

Industry and EPA hazardous waste No.	Hazardous waste	Hazard code
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F037	Petroleum refinery primary oil/water/solids separation sludge—Any sludge generated from the gravitational separation of oil/water/solids during the storage or treatment of process wastewaters and oil cooling wastewaters from petroleum refineries. Such sludges include, but are not limited to, those generated in oil/water/solids separators; tanks and impoundments; ditches and other conveyances; sumps; and stormwater units receiving dry weather flow. Sludge generated in stormwater units that do not receive dry weather flow, sludges generated from non-contact once-through cooling waters segregated for treatment from other process or oily cooling waters, sludges generated in aggressive biological treatment units as defined in § 261.31(b)(2) (including sludges generated in one or more additional units after wastewaters have been treated in aggressive biological treatment units) and K051 wastes are not included in this listing. This listing does include residuals generated from processing or recycling oil-bearing hazardous secondary materials excluded under § 261.4(a)(12)(i), if those residuals are to be disposed of.	(T)
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PART 268—LAND DISPOSAL RESTRICTIONS

5. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

Appendix VII to Part 268 [Amended]

6. In appendix VII to part 268 Table 1 is amended by removing the entry for U048.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301004; FRL–6558–4]

RIN 2070–AB78

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 and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent in or on stone fruit (Crop Group 12). This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on stone fruit. This regulation establishes maximum permissible levels for residues of imidacloprid on these food commodities. The tolerances will expire and are revoked on December 31, 2001.

DATES: This regulation is effective June 8, 2000. Objections and requests for hearings, identified by docket control number OPP–301004, must be received by EPA on or before August 7, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the “SUPPLEMENTARY INFORMATION.” To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301004 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9367; e-mail address: ertman.andrew@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 categories and entities may include, but are not limited to:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select “Laws and Regulations” and then look up the entry for this document under the “**Federal Register**—Environmental Documents.” You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301004. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an

applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for the combined residues of the insecticide imidacloprid, in or on stone fruit at 1.0 part per million (ppm) and the processed commodity prunes at 3.5 ppm. These tolerances will expire and are revoked on December 31, 2001. 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 and the new safety standard to other tolerances and exemptions.

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) 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) 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 Federal Insecticide, Fungicide, and Rodenticide Act (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 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Imidacloprid on Stone Fruit and FFDCA Tolerances

There are two situations that have arisen, resulting in the present emergency condition. First, currently there are no reliable insecticides to control the green peach aphid (GPA) on peaches and nectarines because of insecticide resistance. Second, aphids are a vector for Plum Pox Virus (PPV), a disease that damages the fruits of sensitive cultivars of stone fruits. The mechanism by which aphids transmit PPV is called non-persistent transmission. Once an aphid probes into infected plant tissue and acquires the virus, the virus can only remain infectious and be transmitted for a short period of time (minutes). Each aphid must feed directly on an infected plant, acquire sufficient virus, and then fly immediately to the next plant in order to effect a transmission.

PPV was discovered for the first time in the United States in 18 stone fruit orchards in Adams County, Pennsylvania in the fall of 1999. Indications are that PPV has been in Pennsylvania for several years, and it is possible that undetected infections of PPV exist in peach and nectarine orchards in New Jersey, New York, and West Virginia. EPA has authorized under FIFRA section 18 the use of imidacloprid on stone fruit for control of aphids in New Jersey, New York, Pennsylvania and West Virginia. After having reviewed the submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of imidacloprid in or on stone fruit. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on each 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). Although these tolerances will expire and are

revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on stone fruit 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 stone fruit or whether permanent tolerances for this use 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 New Jersey, New York, Pennsylvania, and West Virginia to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing 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 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), 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), for a time-limited tolerance for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent in or on stone fruit at 1.0 ppm and prunes 3.5 ppm. EPA's assessment

of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by imidacloprid are discussed in this unit.

B. Toxicological Endpoint

Only acute and chronic dietary endpoints were defined. The 10x FQPA factor was reduced to 3x for acute and chronic exposure, and applies to all population subgroups.

1. *Acute toxicity.* The acute reference dose (RfD) is 0.42 milligram/kilogram body weight/day (mg/kg bwt/day) based on a lowest observed adverse effect level (LOAEL) of 42 mg/kg bwt/day based on decreased motor activity in female rats. An additional 3x FQPA factor was incorporated for all population subgroups to account for neurotoxicity, structure-activity concerns and lack of a no observed adverse effect level (NOAEL). The acute population adjusted dose (aPAD), which is the reference dose (RfD)/3 was calculated to be 0.14 mg/kg bwt/day. Acceptable acute dietary exposure (food plus water) of 100% or less of the aPAD is required for all population subgroups.

2. *Short- and intermediate-term toxicity.* Dermal and inhalation short- and intermediate-term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity; however, because imidacloprid is registered for use on turf, home gardens and pets, EPA has identified potential short-term oral exposures to children for these uses.

