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) (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 of 1995 (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: November 27, 2012.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.559, in paragraph (a), revise the introductory text; and in the table, revise the entry for ''Wheat, grain'' to read as follows:

§ 180.559 Clodinafop-propargyl; tolerances for residues.

(a) *General.* Tolerances are established for clodinafop-propargyl, 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 clodinafop-propargyl [(2*R*)-2-[4-[(5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]propanoic acid, 2-propynyl ester] and its metabolite clodinafop [(2*R*)-2-[4-[(5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]propanoic acid].

Commodity	Parts per million
* * * * *	
Wheat, grain	0.02
* * * * *	

* * * * *

[FR Doc. 2012–29248 Filed 12–4–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0458; FRL–9370–8]

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 which are identified and discussed later in this document. E.I. du Pont de Nemours & Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2012. Objections and requests for hearings must be received on or before February 4, 2013, 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–2010–0458, 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), EPA West 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: Grant Rowland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0254; email address: *rowland.grant@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://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–2010–0458 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 February 4, 2013. 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–2010–0458, 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.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 June 23, 2010 (75 FR 35801) (FRL–8831–3), 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 0F7722) by E.I. du Pont de Nemours & Company 1007 Market Street, Wilmington, DE 19898, proposed to establish tolerances in 40 CFR part 180 for residues of the fungicide picoxystrobin, in or on the cereal grains crop group (crop group 15) except rice at 0.2 parts per million(ppm); the cereal forage and fodder crop group (crop group 16) except rice at 13.0 ppm; cereal grain aspirated grain fractions at 4.5 ppm; cereal grain oil at 1.5 ppm; the dry legume vegetables crop subgroup (crop group 6, subgroup C) except soybean at 0.1 ppm; the legume vegetable foliage crop group (crop group 7) at 18.0 ppm; soybean seed at 0.05 ppm; soybean forage at 0.8 ppm; soybean hay at 2.5 ppm; soybean aspirated grain fractions at 3.2 ppm; soybean hulls at 10.0 ppm; soybean oil at 0.05 ppm; canola seed at 0.05 ppm; meat and meat byproducts except liver of cattle, goat, hog, horse, and sheep at 0.01 ppm; fat of cattle, goat, hog, horse, and sheep at 0.05 ppm; liver of cattle, goat, hog, horse, and sheep at 0.8 ppm; meat, meat byproducts, fat, and eggs of poultry at 0.01 ppm; milk at 0.01 ppm, and cream, at 0.03 ppm. That notice referenced a summary of the petition prepared by E.I. du Pont de Nemours & Company, 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 revised the proposed tolerance levels for several commodities. 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 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 which disrupt 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 the severe eye irritation effect seen in the primary eye irritation study on picoxystrobin.

Picoxystrobin caused changes in behavioral effects in both the acute and subchronic neurotoxicity studies with no neuropathological findings. The effects observed with acute exposure

were transient (i.e. lasted for a day) and consisted of low arousal and decreased motor activities in males and decreased rearing in females, and, with subchronic exposure, included decreased male forelimb grip and increased female hindlimb splay. In the absence of any neuropathological findings, the behavioral effects were attributed to general malaise (probably related to energy production perturbations) as evidenced by the associated decreased body weight and body weight gain.

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 reproductive toxicity was seen.

Picoxystrobin induced a treatment-related increase in testicular interstitial cell benign tumors only in the high dose male rats. No tumors were seen in females; no treatment related-increase in any type of tumor incidence was seen in male and female mice at doses that were considered to be adequate for the assessment of carcinogenicity of picoxystrobin. There is no mutagenic concern. Based on these data, EPA has concluded that quantification of cancer risk based on a non-linear approach (i.e., reference dose (RfD) will adequately account for all chronic toxicity, including carcinogenicity, that which 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 Uses on Canola, Cereal Grains Except Rice, Dried Shelled Peas and Beans, and Soybeans.'' at pages 17–22 in docket ID number EPA–HQ–OPP–2010–0458.

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.* 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 13–49 years of age).	There were no appropriate toxicological effects attributable to a single exposure (dose) observed in available toxicity studies. Therefore, a dose and endpoint were not identified for this risk assessment.		
Acute dietary (General population including infants and children).	LOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 10x	aRfD = 0.2 mg/kg/day 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 body-weight 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 FQPA SF = 1x	cRfD = 0.046 mg/kg/day cPAD = 0.046 mg/kg/day	Chronic Toxicity—Dog LOAEL = 15.7 mg/kg/day based on decreased body weights, weight gains, and food consumption in both sexes.
Cancer (Oral, dermal, inhalation)	Classification: ''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 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. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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. 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 for the general population, including infants and children, EPA used food consumption information from the U.S. 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 total highest field trial total residues (parent and metabolite) for all proposed crops. In addition, 100 percent crop treated (PCT) was assumed. Dietary Exposure Evaluation Model (DEEM) version 7.81 default processing factors were assumed except for where tolerances were established for processed commodities or when processing studies showed no concentration. A separate tolerance was set for wheat bran, wheat germ, barley bran and corn oil. Tolerance levels were used for livestock commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used total highest average field trial total residues (parent and metabolite) for all proposed crops. In addition, 100 PCT was assumed. DEEM version 7.81 default processing factors were assumed except for where tolerances were established for processed commodities. Tolerance levels were used for livestock 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. Cancer risk is 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 is 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 a nonlinear RfD approach is appropriate for assessing cancer risk for picoxystrobin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

