



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0429; FRL-9980-47]

Picoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of picoxystrobin in or on multiple commodities that are identified and discussed later in this document. E.I. DuPont De Nemours and Company 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-2017-0429, 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, P.E., 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. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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-2017-0429 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any

Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0429, 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 November 27, 2017 (82 FR 56017) (FRL-9968-55), 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 7F8557) by E.I. Du Pont De Nemours and Company, Chestnut Run Plaza, 974 Centre Road, Wilmington, DE 19805. The petition requested 40 CFR 180.669 be amended by establishing tolerances for residues of

the fungicide picoxystrobin, methyl (α E)- α -(methoxymethylene)-2-[[[6-(trifluoromethyl)-2-pyridinyl]oxy]methyl]benzeneacetate, in or on alfalfa, forage at 4 parts per million (ppm); alfalfa, hay at 5 ppm; alfalfa, seed at 9 ppm; almond hulls at 15 ppm; cotton, gin by-products at 40 ppm; cottonseed (Crop Subgroup 20C) at 4 ppm; grass, forage (Grown for Seed) at 40 ppm; grass, hay (Grown for Seed) at 80 ppm; head lettuce at 7 ppm; onion, bulb (Crop Subgroup 3-07A) at 0.8 ppm; onion, green (Crop Subgroup 3-07B) at 15 ppm; pea and bean, succulent shelled (Crop Subgroup 6B) at 3 ppm; peanut at 0.1 ppm; peanut, hay at 40 ppm; sunflower (Crop Subgroup 20B) at 3 ppm; tree nut except hulls (Crop Group 14-12) at 0.15 ppm; vegetable, brassica head and stem (Crop Group 5-16) at 5 ppm; vegetable, cucurbit (Crop Group 9) at 0.7 ppm; vegetable, fruiting (Crop Group 8-10) at 1.5 ppm; vegetable, leaf petiole (Crop Subgroup 22B) at 40 ppm; vegetable, leafy except head lettuce (Crop Group 4-16) at 60 ppm; vegetable, leaves of root and tuber (Crop Group 2) at 40 ppm; vegetable, legume, edible podded (Crop Subgroup 6A) at 4 ppm; vegetable, root (Crop Subgroup 1A) at 0.6 ppm; and vegetable, tuberous and corm (Crop Subgroup 1C) at 0.06 ppm. That document referenced a summary of the petition prepared by E.I. Du Pont De Nemours and Company, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Notice of this same petition was provided again in the **Federal Register** of January 26, 2018 (83 FR 3658) (FRL-9971-46). The only difference between the two notifications is that the second notification spelled out the analytical method, whereas the November 2017 notification used just the abbreviations. Both documents provided notice

for the same petition and same tolerances. That document is also available in the docket, <http://www.regulations.gov>. One comment was received on this second notification, but it did not raise any issues relevant to this rulemaking.

Based upon review of the data supporting the petition, EPA is establishing tolerances at levels lower than requested, except for the commodities of alfalfa forage, hay, and seed, and using commodity terms consistent with the Agency's food and feed commodity vocabulary. The reasons for these changes are 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 picoxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with picoxystrobin 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 most consistently observed effects of picoxystrobin exposure across species, genders, and treatment durations were decreased body-weight, body-weight gain and food consumption, and diarrhea. The effects on body-weight and food consumption were consistent with the commonly observed findings for compounds that disrupt the mitochondria respiration system and the resulting disruption of energy production. Similar to some other strobilurins, picoxystrobin causes intestinal disturbance as indicated by increased incidence of diarrhea or duodenum mucosal thickening. These intestinal effects appeared to be related to the irritating action on the mucus membranes as demonstrated by severe eye irritation effect seen in the primary eye irritation study on picoxystrobin.

In the rat, developmental toxicity was expressed as misaligned 5th sternebrae at doses causing maternal toxicity (i.e. diarrhea and decreased body weight gain, and food consumption). In the rabbit, developmental toxicity seen at doses causing maternal

toxicity (i.e. decreased body weight and clinical signs of toxicity) consisted of long 13th rib length and incompletely ossified odontoids and 27 pre-pelvic vertebrae. In the reproduction study, parental/systemic toxicity manifested as decreased body weight and body weight gain in both the parents and offspring; no reproductive toxicity was seen.

