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 15, 2010.

G. Jeffery Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.532, in paragraph (a), alphabetically add the following commoditiy to the table to read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Canola, seed[1]	0.03
* * *	* *

[1] Import only

* * * * *

[FR Doc. 2010–9835 Filed 4–27–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0772; FRL–8818–5]

Imidacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of imidacloprid in or on vegetables, bulb, group 3; cereal grains, group 15 and cereal grains, forage, fodder and straw, group 16. This regulation also deletes tolerances for various commodities and tolerances from direct/inadvertent residues on cereal grains, group 15 and cereal grains, forage, fodder and straw, group 16, as they will be superseded by group tolerances. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 28, 2010. Objections and requests for hearings must be received on or before June 28, 2010, 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–2008–0772. 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., 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*.

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).
- 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 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?

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 cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0772 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 June 28, 2010.

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–2008–0772, 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.

II. Petition for Tolerance

In the **Federal Register** of December 3, 2008 (73 FR 73640) (FRL–8390–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 8F7414, 8F7415) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petitions requested that 40 CFR 180.472 be amended by establishing tolerances for combined residues of the insecticide imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, in or on vegetable, bulb, group 3 at 2.5 parts per million (ppm) (PP 8F7414) and cereal, grains, group 15 at 0.05 ppm (PP 8F7415). That notice referenced a summary of the petitions prepared by Bayer CropScience, 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, EPA has determined that the available toxicology, occupational/residential, and residue chemistry databases support the establishment of permanent tolerances of imidacloprid in or on onion, green, subgroup 3-07B at 2.5 ppm, onion, dry bulb, subgroup 3-07A at 0.15 ppm and grain, cereal, except rice, group 15 at 0.05 ppm. The reasons 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 section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for combined residues of imidacloprid in or on onion, green, subgroup 3-07B at 2.5 ppm, onion, dry bulb, subgroup 3-07A at 0.15 ppm and grain, cereal, except rice, group 15 at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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. Specific information on the studies received and the nature of the adverse effects caused by imidacloprid 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 "Imidacloprid: Human-Health Risk Assessment," pages 43 - 46 in docket ID number EPA–HQ–OPP–2008–0772.

Imidacloprid has low acute toxicity via the dermal and inhalation routes and moderate acute toxicity via the oral route. It is not an eye or dermal irritant and is not a dermal sensitizer. The nervous system is the primary target organ of imidacloprid. Nervous system effects evidenced as changes in clinical signs and functional observation battery (FOB) assessments were seen in rat acute and subchronic neurotoxicity studies. Also, in the rat developmental neurotoxicity study, a decrease in the caudate/putamen width was noted in female pups. Retinal atrophy was seen in high-dose females in the rat combined chronic toxicity/carcinogenicity study. No nervous system effects were noted in the mouse carcinogenicity or the reproduction and developmental studies or in the rabbit dermal or rat inhalation studies. The dog was less sensitive than rodents to the effects of imidacloprid. The rabbit appeared to be very sensitive as there was increased mortality in the oral developmental study at the highest dose tested. Increased incidence of mineralized particles in the thyroid colloid was noted in the rat combined chronic toxicity/carcinogenicity study. Body weight decrements were noted in the rat and/or mouse chronic and carcinogenicity studies, the rat subchronic neurotoxicity study, and the developmental, developmental neurotoxicity and reproduction studies. No effects were observed in the rabbit dermal or rat inhalation studies. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies, and there is no concern for mutagenicity. There was no evidence of increased qualitative or quantitative susceptibility of rats or rabbits to *in utero* exposure to imidacloprid and no evidence of qualitative or quantitative increased susceptibility of rat offspring in the reproduction study. There was evidence of an increased qualitative susceptibility in the rat developmental neurotoxicity study. At the highest dose tested, maternal effects consisted largely of slight decreases in food consumption and body-weight gain during early lactation, while pup effects included decreased body weight, decreased motor activity, and decreased caudate/putamen width in females.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the

margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 imidacloprid used for human risk assessment can be found at *http://www.regulations.gov* in document "Imidacloprid: Human-Health Risk Assessment," pages 16 - 17 in docket ID number EPA–HQ–OPP–2008–0772.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to imidacloprid, EPA considered exposure under the petitioned-for tolerances as well as all existing imidacloprid tolerances in (40 CFR 180.472). EPA assessed dietary exposures from imidacloprid 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted an unrefined, acute dietary exposure assessment using tolerance-level residues and assuming 100% crop treated (CT) for all registered and proposed commodities for the general U.S. population and various population subgroups.

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 conducted a partially refined, chronic dietary exposure assessment using tolerance-level residues for all registered and proposed commodities and percent crop treated (PCT) for some registered commodities.

iii. *Cancer*. A cancer exposure assessment was not performed because imidacloprid is not carcinogenic. On November 11, 1993, the Agency classified imidacloprid as a Group E chemical, "Evidence of non-carcinogenicity for humans," by all routes of exposure based upon lack of evidence of carcinogenicity in rats and mice.

iv. *Percent crop treated (PCT) information*. Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Commodity	Average percent Crop Treated Data
Almonds	<1
Apples	25
Artichokes	5
Avocados	<1
Blueberries	10
Broccoli	50
Cabbage	20
Cantaloupe	40
Cauliflower	50
Celery	10
Cherries	10
Cotton	10
Cucumbers	5
Eggplant	35
Field corn	<2.5
Filberts (hazelnuts)	<1
Grapefruit	10
Grapes	30
Honeydew	30
Lemons	5
Lettuce	65
Oranges	10
Peaches	5
Pears	5
Pecans	10
Peppers	30
Potatoes	35
Prunes	<1
Pumpkin	10
Soybeans	<1
Spinach	20
Squash	10
Strawberries	10
Sugar beets	<1
Sweet corn	<1
Tangerines	5
Tobacco	20
Tomatoes	15
Walnuts	<1
Watermelon	15

In most cases, EPA uses available data from the United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which imidacloprid may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for imidacloprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of imidacloprid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of imidacloprid for acute exposures are estimated to be 36.0 parts per billion (ppb) for surface water and 2.09 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 36.0 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 17.2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Imidacloprid is currently registered for the following uses that could result in residential exposures: Indoor and outdoor ornamental plantings, ornamental lawns and turf, pre- and post-construction termiticide applications, spot-on treatments for dogs and cats, and crack and crevice treatments. Additionally, it is registered for use on mattresses for bed bug control. EPA assessed residential exposure using the assumption that residential pesticide handlers (i.e., persons who might mix, load and, or apply a pesticide material) could be exposed to several formulations that contain imidacloprid. The Agency also assessed post-application exposure for adults and children contacting surfaces, foliage, or pets that were treated with imidacloprid. Residential exposures are expected to be short-term (i.e., 1 to 30 days) or intermediate-term (1 to 6 months) based upon the pest spectra, sites of application, methods of application, formulations and the retreatment intervals. Since the indoor crack and crevice and mattress scenarios resulted in the highest potential exposures, these assessments are protective of all residential exposures from imidacloprid.

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

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA 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 was no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There was no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study. There was evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study; however, the concern is low for the following reasons:

i. The effects in pups are well-characterized with a clear NOAEL;

ii. The pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in both pups and dams; and

iii. The doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the developmental neurotoxicity study. Therefore, there are no residual uncertainties for prenatal/postnatal toxicity in this study.