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

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.*

The drinking water assessment used a total toxic residue approach to include parent and the major environmental degradates: Compound 2, Compound 3, Compound 7, and Compound 8. Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System and Screening Concentration in Ground Water models, the estimated drinking water concentrations of picoxystrobin for:

- Acute exposures are estimated to be 7.95 parts per billion (ppb) for surface water and 0.041 ppb for ground water.
- Chronic exposures for non-cancer assessments are estimated to be 2.41 ppb for surface water and 0.041 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 7.95 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2.41 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 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 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA 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 prenatal and postnatal toxicity studies include rat and rabbit prenatal development studies, in addition to reproduction and fertility effects studies in rats. No evidence of increased qualitative or quantitative susceptibility/sensitivity was 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 Safety factor were reduced to 1X for chronic dietary exposure. For acute dietary exposures for the general population, including infants and children where the acute neurotoxicity is study used as an endpoint for risk assessment, EPA is

retaining a 10X FQPA safety factor. That decision is based on the following findings:

i. Although all required toxicity studies for picoxystrobin have been submitted, the acute neurotoxicity study used for acute dietary risk assessment did not demonstrate a NOAEL, and a LOAEL was used as an endpoint. Therefore, the 10X FQPA safety factor was retained for use of a LOAEL to extrapolate a NOAEL.

ii. There is no indication that picoxystrobin is a neurotoxic chemical and 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, total highest field trial total residues for acute exposures, total highest average field trial total residues for chronic exposures, and tolerance levels for livestock commodities. 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 1.3% 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 2.8% 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 risks.* Short- and intermediate— term risk aggregate exposures take 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 effects were identified, 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.

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, (a liquid chromatography tandem mass spectrometry method (LC/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. No Codex MRLs have been established for picoxystrobin.

C. Revisions to Petitioned-for Tolerances

The Agency has revised several of the commodity definitions and modified the levels for which tolerances are being established as follows: Vegetable, legume, dried shelled, except soybean, (group 6C) at 0.1 ppm is revised to pea and bean, dried shelled, except soybean, subgroup 6C at 0.06 ppm; soybean forage at 0.08 ppm is revised to soybean, forage at 1.0 ppm; soybean hay at 2.5 ppm is revised to soybean, hay at 3.0 ppm; soybean hulls at 10 ppm is revised to soybean, hulls at 0.2 ppm; canola, seed at 0.05 ppm is revised to rapeseed subgroup 20A at 0.08 ppm; barley, grain which was proposed as crop group 15 at 0.2 ppm is revised to barley, grain at 0.3 ppm. Tolerance for soybeans oil was proposed at 0.8 ppm, but EPA has determined that a tolerance is not needed. These tolerances have been revised based on the use of the *Organization for Economic Co-operation and development tolerance calculation procedure* (OECD TCP). Further, EPA determined that the proposed tolerance for crop group 15 (grain, cereal, except rice), and crop subgroup 7A group/subgroup (vegetable, foliage of legume) each be modified and established as follows: Grain, cereal, group 15, except rice and barley at 0.04 ppm; vegetable, foliage of legume, except soybean, subgroup 7A at 40.0 ppm. Crop group 16 (grain, cereal, forage and fodder except rice) however, should each be broken up and established with individual tolerances. These tolerances are revised as follows: Grain, cereal, forage, fodder, and straw, group 16, straw at 2.0 ppm; grain, cereal, forage fodder, and straw, group 16, stover at 10.0 ppm; grain, cereal, forage, fodder and straw group 16, hay at 5.0 ppm; grain, cereal forage, fodder, and straw, group 16, forage at 15.0 ppm;

Based on the corn processing study, the proposed tolerance for cereal grain oil at 1.5 ppm is revised to corn, field, refined oil at 0.07 ppm.

The proposed tolerance for cereal (wheat), aspirated grain fractions at 4.5 ppm is being established as grain, aspirated grain fractions at 10 ppm; soybean, aspirated grain fractions at 3.2 ppm is revised to grain, aspirated grain fractions at 10 ppm as well.

Though not proposed, the Agency has determined it was appropriate to establish tolerances for wheat, bran at 0.06 ppm; wheat, germ at 0.09 ppm; and barely, bran at 0.5 ppm.