There was no evidence that picoxystrobin directly affects the nervous system; behavioral changes observed in the acute and subchronic neurotoxicity studies were attributed to general malaise. Picoxystrobin has no effects on the immune system in rats and mice, and is not mutagenic or genotoxic. No adverse dermal or systemic effects were identified in the rat following dermal exposure at the limit-dose. In the inhalation toxicity study, rats showed no portal of entry, respiratory or systemic toxicity. Chronic picoxystrobin exposure induced a treatment-related increase in testicular interstitial cell benign tumors in male rats at the high-dose only. No tumors were seen in female rats or in male and female mice, and there is no mutagenic concern. Based on this information, EPA has classified picoxystrobin as “suggestive evidence of carcinogenic potential”, for which quantification of cancer risk based on a non-linear approach (i.e., the chronic reference doses (RfD)) is appropriate. Use of the chronic RfD will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to picoxystrobin. Specific information on the studies received and the nature of the adverse effects caused by picoxystrobin 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 “**Picoxystrobin: Human Health Risk Assessment for Proposed New Uses on Root Vegetables, Subgroup 1A;**

Tuberous and Corm Vegetables, Subgroup 1C; Leaves of Root and Tuber Vegetables, Group 2; Bulb Onion, Subgroup 3-07A; Green Onion, Subgroup 3-07B; Leafy Vegetables, except Head Lettuce, Group 4-16; Head and Stem *Brassica* Vegetables, Group 5-16; Edible Podded Legume Vegetables, Subgroup 6A; Succulent Shelled Pea and Bean, Subgroup 6B; Fruiting Vegetables, Group 8-10; Cucurbit Vegetables, Group 9; Tree Nuts, Group 14-12; Sunflower, Subgroup 20B; Cottonseed, Subgroup 20C; Leaf Petiole Vegetables, Subgroup 22B; Head Lettuce; Almond; Alfalfa; Peanut; and Grass, Forage, Fodder, and Hay, Group 17” in docket ID number EPA-HQ-OPP-2017-0429.

B. Toxicological Points of Departure/Levels of Concern

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

description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>. A summary of the toxicological endpoints for picoxystrobin used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for picoxystrobin 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 (Females 13-50 years of age)	An acute dietary risk assessment is not required since no endpoint attributable to a single exposure was identified from the relevant studies.		
Acute dietary (General population including infants and children)	$UF_A = 10x$ $UF_H = 10x$ $FQPA\ SF/UF_L = 10x$	Acute RfD/aPAD = 0.2 mg/kg/day	Acute Neurotoxicity – Rat LOAEL = 200 mg/kg/day based on low arousal and decreased motor activities in males, decreased rearing in females, in addition to decreased bodyweight gain and food consumption in both sexes on Day 1.
Chronic dietary (All populations)	NOAEL= 4.6 mg/kg/day $UF_A = 10x$ $UF_H = 10x$	Chronic RfD = 0.046 mg/kg/day cPAD =	Chronic Toxicity – Dog LOAEL = 15.7 mg/kg/day based on decreased body weights, body weight gains, and food consumption in

	FQPA SF = 1x	0.046 mg/kg/day	both sexes.
Cancer (Oral, dermal, inhalation)	“Suggestive Evidence of Carcinogenic Potential” based on tumors in one species and one sex: a treatment-related increase in testicular interstitial cell benign tumors in high dose male rats. Quantification of cancer risk is based on a non-linear (i.e., RfD) approach.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_L = use of a LOAEL to extrapolate a NOAEL

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to picoxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing picoxystrobin tolerances in 40 CFR 180.669. EPA assessed dietary exposures from picoxystrobin 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 picoxystrobin. 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). As to residue levels in food, EPA’s assumption of this dietary assessment included tolerance-level residues for all crops. In addition, default processing factors and 100% percent crop treated (PCT) were assumed 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 used tolerance-level residues for all crops. In addition, default processing factors and 100 PCT were assumed for all commodities.