A short-term oral endpoint was not identified for imidacloprid. According to current EPA policy, if an oral endpoint is needed for short-term risk assessment (for incorporation of food, water, or oral hand-to-mouth type exposures into an aggregate risk assessment), the acute oral endpoint (LOAEL = 42 mg/kg bwt/day) will be used to incorporate the oral component into aggregate risk.

3. *Chronic toxicity.* EPA has established the RfD for imidacloprid at 0.057 milligrams/kilograms/day (mg/kg/day). This RfD is based on increased

number of thyroid lesions at the LOAEL of 16.9/24.9 mg/kg bwt/day (males and females, respectively). An additional 3x FQPA factor was used for all population subgroups. The chronic population adjusted dose (cPAD), which is the RfD/3, was calculated to be 0.019 mg/kg bwt/day. Acceptable chronic dietary exposure (food plus water) of 100% or less of the cPAD is required for all population subgroups.

4. *Carcinogenicity.* Imidacloprid has been classified by the Agency as a Group E chemical, no evidence of carcinogenicity for humans, thus, a cancer risk assessment is not required.

C. Exposures and Risks

1. From food and feed uses.

Tolerances, some time-limited, are currently established (40 CFR 180.472) for the combined residues of the insecticide imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, in or on a variety of raw agricultural and animal commodities at levels ranging from 0.02 ppm in eggs to 15 ppm in raisins, waste. Risk assessments were conducted by EPA to assess dietary exposures and risks from imidacloprid as follows:

i. *Acute exposure and risk.* 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 1-day or single exposure. In conducting the acute dietary (food) risk assessment, EPA used the Theoretical Maximum Residue Contribution (TMRC) which assumes tolerance level residues and 100% crop-treated (Tier 1). The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 95th percentile) and percentage of aPAD utilized ranged from 23% for the U.S. population to 45% for children 1–6 years old.

ii. *Chronic exposure and risk.* In conducting the chronic dietary (food only) risk assessment, EPA used: Tolerance level residues for imidacloprid and percent crop-treated (PCT) information for some of these crops.

The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The percentages of cPAD consumed for the

general population and subgroups of interest ranged from 11% for nursing infants <1 year old to 51% for children 1–6 years old.

Section 408(b)(2)(F) 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.

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), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows.

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 underestimated. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulation 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. *From drinking water.* There is no established Maximum Contaminant Level for residues of imidacloprid in drinking water. No health advisory levels for imidacloprid in drinking water have been established.

Imidacloprid is persistent, water soluble, and fairly mobile. Thus, residues of imidacloprid may be transported to both surface and ground waters. As a condition of registration, the Agency is requiring the submission of the results of two prospective ground water monitoring studies. Results from these studies are not yet available.

i. *Acute exposure and risk.* Estimated concentrations of imidacloprid in surface and ground water used for the acute exposure analysis were 4.1 and 1.1 micrograms per liter ($\mu\text{g/L}$) (parts per billion (ppb)), respectively. These estimated concentrations of imidacloprid in surface and ground water were based upon an application rate of 0.5 lbs active ingredient/acre/year (ai/acre/year).

For purposes of risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 4.1 $\mu\text{g/L}$) should be used for comparison to the back-calculated human health drinking water levels of concern (DWLOCs) for the acute endpoint. The DWLOCs ranged from 800 $\mu\text{g/L}$ for children 1–6 years old to 3,900 $\mu\text{g/L}$ for the U.S. population. These figures are well above the drinking water estimate concentration (DWE) of 4.1 $\mu\text{g/L}$.

ii. *Chronic exposure and risk.* Estimated concentrations of imidacloprid in surface and ground water for chronic exposure analysis were 0.1 and 1.1 $\mu\text{g/L}$ (ppb), respectively. These estimated concentrations of imidacloprid in surface and ground water were based upon an application rate of 0.5 lbs ai/acre/year.

For purposes of chronic risk assessment, the estimated maximum concentration for imidacloprid in

ground waters (which is 1.1 $\mu\text{g/L}$) should be used for comparison to the back-calculated human health DWLOCs for the chronic (non-cancer) endpoint. The DWLOCs ranged from 90 $\mu\text{g/L}$ for children 1–6 years old to 490 $\mu\text{g/L}$ for the U.S. population. These figures are well above the DWE of 1.1 $\mu\text{g/L}$.

