06 ppm; oat, straw at 0.01 ppm; rye, forage at 0.015 ppm and rye, straw at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: June 8, 2012.

Steven Bradbury,

Director, 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. Section 180.665 is added to read as follows:

§ 180.665 Sedaxane; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide sedaxane, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only sedaxane, *N*-[2-[1,1′-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide, as the sum of its *cis*- and *trans*-isomers in or on the commodity.

Commodity	Parts per million
Barley, grain	0.01
Barley, hay	0.04
Barley, straw	0.01
Canola, seed	0.01
Oat, forage	0.015
Oat, grain	0.01
Oat, hay	0.06
Oat, straw	0.01
Rye, forage	0.015

Rye, grain	0.01
Rye, straw	0.01
Soybean, forage	0.05
Soybean, hay	0.04
Soybean, seed	0.01
Wheat, forage	0.015
Wheat, grain	0.01
Wheat, hay	0.06
Wheat, straw	0.01

(*b*) *Section 18 emergency exemptions.* [Reserved]

(*c*) *Tolerances with regional registrations.* [Reserved]

(d) Indirect inadvertent residues. [Reserved]

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