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 for all exposure scenarios, except acute dietary (all populations). That decision is based on the following findings:

i. The toxicological database for imidacloprid is complete, with the exception of an immunotoxicity study.

ii. The toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. An immunotoxicity study is required as a part of new data requirements in 40 CFR part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment. Therefore, a database uncertainty factor (UF_{DB}) is not needed to account for lack of this study.

iii. There is no evidence that imidacloprid results in increased susceptibility *in utero* to rats or rabbits in the prenatal developmental studies or in offspring in the 2–generation reproduction study.

iv. A developmental neurotoxicity study was performed with imidacloprid and well-defined NOAELs were achieved in the study.

v. There was evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study; however, the concern is low for reasons stated above.

vi. There are no residual uncertainties for prenatal/postnatal toxicity.

vii. The acute dietary food exposure assessment utilizes existing and proposed tolerance-level residues and 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

viii. The chronic food exposure assessment utilizes and proposed tolerance-level residues and %CT data for several existing uses. For all proposed uses, 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.

ix. The dietary drinking water assessment utilizes water concentration

values generated by model and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimatesof water concentrations which will not likely be exceeded.

x. The residential handler assessment is based upon the residential standard operating procedures (SOPs) in conjunction with chemical-specific study data in some cases and Pesticide Handler Exposure Database (PHED) unit exposures in other cases. The majority of the residential post-application assessment is based upon chemical-specific Turf Transfer Residue (TTR) data or other chemical-specific post-application exposure study data. The chemical-specific study data as well as the surrogate study data used are reliable and also are not expected to underestimate risk to adults as well as to children. In a few cases where chemical-specific data were not available, the SOPs were used alone. The residential SOPs are based upon reasonable "worst-case" assumptions and are not expected to underestimate risk. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to imidacloprid.

A 3X FQPA SF was retained in the form of a UFL (uncertainty factor due to extrapolation from a LOAEL in the absence of a NOAEL) for the acute dietary (all populations) exposure scenario only, since a NOAEL was not observed in the relevant study for that exposure scenario (acute neurotoxicity study in rats). A 3X uncertainty factor was judged to be adequate (as opposed to a 10X) for the following reasons:

1. The LOAEL (42 mg/kg) is comparable to the LOAELs seen in adults in the developmental rat study (30 mg/kg/day) and the 2–generation reproduction study [47/52 milligrams/kilograms/day (mg/kg/day) (male/female)] and in the offspring in the DNT study (55 mg/kg/day);

2. The extrapolated NOAEL of 14 mg/kg (42/3 = 14) is comparable to the NOAEL of 20 mg/kg/day established in the offspring in the DNT; and,

3. The neurotoxic effects in this study showed a good dose response which resulted in minimal effects on motor activity and locomotor activity at the LOAEL.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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, imidacloprid is not expected to pose an acute risk. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to imidacloprid will occupy 70% of the aPAD for (children 1 to 2 years old) the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to imidacloprid from food and water will utilize 32% of the cPAD for (children 1 to 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 imidacloprid 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).

Imidacloprid is currently registered for crack and crevice uses and bed bug uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to imidacloprid. Using the exposure assumptions described in Unit III.C.3. for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 430 for adults and 170 for children. Toddlers' residential short-term aggregate exposure includes dermal and inhalation exposure from the crack and crevice uses, dermal exposure from the bed-bug uses, and incidental oral exposure from hand-to-mouth contact with treated surfaces. Adult short-term aggregate exposure includes dermal and inhalation exposure from indoor crack and crevice uses, and dermal exposure from the bed-bug uses. These exposures were higher than those calculated for all other residential uses of imidacloprid. Therefore, the crack and crevice and bed bug treatment exposure estimates were aggregated with the chronic dietary to provide a worst-case estimate of short-term aggregate risk for the U.S. population and children 1 to 2 years old. The combined short-term residential MOEs for these scenarios were 580 for adults and 240 for children.

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).

Imidacloprid is currently registered for crack and crevice uses and bed bug uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to imidacloprid.

