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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0635; FRL-9395-1]

Chlorantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide chlorantraniliprole in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes established tolerances for certain commodities/groups superseded by this action. The Interregional Research Project Number 4 (IR-4) 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-2012-0635, 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090 email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0635 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-2012-0635, 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 Wednesday, November 7, 2012 (77 FR 66781) (FRL-9367-5), 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 2E8064) by Interregional Research Project Number 4 (IR-4), IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.628 be amended by establishing tolerances for residues of the insecticide chlorantraniliprole, 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, including its metabolites and degradates, in or on cereal grain group 15, except rice at 6.0 parts per million (ppm); grain, cereal, forage, fodder and straw, group 16 at 30.0 ppm; fruit, citrus, group 10-10 at 1.4 ppm; and fruit, pome, group 11-10 at 1.2 ppm. In addition, petition 2E8064 proposed, upon approval of above tolerances, to remove established tolerances in or on the raw agricultural

commodities/groups: Mayhaw at 0.6 ppm; field corn forage, field corn stover, pop corn forage , pop corn stover, sweet corn forage, sweet corn stover at 14 ppm; field corn grain, pop corn grain at 0.04 ppm; sweet corn kernels plus cob with husk removed at 0.02 ppm; field corn milled byproducts at 0.1 ppm; citrus fruit group 10 at 1.4 ppm; and pome fruit group 11 except mayhaw at 1.2 ppm. That document referenced a summary of the petition prepared by E. I. DuPont de Nemours and Company, DuPont Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified, removed and/or established chlorantraniliprole tolerances for certain 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 chlorantraniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with chlorantraniliprole 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.

No mutagenicity concerns were reported in the genotoxicity studies. Nor does chlorantraniliprole exhibit immunotoxicity, neurotoxicity, carcinogenicity, or developmental toxicity.

In oral and dermal toxicity studies in rats, minimally increased microvesiculation of adrenal cortex was observed in males only; however, supporting data demonstrated no effect on the capacity of the adrenal gland to produce corticosterone under either basal or following adrenocorticotropic hormone (ACTH) stimulation. Therefore, adrenal cortex effects observed in rat studies were not considered adverse.

Chlorantraniliprole does not exhibit pre- or postnatal toxicity as there were no maternal or fetal effects in studies conducted in rats and rabbits. The relative absence of

mammalian hazard may be due in part to chlorantranilprole's selectivity for insect ryanodine receptor (RyR) over mammalian counterparts. In short-term studies, the most consistent effects are those associated with non-adverse pharmacological response to the xenobiotic, induction of liver enzymes and subsequent increase in liver weights.

Chlorantraniliprole is classified as "Not likely to be Carcinogenic to Humans" based on the weight of evidence of data: no treatment-related tumors were reported in the submitted chronic and oncogenicity studies in rats and mice (18-month carcinogenicity study) or in the subchronic studies in mice, dogs and rats.

Specific information on the studies received and the nature of the adverse effects caused by chlorantraniliprole 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 "Chlorantraniliprole: Human Health Risk Assessment for Proposed Uses on Cereal Grains Group 15 (except Rice) and Cereal Grains Forage, Fodder, and Straw Group 16, and Conversion of Citrus and Pome Fruit Groups," dated May 12, 2013 at p.25 in docket ID number EPA-HQ-OPP-2012-0635-0005.

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 chlorantraniliprole used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of July 27, 2011 (76 FR 44815) (FRL-8875-5).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to chlorantraniliprole, EPA considered exposure under the petitioned-for tolerances as well as all existing chlorantraniliprole tolerances in 40 CFR 180.628. EPA assessed dietary exposures from chlorantraniliprole 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.

No such effects were identified in the toxicological studies for chlorantraniliprole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 2003 – 2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEA). As to residue levels in food, EPA assumed tolerance levels residues for the proposed and registered crops, and assumed 100 percent crop treated (PCT). Where processing data indicated a reduction (or no increase) in residue upon processing, the residue level of the raw agricultural commodity (RAC) was used without reduction, for example mint oil from spearmint. Where processing data indicated an increase in residue in the processed commodity, tolerance-level residues based on tolerances established for those commodities were used, e.g., raisins from grapes. Where adequate processing data did not exist, Dietary Risk Evaluation System (DEEM) default concentration factors were used if available.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that chlorantraniliprole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for chlorantraniliprole. Tolerance level residues and 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 chlorantraniliprole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of chlorantraniliprole. 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 First Index Reservoir Screening Tool (FIRST), Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of chlorantraniliprole for chronic exposures for non-cancer assessments are estimated to be 39.87 ppb for surface water and 0.842 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. No acute dietary risk assessment was performed because no acute hazard was identified. For chronic dietary risk assessment, the water concentration value of 39.87 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).

