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: January 24, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.578, amend the table in paragraph (a)(1) as follows:
■ a. Remove the entries for ''*Brassica,* head and stem, subgroup 5A'' and ''Brassica, leafy greens, subgroup 5B'';
■ b. Add alphabetically the entry ''*Brassica,* leafy greens, subgroup 4–16B'';
■ c. Remove the entry for ''Canola, seed'';
■ d. Add alphabetically the entries ''Celtuce'' and ''Cottonseed subgroup 20C'';
■ e. Remove the entry for ''Cotton, undelinted seed'';
■ f. Add alphabetically the entries ''Fennel, florence, fresh leaves and stalk'' and ''Fruit, stone, group 12–12'';
■ g. Remove the entry for ''Fruit, stone, group 12, except plum, prune'';
■ h. Add alphabetically the entries ''Kohlrabi''; ''Leaf petiole vegetable subgroup 22B''; and ''Leafy greens subgroup 4–16A'';
■ i. Remove the entries for ''Mustard, seed'' and ''Nut, tree, group 14'';
■ j. Add alphabetically the entry ''Nut, tree, group 14–12'';
■ k. Remove the entries for ''Pistachio''; ''Plum, prune, dried''; and ''Plum, prune, fresh'';
■ l. Add alphabetically the entries ''Rapeseed subgroup 20A'' and ''Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B'';
■ m. Remove the entry for ''Turnip greens'';
■ n. Add alphabetically the entry ''Vegetable, *brassica,* head and stem, group 5–16''; and
■ o. Remove the entry for ''Vegetable, leafy, except brassica, group 4''.

The revisions and additions read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B	15
* * * * *	
Celtuce	3
* * * * *	
Cottonseed subgroup 20C	0.7
Fennel, florence, fresh leaves and stalk	3
* * * * *	
Fruit, stone, group 12–12	1.5
* * * * *	
Kohlrabi	1.2
Leaf petiole vegetable subgroup 22B	3
Leafy greens subgroup 4–16A	3
Nut, tree, group 14–12	0.1
* * * * *	
Rapeseed subgroup 20A	0.01
* * * * *	
Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B	0.5
Vegetable, *brassica,* head and stem, group 5–16	1.2
* * * * *	

* * * * *

[FR Doc. 2020–02038 Filed 2–13–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0129; FRL–10002–96]

Ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate]; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] when used as an inert ingredient (stabilizer) limited to 1% (by weight) in pesticide formulations applied to growing crops, and raw agricultural commodities after harvest. Syngenta Crop Protection, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] when used in accordance with the terms of this exemption.

DATES: This regulation is effective February 14, 2020. Objections and requests for hearings must be received on or before April 14, 2020, 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–2019–0129, 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 L. 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 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–2019–0129 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 April 14, 2020. 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–2019–0129, 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. Petition for Exemption

In the **Federal Register** of June 7, 2019 (84 FR 26630) (FRL–9993–93), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11245) by Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested the establishment of an exemption from the requirement of a tolerance for residues of ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] (CAS Reg. No. 36443–68–2) when used as an inert ingredient (stabilizer) at no more than 1% by weight in pesticide formulations applied to or on raw agricultural commodities and growing crops under 40 CFR 180.910. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the petitioner, which is available in the docket at *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that

occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by ethylenebis(oxyethylene) bi[3-(5-tert-butyl-4-hydroxy-m-tolyl)propionate] 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 this unit.

Acute toxicity is low for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate]. In rats, the lethal dose (LD_{50}) for acute oral and dermal toxicity is greater than 7,000 and 2,000 milligrams/kilogram/day (mg/kg/day), respectively. It is not a dermal or eye irritant, or a sensitizer.

Subchronic exposure to ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] in rats resulted in increased liver weights and alanine aminotransferase (ALAT) activity at 112 mg/kg/day and minimal thyroid follicular hypertrophy at doses greater than 250 mg/kg/day. The NOAELs were 37.4 and 50 mg/kg/day, respectively. In dogs, no toxicity is seen at doses up to 300 mg/kg/day, the highest dose tested.

No fetal susceptibility was observed in the developmental studies. Maternal toxicity (reduced bodyweight gain and food consumption) occurs at 100 mg/kg/day while developmental toxicity (reduced bodyweight and delayed skeletal maturation) occurs at 300 mg/kg/day. The maternal NOAEL was not established, and the developmental NOAEL is 100 mg/kg/day.