EPA also revised livestock tolerances as follows, based on the calculated dietary burden to account for the transfer of residues to livestock matrices (tissues and milk): Cattle, fat from 0.05

ppm to 0.01 ppm; goat, fat from 0.05 ppm to 0.01 ppm; hog, fat from 0.05 ppm to 0.01 ppm. horse, fat from 0.5 ppm to 0.01 ppm; sheep, fat from 0.05 ppm to 0.01 ppm; horse, liver at 0.8 ppm and horse, meat byproduct, except liver at 0.01 ppm were combined as horse, meat byproduct at 0.01 ppm. Sheep, liver at 0.8 ppm and sheep, meat byproducts, except liver at 0.01 ppm were combined as sheep, meat byproducts, at 0.01 ppm. Goat, liver at 0.8 ppm and goat, meat byproducts, except liver at 0.01 ppm were combined as goat, meat byproducts at 0.01 ppm.; hog, liver at 0.8 ppm and hog, meat byproducts, except liver at 0.01 were combined as hog, meat byproducts at 0.01 ppm. Cattle, liver at 0.8 ppm and cattle, meat byproduct, except liver at 0.01 ppm were combined as cattle, meat byproducts at 0.01 ppm. Finally a tolerance was proposed on cream at 0.03 ppm; however EPA has determined that no tolerance is needed.

V. Conclusion

Therefore, tolerances are established for residues of picoxystrobin, methyl (αE)-α-(methoxymethylene)-2-[[[6-(trifluoromethyl)-2-pyridinyl]oxy]methyl]benzeneacetate in or on barley, bran at 0.5 ppm; barley, grain at 0.3 ppm; rapeseed subgroup 20A at 0.08 ppm; cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, at 0.01 ppm; corn, field, refined oil at 0.07 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat meat byproduct, at 0.01 ppm; grain, aspirated grain fractions at 10 ppm; grain, cereal, group 15, except rice and barely at 0.04 ppm; grain, cereal, forage, fodder, and straw, group 16, hay at 5.0 ppm; grain, cereal, forage, fodder, and straw, group 16, forage at 15 ppm; grain, cereal, forage, fodder, and straw group 16, stover at 10 ppm; grain, cereal, forage, fodder, and straw, group 16, straw at 2 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, at 0.01 ppm; milk at 0.01 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.06 ppm; eggs at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts, at 0.01 ppm; soybean, forage at 1 ppm; soybean, hay at 3 ppm; soybean, hulls at 0.2 ppm; soybean, seed at 0.05 ppm; vegetable, foliage of legume, except soybean, subgroup 7A at 40 ppm; wheat, bran at 0.06 ppm; and wheat, germ at 0.09 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) (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 of 1995 (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: November 26, 2012.

Steven Bradbury,

Director, Office of Pesticides 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. Add § 180.669 to subpart C to read as follows:

§ 180.669 Picoxystrobin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide picoxystrobin, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only picoxystrobin, methyl (α*E*)-α-(methoxymethylene)-2-[[[6-(trifluoromethyl)-2-pyridinyl]oxy]methyl]benzeneacetate.

Commodity	Parts per million
Barley, bran	0.5
Barley, grain	0.3
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Corn, field, refined oil	0.07
Eggs	0.01
Goat, fat	0.01
Goat, meat	0.01

Commodity	Parts per million
Goat, meat byproducts	0.01
Grain, aspirated grain fractions	10
Grain, cereal, forage, fodder, and straw, group 16, forage	15
Grain, cereal, forage, fodder, and straw, group 16, hay	5
Grain, cereal, forage, fodder, and straw, group 16, stover	10
Grain, cereal, forage, fodder, and straw, group 16, straw	2
Grain, cereal, group 15, except rice and barley	0.04
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Pea and bean, dried shelled, except soybean, subgroup 6C	0.06
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Rapeseed subgroup 20A	0.08
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01
Soybean, forage	1
Soybean, hay	3
Soybean, hulls	0.2
Soybean, seed	0.05
Vegetable, foliage of legume, except soybean, subgroup 7A	40
Wheat, bran	0.06
Wheat, germ	0.09

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

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

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012–29250 Filed 12–4–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0743; FRL–9364–7]

Dodine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dodine, (*N*-dodecyl guanidine acetate) in or on multiple commodities and also removes multiple, previously established tolerances which are identified and discussed later in this document. Agriphar S.A., c/o Ceres International LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2012. Objections and requests for hearings must be received on or before February 4, 2013, 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–2011–0743, 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), EPA West 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: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–9096; email address: *gibson.tamue@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://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–2011–0743 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 February 4, 2013. 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–2011–0743, 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.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 22, 2012 (77 FR 50661) (FRL–9358–9), 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 1F7872) by Agriphar S.A.,