Using the exposure assumptions described in Unit III.C.3. for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 400 for adults and 150 for children. Toddlers' residential intermediate-term aggregate exposure includes dermal and inhalation exposure from the crack and crevice uses, dermal exposure from the bed-bug uses, and incidental oral exposure from hand-to-mouth contact with treated surfaces. Adult intermediate-term aggregate exposure includes dermal and inhalation exposure from indoor crack and crevice uses, and dermal exposure from the bed-bug uses. These exposures were higher than those calculated for all other residential uses of imidacloprid. Therefore, the crack and crevice and bed bug treatment exposure estimates were aggregated with the chronic dietary exposure to provide a worst-case estimate of intermediate-term aggregate risk for the U.S. population and children 1 to 2 years old. The combined intermediate-term residential MOEs for these scenarios were 540 for adults and 260 for children.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, imidacloprid was classified as "not likely to be carcinogenic to humans," and is not expected to pose a cancer risk to humans. Therefore, a

quantitative cancer risk assessment is not needed.

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 imidacloprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies, Bayer Gas Chromatography/Mass Spectrometry (GC/MS) Method 00200 and Bayer GC/MS Method 00191, 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 established Mexican maximum residue limits (MRLs) for the proposed new uses. There are established Codex MRLs for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety expressed as imidacloprid, in or on cereal grain at 0.05 ppm, leeks at 0.05 ppm, and bulb onions at 0.1 ppm. There are also established Canadian MRLs for 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-1H-imidazol-2-amine, including metabolites containing the 6-chloropicolyl moiety in or on sweet corn at 0.05 ppm and field corn at 0.05 ppm. With the exception of onions, there is no harmonization issue for these petitions. The Codex MRLs for leeks (0.05 ppm) and bulb onions (0.1 ppm) can not be harmonized as the U.S. use pattern necessitates higher tolerances (0.15 ppm for onion, dry bulb, subgroup 3-07A; and 2.5 ppm for onion, green, subgroup 3-07B).

C. Response to Comments

There were no comments submitted in response to the Notice of Filing published in the **Federal Register** on December 3, 2008.

D. Revisions to Petitioned-For Tolerances

Due to residues on dry bulb onions and green onions varying by greater than 5X, the establishment of a crop group tolerance for crop group 3 was not appropriate. The Agency determined that the available toxicology, occupational/residential, and residue chemistry databases support the establishment of permanent tolerances of imidacloprid in or on onion, green, subgroup 3-07B at 2.5 ppm and onion, dry bulb, subgroup 3-07A at 0.15 ppm.

No new field trial data were submitted in support of the proposed tolerance for cereal grains, however there are existing tolerances of combined residues of imidacloprid in or on barley, grain; corn, field, grain; corn, pop, grain; corn, sweet, kernel plus cob with husks removed; millet, pearl, grain; millet, proso, grain; oats, grain, grain; rye, grain; sorghum, grain; and wheat, grain at 0.05 ppm. There are no existing field trial data on rice, another member of the cereal grains crop group. In the absence of rice data, the available toxicology, occupational/residential, and residue chemistry databases support the establishment of permanent tolerances of imidacloprid in or on grain, cereal, except rice, group 15 at 0.05 ppm. In connection with the imidacloprid petition for cereal grain group tolerance, EPA has reviewed the available cereal grain data on forage, fodder, and straw of cereal grains. Individual imidacloprid tolerances now exist for many forage, fodder, and straw cereal grain commodities. EPA has determined that sufficient data are available to establish the following group tolerances associated with the cereal grain group tolerance: Grain, cereal, forage, fodder and straw, group 16, forage at 7.0 ppm; grain, cereal, forage, fodder and straw, group 16, hay at 6.0 ppm; grain, cereal, forage, fodder and straw, group 16, stover at 0.3 ppm and grain, cereal, forage, fodder and straw, group 16, straw at 3.0 ppm. The Crop Group 16 tolerances are being limited like the Crop Group 15 tolerance to exclude rice.

