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 FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this 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 6, 2000). Executive Order 13175, 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 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 rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of 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, copper sulfate pentahydrate.

Dated: August 3, 2006.

Frank Sanders,

Director, Antimicrobials 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 180.1021 is amended by revising paragraph (c) to read as follows:

§ 180.1021 Copper; exemption from the requirement of a tolerance.

* * * * *

(c) Copper sulfate pentahydrate (CAS Reg. No. 7758–99–8) is exempt from the requirement of a tolerance when applied as a fungicide to growing crops or to raw agricultural commodities after harvest, and as a bactericide/fungicide in or on meat, fat and meat by-products of cattle, sheep, hogs, goats, horses and poultry, milk and eggs when applied as a bactericide/fungicide to animal premises and bedding.

* * * * *

[FR Doc. E6–13082 Filed 8–10–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0542; FRL–8081–8]

Imidacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent in or on caneberry subgroup 13A; coffee, green bean; seed of: Black mustard, borage, crambe, field mustard, flax, Indian mustard, Indian rapeseed, rapeseed, safflower, and sunflower; atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple; almond hulls, pistachio and tree nut group 14; pomegranate; banana; herbs subgroup 19A dried; and herbs subgroup 19A fresh. Interregional Research Project No. 4 (IR–4), requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 11, 2006. Objections and requests for hearings must be received on or before October 10, 2006, 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–2005–0542. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), 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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather 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. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0542 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 10, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2005–0542, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of March 22, 2006 (71 FR 14524) (FRL–7769–7), 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 3E6543, PP 3E6561, PP 3E6738, PP 3E6760, PP 5E6920, PP 5E6921, PP 5E6922, PP 5E6923) by Interregional Research Project No. 4 (IR–4), 681 U.S. Highway No. 1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.472 be amended by establishing tolerances for residues of the insecticide imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid in or on the raw agricultural commodities as follows: Caneberry subgroup 13A at 0.05 parts per million (ppm) (PP 3E6543); coffee at 0.6 ppm (PP 3E6561); seed of: Black mustard, borage, crambe, field mustard, flax, Indian mustard, Indian rapeseed, rapeseed, safflower, and sunflower at 0.05 ppm (PP 3E6738); atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.2 ppm (PP 3E6760); almond hulls at 2.5 ppm; and pistachio and tree nut group 14 at 0.01 ppm (PP 5E6920); pomegranate at 0.7 ppm (PP 5E6921); banana at 0.6 ppm (PP 5E6922); herbs subgroup 19A dried at 62.0 ppm and herbs subgroup 19A fresh at 6.0 ppm (PP 5E6923).

Tolerances were later amended as follows: Coffee at 0.80 ppm (PP 3E6561); atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.30 ppm (PP 3E6760); almond hulls at 4.0 ppm; and pistachio and tree nut group 14 at 0.05 ppm (PP 5E6920); pomegranate at 0.90 ppm (PP 5E6921); banana at 0.50 ppm (PP 5E6922); herb subgroup, 19A, herbs, dried at 48.0 ppm and herb subgroup, 19A, herbs, fresh at 8.0 ppm (PP 5E6923).

In addition to establishing tolerances, EPA is also deleting several established tolerances from the tables in § 180.472(a), (b), and (d) that are no longer needed as a result of this action. The tolerance deletions under § 180.472(b) are time-limited tolerances established under section 18 emergency exemptions that are superceded by the establishment of general tolerances for imidacloprid and its metabolites under § 180.472(a).

