not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 28, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, and Reporting and recordkeeping requirements.

Dated: January 7, 2005.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

■ Chapter I, title 40, *Code of Federal Regulations*, is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart PP—South Carolina

■ 2. Section 52.2120(c) is amended under Regulation No. 62.1, by revising the entries for ''Section I'' and ''Section II'' to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(c) * * *

AIR POLLUTION CONTROL REGULATIONS FOR SOUTH CAROLINA

State citation	Title/subject	State effective date	EPA approval date	**Federal Register** notice
Regulation No. 62.1 Definitions and General Requirements				
Section I	Definitions	10/26/01	1/26/05	[Insert citation of publication].
Section II	Permit Requirements	06/27/03	1/26/05	[Insert citation of publication].
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[FR Doc. 05–1374 Filed 1–25–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0341; FRL–7691–2]

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the 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 parent in or on bananas and sunflowers. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on bananas and sunflower seed. This regulation establishes maximum permissible levels for residues of imidacloprid in these food commodities. The tolerances will expire and are revoked on December 31, 2007.

DATES: This regulation is effective January 26, 2005. Objections and requests for hearings must be received on or before March 28, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0341. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *Sec-18-Mailbox@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 a federal or state government agency involved in administration of environmental quality programs (i.e., Departments of

Agriculture, Environment, etc). Potentially affected entities may include, but are not limited to:

- Federal or State Government Entity, (NAICS 9241), i.e., Departments of Agriculture, Environment, etc.

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is 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 parent, in or on bananas at 1.0 parts per million (ppm) and sunflower at 0.05 ppm. These tolerances will expire and are revoked on December 31, 2007. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the 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 section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the 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 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. * * *''

Section 18 of the 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.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Imidacloprid on Bananas and Sunflower Seed and FFDCA Tolerances

Imidacloprid was requested by the State of Hawaii for use on bananas because of the ineffectiveness of currently registered insecticides in controlling the banana leaf aphid, and the insect's ability to vector Bananas Bunchy Top Virus (BBTV). EPA has authorized under FIFRA section 18 the use of imidacloprid on bananas for control of banana aphids in Hawaii. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

The States of Minnesota, Nebraska, and North Dakota declared crises for use of imidacloprid on sunflower seed to control wireworms due to the loss of the use of lindane and the lack of a viable alternative to control this pest on this crop.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of imidacloprid in or on bananas and sunflowers. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on bananas and/or sunflowers 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 tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether imidacloprid meets EPA's registration requirements for use on bananas and/or sunflower seed or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of imidacloprid by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Hawaii to use this pesticide on bananas and the States of Minnesota, Nebraska, and North Dakota to use this pesticide on sunflower seed 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

EPA performs a number of analyses to determine the risks from aggregate

exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA , EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of imidacloprid and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of imidacloprid in or on bananas at 1.0 ppm and sunflower at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for imidacloprid used for human risk assessment is shown in Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IMIDACLOPRID FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary all populations	LOAEL = 42 mg/kg/day UF = 300 Acute RfD = 0.14 mg/kg	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.14 mg/kg	Acute neurotoxicity - rat LOAEL = 42 mg/kg, based upon the decrease in motor and locomotor activities observed in females.
Chronic dietary all populations	NOAEL= 5.7 mg/kg/day UF = 100 Chronic RfD = 0.057 mg/kg/day	FQPA SF = 1X cPAD = chr RfD ÷ FQPA SF = 0.057 mg/kg/day	Combined chronic tox/carcinogenicity - rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.
Short-term oral (1–30 days)	oral study NOAEL= 10 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	Developmental toxicity - rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body weight gain and corrected body weight gain.
Short-term dermal (1–30 days)	oral study NOAEL= 10 mg/kg/day (dermal absorption rate = 7.2%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Developmental toxicity - rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body weight gain and corrected body weight gain.
Short-term inhalation (1–30 days)	oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Developmental toxicity - rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body weight gain and corrected body weight gain.
Cancer (oral, dermal, inhalation)	Group E	Not applicable	No evidence of carcinogenicity in rats and mice.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.472) for the combined residues of imidacloprid, in or on a variety of raw agricultural commodities. Meat, milk, poultry and egg tolerances have also been established for the combined residues of imidacloprid. In conducting dietary exposure assessments EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The 1994–1996 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment. Risk assessments were conducted by EPA to assess dietary exposures from imidacloprid in food as follows:

i. *Acute exposure*. The following assumptions were made for the acute exposure assessments: A Tier 1, deterministic acute dietary exposure assessment was conducted using tolerance-level residues, 100% crop treated (PCT) information for registered and proposed commodities; and modified DEEM™ (version 2.0) processing factors for some commodities based on guideline processing studies. EPA estimated exposure based on the 95th percentile value from this deterministic exposure assessment.

ii. *Chronic exposure*. The following assumptions were made for the chronic exposure assessments: A Tier 2 partially refined, deterministic assessment using tolerance-level residue and average weighted PCT information and modified DEEM™ (version 2.0) processing factors for some commodities based on guideline processing studies.

iii. *Cancer*. A quantitative cancer aggregate risk assessment was not performed because imidacloprid is not carcinogenic.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: For the acute assessment, 100 PCT was assumed for all registered and proposed commodities. For the chronic assessment, average weighted PCT information was used for the following commodities: Apple 34%; broccoli 35%; brussels sprouts 56%; cabbage 14%; cantaloupe 31%; cauliflower 52%; collards 10%; corn, field 1%; cotton 3%; cucumber 2%; eggplant 36%; grape 32%; grapefruit 3%; honeydew 26%; kale 30%; lemon 1%; lettuce, head 49%; lime 5%; mustard greens 16%; orange 1%; pear 16%; pepper 62%; pumpkin 7%; spinach 15%; squash 7%; sugarbeet 1%; tangerine 9%; tomato 9%; watermelon 6%; wheat 1%. A default value of 1% was used for all commodities which were reported as having <1 PCT.

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. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. 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 exposure data to complete a comprehensive dietary exposure analysis and risk assessment for imidacloprid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of imidacloprid.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a

coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to imidacloprid they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of imidacloprid for acute exposures are estimated to be 36.04 parts per billion (ppb) for surface water and 2.09 ppb for ground water. The EECs for chronic exposures are estimated to be 17.24 ppb for surface water and 2.09 ppb for ground water.

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

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

As these products are intended for use by commercial applicators only, they are not 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 to result in exposure durations that would result in intermediate- or long-term exposure.

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

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

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

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

4. *Cumulative exposure to 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.''

EPA does not have, at this time, available data to determine whether imidacloprid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, imidacloprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that imidacloprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

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

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

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

iii. The doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the developmental neurotoxicity study.

Therefore, there are no residual uncertainties for pre-natal/post-natal toxicity in this study.

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

- The toxicological database is complete for FQPA assessment.
- The acute dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100 PCT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- The chronic dietary food exposure assessment utilizes existing and proposed tolerance level residues and PCT data verified by the Agency for several existing uses. For all proposed uses, 100 PCT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.
- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- The residential handler assessment is based upon the residential standard operating procedures (SOPs) in conjunction with chemical-specific study data in some cases and the Pesticide Handlers Exposure Database (PHED) unit exposures in other cases. The majority of the residential post-application assessment is based upon chemical-specific turf transferrable residue data or other chemical-specific post-application exposure study data. The chemical-specific study data as well as the surrogate study data used are reliable and also are not expected to underestimate risk to adults as well as to children. In a few cases where chemical-specific data were not available, the SOPs were used alone. The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to imidacloprid.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to imidacloprid in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of imidacloprid on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to imidacloprid will occupy 26% of the aPAD for the U.S. population, 17% of the aPAD for females 13 to 49 years, 57% of the aPAD for infants < 1 year old and 67% of the aPAD for children 1–2 years. In addition, despite the potential for acute dietary exposure to imidacloprid in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of imidacloprid in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO IMIDACLOPRID

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.14	26	36.04	2.09	3,625
Females 13–49 years	0.14	17	36.04	2.09	3,483
Infants <1 year	0.14	57	36.04	2.09	603
Children 1–2 years	0.14	67	36.04	2.09	472

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to imidacloprid from food will utilize 12% of the cPAD for the U.S. population, 29% of the cPAD for infants <1 year and 38% of the cPAD for children 1–2 years. Based the use pattern, chronic residential exposure to residues of imidacloprid is not expected. In addition, there is potential for chronic dietary exposure to

imidacloprid in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IMIDACLOPRID

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.057	12	17.24	2.09	1755
Infants <1 year	0.057	29	17.24	2.09	405
Children 1–2 years	0.057	38	17.24	2.09	353
Females 13–49 years	0.057	10	17.24	2.09	1,548

3. *Short-term risk*. The short-term aggregate risk assessment estimates risks likely to result from 1 to 30 day exposure to imidacloprid residues from food, drinking water, and residential pesticide uses. High-end estimates of the residential exposure are used in the short-term assessment, and average values are used for food and drinking water exposures.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 320 for the U.S. population, and 170 for children 1–2 years. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of imidacloprid in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC, as shown in Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO IMIDACLOPRID

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	270	100	17.24	2.09	2,200
Children 1–2 years old	130	100	17.24	2.09	205

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

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

5. *Aggregate cancer risk for U.S. population*. There is no evidence of carcinogenicity to humans based on carcinogenicity studies in male and female rats and mice. The Agency concludes that pesticidal uses of imidacloprid are not likely to pose a cancer risk to humans.

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

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRLs) for imidacloprid on bananas or sunflower.

VI. Conclusion

Therefore, the tolerance is 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 parent, in or on bananas at 1.0 ppm and sunflower at 0.05 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0341 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 28, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII..A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2004–0341, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct

effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 14, 2005.

Betty Shackleford,

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 alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
* *	*	* *
Banana	1.0	12/31/07
* *	*	* *
Sunflower, seed	0.05	12/31/07
* *	*	* *

* * * * *

[FR Doc. 05–1438 Filed 1–25–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0008; FRL–7695–2]

Fluroxypyr; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr in or on onion. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on onion. This regulation establishes a maximum permissible level for residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr in this food commodity. The tolerance will expire and is revoked on June 30, 2007.

DATES: This regulation is effective January 26, 2005. Objections and requests for hearings must be received on or before March 28, 2005

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0008. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions above. 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a,