Qualitative fetal susceptibility was observed in the 2-generation reproduction toxicity study. Pup mortality and reduced body weight were observed in offsprings at 900 parts per million (ppm) (~54 to 62 mg/kg/day). In parents, decreased bodyweight gain and food consumption occurred at the same dose. However, the established chronic reference dose (cRfD) of 0.15 mg/kg/day will be protective of offspring effects. The parental and offspring NOAELs are 300 ppm (~21 to 26 mg/kg/day). Reproduction toxicity was not observed up to 1,800 ppm (~108 to 124 mg/kg/day), the highest dose tested.

The combined chronic/carcinogenicity study showed focal cystic dilatation of the liver sinusoids and thyroid follicle hyperplasia at doses greater than 50 mg/kg/day. The NOAEL is 15 mg/kg/day. There was a treatment-related increase in thyroid tumor incidence at 100 mg/kg/day in both sexes. However, it is well established that alterations in rat thyroid hormones can alter the thyroid gland resulting in tumor formation. Based on the mechanistic studies, the postulated mode of action is that ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] disrupts the rat thyroid-pituitary axis primarily through interference of peripheral T4 metabolism. The relevancy of thyroid tumors to man is limited, as rats are very sensitive to small changes in plasma T4 levels while humans are insensitive due to a number of physiological differences including the amount of thyroxin-binding globulin present, half-life of T4 between different species, and difference in responsiveness to thyrotropin releasing hormone. Therefore, the thyroid gland tumors observed in this study are not considered relevant to humans.

The Ames test, mammalian cell gene mutation and micronucleus assays were conducted with ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate]. These studies were negative; therefore, it is not expected to be mutagenic.

Neurotoxicity and immunotoxicity studies are not available for review. However, evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies.

In a metabolism study in rats, ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] administered orally is rapidly absorbed and metabolized. It is primarily excreted in the urine and feces. Metabolites were not identified in this study; however, it is a phenolic antioxidant and based on the classical metabolic pathway for this class of chemicals, it would be subject to glucuronide or sulphate conjugation, hydroxylation of the phenyl ring, and side chain oxidation. The resulting metabolites are expected to be 3-(3-tert-butyl-4-hydroxy-5-methyl-phenyl)propanoic acid and 2-[2-(2-hydroxyethoxy)ethoxy]ethanol (triethylene glycol).

Dermal absorption rate was calculated to be 0.53% in a dermal absorption study in miniature pigs.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

The chronic/carcinogenicity toxicity study in rats was selected for all exposure scenarios. The NOAEL is 15 mg/kg/day, and the LOAEL is 50 mg/kg/day based on focal cystic dilatation of the liver sinusoids and thyroid follicle hyperplasia. This represents the lowest NOAEL in the database in the most sensitive species. However, in the developmental study, the maternal

NOAEL is not established and the maternal LOAEL is 100 mg/kg/day based on decreased bodyweight gain and food consumption. Also, decreased bodyweight gain and food consumption are observed in parental animals at 900 ppm (~ 54 to 62 mg/kg/day) in the two-generation reproduction toxicity study, the NOAEL is 300 ppm (~ 21 to 26 mg/kg/day). Since, maternal and parental effects are the same in both studies, a parental NOAEL is established and treatment duration is longer in the two-generation reproduction toxicity study, it is considered adequate to address the lack of a maternal NOAEL in the developmental study. The standard inter- and intra-species uncertainty factors of 10x are applied; as discussed below in Unit IV.D., the Agency applied a 1X Food Quality Protection Act Safety Factor (FQPA) SF. The dermal absorption factor of 0.53% is applied based on a dermal absorption study in miniature pigs. The default factor of 100% is applied for the inhalation absorption rate.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate], EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] in food as follows:

No adverse effects attributable to a single exposure of endpoint was identified for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate]; therefore, an acute dietary exposure assessment was not conducted.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM–FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate]. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

Although EPA is assessing ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate at 1.75% (to account for the requested 1% (by weight) limitation in pesticide formulations and up to 0.75% limitation for the FDA approved uses as an antioxidant and/or stabilizer for polymers used for food contact applications, the Agency believes the assumptions used to estimate dietary exposures lead to an very conservative assessment of dietary risk due to other conservative assumptions.

