

submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 7, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: April 22, 2008.

**Robert W. Varney,**

*Regional Administrator, EPA New England.*

■ Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 et seq.

#### Subpart H—Connecticut

■ 2. Section 52.387 is added to read as follows:

##### § 52.387 Interstate Transport for the 1997 8-hour ozone and PM<sub>2.5</sub> NAAQS.

On March 13, 2007, the State of Connecticut submitted a State Implementation Plan (SIP) revision addressing the Section 110(a)(2)(D)(i) interstate transport requirements of the Clean Air Act for the 1997 8-hour ozone and PM<sub>2.5</sub> National Ambient Air Quality Standards (NAAQS). There are four distinct elements related to the impact of interstate transport of air pollutants.

These include prohibiting significant contribution to downwind nonattainment of the NAAQS, interference with maintenance of the NAAQS, interference with plans in another state to prevent significant deterioration of air quality, and interference with efforts of other states to protect visibility. EPA has found that Connecticut's March 13, 2007 submittal adequately addresses these four distinct elements and has approved the submittal as meeting the requirements of Section 110(a)(2)(D)(i) for the 1997 8-hour ozone and PM<sub>2.5</sub> NAAQS.

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#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 180

[EPA-HQ-OPP-2007-0275; FRL-8357-3]

##### Chlorantraniliprole; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of chlorantraniliprole in or on apple, wet pomace; brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; cotton, gin byproduct; cotton, hulls; cotton undelinted seed; fruit, pome, group 11; fruit, stone, group 12; grape; grape, raisin; potato; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; vegetable, leafy, except brassica, group 4; milk; meat; meat byproduct; fat. E.I. DuPont de Nemours and Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes existing time-limited tolerances for residues of chlorantraniliprole in or on apple; apple, wet pomace; celery; cucumber; lettuce, head; lettuce, leaf; pear; pepper; spinach; squash; tomato and watermelon and modifies 40 CFR 180.628 by removing the third column (Expiration/Revocation Date) from the table in paragraph (a), since it is no longer applicable. In addition, this action establishes a time-limited tolerance for residues of chlorantraniliprole in or on rice in response to the approval of a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the use of the insecticide on rice to control rice water weevil, *Lissorhoptrus oryzophilus*. This regulation establishes

a maximum permissible level of residues of chlorantraniliprole in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2011.

**DATES:** This regulation is effective May 7, 2008. Objections and requests for hearings must be received on or before July 7, 2008, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0275. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Kable Bo Davis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0415; e-mail address: [davis.kable@epa.gov](mailto:davis.kable@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

#### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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-2007-0275 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before July 7, 2008.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0275, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Petition for Tolerance**

In the **Federal Register** of April 30, 2007 (72 FR 21263) (FRL-8124-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7181) by E.I. DuPont de Nemours and Company, DuPont Crop Protection, 1090 Elkton Road, Newark, DE 19711. The petition requested that 40 CFR 180.628 be amended by exempting the requirement of tolerances for residues of the insecticide chlorantraniliprole, 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino) carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1 H-pyrazole-5-carboxamide, in or on commodities. That notice referenced a summary of the petition prepared by E.I. DuPont de Nemours and Company, the registrant, which is available to the public 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, the Agency concluded that the request for exemption of tolerances for chlorantraniliprole is not appropriate. The appropriate tolerance levels for chlorantraniliprole residues in or on pending crops should be established as follows: Apple, wet pomace at 0.60 ppm, brassica, head and stem, subgroup 5A at 4.0 ppm, brassica, leafy greens,

subgroup 5B at 11 ppm, cotton, gin byproduct at 30 ppm, cotton, hulls at 0.40 ppm, cotton, undelinted seed at 0.30 ppm, fruit, pome, group 11 at 0.30 ppm, fruit, stone, group 12 at 1.0 ppm, grape at 1.2 ppm, grape, raisin at 2.5 ppm, potato at 0.01 ppm, vegetable, cucurbit, group 9 at 0.25 ppm, vegetable, fruiting, group 8 at 0.70 ppm, vegetable, leafy, except brassica, group 4 at 13 ppm, milk at 0.01 ppm, meat at 0.01 ppm, meat byproducts at 0.01 ppm and fat at 0.01 ppm.

