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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0968; FRL–8135–5]

Imidacloprid; Pesticide Tolerance

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 peanut, peanut hay and peanut meal; pearl millet grain, forage, hay and straw; proso millet grain, forage, hay and straw; kava roots and leaves; raspberry, wild; soybean forage and hay; and aspirated grain fractions. It also amends existing tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in or on caneberry subgroup 13-A and soybean seed. Bayer CropScience LLC and Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also corrects a typographical error in the commodity term for the existing tolerance on the herbs subgroup, fresh herbs.

DATES: This regulation is effective June 20, 2007. Objections and requests for hearings must be received on or before August 20, 2007, 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–2006–0968. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*,or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: 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 those engaged in the following activities:

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

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

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

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0968 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 August 20, 2007.

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–2006–0968, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of December 20, 2006 (71 FR 76321) (FRL–8104–4), 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 6E7108 and PP 6E7116) 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 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 peanut at 0.45 parts per million (ppm); peanut, hay at 70 ppm; peanut, meal at 0.9 ppm; kava, roots at 0.4 ppm; kava, leaves at 4.0 ppm; millet, pearl, grain at 0.05 ppm; millet, proso, grain at 0.05 ppm; and oat, grain at 0.05 (all requested in PP 6E7116); and on caneberry subgroup 13A and raspberry, wild at 2.5 ppm (requested in PP 6E7108). That notice included summaries of the petitions prepared by IR-4, which are available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of July 14, 2006 (71 FR 40099) (FRL–8060–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F7049) by Bayer CropScience LLC, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. The petition 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, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid, in or on soybean, aspirated grain fractions at 240.0 parts per million (ppm); soybean, forage at 8.0 ppm; soybean, hay at 30.0 ppm; and soybean, seed at 1.6 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience LLC, 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 petitions, EPA has modified the proposed tolerances. The modifications and reasons for these changes are explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 the 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 the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2- imidazolidinimine, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in or on peanut at 0.45 ppm; peanut, hay at 35 ppm; peanut, meal at 0.75 ppm; millet, proso, grain at 0.05 ppm; millet, proso, forage at 2.0 ppm; millet, proso, hay at 6.0 ppm; millet, proso, straw at 3.0 ppm; millet, pearl, grain at 0.05 ppm; millet, pearl, forage at 2.0 ppm; millet, pearl, hay at 6.0 ppm; millet, pearl, straw at 3.0 ppm; kava, roots at 0.40 ppm; kava, leaves at 4.0 ppm; caneberry, subgroup 13-A at 2.5 ppm; raspberry, wild at 2.5 ppm; soybean, seed at 3.5 ppm; soybean, forage at 8.0 ppm; soybean hay at 35 ppm and aspirated grain fractions at 240 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 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 are discussed in the final rule published in the **Federal Register** of June 13, 2003 (68 FR 35303), (FRL–7310–8); available 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 toxicological level of concern (LOC) is derived from the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL of concern are identified is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for 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); available 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*. 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 assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996, and 1998 Nationwide CSFII. As to residues in food, EPA assumed tolerance-level residues for all registered and proposed commodities. EPA relied on percent crop treated (PCT) information for some registered commodities but assumed 100 PCT for all proposed new uses.

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:

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 such pesticide residue;

b. The exposure estimate does not underestimate exposure for any significant subpopulation group; and

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 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 dietary 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: Apples (30%), artichokes (5%), garden beets (15%), blueberry (10%), broccoli (35%), brussels sprouts (55%), cabbage (20%), cantaloupe (30%), carrots (<1%), cauliflower (40%), celery (5%), cherries (5%), collards (10%), corn, field and sweet (<1%), cotton (5%), cucumbers (5%), eggplant (45%), grapefruit (5%), grapes (30%), honeydew (10%), hops (90%), kale (30%), lemons (<1%), lettuce (60%), oranges (5%), peaches (5%), pears (10%), peppers (25%), potatoes (35%), pumpkin (5%), spinach (20%), squash (10%), sugar beets (<1%), tangerines (10%), tomatoes (15%), and 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 five percent except for those situations in which the average PCT is less than one. 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 five percent. In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, 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 2 and 3, 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 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 lacks sufficient monitoring 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 environmental fate 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 Screening Tool Reservoir (FIRST) and Screening Concentration in groundwater (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. 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 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 (RTU) potting medium for indoor and outdoor plant containers; liquid concentrate for application to lawns, trees, shrubs and flowers; and 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 handler.