First, EPA assumes that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Also, EPA's assumes that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate], a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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). Ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl)propionate] is registered for use as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, specifically lawn, turf, and garden use, and in indoor cleaning products. A conservative residential exposure and risk assessment was completed for pesticide products containing ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] as inert ingredients. The Agency assessed ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios) at no more than 1% in the final formulation. The Agency's assessment of adult residential exposure combines high end dermal and inhalation handler exposure from indoor hard surface, aerosol spray with a high-end post application dermal exposure from contact with treated lawns. The Agency's assessment of children's residential exposure includes total post-application exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures).

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 ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] to share a common mechanism of toxicity with any other substances, and ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] 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

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.

The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10X is reduced to 1X for all exposure scenarios for the following reasons. The toxicity database for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] contains subchronic, developmental, reproduction, chronic/carcinogenicity, and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies; therefore, there is no need to require an immunotoxicity or neurotoxicity study. Fetal susceptibility is not observed in developmental toxicity studies in the rat. Developmental toxicity (reduced fetal body weight and delayed skeletal maturation) occurred at a higher dose, 300 mg/kg/day, than maternal toxicity (reduced body weight gain), which occurred at 100 mg/kg/day. Qualitative fetal susceptibility toxicity is observed 2-generation reproduction toxicity study. Pup mortality and reduced pup body weight is observed at 900 ppm (~54–62 mg/kg/day), while parental toxicity is manifested as decreased bodyweight gain and food consumption at the same dose. However, the established cRfD of 0.15 mg/kg/day will be protective of any offspring effects seen at 900 ppm (~54–62 mg/kg/day). Therefore, there is no concern for fetal susceptibility. Reproduction toxicity is not observed up to 1,800 ppm (87–221 mg/kg/day), the highest dose tested. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment, and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10X is reduced to 1X.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] from food and water will utilize 18.4% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

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).

Ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate].

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,235 for adult males and females. Adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, aerosol spray with a high-end post-application dermal exposure from contact with treated lawns. The combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 511 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's level of concern for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] is a MOE of 100 or below, these MOEs are not of concern.

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).

Ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate].

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 1,729 for adult males and females. Adult residential exposure includes high-end post-

application dermal exposure from contact with treated lawns. The combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 413 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's level of concern for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] is a MOE of 100 or below, these MOEs are not of concern.]

5. *Aggregate cancer risk for U.S. population.* In a chronic/carcinogenicity study, thyroid gland tumors are observed at 100 mg/kg/day in rats. However, based on the postulated mode of action for these tumors, they are not considered relevant to humans. Also, ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] is not mutagenic. Therefore, ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] is not expected to pose a cancer risk to humans.

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 ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] in or on any food commodities. EPA is establishing limitations on the amount of ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] that may be used in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops and raw agricultural commodities after harvest for sale or distribution that exceeds 1% by weight of ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] unless additional data are submitted.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] (CAS Reg No. 36443–68–2) when used as an inert ingredient (stabilizer), limited to 1% (by weight) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance 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 exemption 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).

VIII. 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: January 17, 2020.

Donna Davis,

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 § 180.910, add alphabetically the inert ingredient ''Ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] (CAS Reg. No. 36443–68–2)'' to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients					Limits	Uses
*	*	*	*	*	*	*
Ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate] (CAS Reg. No. 36443–68–2).					1% by weight	Stabilizer.
*	*	*	*	*	*	*

[FR Doc. 2020–02043 Filed 2–13–20; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0718 and EPA–HQ–OPP–2019–0076; FRL–10002–06]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on vegetable, root, subgroup 1A, except ginseng; vegetable, leaves of root and tuber, group 2; and tea, dried. In addition, this regulation amends the tolerances for residues of difenoconazole in or ginseng; cattle, liver; goat, liver; horse, liver; and sheep, liver. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 14, 2020. Objections and requests for hearings must be received on or before April 14, 2020, 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–2018–0718 and EPA–HQ–OPP–2019–0076, 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–2018–0718 and EPA–HQ–OPP–2019–0076 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 April 14, 2020. 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–2018–0718 and EPA–HQ–OPP–2019–0076, 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 June 7, 2019 (84 FR 26630) (FRL–9993–93) and in the **Federal Register** of May 9, 2019 (84 FR 20320) (FRL–9992–36), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 8F8695 and 8E8728, respectively) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. Pesticide