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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA-HQ-OPP-2012-0204; FRL-9387-9]**

#### **Imidacloprid; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of imidacloprid in or on fish and fish-shellfish, mollusc requested by the Interregional Research Project Number 4 (IR-4) under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this regulation establishes time-limited tolerances for residues of imidacloprid in or on sugarcane, cane and sugarcane, molasses. This action is associated with the use of the pesticide on sugarcane under a crisis exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The time-limited tolerances expire on December 31, 2015.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0204, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm.

3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; email address: *jackson.sidney@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

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

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0204 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0204, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at  
<http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of May 23, 2012 (77 FR 30481) (FRL-9347-8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E7988) by IR-4, IR-4 Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition 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, in or on fish at 0.05 parts per million (ppm), and fish-shellfish, mollusc at 0.05 ppm. That document referenced a summary of the petition prepared by the Willapa-Grays Harbor Oyster Growers Association, the registrant, which is available in the docket, <http://www.regulations.gov>.

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

## **III. Time-Limited Tolerance for Sugarcane**

Also in this action, EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-

limited tolerances for residues of imidacloprid in or on sugarcane, cane at 6.0 ppm and sugarcane, molasses at 50 ppm. These time-limited tolerances expire on December 31, 2015.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party. Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

The Agency is establishing these time-limited tolerances in response to a crisis exemption request under FIFRA section 18 on behalf of the Louisiana Department of Agriculture and Forestry, for the emergency use of imidacloprid on sugarcane to control West Indian cane fly (*Saccharosydne saccharivora*). This was the first emergency exemption request for the use of imidacloprid on sugarcane.

As part of its assessment of the emergency exemption request, EPA assessed the potential risks presented by the residues of imidacloprid in or on sugarcane, cane and

sugarcane, molasses. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary time-limited tolerances under section 408(1)(6) of the FFDCA would be consistent with the safety standard. Consistent with the need to move quickly on the emergency exemption in order to address the urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these time-limited tolerances without notice and opportunity for public comment, as provided for in section 408(1)(6). Although, these time-limited tolerances expire and are revoked on December 31, 2015, under section 408(1)(5) of the FFDCA, residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on sugarcane, cane and sugarcane, molasses after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data, or other relevant information on this pesticide indicates that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether imidacloprid meets EPA's registration requirements for use on sugarcane or whether permanent tolerances for this use would be appropriate. Under this circumstance, EPA does not believe that the time-limited tolerances provide a basis for registration of sugarcane by a State for special local needs under FIFRA section 24(c). Nor do the time-limited tolerances serve as the basis for any State other than Louisiana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA

section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for imidacloprid, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for imidacloprid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with imidacloprid follows.

##### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their 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.

The main targets of toxicity following oral administration of imidacloprid in mammalian systems were the nervous system and the thyroid. The most sensitive species tested was the rat. Evidence of neurotoxicity was reported in the rat acute neurotoxicity (ACN) study as changes in clinical signs and functional-observation battery (FOB) measurements, including decreased motor and locomotor activities, tremors, gait abnormalities, increased righting reflex impairments and body temperature, decreased number of rears and response to stimuli, and decreases in forelimb and hindlimb grip strength. Also, in a rat developmental neurotoxicity (DNT) study where imidacloprid was administered to pregnant/lactating dams in the diet, there were decreases in offspring motor activity measurements and a small but statistically significant decrease in the caudate/putamen width in the brain of female pups. No neurotoxic effects were reported in any other toxicity study including the rat subchronic neurotoxicity study. Long-term dietary exposure to imidacloprid in chronic toxicity studies resulted in an increased incidence of mineralized particles in the thyroid colloid in rats, decreased body weights in mice, and no toxic effects in dogs. No toxic effects were reported via the dermal route in rabbits or via the inhalation route in rats at the highest dose or concentration tested. No evidence of increased qualitative or quantitative susceptibility was found in either rats or rabbits in prenatal developmental toxicity studies or in rats in a two-generation

reproductive toxicity study. Increased qualitative susceptibility was indicated in the rat DNT study, however; the neurotoxic offspring effects noted above occurred in the presence of maternal decreased food consumption and body weight gain, and a clear maternal no-observed-adverse-effect level (NOAEL) was established. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies, and imidacloprid was not genotoxic in a variety of assays.

The toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. Results of an acceptable immunotoxicity study in rats showed no immunotoxic effects at the highest dose level tested.

Specific information on the studies received and the nature of the adverse effects caused by imidacloprid as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Imidacloprid - Section 3 Request for use on Oyster Beds in Washington (WA), and Section 18 Emergency Exemption Request for use on Sugarcane in Louisiana (LA). Human-Health Risk Assessment,” dated March 7, 2013 at pp. 41-44 in docket ID number EPA-HQ-OPP-2012-0204-0008.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which

the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for imidacloprid used for human risk assessment is shown in Table 1 of this unit.

**Table 1.--Summary of Toxicological Doses and Endpoints for imidacloprid for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	LOAEL = 42 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 3x	Acute RfD = 0.14 mg/kg/day  aPAD = 0.14 mg/kg/day	Acute neurotoxicity – rat LOAEL = 42 mg/kg/day based upon the decrease in motor and locomotor activities observed in females
Chronic dietary (All populations)	NOAEL= 5.7 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.057 mg/kg/day  cPAD = 0.057 mg/kg/day	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males

Incidental Oral Short-term (1-30 days) Intermediate-term (1 to 6 months)	NOAEL= 10 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Prenatal developmental toxicity – rat LOAEL = 30 mg/kg/day based on decreased maternal body weight gain
Incidental Oral Long Term (> 6 months)	NOAEL= 5.7 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males
Dermal Short-term (1 to 30 days) Intermediate-term (1 to 6 months)	Oral study NOAEL = 10 mg/kg/day (dermal absorption = 7.2%) NOAEL = 10 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Prenatal developmental toxicity – rat LOAEL = 30 mg/kg/day based on decreased maternal body weight gain
Dermal Long-term (> 6 months)	Oral study NOAEL= 5.7 mg/kg/day (dermal absorption = 7.2%) NOAEL= 5.7 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males
Inhalation Short- (1 - 30 days) & Intermediate- (1-6 months) terms	Oral study NOAEL= 10 mg/kg/day (inhalation absorption = 100%) $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Prenatal developmental toxicity – rat LOAEL = 30 mg/kg/day based on decreased maternal body weight gain
Long-Term Inhalation (> 6 months)	Oral study NOAEL = 5.7 mg/kg/day (inhalation absorption = 100%) $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in

			thyroid colloid in males
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans" based on no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### *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, the use on sugarcane under the FIFRA section 18 emergency exemption authorized by EPA, 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.

Such effects were identified for imidacloprid. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined, acute dietary exposure assessment using tolerance-level residues and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA conducted a partially refined chronic dietary exposure assessment using tolerance-level residues for all commodities and PCT information for some registered commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that imadicloprid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

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

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

The Agency estimated the PCT for existing uses as follows: For the chronic assessment, the following average weighted PCT information was used: Almonds 1%;

apples: 30%; artichokes: 5%; avocados: 1%; beans, green: 5%; blueberries: 10%; broccoli: 55%; cabbage: 25%; caneberries: 10%; cantaloupe: 40%; carrots: 1%; cauliflower: 50%; celery: 10%; cherries: 15%; corn (seed treatment): 2.5%; cotton: 5%; cotton : 5%; cucumbers: 5%; dry beans/peas: 1%; eggplant: 60%; filberts (hazelnuts): 2.5%; grapefruit: 25%; grapes: 30%; honeydew: 30%; lemons: 5%; lettuce: 65%; onions: 1%; oranges: 20%; peaches: 5%; peanuts: 1%; pears: 5%; peas, green: 2.5%; pecans: 15%; peppers: 15%; pistachios: 1%; potatoes: 35%; prunes: 1%; pumpkin: 10%; sorghum: 15%; soybeans: 5%; spinach: 20%; squash: 15%; strawberries: 10%; sugar beets: 2.5%; sweet corn: 1%; tangerines: 10%; tobacco: 25%; tomatoes: 25%; walnuts: 5%; watermelon: 20%; wheat: 10%.

In most cases, EPA uses available data from the United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

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

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

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water

concentrations (EDWCs) of imidacloprid for acute exposures are estimated to be 36.0 parts per billion (ppb) for surface water and 2.09 ppb for ground water.

For chronic exposures, assessments 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). The proposed use of imidacloprid on oyster beds is professionally applied and not expected to result in residential handler exposure, but can result in residential post-application exposures via potential contact with residues in the oyster bed water or sediment during recreational swimming, or in the case of subsistence fishermen or local Native American tribes, collecting oysters. There are no residential uses associated with the proposed Section 18 Emergency Exemption use on sugarcane. Imidacloprid is currently registered for the following uses that could result in residential exposures: Residential lawns and gardens, indoor uses for bed bugs and crack-and-crevice treatments, pet uses in spot-on treatments and collars, and pre- and post-construction termiticide and wood preservative uses. EPA assessed residential exposure using the assumption that residential pesticide handlers (i.e., persons who might mix, load and, or apply a pesticide material) could be

exposed to several formulations that contain imidacloprid as well as the pest spectra, sites of application, methods of application, formulations and the retreatment intervals.

For the registered imidacloprid residential uses, in general, short-term dermal, inhalation, and incidental oral post-application exposures are expected. Intermediate- and long-term dermal, incidental oral and inhalation exposures are expected from the pet collar use, as it presents the potential for prolonged exposure via a continuous source and frequent contact (i.e., playing with pets). Short-term dermal and inhalation handler exposures are expected. The Agency also assessed potential for post-application exposure for adults and children as a result of both the proposed use on oyster beds and from existing residential uses. Based on the proposed oyster bed use pattern, only short-term post-application dermal, incidental oral, and inhalation exposures to imidacloprid residues in affected water and sediment are expected. The exposure assessment used equations and inputs that are generally derived from SWIMODEL 3.0, developed by EPA as a screening tool to conduct exposure assessments of pesticides found in swimming pools and spas and EPA's Risk Assessment Guidance for Superfund – Part E, Supplemental Guidance for Dermal Risk Assessment ("RAGS-E").

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

#### *4. Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning

the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased quantitative or qualitative susceptibility was found in rats and rabbits in the prenatal developmental toxicity studies or in rats in the two-generation reproductive toxicity study, where developmental effects were observed at the same or higher doses than those causing

maternal effects. Increased qualitative susceptibility was found in the rat DNT study, but the concern is low based on the following observations:

i. The pup effects (body-weight deficits, decreased motor activity, and small decrease in female caudate/putamen width) which occurred only in the presence of maternal toxicity (decreased body weight gain and food consumption) are well-characterized with a clear maternal NOAEL that is protective of both maternal and pup effects.

ii. The doses selected for regulatory purposes are lower and thus protective of the pup effects noted in the DNT study, which occurred at higher doses of imidacloprid.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all exposure scenarios, except for the acute dietary assessment. For the acute dietary assessment, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3X. Those decisions are based on the following findings:

i. The toxicity database for imidacloprid contains all the required studies, although the acute neurotoxicity study, which was selected for determining the acute dietary endpoint, lacks a NOAEL. An FQPA SF of 3X is retained for the acute dietary endpoint in the form of a database uncertainty factor (UF) for lack of a NOAEL. EPA has determined that an FQPA safety factor of 3X is adequate to protect infants and children because the effect (decreased motor and locomotor activity), which occurred at the LOAEL is minimal and not statistically different from the control group.

Furthermore, the LOAEL of 42 mg/kg/day is comparable to the LOAEL of 55 mg/kg/day

for offspring effects (which includes decreased motor activity) in the rat DNT study, and the extrapolated NOAEL from the acute neurotoxicity study of 14 mg/kg/day ( $42/3 = 14$ ) is comparable to and more protective than the NOAEL of 20 mg/kg/day established in the DNT for offspring effects.

ii. There was evidence of neurotoxicity in the rat neurotoxicity studies.

Evidence of neurotoxicity was reported in the rat acute neurotoxicity study as discussed above in Unit IV.A. Also, in a rat DNT study where imidacloprid was administered to pregnant/lactating dams in the diet, there were decreases in offspring motor activity measurements and a small but statistically significant decrease in the caudate/putamen width in the brain of female pups. Well-defined NOAELs were achieved in the study, therefore the concern is low. No adverse neurotoxic effects were reported in any other toxicity study including the rat subchronic neurotoxicity study.

iii. Although the prenatal developmental studies in rats and rabbits and the 2-generation reproduction study in rats did not show evidence that imidacloprid results in increased susceptibility *in utero* or in offspring, respectively, the rat DNT study showed evidence of increased qualitative susceptibility in pups. For the reasons discussed in Unit IV.D.2, however, the concern for this susceptibility is low. Therefore, there are no residual uncertainties for prenatal/postnatal toxicity in this study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment utilizes tolerance-level residues and 100 PCT information for all commodities. The chronic food exposure assessment utilizes tolerance-level residues for all commodities and PCT data for some existing uses and 100 PCT for all proposed uses. EPA made conservative (protective) assumptions in the

dietary drinking water assessment utilizing water concentration values generated by models and associated modeling parameters, which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by imidacloprid.

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

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 74% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic dietary exposure, EPA has concluded that chronic exposure to imidacloprid from food and water will utilize 28% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of imidacloprid (food and drinking water) and long-term residential uses. High-end estimates of residential exposure are

used, and average values are used for food and drinking water exposures. Based on the proposed and existing use patterns, there is potential for long-term residential exposure from the pet-collar use, as it presents the potential for prolonged exposure via a continuous source and frequent contact (i.e., playing with pets). Using the exposure assumptions described in this unit for long-term exposures, EPA has concluded the combined average food and water and long-term residential exposures result in aggregate MOEs of 760 for adults and 230 for children 1-2 years old, the population subgroup receiving the greatest exposure. Because EPA's level of concern for imidacloprid is a MOE of 100 or below, these MOEs are not of concern.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Imidacloprid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to imidacloprid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 240 for adults from the combined dermal post-application exposures from contacting treated lawns and gardens which resulted in the highest short-term exposure and an aggregate MOE of 120 for children from the combined dermal and hand-to-mouth exposure from contacting treated wood surfaces which resulted in the highest short-term exposure. Because EPA's level of concern for imidacloprid is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Although there is potential for intermediate-term residential exposure from the registered pet collar use, an intermediate-term aggregate assessment was not conducted. The short- and intermediate-term toxicological endpoints are the same; therefore, the exposures assessed in the short-term aggregate (adults - combined dermal post-application exposures from contacting treated lawns and gardens; and children - combined dermal and hand-to-mouth from contacting treated wood surfaces) are protective of those for intermediate-term duration exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, imidacloprid is not expected to pose a cancer risk to humans. Therefore, a quantitative cancer risk assessment is not needed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to imidacloprid residues.

## **V. 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 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; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no established Codex, MRLs for imidacloprid on fish; fish-shellfish, mollusc; or sugarcane.

#### **VI. Conclusion**

Therefore, tolerances are established for residues of imidacloprid (1-[6-chloro-3-pyridinyl] methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, in or on fish at 0.05 ppm, and fish-shellfish, mollusc at 0.05 ppm.

In addition, this regulation establishes time-limited tolerances for residues of imidacloprid in or on sugarcane, cane at 6.0 ppm and sugarcane, molasses at 50 ppm.

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

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

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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 FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action 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: May 23, 2013.

G. Jeffrey Herndon,

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

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

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

2. Section 180.472 is amended by adding alphabetically the following commodities to the table in paragraph (a) and adding paragraph (b) to read as follows:

**§ 180.472 Imidacloprid; tolerances for residues**

(a) \* \* \*

<b>Commodity</b>	<b>Parts per million</b>
* * *	* *
Fish	0.05
Fish-shellfish, mollusc	0.05
* * *	* *

- (b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide imidacloprid, including its metabolites and degradates in connection with use of the pesticide under a Section 18 emergency exemption granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl] methyl)-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid. These tolerances will expire and are revoked on the dates specified in the following table:

<b>Commodity</b>	<b>Parts per million</b>	<b>Expiration/Revocation Date</b>
Sugarcane, cane	6.0	12/31/15
Sugarcane, molasses	50	12/31/15

\* \* \* \*

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