Chlorantraniliprole is currently registered for the following uses that could result in residential exposures: Termiticide, sod farms/turf, landscape ornamentals and interiorscapes. Residential exposure is expected to occur for short-term and intermediate-term durations; however, due to the lack of toxicity identified for short- and intermediate-term durations via relevant routes of exposure, residential exposure was not assessed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 chlorantraniliprole to share a common mechanism of toxicity with any other substances, and chlorantraniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlorantraniliprole does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There were no effects on prenatal fetal growth or postnatal development up to the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day) in rats or rabbits in the development or 2-generation reproduction studies. Moreover, there were no treatment related effects on the numbers of litters, fetuses (live or dead), resorptions, sex ratio, or post-implantation loss. There were no effects on fetal body weights, skeletal ossification, and external, visceral, or skeletal malformations or variations.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for chlorantraniliprole is complete.

ii. There is no indication that chlorantraniliprole 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 chlorantraniliprole 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 chronic dietary assessment utilized tolerance level residues for all crops and assumed 100 PCT of the proposed and registered crops were treated with chlorantraniliprole. Default processing factors were used as appropriate. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to chlorantraniliprole in drinking water. Moreover, there is a lack of toxicity via the dermal

route, as well as the lack of toxicity over the acute-, short- and intermediate-term via the oral route. These assessments will not underestimate the exposure and risks posed by chlorantraniliprole.

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, chlorantraniliprole 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 chlorantraniliprole from food and water will utilize 6.3 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of chlorantraniliprole is not expected.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposures take into account short-term and intermediate-term 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, the aggregate short-term or intermediate-term risk is the same as the dietary risk, which will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, chlorantraniliprole is not expected to pose a cancer risk to humans.

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 chlorantraniliprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography mass spectrometry (LC/MS/MS)); Method DuPont-11374) 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.

Codex has established chlorantraniliprole maximum residue limits (MRLs) for a number of crop and animal commodities. The Codex MRLs for cereal grains, citrus fruit, and pome fruit are significantly lower than the recommended corresponding US tolerances. Because the permitted domestic use on these crops in accordance with the approved pesticide label results in residue levels higher than the Codex MRLs, the US tolerance cannot be harmonized (lowered) since doing so would result in residues in excess of the approved tolerance in spite of use consistent with label directions. Because the US tolerances for cereal grains are higher than the Codex MRLs for cereal grains, the US livestock tolerances at the values recommended are necessary to encompass possible residue levels from use of the pesticide according to label directions.

C. Revisions to Petitioned-For Tolerances

EPA converted, modified, removed and/or established chlorantraniliprole tolerances for certain commodities and, in some cases, re-defined the crop group tolerance expression and/or corrected the commodity definition, as needed.

EPA determined that the proposed tolerance for grain, cereal, group 15, except rice at 6.0 ppm is not appropriate. Establishing the proposed tolerance would raise tolerance levels for corn, field, grain; corn, pop, grain, and corn, sweet, kernel plus cobs with husk removed much in excess of their actual residue levels: corn, field, grain and corn, pop, grain at 0.04 ppm and corn, sweet, kernel plus cobs with husk removed at 0.02

ppm. Therefore, the Agency determined that the grain, cereal, group 15 tolerance must exclude corn (including corn, field, grain; corn, pop, grain; and corn, sweet), and re-defined the crop group tolerance expression as "grain, cereal, group 15, except rice and corn" at 6.0 ppm. Accordingly, although the petitioner requested the removal of the established tolerances for corn, field, grain at 0.04 ppm and corn, pop, grain at 0.04 ppm and field corn milled byproducts at 0.1 ppm because they would be subsumed within the proposed tolerance for grain, cereal, group 15, EPA is not leaving those tolerances in place.

Based on field trial data and using the Organization of Economic Cooperation and Development (OECD) tolerance calculation procedures, EPA determined that the proposed tolerance on grain, cereal, forage, fodder, and straw, group 16 at 30 ppm should be increased 40 ppm.

Upon the establishment of fruit, pome, group 11-10, the petitioner proposed that the tolerance for fruit, pome, group 11 and mayhaw, be deleted. The existing tolerance is for fruit, pome, group 11, except mayhaw at 1.2 ppm and there is a separate tolerance for mayhaw at 0.6 ppm. These two tolerances will now be superseded by establishment of the group tolerance "fruit, pome, group 11-10" at 1.2 ppm.