The following established tolerances are being deleted because they are superseded by inclusion in groups 15 and 16: Barley, grain at 0.05 ppm; barley, hay at 0.5 ppm; barley, straw at 0.5 ppm; corn, field, forage at 0.10 ppm; corn, field, grain at 0.05 ppm; corn, field, stover at 0.20 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 0.20 ppm; corn, sweet, forage at 0.10 ppm; corn, sweet, kernel plus cob with husks removed at 0.05 ppm; corn, sweet, stover at 0.20 ppm; millet, pearl, forage at 2.0 ppm; millet, pearl, grain at 0.05 ppm; millet, pearl, hay at 6.0 ppm; millet, pearl, straw at 3,0 ppm; millet, proso, forage at 2.0 ppm; millet, proso, grain at 0.05 ppm; millet, proso, hay at 6.0 ppm; millet, proso, straw at 3.0 ppm; oat, forage at 2.0 ppm; oat, grain at 0.05 ppm; oat, hay at 6.0 ppm; oat, straw at 3.0 ppm; rye, forage at 2.0 ppm; rye, grain at 0.05 ppm; rye, hay at 6.0 ppm; rye, straw at 3.0 ppm; sorghum, forage at 0.10 ppm; sorghum, grain, grain at 0.05 ppm; sorghum, grain, stover at 0.10 ppm; wheat, forage at 7.0 ppm; wheat, grain at 0.05 ppm; wheat, hay at 0.5 ppm and wheat, straw at 0.5 ppm.

Additionally, the following tolerances from indirect or inadvertent residues are also being deleted: Corn, sweet, kernel plus cob with husks removed at 0.05 ppm; grain, cereal, forage, fodder and straw, group 16, forage at 2.0 ppm; grain, cereal, forage, fodder and straw, group 16, hay at 6.0 ppm; grain, cereal, forage, fodder and straw, group 16, stover at 0.3 ppm; grain, cereal, forage, fodder and straw, group 16, straw at 3.0 ppm and grain, cereal, group 15 at 0.05 ppm. The following tolerance from indirect or inadvertent residues is being added: Rice, grain at 0.05 ppm.

V. Conclusion

Therefore, tolerances are established for combined residues of imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, in or on onion, dry bulb, subgroup 3-07A at 0.15 ppm; onion, green, subgroup 3-07B at 2.5 ppm; grain, cereal, except rice, group 15 at 0.05 ppm; grain, cereal, forage, fodder and straw, except rice, group 16, forage at 7.0 ppm; grain, cereal, forage, fodder and straw, except rice, group 16, hay at 6.0 ppm; grain, cereal, forage, fodder and straw, except rice, group 16, stover at 0.3 ppm and grain, cereal, forage, fodder and straw, except rice, group 16, straw at 3.0 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 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 section 408(d) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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 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) (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 15, 2010.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.472 is revised to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl) methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid, in or on the following commodities:

Commodity	Parts per million
Acerola	1.0
Almond, hulls	4.0
Apple	0.5
Apple, wet pomace	3.0
Artichoke, globe	2.5
Aspirated grain fractions	240
Atemoya	0.30
Avocado	1.0
Banana	0.50
Beet, sugar, molasses	0.30
Beet, sugar, roots	0.05
Beet, sugar, tops	0.50
Biriba	0.30
Blueberry	3.5
Borage, seed	0.05
Caneberry, subgroup 13-A	2.5
Canistel	1.0
Canola, seed	0.05
Cattle, fat	0.30
Cattle, meat	0.30
Cattle, meat byproducts	0.30
Cherimoya	0.30
Citrus, dried pulp	5.0
Coffee, bean, green	0.80
Cotton, gin byproducts	4.0
Cotton, meal	8.0
Cotton, undelinted seed	6.0
Crambe, seed	0.05
Cranberry	0.05
Currant	3.5
Custard apple	0.30
Egg	0.02
Elderberry	3.5
Feijoa	1.0
Flax, seed	0.05
Fruit, citrus, group 10	0.70
Fruit, pome, group 11	0.6
Fruit, stone, group 12	3.0
Goat, fat	0.30
Goat, meat	0.30
Goat, meat byproducts	0.30
Gooseberry	3.5
Grain, cereal, forage, fodder and straw, group 16, forage, except rice	7.0
Grain, cereal, forage, fodder and straw, group 16, hay, except rice	6.0
Grain, cereal, forage, fodder and straw, group 16, stover, except rice	0.30
Grain, cereal, forage, fodder and straw, group 16, straw, except rice	3.0
Grain, cereal, group 15, except rice	0.05
Grape	1.0
Grape, juice	1.5
Grape, raisin	1.5
Guava	1.0
Herbs subgroup 19A, dried herbs	48
Herbs subgroup 19-A, fresh herbs	8.0
Hog, fat	0.30
Hog, meat	0.30
Hog, meat byproducts	0.30
Hop, dried cones	6.0
Horse, fat	0.30
Horse, meat	0.30
Horse, meat byproducts	0.30
Huckleberry	3.5
Ilama	0.30
Jaboticaba	1.0
Juneberry	3.5
Kava, leaves	4.0
Kava, roots	0.40
Leaf petioles subgroup 4B	6.0
Leafy greens subgroup 4A	3.5
Lettuce, head	3.5
Lettuce, leaf	3.5
Lingonberry	3.5
Longan	3.0
Lychee	3.0
Mango	1.0
Milk	0.10
Mustard, black, seed	0.05
Mustard, field, seed	0.05
Mustard, Indian, seed	0.05
Mustard, rapeseed, seed	0.05
Mustard, seed	0.05
Nut, tree, group 14	0.05
Okra	1.0
Onion, dry bulbs, subgroup 3-07A	0.15
Onion, green, subgroup 3-07B	2.5
Papaya	1.0
Passionfruit	1.0
Peanut	0.45
Peanut, hay	35

Commodity	Parts per million
Peanut, meal	0.75
Pecan	0.05
Persimmon	3.0
Pistachio	0.05
Pomegranate	0.90
Potato, chip	0.40
Potato, processed potato waste	0.90
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Pulasan	3.0
Rambutan	3.0
Rapeseed, seed	0.05
Raspberry, wild	2.5
Safflower, seed	0.05
Salal	3.5
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
Sheep, fat	0.30
Sheep, meat	0.30
Sheep, meat byproducts	0.30
Soursop	0.30
Soybean, forage	8.0
Soybean, hay	35
Soybean, meal	4.0
Soybean, seed	3.5
Spanish lime	3.0
Star apple	1.0
Starfruit	1.0
Strawberry	0.50
Sugar apple	0.30
Sunflower, seed	0.05
Tomato, paste	6.0
Tomato, puree	3.0
Vegetable, brassica leafy, group 5	3.5
Vegetable, cucurbit, group 9	0.5
Vegetable, fruiting, group 8	1.0
Vegetable, leaves of root and tuber, group 2	4.0
Vegetable, legume, group 6, except soybean	4.0
Vegetable, root and tuber, group 1, except sugar beet	0.40
Watercress	3.5
Watercress, upland	3.5
Wax jambu	1.0

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the insecticide imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl) methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid, in or on the following commodities, when present therein as a result of the application of the pesticide to growing crops listed in this section and other non-food crops as follows:

Commodity	Parts per million
Rice, grain	0.05
Vegetable, foliage of legume, group 7	2.5
Vegetable, legume, group 6	0.3

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0866; FRL–8801–6]

Cyromazine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyromazine in or on succulent beans at 2.0 parts per million (ppm). Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 28, 2010. Objections and requests for hearings must be received on or before June 28, 2010, 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–2008–0866. 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., 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: Barbara Madden, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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).
- 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 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 electronically available documents 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 e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

To access the OPPTS harmonized test guidelines referenced in this document electronically please go to *http://www.epa.gov/oppts* and select "Test Methods & Guidelines" on the left-side navigation menu.