(4) In the event that a record company authorizes promotional uses in excess of the time limitations of paragraph (b) of this section, the record company, and not the third-party service it has authorized, shall be liable for any payment due for such uses; provided, however, that all rights and remedies of the copyright owner with respect to unauthorized uses shall be preserved. In the event that a third-party service exceeds the scope of any authorization by a record company, the service, and not the record company, shall be liable for any payment due for such uses; provided, however, that all rights and remedies of the copyright owner with respect to unauthorized uses shall be preserved.

(c) *Interactive streaming of full-length musical works through record company and artist services.* In addition to those of paragraph (a) of this section, the provisions of this paragraph (c) apply to interactive streaming conducted or authorized by record companies under the promotional royalty rate through a service (e.g., a Web site) directly owned or operated by the record company, or directly owned or operated by a recording artist under the authorization of the record company, and that is not subject to paragraph (d) of this section. For the avoidance of doubt and without limitation, an artist page or site on a third-party service (e.g., a social networking service) shall not be considered a service operated by the record company or artist. Such interactive streams may be made or authorized by a record company under the promotional royalty rate only if—

(1) The interactive streaming subject to this paragraph (c) of a particular sound recording is offered or authorized by the record company on no more than 90 days total for all services (i.e., interactive streaming under this paragraph (c) of a particular sound recording may be authorized on no more than a total of 90 days, which need not be consecutive, and on any such day, interactive streams may be offered on one or more services operated by the record company or artist, subject to the provisions of paragraph (b)(2) of this section); provided, however, that an additional 90 days shall be available each time the sound recording is re-released by the record company in a remastered form or as part of a compilation with a different set of sound recordings than prior compilations that include that sound recording;

(2) In the case of interactive streaming through a service devoted to one featured artist, the interactive streams subject to this paragraph (c) of this section of a particular sound recording are made or authorized by the record company on no more than one official artist site per artist and are recordings of that artist; and

(3) In the case of interactive streaming through a service that is not limited to a single featured artist, all interactive streaming on such service (whether eligible for the promotional royalty rate or not) is limited to sound recordings of a single record company and its affiliates and the service would not reasonably be considered to be a meaningful substitute for a paid music service.

(d) *Interactive streaming of clips.* In addition to those in paragraph (a) of this section, the provisions of this paragraph (d) apply to interactive streaming conducted or authorized by record companies under the promotional royalty rate of segments of sound recordings of musical works with a playing time that does not exceed the greater of

(1) 30 seconds, or

(2) 10% of the playing time of the complete sound recording, but in no event in excess of 60 seconds. Such interactive streams may be made or authorized by a record company under the promotional royalty rate without any of the temporal limitations set forth in paragraphs (b) and (c) of this section (but subject to the other conditions of paragraphs (b) and (c) of this section, as applicable). For clarity, this paragraph (d) is strictly limited to the uses described herein and shall not be construed as permitting the creation or use of an excerpt of a musical work in violation of 17 U.S.C. 106(2) or 115(a)(2) or any other right of a musical work owner.

(e) *Activities prior to the publication date.* Notwithstanding paragraphs (a) through (d) of this section, in the case of licensed activity prior to the publication date, the promotional royalty rate shall apply to promotional interactive streams, and to limited downloads offered in the context of a free trial period for a digital music subscription service, that in either case are authorized by the relevant record company, if the condition set forth in paragraph (a)(1)(i) of this section is satisfied, subject only to the additional condition in paragraph (b)(1) of this section, and provided that a free trial period for a digital music subscription service authorized by the relevant record company shall be considered to be of 30 days' duration. In the event of a dispute concerning the eligibility of licensed activity prior to the publication date for the promotional royalty rate, a service asserting that its licensed activity is eligible for the promotional royalty rate shall bear the burden of proving that its licensed activity was authorized by the relevant record company and shall certify that the condition in paragraph (b)(1) of this section was satisfied.

§ 385.15 Timing of payments.

Payment for any accounting period for which payment otherwise would be due more than 180 days after the publication date shall be due as otherwise provided under 17 U.S.C. 115 and its implementing regulations. Payment for any prior accounting period shall be due 180 days after the publication date.

§ 385.16 Reproduction and distribution rights covered.

A compulsory license under 17 U.S.C. 115 extends to all reproduction and distribution rights that may be necessary for the provision of the licensed activity, solely for the purpose of providing such licensed activity (and no other purpose).

