

[FR Doc. 2012-23988 Filed 10-2-12; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0029; FRL-9362-5]

### Chlorantraniliprole; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of chlorantraniliprole in or on multiple commodities which are identified and discussed later in this document. E.I. DuPont de Nemours and Company, DuPont Crop Protection, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 3, 2012. Objections and requests for hearings must be received on or before December 3, 2012, 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-2012-0029, 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:** Jennifer Urbanski, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 347-0156; email address: [urbanski.jennifer@epa.gov](mailto:urbanski.jennifer@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](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-2012-0029 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 December 3, 2012. 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-2012-0029, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI)

or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (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 April 4, 2012 (77 FR 20344) (FRL-9340-4), 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 1F7954) by E.I. DuPont de Nemours and Company, DuPont Crop Protection, 1007 Market Street, Wilmington, DE 19898. 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, in or on oilseed, rapeseed subgroup 20A at 2.0 parts per million (ppm); oilseed, sunflower subgroup 20B at 2.0 ppm; oilseed, cottonseed subgroup 20C at 0.3 ppm; soybean aspirated grain fractions at 300 ppm; vegetable, legume, group 6 at 2.0 ppm; vegetable, foliage of legume, group 7 at 30 ppm; and forage, vegetable, foliage of legume, group 7 at 90 ppm. That document referenced a summary of the petition prepared by E. I. DuPont 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.

Based upon review of the data supporting the petition, EPA has revised the tolerance associated with aspirated grain fractions to 640 ppm. EPA is also increasing the existing tolerances in cattle, fat; goat, fat; horse, fat; and sheep, fat to 0.5 ppm. EPA has also increased the existing tolerances in cattle, meat; goat, meat; horse, meat; and sheep, meat to 0.1 ppm. The reason 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 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 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. Chlorantraniliprole is not genotoxic, neurotoxic, immunotoxic, carcinogenic, or developmentally toxic. Chlorantraniliprole is not acutely toxic via oral, dermal or inhalation routes of exposure, and is not an eye or skin irritant nor a dermal sensitizer. There was only one animal toxicity study (18-month carcinogenicity study in mice) in the toxicology database which evidenced any adverse effect of chlorantraniliprole. This study was used to establish a point of departure (POD), based on hepatocellular effects, for the chronic dietary exposure scenario.

Although residential and occupational exposure is expected over the short- and intermediate-term (via the dermal and/or incidental oral route), there is no hazard expected via these routes/durations, and therefore no risk associated with these scenarios.

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 Oilseeds (Subgroups 20A through C) and Soybean (Crop group 6 and 7),” page 16 in docket ID number EPA–HQ–OPP–2012–0029.

#### B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological 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) 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance levels residues and 100% crop treated (CT). Dietary Risk Evaluation System (DEEM) default processing factors were used.

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 and/or PCT information in the dietary assessment for chlorantraniliprole. Tolerance level residues and/or 100% CT 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/oppfed1/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 acute exposures are estimated to be 55.30 parts per billion (ppb) for surface water and 0.842 ppb for ground water, and for chronic exposures for cancer and 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. For chronic dietary risk assessment, the water concentration of value 39.87 ppb was used to assess the contribution to drinking water. No acute dietary risk assessment was performed because no acute hazard was identified.

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, ornamentals, and turfgrass. EPA assessed residential exposure using the following assumptions: Residential exposure could 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, no risk is expected from these exposures. 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 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 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.* There were no effects on 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. Additionally, there were no treatment related effects on the numbers of litters, fetuses (live or dead), resorptions, sex ratio, or post-implantation loss and 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. A poultry feeding study is needed, but the results of the poultry metabolism study conducted at a feeding level twice the expected dietary burden and at a duration of 14 days, well in excess of the mandatory 3 days, are used to provide a conservative estimate of residues in poultry commodities. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to chlorantraniliprole in drinking water. EPA used similarly conservative assumptions to assess postapplication

exposure of children as well as incidental oral exposure of toddlers. 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% 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 risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, chlorantraniliprole is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, chlorantraniliprole is not expected to pose a intermediate-term risk.

5. *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.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorantraniliprole residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography mass spectrometry (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](mailto: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 established MRLs for chlorantraniliprole in or on the oilseed cottonseed subgroup 20C at 0.3 ppm. This MRL is the same as the tolerance being established for chlorantraniliprole the oilseed cottonseed subgroup 20C in the United States by this action.

The Codex has established MRLs for chlorantraniliprole in or on meat (fat) at 0.2 ppm. These MRLs are different than the tolerances being established for chlorantraniliprole in the United States on cattle, horse, sheep and goat fat (0.5 ppm) by this action. This results from the differences in treated commodities used in the livestock dietary exposure calculation and in the methods of diet calculation. The United States tolerances include more livestock feed items than Codex. Codex calculates the dietary burden based on the worst possible case, whereas NAFTA

countries utilize a reasonably balanced diet that considered nutritional needs of livestock.