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 use to 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 compared to exposures using a garden hose-end sprayer and is, therefore, not assessed separately).

Dermal and inhalation exposure from using a water can/bucket for soil drench applications.

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 of 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 oral 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 pet.
- Toddler incidental oral exposure from contacting treated pet.
- Toddler dermal exposure from hugging treated pet/contacting treated pet.
- Toddler dermal exposure from contacting treated turf.
- Adult dermal exposure from contacting treated turf.
- Adult golfer dermal exposure from contacting treated turf.
- Adolescent golfer dermal exposure from contacting treated turf.
- 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (10X) tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the 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. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety 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 2-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 pre-natal/post-natal toxicity in this study

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for imidacloprid is complete.

ii. Although there is evidence of qualitative susceptibility in the developmental neurotoxicity study in the rat, the concern is low and there are no residual uncertainties for pre-natal/post-natal toxicity, as discussed in Unit III.

iii. There is no evidence that imidacloprid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. 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 assumptions, 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. Conservative ground and surface water modeling estimates were used to estimate both acute and chronic exposures to residues of imidacloprid in drinking water. 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 transferable residue data or other chemical-specific post-application exposure study data. The chemical-specific study data and surrogate study data used are reliable and are not expected to underestimate risk to adults or 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 will not underestimate the exposure and risks posed by imidacloprid.

E. Aggregate Risks and Determination of Safety

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

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 70% of the aPAD for the population group (children, 1 to 2 years old) receiving the greatest exposure. Therefore, 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 38% of the cPAD for the population group (children, 1 to 2 years old) receiving the greatest exposure. Based on the residential use patterns, chronic residential exposure to residues of imidacloprid is not expected. Therefore, 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, water, and residential exposures aggregated result in aggregate MOEs of 310 for the general U.S. population and 170 for children, 1 to 2 years old, the population with the highest estimated aggregate short-term exposure to imidacloprid. These aggregate MOEs are based on the pet-treatment scenario, the use scenario resulting in the highest estimated residential exposures for adults and children. Post-application exposures from pet treatment and turf treatment were not combined in the short-term aggregate assessment, because of the low probability of these exposures co-occurring.

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-term and long-term aggregate risk assessments were not performed because, based on the current use patterns for imidacloprid, the Agency does not expect exposures of intermediate- or long-term durations to occur.

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, or 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 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 Canadian or Mexican Maxium Residue Levels (MRLs) for the proposed uses. There is an established Codex MRL for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid, in/on cereal grain at 0.05 ppm, which is consistent with U.S. tolerances on cereal grains.

V. Conclusion

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as follows: 1. Added tolerances for millet, proso, forage at 2.0 ppm; millet, proso, hay at 6.0 ppm; millet, proso, straw at 3.0 ppm; millet, pearl, forage at 2.0 ppm; millet, pearl, hay at 6.0 ppm; and millet, pearl, straw at 3.0 ppm (all in PP 6E7116); 2. Revised tolerances for peanut, hay at 35 ppm and peanut, meal at 0.75 ppm (PP 6E7116); soybean, hay at 35 ppm and soybean, seed at 3.5 ppm (PP 6F7049); and 3. Changed the commodity term ''soybean, aspirated grain fractions'' (PP 6F7049) to ''aspirated grain fractions'', the recommended commodity term in the Office of Pesticide Program's Food and Feed Commodity Vocabulary. The proposed tolerance on oat grain (PP 6E7116) is not needed, since a tolerance of 0.05 ppm for oat, grain already exists. EPA determined that tolerances for millet forage, hay and straw are needed based on residue data for similar grain crops showing residues in these commodities. EPA determined that the proposed tolerances for peanut hay/meal and soybean hay/seed were inappropriate and should be revised based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP).

Therefore, tolerances are established for combined residues of 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 peanut at 0.45 ppm; peanut, hay at 35 ppm; peanut, meal at 0.75 ppm; millet, proso, grain at 0.05 ppm; millet, proso, forage at 2.0 ppm; millet, proso, hay at 6.0 ppm; millet, proso, straw at 3.0 ppm; millet, pearl, grain at 0.05 ppm; millet, pearl, forage at 2.0 ppm; millet, pearl, hay at 6.0 ppm; millet, pearl, straw at 3.0 ppm; kava, roots at 0.40 ppm; kava, leaves at 4.0 ppm; caneberry, subgroup 13-A at 2.5 ppm; raspberry, wild at 2.5 ppm; soybean, seed at 3.5 ppm; soybean, forage at 8.0 ppm; soybean hay at 35 ppm and aspirated grain fractions at 240 ppm.

In the **Federal Register** of August 11, 2006 (71 FR 46110) (FRL–8081–8), EPA established a tolerance for residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in or on the commodity ''Herbs subgroup 19B, fresh herbs''. The correct commodity term is ''Herbs subgroup 19-A, fresh herbs''. Therefore, the tolerance for this commodity is revised to read ''Herbs subgroup 19-A, fresh herbs'' at 8.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 11, 2007.

Donald R. Stubbs,

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, the table in paragraph (a) is amended by alphabetically adding commodities; by revising the entries for ''Caneberry, subgroup 13A'' and ''Soybean'' seed, and revising the entry ''Herbs, subgroup 19B, fresh herbs'', to read ''Herbs, subgroup 19-A, fresh herbs''.

The amendments read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Aspirated grain fractions	240
* * * * *	
Caneberry, subgroup 13-A	2.5
* * * * *	
Herbs subgroup 19-A, fresh herbs	8.0
* * * * *	
Kava, leaves	4.0

Commodity	Parts per million
Kava, roots	0.40
* * * * *	
Millet, pearl, forage	2.0
Millet, pearl, grain	0.05
Millet, pearl, hay	6.0
Millet, pearl, straw	3.0
Millet, proso, forage	2.0
Millet, proso, grain	0.05
Millet, proso, hay	6.0
Millet, proso, straw	3.0
* * * * *	
Peanut	0.45
Peanut, hay	35
Peanut, meal	0.75
* * * * *	
Raspberry, wild	2.5
* * * * *	
Soybean, forage	8.0
Soybean, hay	35
* * * * *	
Soybean, seed	3.5
* * * * *	

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[FR Doc. E7–11792 Filed 6–19–07; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[FCC 07–94]

Increase of Forfeiture Maxima for Obscene, Indecent, and Profane Broadcasts to Implement the Broadcast Decency Enforcement Act of 2005

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the Commission's Rules to increase the maximum forfeiture penalties for obscene, indecent, and profane broadcasts from $32,500 to $325,000 for each violation or each day of a continuing violation, except that the amount assessed for any continuing violation cannot exceed $3,000,000. This action is necessary to implement The Broadcast Decency Enforcement Act of 2005, signed into law by President George W. Bush on June 15, 2006. This document is limited to revising the Commission's Rules pursuant to the Broadcast Decency Enforcement Act, which concerns only penalties for obscenity, indecency, and profanity broadcast violations. The existing penalty limits described in the Commission's Rules would remain as the applicable maxima for all other broadcast violations subject to those Rules.

DATES: Effective July 20, 2007.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Hillary S. DeNigro, Enforcement Bureau, Investigations and Hearings Division, (202) 418–7334.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, FCC 07–94, adopted on May 17, 2007, and released on June 1, 2007. The complete text of this Order is available for inspection and copying during normal business hours in the FCC Reference Information Center, Courtyard Level, 445 12th Street, SW., Washington, DC 20554 and also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., at 1–800–378–3160, CY–B402, 445 12th Street, SW., Washington, DC 20554.

On June 15, 2006, President George W. Bush signed into law The Broadcast Decency Enforcement Act of 2005 (''Broadcast Decency Enforcement Act''). (*See* Pub. L. 109–235, 120 Stat. 491 (2006)). The legislation amends section 503(b)(2) of the Communications Act of 1934, as amended (''Communications Act''), 47 U.S.C. 503(b)(2), to increase the maximum forfeiture penalties for obscene, indecent, and profane broadcasts. This Order amends section 1.80(b)(1) of the Commission's Rules (''Rules''), 47 CFR 1.80(b)(1), to reflect the new penalties.

Section 1.80(b)(1) of the Rules specifies the maximum possible forfeiture penalties for a range of violations, including, but not limited to: Failure to comply with the terms and conditions of any Commission license, permit, certificate or instrument of authorization; failure to comply with any provision of the Communications Act or any Commission rule, regulation or order; and violation of section 1304 (broadcast of lottery information), 1343