§ 385.17 Effect of rates.

In any future proceedings under 17 U.S.C. 115(c)(3)(C) and (D), the royalty rates payable for a compulsory license shall be established de novo.

Dated: September 25, 2008.

James Scott Sledge,

Chief Copyright Royalty Judge.

[FR Doc. E8–23184 Filed 9–30–08; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0647; FRL–8382–4]

Chlorantraniliprole; Proposed Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish time-limited tolerances for residues of chlorantraniliprole in or on cowpeas, forage and hay; field peas, vines and hay; forage, fodder and straw of cereal grains, crop group 16; grass forage, fodder and hay, crop group 17; leaves of root and tuber vegetables, crop group 2, leeks, nongrass animal feeds (forage, fodder, straw and hay), crop group 18; okra; onions, green; onions, Welsh; peanuts, hay; shallots; soybeans, forage and hay; strawberries and sugarcane, sugar under the Federal Food, Drug, and Cosmetic Act (FFDCA). The tolerances expire on April 25, 2010.

DATES: Comments must be received on or before December 1, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2008–0647, 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 Facility'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.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2008–0647. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., 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 either 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 hours of operation of this Docket Facility are 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.*

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. 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. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background and Statutory Findings

EPA on its own initiative, under section 408(e) of FFDCA, 21 U.S.C. 346a(e), is proposing to establish a 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 cowpeas, forage and hay at 0.20 parts per million (ppm); field peas, vines and hay at 0.20 ppm; forage, fodder and straw of cereal grains, crop group 16 at 0.20 ppm, grass forage, fodder and hay, crop group 17 at 0.20 ppm; leaves of root and tuber vegetables, crop group 2 at 0.20 ppm; leeks at 0.20 ppm; nongrass animal feeds (forage, fodder, straw and hay), crop group 18 at 0.20 ppm; okra at 0.70 ppm; onions, green at 0.20 ppm; onions,

Welsh at 0.20 ppm; peanuts, hay at 0.20 ppm; shallots at 0.20 ppm; soybeans, forage and hay at 0.20 ppm; strawberries at 1.2 ppm; and sugarcane, sugar at 0.20 ppm.

Recently, EPA established tolerances for chlorantraniliprole 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, raisen; potato; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; vegetable, leafy, except brassica, group 4; milk; meat; meat byproduct and fat. At that time EPA determined rotational crop tolerances were required, and that the petitioner needed to conduct extensive field rotational crop trials. The Agency concluded that until the requested data are submitted, a restriction should be imposed on labels prohibiting the rotation to any crop not on the label. In response, the registrant submitted proposals for the establishment of tolerances for inadvertent residues for a number of crops pending submission of the requested data. After considering the registrant's submission, EPA is now proposing time-limited tolerances to address rotated crops.

EPA has decided to propose time-limited rotational crop tolerances for chlorantraniliprole. Rotational crop trials (2003, 2004, 2005) were conducted in Canada and the United States on leafy vegetables (Swiss chard, lettuce, spinach), root vegetables (radish, beet, turnip), cereal grains (wheat, oat) and soybean. Based on the data on chlorantraniliprole, the Agency believes that the residue data would not underestimate residues on rotated crops. Thus the Agency believes that the 0.20 ppm tolerances on rotational crops are appropriate and protective. EPA also determined that adding these proposed tolerances would not change its prior safety finding for chlorantraniliprole. EPA's updated risk assessment can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0647.

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. . . . ''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, 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, consistent with section 408(b)(2) of FFDCA, for a tolerance 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 cowpeas, forage and hay at 0.20 ppm; field peas, vines and hay at 0.20 ppm; forage, fodder and straw of cereal grains, crop group 16 at 0.20 ppm, grass forage, fodder and hay, crop group 17 at 0.20 ppm; leaves of root and tuber vegetables, crop group 2 at 0.20 ppm; leeks at 0.20 ppm; nongrass animal feeds (forage, fodder, straw and hay), crop group 18 at 0.20 ppm; okra at 0.70 ppm; onions, green at 0.20 ppm; onions, Welsh at 0.20 ppm; peanuts, hay at 0.20 ppm; shallots at 0.20 ppm; soybeans, forage and hay at 0.20 ppm; strawberries at 1.20 ppm; and sugarcane, sugar at 0.20 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. 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_{50} 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 milligram/kilogram/day (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 toxic 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-term, intermediate-term, 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* 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 United States Department of Agriculture (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.