EPA is also establishing a time-limited tolerance for residues of the insecticide chlorantraniliprole in or on rice, grain at 0.10 ppm and rice, straw at 0.25 ppm. This tolerance expires and is revoked on December 31, 2011. The Agency is establishing this time-limited tolerance in response to two specific exemption requests under FIFRA section 18 on behalf of the Louisiana Department of Agriculture and Forestry and the Texas Department of Agriculture for emergency use of chlorantraniliprole on rice seed to control rice water weevil, *Lissorhoptrus oryzophilus*.

According to Louisiana, the current emergency situation with respect to rice water weevil management has arisen primarily from the continuing, and probably increasing, practice of cultivating crawfish in ponds in close proximity to rice fields in southern Louisiana and the phase-out of pyrethroid seed treatments as an alternative for control. All of the alternative insecticides, the liquid and fertilizer impregnated pyrethroid formulations, currently registered and available for use against weevil in Louisiana are toxic to crawfish and have a very short treatment window which frequently precludes their timely use due to unfavorable weather and insufficient availability of aerial applicators. Another constraint is that these insecticides only offer protection for 4 to 7 days, while adult weevil movement into flooded rice fields may occur over a several week period. Additionally, drift of foliar applied liquid insecticide alternatives to adjacent crawfish ponds have resulted in numerous crawfish kills. The Applicant claims that rice water weevil populations have historically plagued the state and that registered insecticides for this use and/or cultural practices are inadequate.

According to Texas, the current emergency situation with respect to rice water weevil management has arisen primarily from the continuing, and probably increasing, practice of cultivating fish (catfish and hybrid stripped bass) and crawfish for

commercial production in ponds in close proximity to rice fields and the loss of a registered seed treatment as an alternative for control. A great majority of the fish and crawfish ponds are close enough to rice fields to be affected by the management practices used in rice. All insecticides currently registered for use against weevil in Texas are toxic to fish and crawfish, and also are subject to the same timing and logistical challenges noted by Louisiana. The Applicant claims that the registered insecticides for this use and/or cultural practices are inadequate to control rice water weevil.

As part of its assessment of the emergency exemption request, EPA assessed the potential risks presented by the residues of chlorantraniliprole in or on rice. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary time-limited tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address the urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this time-limited tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although, this time-limited tolerance expires and is revoked on December 31, 2011, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on rice after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data, or other relevant information on this pesticide indicates that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether chlorantraniliprole meets EPA's registration requirements for use on rice or whether a permanent tolerance for this use would be appropriate. Under this circumstance, EPA does not believe that the time-limited tolerance serves as a basis for registration of chlorantraniliprole by a State for special local needs under FIFRA section 24(c). Nor does the time-limited tolerance serve as the basis for any State other than Louisiana and Texas to use this pesticide on this crop under section 18

of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166.

### 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..." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 the petitioned-for tolerance for residues of chlorantraniliprole on apple, wet pomace at 0.60 ppm, brassica, head and stem, subgroup 5A at 4.0 ppm, brassica, leafy greens, subgroup 5B at 11 ppm, cotton, gin byproduct at 30 ppm, cotton, hulls at 0.40 ppm, cotton, undelinted seed at 0.30 ppm, fruit, pome, group 11 at 0.30 ppm, fruit, stone, group 12 at 1.0 ppm, grape at 1.2 ppm, grape, raisin at 2.5 ppm, potato at 0.01 ppm, vegetable, cucurbit, group 9 at 0.25 ppm, vegetable, fruiting, group 8 at 0.70 ppm, vegetable, leafy, except brassica, group 4 at 13 ppm, milk at 0.01 ppm, meat at 0.01 ppm, meat byproducts at 0.01 ppm and fat at 0.01 ppm as well as the time-limited tolerance for residues of chlorantraniliprole on rice, grain at 0.10 pp and rice, straw at 0.25 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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 has no significant acute toxicity via the oral, dermal, and inhalation routes of exposure. The LD<sub>50</sub> for oral and dermal acute exposure is ≤5,000 mg/kg/day and the LC<sub>50</sub> for acute inhalation exposure is ≤5.1 mg/L. This substance is not an eye or skin irritant and does not cause skin sensitization. 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 not genotoxic, neurotoxic, immunotoxic, carcinogenic, or teratogenic. Furthermore, it is not uniquely toxic to the conceptus as there were no maternal or fetal effects in studies conducted in rats and rabbits. Based on the results of a 28-day dermal study in rats, as well as the dermal LD<sub>50</sub> study, chlorantraniliprole has relatively low dermal toxicity.