##### C. Response to Comments

The EPA received a comment from a private citizen stating that pesticides should be banned. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

##### D. Revisions to Petitioned-for Tolerances

The petition requested an aspirated grain fractions tolerance of 300 ppm. EPA is establishing a 640 ppm tolerance in aspirated grain fractions based on evaluation of the soybean processing data. A processing study submitted for the generation of aspirated grain dust from soybeans provided a processing factor (320) that was used with the crop group 6 tolerance (2.0 ppm) to obtain a tolerance estimate ( $320 \times 2 = 640$  ppm) for aspirated grain fractions. Thus, soybeans with residues at the tolerance level (2 ppm) would yield aspirated grain fractions with residues of 640 ppm.

EPA is increasing the tolerance levels for certain livestock commodities because of the addition of soybean aspirated grain fractions as a feed item and the resulting increase in certain livestock dietary burdens. Previously, aspirated grain fractions (corn) contributed to the dietary burden; this is now replaced by soybean aspirated grain fractions which results in a greater dietary contribution. The beef cattle dietary burden is now elevated from 73 ppm to 110 ppm. This increase in the cattle dietary burden necessitates an increase in the tolerances of the meat and fat of cattle, sheep, horses, and goats. The existing tolerances for liver and kidney will cover the increased dietary exposure of cattle. The milk tolerance is not affected, because aspirated grain fractions are not a significant dairy cow feed item.

#### 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, in or on the following commodities: oilseed, rapeseed subgroup 20A at 2.0 ppm; oilseed, sunflower subgroup 20B at 2.0 ppm; oilseed, cottonseed subgroup 20C at 0.3 ppm; soybean aspirated grain fractions at 640 ppm; vegetable, legume, group 6 at 2.0 ppm; vegetable, foliage of legume, group 7, forage at 30 ppm; vegetable, foliage of legume, group 7, hay at 90 ppm; cattle, goat, horse and sheep, fat at 0.5 ppm, and cattle, goat, horse and sheep, meat at 0.1 ppm. Consistent with the petitioner's request, EPA is also deleting certain chlorantraniliprole tolerances that are no longer needed as a result of the crop group tolerances added by this action.

#### 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: September 21, 2012.

**Daniel J. Rosenblatt,**  
*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. Section 180.628 is amended as follows:

■ i. Remove the entries for crambe, seed; grain, aspirated fractions; hare's ear mustard, seed; jojoba, seed; lesquerella, seed; milkweed, seed; mustard, seed; oil, radish, seed; poppy, seed; rapeseed, seed; rose hip, seed; sesame, seed; tallowwood, seed; tea oil plant, seed;

vegetable, foliage of legume, except soybean, subgroup 7A, forage; vegetable, foliage of legume, except soybean, subgroup 7A, hay; and vegetable, legume, group 6, except soybeans; from the table in paragraph (a).

■ ii. Revise the tolerances for cattle, fat; cattle, meat; goat, fat; goat, meat; horse, fat; horse, meat; sheep, fat; sheep, meat; in the table in paragraph (a).

■ iii. Add alphabetically entries for cottonseed subgroup 20C, grain, aspirated grain fractions; rapeseed subgroup 20A; sunflower subgroup 20B; vegetable, legume, group 6; vegetable, foliage of legume, group 7, forage; and vegetable, foliage of legume, group 7, hay; to the table in paragraph (a).

■ iv. Remove the entries for soybean, forage, and soybean, hay, from the table in paragraph (d).

The added and revised text read as follows:

**§ 180.628 Chlorantraniliprole; tolerances for residues.**

Commodity	Parts per million
* * * *	*
Cattle, fat .....	0.5
Cattle, meat .....	0.1
* * * *	*
Cottonseed subgroup 20C .....	0.3
* * * *	*
Goat, fat .....	0.5
Goat, meat .....	0.1
* * * *	*
Grain, aspirated grain fractions	640
* * * *	*
Horse, fat .....	0.5
Horse, meat .....	0.1
* * * *	*
Rapeseed subgroup 20B .....	2.0
* * * *	*
Sheep, fat .....	0.5
Sheep, meat .....	0.1
* * * *	*
Sunflower subgroup 20C .....	0.3
* * * *	*
Vegetable, legume, group 6 .....	2.0
Vegetable, foliage of legume, group 7, forage .....	30
Vegetable, foliage of legume, group 7, hay .....	90
* * * *	*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 412, 413, 424, and 476**

[CMS-1588-CN2]

RIN 0938-AR12

**Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; Corrections**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects technical errors in the final rule that appeared in the August 31, 2012 **Federal Register** entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers."

**DATES:** *Effective Date:* October 1, 2012.

**FOR FURTHER INFORMATION CONTACT:** Tzvi Hefter, (410) 786-4487.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In FR Doc. 2012-19079 of August 31, 2012 (77 FR 53258), there were a number of technical errors that are identified and corrected in the Correction of Errors section of this correcting document. The provisions in this correcting document are effective as if they had been included in the final rule appearing in the August 31, 2012 **Federal Register**. Accordingly, the corrections are effective October 1, 2012.

**II. Summary of Errors and Corrections Posted on the CMS Web Site**

*A. Errors in the Preamble*

On page 53268, in our summary of the provisions of the Hospital Inpatient Quality Reporting (IQR) Program, we inadvertently referenced hospital-acquired condition (HAC) measure sets