The inclusion of additional livestock feeds such as forage, fodder and straw from cowpea, field pea, soybean, cereal grains, nongrass animal feeds or peanut does not increase the livestock dietary burdens and thus the meat and milk tolerances. While the addition of strawberries, sugarcane, leek, onions, shallot, and okra that are considered human food results in a miniscule increase in exposure, a DEEM analysis that incorporates all the new commodities does not change the risk outcome which remains at 1% of the cPAD for the most highly exposed population, children ages 1-2. In addition, the dietary exposure from leeks, onions and shallots is negligible.

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

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 registered 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-term 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* (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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances

found to have a common mechanism on 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 (10X) tenfold 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 postnatal 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 prenatal and postnatal risks to infants and children.

ii. No susceptibility was identified in the toxicological database, and there are no residual uncertainties re: prenatal 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 percent crop treated (PCT) information for all commodities. The submitted field rotational crop studies do not match those recommended in the guidelines. However, data from confined rotational crop studies and field rotational crop studies show that uptake of chlorantraniliprole is below the quantification level in roots and grains, and range of 0.01 to 0.15 ppm in tops of root vegetables and forage, fodder and straw of cereal grains and soybean. The 0.20 ppm tolerances based on the collective data should be conservative. Also, the tolerances on rotational crops strawberry and okra are conservative since the strawberry tolerance is based on residues in grape from direct application of chlorantraniliprole and the okra tolerance is based on residues resulting from direct treatment on tomato and pepper. An exposure assessment using conservative residue values is expected to be protective.

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-term, intermediate-term, 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 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-term and intermediate-term post-application 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-term 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) 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*.

B. International Residue Limits

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

C. Conditions

Tolerances may be made permanent following submission of rotational crop residue data suitable for establishing tolerances.

V. Conclusion

Time-limited tolerances are proposed 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 cowpea, forage and hay at 0.20 ppm; field pea, vines and hay at 0.20 ppm; forage, fodder and straw of cereal grains, crop group 16 at 0.20 ppm, grass forage, fodder and hay,

crop group 17 at 0.20 ppm; leaves of root and tuber vegetables, crop group 2 at 0.20 ppm; leek at 0.20 ppm; nongrass animal feeds (forage, fodder, straw and hay), crop group 18 at 0.20 ppm; okra at 0.70 ppm; onion, green at 0.20 ppm; onion, Welsh at 0.20 ppm; peanut, hay at 0.20 ppm; shallot at 0.20 ppm; soybean, forage and hay at 0.20 ppm; strawberries at 1.20 ppm; and sugarcane, sugar at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This proposed rule establishes a tolerance 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). The Agency hereby certifies, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that this proposed action will not have significant negative economic impact on a substantial number of small entities. A tolerance is one of the regulatory requirements needed for use of a pesticide and thus establishing a tolerance is expected to have no adverse economic impact. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). Executive Order 3175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

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 19, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be 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 paragraph (d) to read as follows:

§ 180.628 Chlorantraniliprole; tolerances for residues.

* * * * *

(d) *Indirect or inadvertent resisues.* Time-limited tolerances are established for indirect or inadvertent 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 the following commodities. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Animal feed, nongrass, group 18	0.20	4/25/10
Cowpea, forage	0.20	4/25/10
Cowpea, hay	0.20	4/25/10
Field pea, hay	0.20	4/25/10
Field pea, vine	0.20	4/25/10
Grain, cereal, forage, fodder and straw, group 16	0.20	4/25/10
Grass, forage, fodder and hay, group 17	0.20	4/25/10
Leek	0.20	4/25/10
Okra	0.70	4/25/10
Onion, green	0.20	4/25/10

Commodity	Parts per million	Expiration/revocation date
Onion, Welsh	0.20	4/25/10
Peanut, hay	0.20	4/25/10
Shallot	0.20	4/25/10
Soybean, forage	0.20	4/25/10
Soybean, hay	0.20	4/25/10
Strawberry	1.20	4/25/10
Sugarcane	0.20	4/25/10
Vegetable, leaves of root and tuber, group 2	0.20	4/25/10

[FR Doc. E8–22946 Filed 9–30–08; 8:45 am]

BILLING CODE 6560–50–S