The tolerances for certain livestock commodities were created or increased because expanded use of chlorantraniliprole to more cereal grains and cereal grain forages, fodders, and straws increased the dietary exposure of livestock. The increased dietary exposure of livestock necessitates increased tolerances for cattle, sheep, horse, and goat meat byproducts from 0.2 ppm to 0.5 ppm and for milk from -0.05 ppm to 0.1 ppm. Due to elevated hog dietary exposure from the crop group tolerance for grain, cereal, group

15, EPA established a hog, meat tolerance at 0.02 ppm and increased both the hog, fat and the hog, meat byproducts tolerance from 0.02 to 0.05 ppm. Likewise, the grain, cereal, group 15 elevated the laying hen dietary exposure and, consequently, the Agency set a tolerance for poultry, meat at 0.05 ppm and increased the tolerance for egg from 0.2 to 1.0 ppm; poultry, fat from 0.01 to 0.2 ppm; and poultry, meat byproducts from 0.02 to 0.2 ppm. In accordance with the Agency commodity terminology, EPA is re-defining existing animal "meat byproducts, except liver" tolerances to "meat byproducts", which includes liver. Thus, EPA is deleting separate tolerances for goat, liver, horse, liver, and sheep, liver since they are covered by the respective meat byproducts tolerances.

Lastly, at 180.628(d), the Agency removed the entry for commodity "Grain, cereal, forage, fodder and straw, group 16 at 0.20 ppm, with expiration/revocation date of 04/10/14, as this time-limited tolerance is superseded by this action.

V. Conclusion

Therefore, tolerances are established for residues of chlorantraniliprole, 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, including its metabolites and degradates, in or on Cattle, meat byproducts at 0.5 parts per million (ppm); Egg at 1.0 ppm; Fruit, citrus, group 10-10 at 1.4 ppm; Fruit, pome, group 11-10 at 1.2 ppm; Goat, meat byproducts at 0.5 ppm; Grain, cereal, group 15, except rice and corn at 6.0 ppm; Grain, cereal, forage, fodder and straw, group 16 at 40.0 ppm; Hog, fat at 0.05 ppm; Hog, meat at 0.02 ppm; Hog, meat byproducts at 0.05 ppm; Horse, meat byproducts at 0.5 ppm; Milk at 0.1 ppm; Poultry, fat at 0.2 ppm; Poultry, meat at 0.05 ppm; Poultry, meat byproducts at 0.2 ppm; and Sheep, meat byproducts at 0.5 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 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 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: September 9, 2013.

Lois Rossi,
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. Section 180.628, the table in paragraph (a), is amended as follows:

i. Remove the following commodities: "Cattle, liver"; "Cattle, meat byproducts, except liver"; "Corn, field forage"; "Corn, field, stover"; "Corn, pop, forage"; "Corn, pop, stover"; "Corn, sweet, forage"; "Corn, sweet, stover"; "Fruit, citrus group 10"; "Fruit, pome group 11, except mayhaw"; "Goat, liver"; "Goat, meat byproducts, except liver"; "Horse, liver"; "Horse, meat byproducts, except liver"; "Mayhaw"; "Sheep, liver"; and "Sheep, meat byproducts, except liver."

ii. Revise the following commodities: "Egg"; "Hog, fat"; "Hog, meat byproducts"; "Milk"; "Poultry, fat"; and "Poultry, meat byproducts."

iii. Add alphabetically the commodities: "Cattle, meat byproducts"; "Fruit, citrus, group 10-10"; "Fruit, pome, group 11-10"; "Goat, meat byproducts"; "Grain, cereal, except rice and corn, group 15"; "Grain, cereal, forage, fodder and straw, group 16"; "Hog, meat"; "Horse, meat byproducts"; Poultry, meat"; and "Sheep, meat byproducts."

3. Section 180.628, the table in paragraph (d) is amended by removing the entry "Grain, cereal, forage, fodder and straw, group 16."

The additions and revisions read as follows:

§ 180.628 Chlorantraniliprole; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Cattle, meat byproducts	0.5
* * * * *	
Fruit, citrus, group 10-10	1.4
Fruit, pome, group 11-10	1.2
* * * * *	
Goat, meat byproducts	0.5
* * * * *	
Grain, cereal, except rice and corn, group 15	6.0
Grain, cereal, forage, fodder and straw, group 16	40
* * * * *	
Hog, fat	0.05
Hog, meat	0.02
Hog, meat byproducts	0.05
* * * * *	
Horse, meat byproducts	0.5
* * * * *	
Milk	0.1
* * * * *	
Poultry, fat	0.2
Poultry, meat	0.05
Poultry, meat byproducts	0.2
* * * * *	
Sheep meat byproducts	0.5
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