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

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for picoxystrobin. Tolerance-level residues and/or 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 picoxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of picoxystrobin. 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 Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of picoxystrobin for acute exposures are estimated to be 15.7 parts per billion (ppb) for surface water and 1.40 ppb for ground water. Chronic exposures for non-cancer

assessments are estimated to be 5.53 ppb for surface water and 1.36 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 15.7 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 5.53 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).

Picoxystrobin 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 FFDCFA 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 picoxystrobin to share a common mechanism of toxicity with any other substances, and picoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that picoxystrobin 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 Food Quality Protection Act Safety Factor (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.* The prenatal and postnatal toxicity studies include rat and rabbit prenatal developmental studies in addition to reproduction and fertility effects studies in rats. In the rat- and rabbit-developmental toxicity studies, developmental toxicity was expressed as skeletal variations at doses causing maternal toxicity (i.e. diarrhea, decreased body-weight, body -weight gain, food consumption, and clinical signs of toxicity). In the reproduction study, parental/systemic toxicity manifested as decreased body-weight and body-weight gain in both the parents and offspring. No evidence of increased susceptibility/sensitivity is seen in any of these studies.

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 for chronic dietary. For acute dietary exposures for the general population, including infants and children where the acute neurotoxicity study is used as an endpoint for risk assessment, EPA is retaining a 10x FQPA SF. That decision is based on the following findings:

- i. The toxicity database for picoxystrobin is complete, except for the lack of a NOAEL in the acute neurotoxicity test, which is used to establish a toxicological endpoint for acute dietary exposure scenarios.
- ii. Although there is some effect on behavior after exposure to picoxystrobin, EPA has concluded that picoxystrobin is not a neurotoxic chemical due to lack of neuropathological findings; there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that picoxystrobin 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 picoxystrobin in drinking water. These assessments will not underestimate the exposure and risks posed by picoxystrobin.

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 picoxystrobin will occupy 23% of the aPAD for children 1-2 years 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 picoxystrobin from food and water will utilize 36% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for picoxystrobin.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term or intermediate-term adverse effect was identified and picoxystrobin is not registered for any residential uses, picoxystrobin is not expected to pose a short- or intermediate-term risk.

4. *Aggregate cancer risk for U.S. population.* The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of any aggregate

cancer risk. As chronic risks are below the Agency's level of concern, the Agency concludes there is no cancer risk of concern from aggregate exposure to picoxystrobin.

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 picoxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography with tandem mass spectrometry (HPLC/ESI-MS/MS)) is available to enforce the tolerance expression.

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 a MRL for picoxystrobin.

C. Response to Comments

Comments were received in response to the Notices of Filing of E.I. Du Pont De Nemours and Company's petition. Two comments were filed within the comment period, one irrelevant and one expressing confusion about whether this action duplicated a previous action. The comment copied an excerpt from a tolerance rulemaking that was finalized in 2012; the tolerances requested in this petition are not the same as those finalized in 2012. Several other comments were submitted after the comment period had closed.

D. Revisions to Petitioned-For Tolerances

The Agency has revised several of the commodity definitions to be consistent with the food and feed commodity vocabulary the Agency uses to establish tolerances. The Agency is also establishing tolerance levels that are slightly lower than the petitioner requested because Agency calculated tolerances (except alfalfa and sorghum) using proportionality to extrapolate data which would be reflective of a 1x maximum annual application rate rather the exaggerated application rates in the field trial studies for the following commodities: almond hulls at 15 ppm to almond, hulls at 7.0 ppm; cotton, gin by-products at 40 ppm to cotton gin byproducts at 20 ppm; cottonseed (Crop Subgroup 20C) at 4 ppm to cottonseed subgroup 20C at 2.0 ppm; head lettuce at 7 ppm to lettuce,