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 tolerances for combined residues of the insecticide imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid in or on caneberry

subgroup 13A at 0.05 parts per million (ppm); coffee, green bean at 0.80 ppm; seed of: Black mustard, borage, crambe, field mustard, flax, Indian mustard, Indian rapeseed, rapeseed, safflower, and sunflower at 0.05 ppm; atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.30 ppm; almond hulls at 4.0 ppm; pistachio and tree nut group 14 at 0.05 ppm; pomegranate at 0.90 ppm; banana at 0.50 ppm; herb subgroup, 19A, herbs, dried at 48.0 ppm and herb subgroup, 19A, herbs, fresh at 8.0 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. Specific information on the studies received and the nature of the toxic 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.epa.gov/fedrgstr/EPA-PEST/2003/June/Day-13/p14880.htm*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for imidacloprid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 13, 2003 (68 FR 35303) (FRL–7310–8), or at *http://www.epa.gov/fedrgstr/EPA-PEST/2003/June/Day-13/p14880.htm*.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.472) for the combined residues of imidacloprid, in or on a variety of raw agricultural commodities. Meat, milk, poultry, and egg tolerances have also been established for the combined residues of imidacloprid. Risk assessments were conducted by EPA to assess 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.

The Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID™) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An unrefined, acute dietary exposure assessment using tolerance-level residues and assuming 100 pecent crop treated (PCT) for all registered and proposed commodities was conducted for the general U.S. population and various population subgroups. Drinking water was incorporated directly in the dietary assessment using the acute (peak) concentration for surface water generated by the FQPA Index Reservoir Screening Tool (FIRST) model.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A partially refined, chronic dietary exposure assessment using tolerance-level residues for all registered and proposed commodities, and PCT information for some commodities was conducted for the general U.S. population and various population subgroups. Drinking water was incorporated directly into the dietary assessment using the chronic (annual average) concentration for surface water generated by the FIRST model.

iii. *Cancer.* An exposure assessment related to cancer risk is unnecessary. The Agency has classified imidacloprid as a ''Group E'' chemical, no evidence of carcinogenicity for humans, by all routes of exposure based upon lack of evidence of carcinogenicity in rats and mice.

iv. *Anticipated residue and 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 the Agency can make the following findings: Condition 1, that 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 such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

For the acute assessment, 100 PCT was assumed for all registered and proposed commodities. For the chronic assessment, average weighted PCT information was used for the following commodities: Apple 30%; artichokes 5%; beets 15%; blueberries 10%; broccoli 35%; brussels sprouts 55%; cabbage 20%; cantaloupe 30%; carrots 1%; cauliflower 40%; celery 5%; cherries 5%; collards 10%; corn, field 1%; cotton 5%; cucumber 5%; eggplant 45%; grapefruit 5%; grape 30%; honeydew 10%; hops 90%; kale 30%; lemon 1%; lettuce, head 60%; orange 5%; peaches 5%; pear 10%; pepper 25%; potatoes 35%; pumpkin 5%; spinach 20%; squash 10%; strawberries 10%; sugarbeet 1%; sweet corn 1%; tangerine 10%; tomato 15%; watermelon 10%. A default value of 1% was used for all commodities which were reported as having 1 PCT.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, State, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of 5% except for those situations in which the average PCT is less than 1. In those cases 1% is used as the average and 2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available Federal, State, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of 5%. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for imidacloprid 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 physical 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 and screening concentration in ground water (SCI-GROW) models, the estimated environmental concentrations (EECs) 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. The EECs for chronic exposures are estimated to be 17.2 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 (DEEM-FCID™, Version 2.03). For acute dietary risk assessment, the peak water concentration value of 36.0 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the annual average concentration of 17.2 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).

Imidacloprid is currently registered for use on the following residential non-dietary sites: Granular products for application to lawns and ornamental plants; ready-to-use spray for application to flowers, shrubs and house plants; plant spikes for application to indoor and outdoor residential potted plants; ready-to-use potting medium for indoor and outdoor plant containers; liquid concentrate for application to lawns, trees, shrubs and flowers; ready-to-use liquid for directed spot application to cats and dogs. In addition, there are numerous registered products intended for use by commercial applicators to residential sites. These include gel baits for cockroach control; products intended for commercial ornamental, lawn and turf pest control; products for ant control; and products used as preservatives for wood products, building materials, textiles and plastics.