Overall, chlorantraniliprole exhibits minimal mammalian toxicity after long-term exposure. The only consistent observation in the mammalian toxicology studies is an increased degree of microvesiculation of the adrenal cortex after dermal or dietary administration of chlorantraniliprole. Based on the lack of adverse effect on the function of the adrenal gland, this observation was considered treatment related, but not "adverse."

In addition to the adrenal effects, liver effects (e.g., increased liver weight and induction of Cytochrome P450 enzymes) were reported in the 90-day oral subchronic studies across species and only at the highest dose tested (HDT) (<1,000 mg/kg/day). While in the subchronic studies, these effects were considered adaptive, the liver effects were more pronounced in the 18-month chronic mouse study at the HDT. Increased *eosinophilic foci* (preneoplastic foci) were noted in male mice at 935 mg/kg/day and liver hypertrophy and weight increase were evident at the next lower dose (158 mg/kg/day), but progression to tumors was not apparent for these effects. Therefore, the eosinophilic foci appear to be an adverse effect only seen in the HDT and was graded minimal in severity.

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>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0275 in that docket.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for chlorantraniliprole used for human risk assessment can be found at <http://www.regulations.gov> in document *Chlorantraniliprole (DPX-E2Y45): Human Health Risk Assessment for Proposed Uses on Pome fruit, Stone fruit, Leafy vegetables, Brassica leafy*

*vegetables, Cucurbit vegetables, Fruiting vegetables, Cotton, Grapes, Potatoes, Rice, Turf and Ornamentals* at pages 22-24 in docket ID number EPA-HQ-OPP-2007-0275.

### 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 USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

iii. *Cancer.* Because chlorantraniliprole has been classified as a "not likely human carcinogen", a quantitative exposure assessment relative to cancer risk is not required.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for chlorantraniliprole in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of chlorantraniliprole for acute exposures are estimated to be 26.862 parts per billion (ppb) for surface water and 1.06 ppb for ground water. The EECs for chronic exposures are estimated to be

3.650 ppb for surface water and 1.06 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. Because no acute hazard, attributable to a single dose, was identified; acute dietary risk was not assessed. For chronic dietary risk assessment, the water concentration value 3.650 ppb was used to access 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 proposed for use on the following residential non-dietary sites: Turfgrass and ornamental plants. Although residential exposure could occur, due to the lack of toxicity identified for short- and intermediate-term durations via the relevant routes of exposure, no risk is expected from these exposures.

Additional information on residential exposure assumptions can be found at [www.regulations.gov](http://www.regulations.gov) (Docket ID EPA-HQ-OPP-2007-0275, pages 36 through 37).

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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to chlorantraniliprole and 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 not assumed that chlorantraniliprole has 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 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There were no effects on fetal growth or post-natal development up to the limit dose of 1,000 mg/kg/day in rats or rabbits in the developmental 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 that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicology database for chlorantraniliprole is complete for the purposes of this risk assessment and the characterization of potential pre- and postnatal risks to infants and children.

ii. No susceptibility was identified in the toxicological database, and there are no residual uncertainties re: pre-and/or postnatal exposure.

iii. There are no treatment-related neurotoxic findings in the acute and subchronic oral neurotoxicity studies in rats.

iv. The exposure assessment is protective: The dietary food exposure assessment utilizes tolerance level residues and 100% crop treated information for all commodities; the drinking water assessment utilizes values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. By using these screening-level exposure assessments, the chronic dietary (food and drinking water) risk is not underestimated.

v. Although residential exposure is expected over the short- and possibly intermediate-term (via the dermal and/or incidental oral route), there is no

hazard expected via these routes/durations, and therefore no risk for these scenarios.

#### *E. Aggregate Risks and Determination of Safety*

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* No acute risk is expected because no acute hazard, attributable to a single dose, was identified.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to chlorantraniliprole from food and water will utilize <1% of the cPAD for the population group children 1-2 years (the highest exposed subpopulation). Based on the use pattern, chronic residential exposure to residues of chlorantraniliprole is not expected.

3. *Short-term/intermediate risk.* Short-term aggregate and intermediate-term exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

There is potential for short- and intermediate-term postapplication dermal (adults and children) and incidental oral (children only) exposure to chlorantraniliprole. However, due to the lack of toxicity via dermal route, as well as the lack of toxicity over the acute, short- and intermediate-term via the oral route – no risk is expected from these exposures. Inhalation exposure is not expected due to the low vapor pressure of chlorantraniliprole (so applied/deposited residues are not expected to volatilize into the air).