head at 4.0 ppm; onion, bulb (Crop Subgroup 3-07A) at 0.8 ppm to onion, bulb, subgroup 3-07A at 0.50 ppm; onion, green (Crop Subgroup 3-07B) at 15 ppm to onion, green, subgroup 3-07B at 10 ppm; pea and bean, succulent shelled (Crop Subgroup 6B) at 3 ppm to pea and bean, succulent shelled, subgroup 6B at 0.90 ppm; peanut at 0.1 ppm to 0.05 ppm; peanut, hay at 40 ppm to 30 ppm; sunflower (Crop Subgroup 20B) at 3 ppm to sunflower subgroup 20B to 2.0 ppm; tree nut except hulls (Crop Group 14-12) at 0.15 ppm to nut, tree, group 14-12 at 0.08 ppm; vegetable, brassica head and stem (Crop Group 5-16) at 5 ppm to vegetable, brassica, head and stem, group 5-16 at 2.0 ppm; vegetable, cucurbit (Crop Group 9) at 0.7 ppm to vegetable, cucurbit, group 9 at 0.30 ppm; vegetable, fruiting (Crop Group 8-10) at 1.5 ppm to vegetable, fruiting, group 8-10 at 0.70 ppm; vegetable, leaf petiole (Crop Subgroup 22B) at 40 ppm to leaf petiole vegetable subgroup 22B at 20 ppm; vegetable, leafy except head lettuce (Crop Group 4-16) at 60 ppm to vegetable, leafy, group 4-16, except lettuce, head at 30 ppm; vegetable, leaves of root and tuber (Crop Group 2) at 40 ppm to vegetable, leaves of root and tuber, group 2 at 30 ppm; vegetable, legume, edible podded (Crop Subgroup 6A) at 4 ppm to vegetable, legume, edible podded, subgroup 6A at 2.0 ppm; vegetable, root (Crop Subgroup 1A) at 0.6 ppm to vegetable, root, subgroup 1A at 0.50 ppm; and vegetable, tuberous and corm (Crop Subgroup 1C) at 0.06 ppm to vegetable, tuberous and corm, subgroup 1C at 0.03 ppm.

For alfalfa, forage, hay, and seed, the tolerances have been modified to represent the appropriate number of significant figures; however, the numerical value is no different than requested by the petition.

The petition requested “grass, forage (Grown for Seed)” at 40 ppm and “grass, hay (Grown for Seed)” at 80 ppm. Because “grass grown for seed” is ambiguous, the Agency is establishing individual tolerances for the hay and forage forms of specific grasses for which residue data were submitted and that are grown for seed purposes: bluegrass, forage at 30 ppm; bluegrass, hay at 60 ppm, bromegrass, forage at 30 ppm; bromegrass, hay at 60 ppm; fescue, forage at 30 ppm; fescue, hay at 60 ppm; orchardgrass, forage at 30 ppm; orchardgrass, hay at 60 ppm; ryegrass, forage at 30 ppm; ryegrass, hay at 60 ppm; switchgrass, forage at 30 ppm; and switchgrass, hay at 60 ppm.

EPA is also establishing tolerances for beet, sugar, dried pulp at 1.5 ppm and potato, wet peel at 0.10 ppm, pursuant to 40 CFR 180.40(f)(1)(i)(A). These tolerances are necessary to cover concentrated residues in processed commodities of raw agricultural commodities contained in subgroups 1A and 1C, respectively.

V. Conclusion

Therefore, tolerances are established for residues of picoxystrobin, methyl (α E)- α -(methoxymethylene)-2-[[[6-(trifluoromethyl)-2-pyridinyl]oxy]methyl]benzeneacetate, in or on alfalfa, forage at 4.0 ppm; alfalfa, hay at 5.0 ppm; alfalfa, seed at 9.0 ppm; almond, hulls at 7.0 ppm; beet, sugar, dried pulp at 1.5 ppm; bluegrass, forage at 30 ppm; bluegrass, hay at 60 ppm; bromegrass, forage at 30 ppm; bromegrass, hay at 60 ppm; cotton, gin byproducts at 20 ppm; cottonseed subgroup 20C at 2.0 ppm; fescue, forage at 30 ppm; fescue, hay at 60 ppm; leaf petiole vegetable subgroup 22B at 20 ppm; lettuce, head at 4.0 ppm; nut, tree, group 14-12 at 0.08 ppm; onion, bulb, subgroup 3-07A at 0.50 ppm; onion, green, subgroup 3-07B at 10 ppm; orchardgrass, forage at 30 ppm;