As these products are intended for use by commercial applicators only, they are not to be addressed in terms of residential pesticide handlers. The risk assessment was conducted using the following residential exposure assumptions: EPA has determined that residential handlers are likely to be exposed to imidacloprid residues via dermal and inhalation routes during handling, mixing, loading, and applying activities. Based on the current use patterns, EPA expects duration of exposure to be short-term (1–30 days). EPA does not expect imidacloprid to result in exposure durations that would result in intermediate-term or long-term exposure.

The scenarios likely to result in adult dermal and/or inhalation residential handler exposures are as follows:

- Dermal and inhalation exposure from using a granular push-type spreader;
- Dermal exposure from using potted plant spikes;
- Dermal exposure from using a plant potting medium;
- Dermal and inhalation exposure from using a garden hose-end sprayer (dermal and inhalation exposure from using a RTU trigger pump spray is expected to be negligible);
- Dermal and inhalation exposure from using a water can/bucket for soil drench applications; and
- Dermal exposure from using pet spot-on.

EPA has also determined that there is potential for short-term (1 to 30 days), post-application exposure to adults and children/toddlers from the many residential uses of imidacloprid. Due to residential application practices and the half-lives observed in the turf transferable residue study, intermediate-term and long-term post-application exposures are not expected. The scenarios likely to result in dermal (adult and child/toddler), and incidental non-dietary (child/toddler) short-term post-application exposures are as follows:

- Toddler oral hand-to-mouth exposure from contacting treated turf;
- Toddler incidental oral ingestion of granules;
- Toddler incidental oral ingestion of pesticide-treated soil;
- Toddler incidental oral exposure from contacting treated pet;
- Toddler dermal exposure from contacting treated turf;
- Toddler dermal exposure from hugging treated pet/contacting treated pet;
- Adult dermal exposure from contacting treated turf;
- Adult golfer dermal exposure from contacting treated turf;
- Adolescent golfer dermal exposure from contacting treated turf; and
- Adult dermal exposure from contacting treated pet;

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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 imidacloprid and 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 not assumed that imidacloprid 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 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor (SF) value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study. There is evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study, but the concern is low since:

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 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*. There is a complete toxicity data base for imidacloprid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X for the following reasons:

The toxicological data base is complete for FQPA assessment.

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

The chronic dietary food exposure assessment utilizes existing and proposed tolerance level residues and PCT data verified by the Agency for several existing uses. For all proposed uses, 100 PCT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.

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 estimates of water concentrations which will not likely be exceeded.

The residential handler assessment is based upon the residential standard operating procedures (SOPs) in conjunction with chemical-specific study data in some cases and the Pesticide Handlers Exposure Database (PHED) unit exposures in other cases. The majority of the residential post-application assessment is based upon chemical-specific turf transferrable residue 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.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at *http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf*.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs. The risk assessment for imidacloprid used in this tolerance document uses this approach of incorporating water exposure directly into the dietary exposure analysis.

1. *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 26% of the acute population adjusted dose (aPAD) for the U.S. population, 18% of the aPAD for females 13 years and older, 54% of the aPAD for all infants 1 year old, and 67% of the aPAD for children 1–2 years old. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to imidacloprid from food and water will utilize 11% of the chronic population adjusted dose (cPAD) for the U.S. population, 22% of the cPAD for all infants 1 year old, and 33% of the cPAD for children 1–2 years old. Based on the use pattern, chronic residential exposure to residues of imidacloprid is not expected. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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

Imidacloprid is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for imidacloprid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in worst-case aggregate MOEs of 320 for the general U.S. population and 170 for children 1–2 years old, the sub-population at greatest exposure. These

aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food, water and residential uses.