4. *Aggregate cancer risk for U.S. population.* Chlorantraniliprole has been classified as a "not likely human carcinogen." It 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) is available to enforce the tolerance expression. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

There are no international residue limits that affect the Agency's recommendations at this time. There are no Canadian, CODEX or Mexican maximum residue limits (MRLs) for chlorantraniliprole.

Secondary reasons that contribute to harmonization difficulties include use pattern differences (for one crop, application rates and formulations may be different in different countries due to different pest pressures/conditions).

##### *C. Response to Comments*

There were no comments received in response to the notice of filing.

#### **V. Conclusion**

Therefore, the tolerance is established for residues of chlorantraniliprole, 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino) carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1 H-pyrazole-5-carboxamide, in or on apple, wet pomace at 0.60 ppm, brassica, head and stem, subgroup 5A at 4.0 ppm, brassica, leafy greens, subgroup 5B at 11 ppm, cotton, gin byproduct at 30 ppm, cotton, hulls at 0.40 ppm, cotton, undelinted seed at 0.30 ppm, fruit, pome, group 11 at 0.30 ppm, fruit, stone, group 12 at 1.0 ppm, grape at 1.2 ppm, grape, raisin at 2.5 ppm, potato at 0.01 ppm, vegetable, cucumber, group 9 at 0.25 ppm, vegetable, fruiting, group 8 at 0.70 ppm, vegetable, leafy, except brassica, group 4 at 13 ppm, milk at 0.01 ppm, meat at 0.01 ppm, meat byproducts at 0.01 ppm and fat at 0.01 ppm. In addition, this regulation establishes a time-limited tolerance for residues of chlorantraniliprole in or on rice, grain at 0.10 ppm and rice, straw at 0.25 ppm.

#### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under section 408(d) of FFDCA 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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 6, 2000) do not apply to this rule. In addition, This 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) (Public Law 104-4).

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), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: April 24, 2008.

**Debra Edwards,**

*Director, 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 by revising the table in paragraph (a) and

by adding text to paragraph (b) to read as follows:

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

(a) \* \* \*

Commodity	Parts per million
Apple, wet pomace .....	0.60
Brassica, head and stem, subgroup 5A .....	4.0
Brassica, leafy greens, subgroup 5B .....	11
Cattle, fat .....	0.01
Cattle, meat .....	0.01
Cattle, meat byproducts .....	0.01
Cotton, gin byproduct .....	30
Cotton, hulls .....	0.40
Cotton, undelinted seed .....	0.30
Fruit, pome, group 11 .....	0.30
Fruit, stone, group 12 .....	1.0
Goat, fat .....	0.01
Goat, meat .....	0.01
Goat, meat byproduct .....	0.01
Grape .....	1.2
Grape, raisin .....	2.5
Horse, fat .....	0.01
Horse, meat .....	0.01
Horse, meat byproduct .....	0.01
Milk .....	0.01
Potato .....	0.01
Sheep, fat .....	0.01
Sheep, meat .....	0.01
Sheep, meat byproduct .....	0.01
Vegetable, cucurbit, group 9 .....	0.25
Vegetable, fruiting, group 8 .....	0.70
Vegetable, leafy, except brassica, group 4 .....	13

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the residues of the insecticide chlorantraniliprole, 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1 H-pyrazole-5-carboxamide, in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. This tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Rice, grain .....	0.10	12/31/11
Rice, straw .....	0.25	12/31/11

\* \* \* \* \*

[FR Doc. E8-9950 Filed 5-6-08; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2007-0159; FRL-8362-7]

**Bacillus firmus isolate 1582; Exemption from the Requirement of a Tolerance****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus firmus* isolate 1582 or *Bacillus firmus* I-1582 on all food/feed commodities when applied/used as soil applications and seed treatments. AgroGreen submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus firmus* I-1582.

**DATES:** This regulation is effective May 7, 2008. Objections and requests for hearings must be received on or before July 7, 2008, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0159. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at

<http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: [bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@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. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicable provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this "**Federal Register**" document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing

Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

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

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2007-0159 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 7, 2008.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2007-0159, by one of the following methods.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

**II. Background and Statutory Findings**

In the **Federal Register** of March 21, 2007 (72 FR 13277) (FRL-8117-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6F7111) by AgroGreen, Biological Division, Minrav Infrastructures (1993) Ltd., 3 Habossem Str, P.O. Box 153, Ashdod