orchardgrass, hay at 60 ppm; pea and bean, succulent shelled, subgroup 6B at 0.90 ppm; peanut at 0.05 ppm; peanut, hay at 30 ppm; potato, wet peel at 0.10 ppm; ryegrass, forage at 30 ppm; ryegrass, hay at 60 ppm; sunflower subgroup 20B to 2.0 ppm; switchgrass, forage at 30 ppm; switchgrass, hay at 60 ppm; vegetable, brassica, head and stem, group 5-16 at 2.0 ppm; vegetable, cucurbit, group 9 at 0.30 ppm; vegetable, fruiting, group 8-10 at 0.70 ppm; vegetable, leafy, group 4-16, except lettuce, head at 30 ppm; vegetable, leaves of root and tuber, group 2 at 30 ppm; vegetable, legume, edible podded, subgroup 6A at 2.0 ppm; vegetable, root, subgroup 1A at 0.50 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.03 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), 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 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 25, 2018.

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 § 180.669, add alphabetically the following commodities: Alfalfa, forage; Alfalfa, hay; Alfalfa, seed; Almond, hulls; Beet, sugar, dried pulp; Bluegrass, forage; Bluegrass, hay; Bromegrass, forage; Bromegrass, hay; Cotton, gin byproducts; Cottonseed subgroup 20C; Fescue, forage; Fescue, hay; Leaf petiole vegetable subgroup 22B; Lettuce, head; Nut, tree, group 14-12; Onion, bulb, subgroup 3-07A; Onion, green, subgroup 3-07B; Orchardgrass, forage; Orchardgrass, hay; Pea and bean, succulent shelled, subgroup 6B; Peanut; Peanut, hay; Potato, wet peel; Ryegrass, forage; Ryegrass, hay; Sunflower subgroup 20B; Switchgrass, forage; Switchgrass, hay; Vegetable, brassica, head and stem, group 5-16; Vegetable, cucurbit, group 9; Vegetable, fruiting, group 8-10; Vegetable, leafy, group 4-16, except lettuce, head; Vegetable, leaves of root and tuber, group 2; Vegetable, legume, edible podded, subgroup 6A; Vegetable, root, subgroup 1A; and Vegetable, tuberous and corm, subgroup 1C to the table in paragraph (a) to read as follows:

§ 180.669 Picoxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Alfalfa, forage	4.0

Alfalfa, hay	5.0
Alfalfa, seed	9.0
Almond, hulls	7.0
* * * *	* * *
Beet, sugar, dried pulp	1.5
Bluegrass, forage	30
Bluegrass, hay	60
Bromegrass, forage	30
Bromegrass, hay	60
* * * *	* * *
Cotton, gin byproducts	20
Cottonseed subgroup 20C	2.0
* * * *	* * *
Fescue, forage	30
Fescue, hay	60
* * * *	* * *
Leaf petiole vegetable subgroup 22B	20
Lettuce, head	4.0
* * * *	* * *
Nut, tree, group 14-12	0.08
Onion, bulb, subgroup 3-07A	0.50
Onion, green, subgroup 3-07B	10
Orchardgrass, forage	30
Orchardgrass, hay	60

* * * *	* * *
Pea and bean, succulent shelled, subgroup 6B	0.90
Peanut	0.05
Peanut, hay	30
Potato, wet peel	0.10
* * * *	* * *
Ryegrass, forage	30
Ryegrass, hay	60
* * * *	* * *
Sunflower subgroup 20B	2.0
Switchgrass, forage	30
Switchgrass, hay	60
* * * *	* * *
Vegetable, brassica, head and stem, group 5-16	2.0
Vegetable, cucurbit, group 9	0.30
* * * *	* * *
Vegetable, fruiting, group 8-10	0.70
Vegetable, leafy, group 4-16, except lettuce, head	30
Vegetable, leaves of root and tuber, group 2	30
Vegetable, legume, edible podded, subgroup 6A	2.0
Vegetable, root, subgroup 1A	0.50

Vegetable, tuberous and corm, subgroup 1C	0.03
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