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

Intermediate- and long-term aggregate risk assessments were not performed because, based on the current use patterns, the Agency does not expect exposure durations that would result in intermediate- or long-term exposures.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified imidacloprid as a ''Group E'' chemical, no evidence of carcinogenicity for humans, by all routes of exposure based upon lack of evidence of carcinogenicity in rats and mice. Imidacloprid is not expected to pose a cancer risk.

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, and to infants and children from aggregate exposure to imidacloprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plant (Bayer Gas Chromatography/Mass Spectrometry (GC/MS) Method 00200) and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA petition method validations (PMVs), and the registrant has fulfilled the remaining requirements for additional raw data, method validation, independent laboratory validation (ILV), and an acceptable confirmatory method (High Performance Liquid Chromatography/Ultraviolet (HPLC/UV) Method 00357). The validated limit of detection (LOD) and limit of quantitation (LOQ) for the GC/MS Method 00200 are 0.01 and 0.05 ppm, respectively, in plant commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

There are no established Mexican maximum residue limits (MRLs) for the proposed 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 rapeseed at 0.05 ppm and banana at 0.05 ppm. In addition, there is currently Canadian MRLs for: 1-[(6-chloro-3-pyridinyl) methyl]-4,5-dihydro-*N*-nitro-1H-imidazol-2-amine, including metabolites containing the 6-chloropicolyl moiety in or on mustard, seed at 0.05 ppm, rapeseed (canola) at 0.05 ppm and pecans at 0.05 ppm. The Codex and Canadian MRLs for rapeseed (canola) is the same as the U.S. recommended tolerance for rapeseed, seed; and the Canadian MRL for pecans is the same as the U.S. recommended tolerance. However, the Canadian MRL for banana is not equivalent to the U.S. recommended tolerance as the available crop field trial data supported a higher tolerance level. Therefore, harmonization is not possible at this time.

V. Conclusion

Therefore, the tolerances are established for combined residues of the insecticide imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid in or on caneberry subgroup 13A at 0.05 ppm; coffee, green bean at 0.80 ppm; seed of: Black mustard, borage, crambe, field mustard, flax, Indian mustard, Indian rapeseed, rapeseed, safflower, and sunflower at 0.05 ppm; atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.30 ppm; almond hulls at 4.0 ppm; pistachio at 0.05 ppm; tree nut group 14 at 0.05 ppm; pomegranate at 0.90 ppm; banana at 0.50 ppm; herb subgroup, 19A, herbs, dried at 48.0 ppm and herb subgroup, 19A herbs, fresh at 8.0 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 final 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 FFDCA. For these same reasons, the Agency has determined that this 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 6, 2000). Executive Order 13175, 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 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 rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of 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: August 1, 2006.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

§ 180.472 Imidacloprid; tolerances for residues.

(a) *General.* Tolerances are established permitting the combined residues of the insecticide imidacloprid (1-[6-chloro-3-pyridinyl) methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, in or on the following food commodities:

Commodity	Parts Per Million
Acerola	1.0
Almond, hulls	4.0
Apple	0.5
Apple, wet pomace	3.0
Atemoya	0.30
Artichoke, globe	2.5
Avocado	1.0
Banana	0.50
Barley, grain	0.05
Barley, hay	0.5
Barley, straw	0.5
Beet, sugar, roots	0.05
Beet, sugar, tops	0.5
Beet, sugar, molasses	0.3
Biriba	0.30
Blueberry	3.5
Borage, seed	0.05
Caneberry, subgroup 13A	0.05
Canistel	1.0
Canola, seed	0.05
Cattle, fat	0.3
Cattle, meat byproducts	0.3
Cattle, meat	0.3
Cherimoya	0.3
Citrus, dried pulp	5.0
Coffee, green bean	0.80
Corn, field, forage	0.10
Corn, field, grain	0.05
Corn, field, stover	0.20
Corn, pop, grain	0.05
Corn, pop, stover	0.20
Corn, sweet, forage	0.10
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.20
Cotton, gin byproducts	4.0
Cotton, undelinted seed	6.0
Cotton, meal	8.0
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	0.7
Fruit, pome, group 11	0.6
Fruit, stone, group 12	3.0
Goat, fat	0.3
Goat, meat byproducts	0.3
Goat, meat	0.3
Gooseberry	3.5
Grape, juice	1.5
Grape, pomace (wet or dried)	5.0
Grape, raisin	1.5
Grape, raisin, waste	15.0
Grape	1.0
Guava	1.0
Herbs subgroup 19A, dried herbs	48.0
Herbs subgroup 19B, fresh herbs	8.0
Hog, fat	0.3
Hog, meat byproducts	0.3
Hog, meat	0.3
Hop, dried cone	6.0
Horse, fat	0.3
Horse, meat byproducts	0.3
Horse, meat	0.3
Huckleberry	3.5
Ilama	0.30
Jaboticaba	1.0
Juneberry	3.5
Leaf petioles subgroup 4B	6.0
Leafy greens subgroup 4A	3.5
Lettuce, head and leaf	3.5
Lingonberry	3.5
Longan	3.0
Lychee	3.0
Mango	1.0
Milk	0.1
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
Oats, forage	2.0
Oats, grain	0.05
Oats, hay	6.0
Oats, straw	3.0
Okra	1.0
Passionfruit	1.0
Papaya	1.0
Pecans	0.05
Persimmon	3.0
Pistachio	0.05
Pomegranate	0.90
Potato, chip	0.4
Potato, waste	0.9
Poultry, fat	0.05
Poultry, meat byproducts	0.05
Poultry, meat	0.05
Pulasan	3.0
Rambutan	3.0
Rapeseed, seed	0.05
Rye, forage	2.0
Rye, grain	0.05
Rye, hay	6.0
Rye, straw	3.0
Safflower, seed	0.05
Salal	3.5
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
Sheep, fat	0.3
Sheep, meat byproducts	0.3
Sheep, meat	0.3
Sorghum, forage	0.10
Sorghum, grain	0.05
Sorgum, stover	0.10
Soursop	0.30
Soybean, meal	4.0
Soybean, seed	1.0
Spanish lime	3.0
Star apple	1.0
Starfruit	1.0
Strawberry	0.50

Commodity	Parts Per Million
Sugar apple	0.30
Sunflower, seed	0.05
Tomato, paste	6.0
Tomato, pomace (wet or dried)	4.O
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, except soybean, group 6	4.0
Vegetable, root and tuber, group 1, except sugar beet	0.40
Watercress	3.5
Watercress, upland	3.5
Wax jambu	1.0
Wheat, forage	7.0
Wheat, grain	0.05
Wheat, hay	0.5
Wheat, straw	0.5

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent combined residues of the insecticide imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, 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
Forage, fodder, and straw of Grain, cereal crop group (forage)	2.0
Forage, fodder, and straw of Grain, cereal crop group (hay)	6.0
Forage, fodder, and straw of Grain, cereal crop group (stover)	0.3
Forage, fodder, and straw of Grain, cereal crop group (straw)	3.0
Grain, cereal, group 15	0.05
Sweet corn, kernel plus cob with husks removed	0.05
Vegetable, foliage of legume, group 7	2.5
Vegetable, legume, crop group 6	0.3

[FR Doc. E6–13092 Filed 8–10–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0366; FRL–8081–7]

Bifenthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenthrin in or on Vegetable, tuberous and corm, subgroup 1C; Brassica, leafy greens, subgroup 5B; turnip, greens; Pea and bean, dried shelled, except soybean, subgroup 6C; coriander, leaves; coriander, dried leaves; coriander, seed and okra. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting an existing time-limited bifenthrin tolerance that is no longer needed as a result of this action.

DATES: This regulation is effective August 11, 2006. Objections and requests for hearings must be received on or before October 10, 2006, 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–2006–0366. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), 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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather 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. How Can I Access Electronic Copies of this Document?

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA