## Subpart LL—Oklahoma

■ 4. Subpart LL is amended by adding a new undesignated center heading and a new § 62.9180 to read as follows:

### Emissions From Existing Small Municipal Waste Combustion Units

**§ 62.9180 Identification of sources—negative declaration.**

Letter from the Oklahoma Department of Environmental Quality dated October 2, 2001, certifying that there are no existing small municipal waste combustion units subject to 40 CFR part 60, subpart BBBB, under its jurisdiction in the State of Oklahoma.

[FR Doc. 03–15007 Filed 6–12–03; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–2003–0103; FRL–7310–8]**

## Imidacloprid; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent in or on acerola; artichoke, globe; avocado; banana (import); canistel; corn, pop, grain; corn, pop, stover; cranberry; currant; elderberry; feijoa; fruit, stone, group 12; gooseberry; huckleberry; guava; jaboticaba; juneberry; lingonberry; longan; lychee; mango; mustard, seed; okra; papaya; passionfruit; persimmon; pulasan; rambutan; salal; sapodilla; sapote, black; sapote, mamey; Spanish lime; star apple; starfruit; strawberry; vegetable, leaves of root and tuber, group 2; vegetable, legume, group 6, except soybean; vegetable, root and tuber, group 1, except sugar beet; watercress; wax jambu. EPA is also deleting certain imidacloprid tolerances that are no longer needed as result of this action. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) , as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective June 13, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0103, must be received on or before August 12, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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. 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 Get Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0103. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access*. 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 http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

### II. Background and Statutory Findings

In the **Federal Register** of February 5, 2003 (68 FR 5880) (FRL–7287–5) and March 5, 2003 (68 FR 10464) (FRL–7291–1) EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP1E6268, 1E6254, 1E6237, 1E6225, 0E6203, 2E6403, 2E6406, 2E6409, 2E6417, 2E6421, 2E6435, 2E6414, 2E6458, and 2E6506) by IR–4, 681 U.S. Highway 1 South, North Brunswick, NJ 08902–3390 and PP 0E6074 Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. Those notices included summaries of the petitions prepared by Bayer CropScience, the registrant. One comment was received in response to the notice of filing of February 5, 2003, from an individual who requested that information about pesticide tolerances be available in grocery stores next to the food labels.

The petitions requested that 40 CFR 180.472 be amended by establishing tolerances for residues of the insecticide imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, and its metabolites containing the 6-chloropyridinyl

moiety, all expressed as imidacloprid in or on the raw agricultural commodities as follows: Bushberry subgroup 13B, lingonberry, juneberry and salal at 3.5 parts per million (ppm) (PP 1E6268), okra at 1.0 ppm (PP 1E6254), watercress at 3.5 ppm (PP 1E6237), artichoke at 2.5 ppm (PP 1E6225), cranberry at 0.05 ppm (PP 0E6203), vegetable, legume, except soybean, group 6 at 4.0 ppm (PP 2E6403), avocado, papaya, star apple, black sapote, mango, sapodilla, canistel, and mamey sapote at 1.0 ppm, and lychee, longan, Spanish lime, rambutan, pulasan and persimmon at 3.0 ppm (PP 2E6406), vegetable, leaves of root and tuber, group 2 at 4.0 ppm (PP 2E6409), strawberry at 0.5 ppm (PP 2E6417), fruit, stone, group 12 at 3.0 ppm (PP 2E6421), guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, and acerola at 1.0 ppm (PP 2E6435), corn, pop, grain at 0.05 ppm and corn, pop, stover at 0.2 ppm (PP 2E6414), mustard seed at 0.05 ppm (PP 2E6458), and vegetable, root and tuber, except sugar beet, group 1, except sugar beet, at 0.4 ppm (PP 2E6506); imported banana at 0.01 ppm (0E6074). The petition for imported banana was subsequently amended to propose a tolerance at 0.02 ppm.

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

The revisions to § 180.472(a) are as follows:

1. Delete bean, edible, podded at 1.0 ppm and bean, succulent, shelled at 1.0 ppm. Replaced with vegetable, legume, group 6, except soybean at 4.0 ppm.

2. Delete dasheen, leaves at 3.5 ppm and turnip greens at 3.5 ppm. Replaced with vegetable, leaves of root and tuber, group 2 at 4.0 ppm.

3. Delete mango at 0.2 ppm. Replaced with mango at 1.0 ppm.

4. Delete potato at 0.3 ppm and vegetable, tuberous and corm, subgroup at 0.3 ppm. Replaced with vegetable, root and tuber, group 1, except sugar beet at 0.4 ppm.

The revisions to § 180.472(b) are as follows:

1. Delete the time-limited tolerance for fruit, stone at 3.0 ppm. Tolerance for fruit, stone, group 12 at 3.0 ppm is established by this action under 180.472(a).

2. Delete the time-limited tolerance for strawberry at 0.1 ppm. Tolerance for strawberry at 0.5 ppm is established by this action under 180.472(a).

3. Delete the time-limited tolerance for turnip, roots at 0.3 ppm. Tolerance for vegetable, root and tuber, group 1, except sugar beet at 0.4 ppm is established by this action under 180.472(a).

4. Delete the time-limited tolerance for turnip, tops at 3.5 ppm. Tolerance for vegetable, leaves of root and tuber, group 2 at 4.0 ppm is established by this action under 180.472(a).

EPA has received objections to a time-limited tolerance it established for residues of imidacloprid on blueberries in connection with an emergency exemption for such use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* published in the **Federal Register** of January 18, 2002 (67 FR 2580)(FRL–6817–6). The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has initiated a public comment period on them in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL–7167–7), which ended on October 16, 2002. Although that proceeding remains ongoing, prior to acting on this current tolerance action, EPA reviewed the imidacloprid-specific objections raised by NRDC and has addressed them at relevant points throughout this preamble. Since EPA review of the objections to the time-limited tolerance for blueberry is ongoing, EPA is not establishing the proposed tolerance for blueberry at this time. Individual commodity tolerances for the other members of the bushberry subgroup (currant, elderberry, gooseberry and huckleberry) are established by this action.

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....''

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).

## III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for combined residues of imidacloprid on banana (import) at 0.02 ppm; cranberry; mustard, seed; corn, pop, grain at 0.05 ppm; corn, pop, stover at 0.20 ppm; vegetable, root and tuber, group 1, except sugar beet at 0.40 ppm; strawberry at 0.50 ppm; acerola; avocado; canistel; feijoa; guava; jaboticaba; mango; okra; papaya; passionfruit; sapodilla; sapote, black; sapote, mamey; star apple; starfruit; wax jambu at 1.0 ppm; artichoke, globe at 2.5 ppm; fruit, stone, group 12; lychee; longan; Spanish lime; rambutan; pulasan; persimmon at 3.0 ppm; currant; elderberry; gooseberry; huckleberry; juneberry; lingonberry; salal; watercress at 3.5 ppm; vegetable, leaves of root and tuber, group 2; vegetable, legume, group 6, except soybean at 4.0 ppm.

### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by imidacloprid are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3200 | 21/28-Day dermal toxicity (rabbits) | NOAEL = 1,000 mg/kg/day (highest dose tested (HDT))<br>LOAEL = Not identified |
| 870.3465 | 4 Week inhalation toxicity (rat) | NOAEL = 0.191 mg/liter/day (HDT)<br>LOAEL = Not identified |
| 870.3700 | Prenatal developmental toxicity (rats) | Maternal NOAEL = 10 mg/kg/day<br>LOAEL = 30 mg/kg/day based on decreased body weight gain and decreased corrected body weight gain.<br>Developmental NOAEL = 30 mg/kg/day<br>LOAEL = 100 mg/kg/day based on a slight increase in the incidence of wavy ribs. |
| 870.3700 | Prenatal developmental toxicity (rabbits) | Maternal NOAEL = 24 mg/kg/day<br>LOAEL = 72 mg/kg/day based on maternal deaths and decreased maternal absolute body weights, body weight gains, and food consumption.<br>Developmental NOAEL = 24 mg/kg/day<br>LOAEL = 72 mg/kg/day based on abortion, total litter resorptions, increased postimplantation loss due to increased late resorptions, decreased fetal weights, and very low incidences of skeletal alterations. |
| 870.3800 | Reproduction and fertility effects (rats) | Parental/Systemic NOAEL = 16.5 mg/kg/day<br>LOAEL = 47.3 mg/kg/day based on decreased premating weight gain by F0 males and females and F1 females and decreased gestational weight gain by F1 females.<br>Reproductive NOAEL = 47.3 mg/kg/day (HDT)<br>LOAEL = not identified<br>Offspring NOAEL = 16.5 mg/kg/day<br>LOAEL = 47.3 mg/kg/day based on decreased pup body weights in both litters of both generations. |
| 870.4100 | Chronic toxicity (dogs) | NOAEL = 72 mg/kg/day (HDT)<br>LOAEL = Not identified |
| 870.4200 | Carcinogenicity (mice) | NOAEL = Males: 208 mg/kg/day; Females: 274 mg/kg/day<br>LOAEL = Males: 414 mg/kg/day; Females: 424 mg/kg/day based on decreased body weights, food consumption and water intake.<br>No evidence of carcinogenicity. |
| 870.4300 | Combined Chronic/Carcinogenicity (rats) | NOAEL = Males: 5.7 mg/kg/day; Females: 7.6 mg/kg/day<br>LOAEL = Males: 16.9 mg/kg/day; Females: 24.9 mg/kg/day based on thyroid toxicity (increased incidence of mineralized particles in thyroid colloid) in males.<br>No evidence of carcinogenicity. |
| 870.5100<br>870.5300 | Gene Mutation | Negative in a battery of test. |
| 870.5375<br><br>870.5380<br>870.5385<br>870.5395<br>870.5900 | Chromosome aberrations | Negative in battery of tests, except at cytoxic doses in an *in vitro* mammalian chromosome aberration test and an *in vitro* sister chromatid exchange test. |
| 870.5550<br>870.5575 | Other genotoxic effects | Negative in a battery of tests |
| 870.6200 | Acute neurotoxicity screening battery rat | NOAEL = not identified.<br>LOAEL = 42 mg/kg based on decreased motor and locomotor activities observed in females. |
| 870.6200 | Subchronic neurotoxicity screening battery rat | NOAEL = 9.3 mg/kg/day.<br>LOAEL = 63.3 mg/kg/day based on decreased body weight gain. |
| 870.6300 | Developmental neurotoxicity (rat) | Maternal NOAEL = 20 mg/kg/day.<br>LOAEL = 55 mg/kg/day based on decreased food consumption and body weight gain during lactation.<br>Offspring NOAEL = 20 mg/kg/day.<br>LOAEL = 55 mg/kg/day based on decreased body weight and body weight gain, decreased motor activity and decreased caudate/putamen width in females. |

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.7485 | Metabolism and pharmacokinetics rat | Methylene-labeled imidacloprid was rapidly absorbed. There were no biologically significant differences between sexes, dose levels, or route of administration. Urinary excretion was the major route of elimination, with a lesser amount eliminated in feces. Total tissue burden after 48 hours accounted for only approximately 0.5% of the recovered radioactivity, with major sites of accumulation being the liver, kidney, lung, skin, and plasma and minor sites being the brain and testes. There were two major evident routes of biotransformation. The first included an oxidative cleavage of the parent compound to give 6-CNA and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second included the hydroxylation of imidazolidine followed by elimination of water of the parent compound to give NTN 35884.<br>In a comparison between [Methylene-14C] Imidacloprid and [Imidazolidine-4,5-14C] Imidacloprid, the rates of excretion were similar; however, the renal portion was higher with the imidazolidine-labeled test material. The imidazolidine-labeled test material also demonstrated higher accumulation in the tissues, with the major sites of accumulation being the liver, kidney, lung, and skin, and the minor sites being brain and muscle. |

*B. 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 level of concern (LOC). 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 intra species 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 factors (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 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 $1 \times 10^{-6}$ 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 2 of this unit:

TABLE 2.—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 Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute Dietary all populations | LOAEL = 42 mg/kg/day<br>UF = 300<br>Acute RfD = 0.14 mg/kg | FQPA SF = 1X<br>aPAD = aRfD/ FQPA SF = 0.14 mg/kg | Acute neurotoxicity - rat<br>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<br>UF = 100<br>Chronic RfD = 0.057 mg/kg/day | FQPA SF = 1X<br>cPAD = cRfD/FQPA SF = 0.057 mg/kg/day | Combined chronic tox/carcinogenicity - rat<br>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<br>(Residential, includes the FQPA SF) | Developmental toxicity - rat<br>Maternal LOAEL = 30 mg/kg/day, based upon decreased body weight gain and corrected body weight gain. |

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IMIDACLOPRID FOR USE IN HUMAN RISK ASSESSMENT—Continued

| Exposure Scenario | Dose Used in Risk Assessment, UF | * Special FQPA SF and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Intermediate-Term Oral (1–6 months) | oral study NOAEL= 9.3 mg/kg/day | LOC for MOE = 100 (Residential, includes the FQPA SF) | Subchronic neurotoxicity - rat LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain. |
| Short-Term Dermal (1–30 days) | oral study NOAEL= 10 mg/kg/day (dermal absorption rate = 7.2%)2 | 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. |
| Intermediate-Term Dermal (1–6 months) | oral study NOAEL= 9.3 mg/kg/day (dermal absorption rate = 7.2%)2 | LOC for MOE = 100 (Residential, includes the FQPA SF) | Subchronic neurotoxicity - rat LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain. |
| Long-Term Dermal (> 6 months) | oral study NOAEL= 5.7 mg/kg/day (dermal absorption rate = 7.2%)2 | LOC for MOE = 100 (Residential, includes the FQPA SF) | 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 Inhalation (1–30 days) | oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%) | 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. |
| Intermediate-Term Inhalation (1–6 months) | oral study NOAEL= 9.3 mg/kg/day (inhalation absorption rate = 100%) | LOC for MOE = 100 (Residential, includes the FQPA SF) | Subchronic neurotoxicity - rat LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain. |
| Long-Term Inhalation (>6 months) | oral study NOAEL= 5.7 mg/kg/day (inhalation absorption rate = 100%) | LOC for MOE = 100 (Residential, includes the FQPA SF) | Combined chronic tox/carcinogenicity - rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males. |
| Cancer (oral, dermal, inhalation) | no evidence of carcinogenicity for humans | Not applicable | No evidence of carcinogenicity in rats and mice. |

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

In its objections to a separate imidacloprid tolerance action, NRDC claims that EPA erred by regulating on the basis of a LOAEL for acute and chronic toxicity. As can be seen from the above table, NRDC is mistaken with regard to use of a LOAEL for estimating the RfD for chronic risk. The acute toxicity endpoint was based upon a LOAEL of 42 mg/kg/day from an acute neurotoxicity study in rats. This value was adjusted with a safety factor of 3X to approximate the value of a NOAEL. EPA has high confidence that this value of 3x is sufficient for several reasons. The effect seen at the LOAEL in the acute neurotoxicity study (decreased motor activity), occurred only in one sex of the rat (females), was characterized as minimal, and may have been a result of the use of the gavage dosing in the study. The decreased motor activity was not replicated following repeated dietary administration (non-gavage) at lower and higher doses (10, 70 or 200 mg/kg/day) in the subchronic neurotoxicity study in the same species (rats). Further, using a safety factor of 3X produces a regulatory endpoint lower than the acute effect levels in other standard studies for determining an acute endpoint, developmental toxicity studies in two species, and in another study that is on occasion used for such a purpose, the developmental neurotoxicity study in rats.

Also in these objections, NRDC claims that EPA failed to calculate residential risks for some scenarios, based on low toxicity (no endpoints were chosen). On October 8, 2002, the Health Effects Division (HED), Hazard Identification Assessment Review Committee (HIARC) reviewed the hazard database for imidacloprid and established additional endpoints. Endpoints were chosen for each of the following exposure scenarios: acute dietary, chronic dietary, short-term oral, intermediate-term oral, short-term dermal, intermediate-term dermal, long-term dermal, short-term inhalation, intermediate-term inhalation, and long-term inhalation. In the current risk assessment (Unit E of this document), EPA calculated short-term residential risks (oral, dermal, and inhalation) for both adults and children for a wide-range of representative scenarios, including applications to lawns, ornamental plantings, indoor and outdoor potted plants, and dogs and cats. Based on current residential use patterns for imidacloprid, EPA expects the duration of exposure to be short-term (1-30 days), and would not result in intermediate or long-term exposure. EPA also conducted human health aggregate risk assessments for the following exposure scenarios: acute aggregate (food + drinking water), short-term aggregate exposure (food + drinking water + residential), and chronic aggregate exposure (food + drinking water).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* Tolerances have been

established (40 CFR 180.472) for the combined residues of imidacloprid, in or on a variety of raw agricultural commodities. Meat, milk, poultry and egg tolerances have also been established for the combined residues of imidacloprid. In conducting dietary exposure assessments EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID$^{T}$) 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 1994-96 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*. Acute dietary 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA [1994–1996/1998] nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier 1, deterministic acute dietary exposure assessment was conducted using tolerance-level residues, 100% crop treated (CT) information for registered and proposed commodities; and modified DEEMTM (version 7.76) processing factors for some commodities based on guideline processing studies. EPA estimated exposure based on the 95th percentile value from this deterministic exposure assessment.

In its objections to a separate imidacloprid tolerance action, NRDC asserts that EPA erred by relying on the exposure value for the 95th percentile of the population in estimating exposure. NRDC claims that this approach leaves 5 percent of the population unprotected. These comments by NRDC represent a misunderstanding of EPA's exposure assessments. Although EPA estimated exposure using the 95th percentile, EPA most definitely was not, however, acting in a manner designed to protect only 95 percent of the population. To the contrary, EPA's exposure estimates were designed to reasonably capture the full range of exposures in each population subgroup.

As explained in its science policy paper on this subject, EPA, in estimating exposure for population subgroups, generally considers various population percentiles of exposure between 95 and 99.99, depending on the extent of overestimation in the residue data used in the assessment. In each exposure assessment EPA is attempting to reasonably estimate the full range of exposures in a subgroup. Accordingly, as EPA noted in its policy paper, just as when OPP uses the 95th percentile with non-probabilistic exposure assessments OPP is not suggesting that OPP is leaving 5 percent of the population unprotected, OPP is not by choosing the 99.9th percentile for probabilistic exposure assessments concluding that only 99.9 percent of the population deserves protection. Rather, it is OPP's view that, with probabilistic assessments, the use of the 99.9th percentile generally produces a reasonable high-end exposure such that if that exposure does not exceed the safe level, OPP can conclude there is a reasonable certainty of no harm to the general population and all significant population groups. (Office of Pesticide Programs, EPA, *Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern* 31 (March 22, 2000)). Importantly, EPA generally uses a population percentile of 95 when EPA relies on worst case residue values - i.e., all crops covered by the tolerance contain residues at the tolerance value. Even at the 95th percentile of estimated exposure, actual exposure, when based on this assumption tends to be significantly overstated. For example, EPA has found that when it uses realistic residue information (e.g., data from monitoring of the food supply), that exposure estimates are generally substantially lower even at the 99.99th percentile.

As noted above, EPA did use the worst case assumption that all food covered by imidacloprid tolerances would bear residues at the tolerance level. Hence, EPA believes its exposure estimate is unlikely to understate exposure; rather, in all likelihood, the estimate probably substantially overstates exposure.

ii. *Chronic exposure*. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure assessment was performed using published and proposed tolerance levels, DEEM default processing factors, and percent crop treated information on some commodities.

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

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 percent CT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on percent CT.

The Agency used CT information as follows:

For the acute assessment, 100% CT was assumed for all registered and proposed commodities. For the chronic assessment, average weighted percent CT information was used for the following commodities: Apple 34%; brussels sprouts 56%; broccoli 35%; cabbage 14%; cantaloupe 31%; cauliflower 52%; collards 10%; corn, field 1%; cotton 3%; cucumber 2%; eggplant 36%; grapefruit 3%; grape 32%; mustard greens16%; honeydew 26%; kale 30%; lemon 1%; lettuce, head 49%; lime 5%; 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% CT.

The Agency believes that the three conditions listed in Unit. III.E. have been met. With respect to Condition 1, percent CT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average percent CT for chronic dietary exposure estimates. This weighted average percent CT 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 percent CT 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 percent CT over a lifetime. 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 FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will 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. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

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 in Unit.III.E.

Analysis of monitoring data for degradates (ground water only) shows that imidacloprid parent is the dominant residue with imidacloprid urea the most likely degradate. Based on the available information, modeling of total residue results in only modest increases over the exposure estimates with parent alone. Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of imidacloprid (total residue) 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 imidacloprid (parent only) for acute exposures are estimated to be 35.89 parts per billion (ppb) for surface water and 1.43 ppb for ground water. The EECs for imidacloprid (total residue) for chronic exposures are estimated to be 17.24 ppb for surface water and 2.09 ppb for ground water. The EECs for imidacloprid (parent only) for chronic exposures are estimated to be 16.52 ppb for surface water and 1.43 ppb for ground water.

The New York State Department of Environmental Conservation, Division of Solid and Hazardous Materials has submitted extensive water monitoring information from Nassau and Suffolk Counties of New York. Nassau and Suffolk counties have ground water that is exceptionally vulnerable to pesticide contamination and have a long history of a number of pesticides being banned from use in these counties over the years. In general, the kinds of concentrations of imidacloprid (parent only) found in the monitoring/observation and private drinking water wells are in the range expected in highly vulnerable ground water. Imidacloprid has been detected in approximately 20 (including some clusters of wells in the same immediate area) out of about 2,000 public and private water supply and monitoring wells. Imidacloprid was detected in 24 of the approximately 3,500 well samples analyzed for imidacloprid in Nassau and Suffolk Counties. Although detection of imidacloprid in about 20 of 2,000 wells in an area with highly vulnerable ground water does not demonstrate particularly widespread ground water contamination, 3 of 2000 wells in this highly vulnerable ground water have at least one detection greater than the SCI-GROW groundwater screening concentration for imidacloprid (parent only) at 1.43 ppb. The three samples that exceed the SCI-GROW groundwater ECs are reported at 2.06 ppb, 5.98, ppb and 6.69 ppb. Since the surface water model screening levels are greater than the ground water model screening levels and the detection levels reported from the water monitoring from Nassau and Suffolk Counties, New York, the Agency will use the surface water ECs for imidacloprid total residue as a worse case estimate for drinking water in the aggregate risk assessment.

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 effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether imidacloprid has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to imidacloprid and any other substances and imidacloprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that imidacloprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

*D. Safety Factor for Infants and Children*

1.*In general.* Section 408 of 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-/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% CT 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 % CT data verified by the Agency for several existing uses. For all proposed uses, 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.

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.

In its objections to a separate imidacloprid tolerance action, NRDC argues that in light of the outstanding data requirement for prospective groundwater monitoring studies, EPA should have retained a 10X FQPA factor for imidacloprid. EPA disagrees. Two small- scale prospective ground-water monitoring studies were originally requested by the Agency in 1994. This request predates the development of the Tier 1 ground-water screening model in 1997 and the Food Quality Protection Act of 1996. The field phase of these prospective ground-water monitoring studies commenced in 1996. Results from these studies have now been received and the levels of imidacloprid observed (0.1 ppb) are below the screening concentration of 2.09 ppb calculated on the basis of the SCI-GROW, the Tier 1 ground-water screening model. In any event, as noted above, since higher values are predicted for imidacloprid residues in surface water, these higher values were used in conducting the risk assessment.

*E. 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 + residential 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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in 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 25% of the aPAD for the U.S. population, 17% of the aPAD for females 13 to 49 years, 54% of the aPAD for infants < 1 year old and 64% of the aPAD for children 1-2 years. In addition, there is potential for acute 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 aPAD, as shown in Table 3 of this unit:

TABLE 3.—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 | 25 | 36.04 | 2.09 | 3,700 |
| Females 13–49 years | 0.14 | 17 | 36.04 | 2.09 | 3,500 |
| Infants <1 year | 0.14 | 54 | 36.04 | 2.09 | 650 |
| Children 1–2 years | 0.14 | 64 | 36.04 | 2.09 | 510 |

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 11% of the cPAD for the U.S. population, 26% of the cPAD for infants < 1 year and 35% 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 4 of this unit:

TABLE 4.—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 | 11 | 17.24 | 2.09 | 1,800 |
| Infants <1 year | 0.057 | 26 | 17.24 | 2.09 | 420 |
| Children 1-2 years | 0.057 | 35 | 17.24 | 2.09 | 370 |
| Females 13-49 years | 0.057 | 8.3 | 17.24 | 20.9 | 1,600 |

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

Short-term aggregate risk assessments are needed for adults as there is potential for both dermal and inhalation handler exposure, and dermal post-application exposure from the residential uses of imidacloprid on turf and pets. In addition, short-term aggregate risk assessments are needed for children/toddlers because there is a potential for oral and dermal, post-application exposure resulting from the residential uses of imidacloprid on turf and pets. The pet-treatment scenario resulted in the lowest combined MOE for adults (MOE = 400; handler and post-application) and children (MOE = 260; post-application). The turf-treatment resulted in much lower exposures for both adults (MOE = 15,000; handler and post-application) and children (MOE = 1,500; post-application). Therefore, the pet-treatment exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of short-term aggregate risk for the U.S. population and children 1-2 years old (the child population subgroup with the highest estimated chronic dietary food exposure).

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 level of concern 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 and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO IMIDACLOPRID

| Population Subgroup | Aggregate MOE (Food + Residential) | Aggregate Level of Concern (LOC) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Short-Term DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. Population | 320 | 100 | 17.24 | 2.09 | 2,400 |
| Children 1-2 years old | 170 | 100 | 17.24 | 2.09 | 410 |

4. *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.

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

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

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

### *B. International Residue Limits*

There are no established Codex maximum residue limits (MRLs) for imidacloprid in/on the commodities in the subject petitions. There are currently Canadian and Mexican MRLs for imidacloprid and metabolites containing the 6-chloropicolyl moiety in potatoes at 0.3 ppm. The Mexican and Canadian MRLs are not equivalent to the US-recommended tolerance level. Therefore, harmonization is not possible at this time.

## V. Conclusion

Therefore, the tolerances are established for combined residues of imidacloprid, its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in or on banana (import) at 0.02 ppm; cranberry; mustard, seed; corn, pop, grain at 0.05 ppm; corn, pop, stover at 0.20 ppm; vegetable, root and tuber, group 1, except sugar beet at 0.40 ppm; strawberry at 0.50 ppm; acerola; avocado; canistel; feijoa; guava; jaboticaba; mango; okra; papaya; passionfruit; sapodilla; sapote, black; sapote, mamey; star apple; starfruit; wax

jambu at 1.0 ppm; artichoke, globe at 2.5 ppm; fruit, stone, group 12; lychee; longan; Spanish lime; rambutan; pulasan; persimmon at 3.0 ppm; currant; elderberry; gooseberry; huckleberry; juneberry; lingonberry; salal; watercress at 3.5 ppm; vegetable, leaves of root and tuber, group 2; vegetable, legume, group 6, except soybean at 4.0 ppm.

## VI. 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 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–2003–0103 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 August 12, 2003.

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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA–. 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 (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0103, 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 Unit I.B.1. 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).

## VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from*

*Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of 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.

## VIII. Congressional Review Act

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

## List of Subjects in 40 CFR Part 180

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

Dated: June 2, 2003.

**Debra Edwards,**

*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), 346(a) and 371.

■ 2. Section 180.472 is amended:

i. In paragraph (a), in the table, by removing the commodities, ''bean, edible, podded,'' '' bean, succulent, shelled,'' ''dasheen, leaves,'' ''mango,'' ''potato,'' ''turnip, greens,'' and ''vegetable, tuberous and corm, subgroup;'' and by alphabetically adding the following commodities.

ii. In paragraph (b), in the table, by removing the commodities, ''fruit, stone,'' ''strawberry,'' ''turnip, roots,'' and ''turnip, tops.''

The additions read as follows:

**§ 180.472 Imidacloprid; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| Acerola | 1.0 |
| * * * | * * |
| Artichoke, globe | 2.5 |
| Avocado | 1.0 |
| Bananna[1] | 0.02 |
| * * * | * * |
| Canistel | 1.0 |
| * * * | * * |
| Corn, pop, grain | 0.05 |
| Corn, pop, stover | 0.20 |
| * * * | * * |
| Cranberry | 0.05 |
| Currant | 3.5 |
| * * * | * * |
| Elderberry | 3.5 |
| * * * | * * |
| Feijoa | 1.0 |
| * * * | * * |
| Fruit, stone, group 12 | 3.0 |
| Gooseberry | 3.5 |
| * * * | * * |
| Guava | 1.0 |
| * * * | * * |
| Huckleberry | 3.5 |
| Jaboticaba | 1.0 |
| Juneberry | 3.5 |
| * * * | * * |
| Lingonberry | 3.5 |
| Longan | 3.0 |
| Lychee | 3.0 |
| Mango | 1.0 |
| * * * | * * |
| Mustard, seed | 0.05 |
| Okra | 1.0 |
| Passionfruit | 1.0 |
| Papaya | 1.0 |
| * * * | * * |
| Persimmon | 3.0 |
| * * * | * * |
| Pulasan | 3.0 |
| Rambutan | 3.0 |
| Salal | 3.5 |
| Sapodilla | 1.0 |
| Sapote, black | 1.0 |
| Sapote, mamey | 1.0 |
| * * * | * * |
| Spanish lime | 3.0 |
| Star apple | 1.0 |
| Starfruit | 1.0 |
| Strawberry | 0.50 |
| * * * | * * |
| Vegetable, leaves of root and tuber, group 2 | 4.0 |
| Vegetable, legume, except soybean, group 6 | 4.0 |

| Commodity | Parts per million |
|---|---|
| Vegetable, root and tuber, group 1, except sugar beet | 0.40 |
| * * * | * * |
| Watercress | 3.5 |
| Wax jambu | 1.0 |
| * * * | * * |

[1] There are no U.S. registration as of June 13, 2003 for use on banana.

* * * * *

[FR Doc. 03–14880 Filed 6–12–03; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 725

**[OPPT–2002–0041; FRL–7200–3]**

**RIN 2070–AD43**

## Burkholderia Cepacia Complex; Significant New Use Rule

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

**ACTION:** Final rule.

**SUMMARY:** EPA is issuing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for *Burkholderia cepacia* complex (Bcc), a group of naturally-occurring microorganisms. Bcc microorganisms, when encountered in sufficient numbers through an appropriate route of exposure by a member of a sensitive population, such as a cystic fibrosis (CF) patient, have the potential to cause a severe infection, resulting in significantly increased rates of mortality. This rule would require persons who intend to manufacture, import, or process any individual member of Bcc for a significant new use to notify EPA at least 90 days before commencing the manufacturing (including import) or processing of Bcc for a use designated by this SNUR as a significant new use. The required notice would provide EPA with the opportunity to evaluate the intended new use and associated activities and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** This final rule is effective on August 12, 2003.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact*: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

*For technical information contact*: James Alwood, Chemical Control Division, Office of Pollution Prevention and Toxics (7405M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8974; e-mail address: alwood.jim@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture (including import), process, or use products that contain living microorganisms subject to jurisdiction under TSCA, especially if you know that your products contain or may contain members of Bcc. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (NAICS 325), e.g., Persons manufacturing, importing, or processing products for commercial purposes containing Bcc for biofertilizers; biosensors; biotechnology reagents; commodity or specialty chemical production; energy applications; and other TSCA uses.
- Waste management and remediation (NAICS 562), e.g., Waste treatment or pollutant degradation.

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 list of substances excluded by TSCA section (3)(2)(B), and the applicability provisions in 40 CFR 725.105(c) for SNUR related obligations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPPT–2002–0041. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. The OPPTS harmonized test guideline referenced in this document is available at http:/www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 725 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr725_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket identification number.

### II. Background

*A. What Action is the Agency Taking?*

This SNUR will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of any member of Bcc, a group of naturally occurring microorganisms, for any use other than research and development in the degradation of chemicals via injection into subsurface groundwater.