3. *From non-dietary exposure.* Imidacloprid is currently registered for use on the following residential non-food sites: ornamentals (e.g., flowering and foliage plants, ground covers, turf, lawns) tobacco, golf courses, walkways, recreational areas, household or domestic dwellings (indoor/outdoor), and cats/dogs.

i. *Acute exposure and risk.* Occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required owing to the demonstrated absence of dermal and inhalation toxicity.

ii. *Chronic exposure and risk.* Occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required owing to the demonstrated absence of dermal and inhalation toxicity.

iii. *Short- and intermediate-term exposure and risk.* Short- and intermediate-term oral exposure are not expected for adult population subgroups. However, since imidacloprid is registered for use on turf, home gardens and pets, EPA has identified potential short-term oral exposures to children for these uses. Thus, a residential short-term risk assessment via the oral route is required. See Unit IV.E.4. for a full discussion of this exposure and risk.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 more 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).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* EPA has determined that the acute exposure to imidacloprid from food will utilize 23% of the aPAD (95th percentile) for the most highly exposed population subgroup (U.S. population—all seasons). Despite the potential for exposure to imidacloprid in drinking water, the Agency does not expect the aggregate exposure to exceed 100% of the aPAD. The DWLOC calculated for the U.S. population was 3,900 $\mu\text{g/L}$, which is well above the DWE of 4.1 $\mu\text{g/L}$.

2. *Chronic risk.* In conducting the chronic dietary (food only) risk assessment, EPA used: Tolerance level residues for imidacloprid, and PCT information for some of these crops. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The percentage of cPAD consumed for the U.S. population was 24%. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to imidacloprid in drinking water, the Agency does not expect the aggregate exposure to exceed 100% of the cPAD. The DWLOC calculated for the U.S. population was well above the DWE of 1.1 $\mu\text{g/L}$.

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

Dermal and inhalation short- and intermediate-term risk assessments are not required for imidacloprid, as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. Short- and intermediate-term oral exposure are not expected for adult population subgroups. A discussion of short- and intermediate-term oral exposure and

risk for children 1–6 can be found in Unit IV.E.4.

4. *Aggregate cancer risk for U.S. population.* Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans, thus, a cancer risk assessment is not required.

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

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of imidacloprid, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 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 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a developmental toxicity study with Sprague-Dawley rats, groups of pregnant animals (25/group) received oral administration of imidacloprid (94.2%) at 0, 10, 30, or 100 mg/kg bwt/day during gestation days 6 through 16. Maternal toxicity was manifested as

decreased body weight gain at all dose levels and reduced food consumption at 100 mg/kg bwt/day. No treatment-related effects were seen in any of the reproductive parameters (i.e., Cesarean section evaluation). At 100 mg/kg bwt/day, developmental toxicity manifested as wavy ribs (fetus = 7/149 in treated vs. 2/158 in controls and litters, 4/25 vs. 1/25). For maternal toxicity, the LOAEL was 10 mg/kg bwt/day lowest dose tested (LDT) based on decreased body weight gain; a NOAEL was not established. For developmental toxicity, the NOAEL was 30 mg/kg bwt/day and the LOAEL was 100 mg/kg bwt/day based on increased wavy ribs.

In a developmental toxicity study with Chinchilla rabbits, groups of 16 pregnant does were given oral doses of imidacloprid (94.2%) at 0, 8, 24 or 72 mg/kg bwt/day during gestation days 6 through 18. For maternal toxicity, the NOAEL was 24 mg/kg bwt/day and the LOAEL was 72 mg/kg bwt/day based on mortality, decreased body weight gain, increased resorptions, and increased abortions. For developmental toxicity, the NOAEL was 24 mg/kg bwt/day and the LOAEL was 72 mg/kg bwt/day based on decreased fetal body weight, increased resorptions, and increased skeletal abnormalities.

iii. *Reproductive toxicity study.* In a 2-generation reproductive toxicity study, imidacloprid (95.3%) was administered to Wistar/Han rats at dietary levels of 0, 100, 250, or 700 ppm (0, 7.3, 18.3, or 52.0 mg/kg bwt/day for males and 0, 8.0, 20.5, or 57.4 mg/kg bwt/day for females). For parental/systemic/reproductive toxicity, the NOAEL was 250 ppm (18.3 mg/kg bwt/day) and the LOAEL was 750 ppm (52 mg/kg bwt/day), based on decreases in body weight in both sexes in both generations. Based on these factors, the Agency determined that the review be revised to indicate the parental/systemic/reproductive NOAEL and LOAEL to be 250 and 700 ppm, respectively, based upon the body weight decrements observed in both sexes in both generations.

iv. *Prenatal and postnatal sensitivity.* The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to *in utero* exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study data did not identify any increased sensitivity of rats to *in utero* or postnatal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs.

v. *Conclusion.* There is a need for a developmental neurotoxicity study for assessment of potential alterations of functional development. However, the

Agency has determined that this data gap does not preclude the establishment/continuance of tolerances. The 10x safety factor to account for enhanced sensitivity of infants and children (as required by FQPA) was reduced to 3x and the factor applies to all population subgroups.

2. *Acute risk.* Using the conservative TMRC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the acute exposure to imidacloprid from food for the most highly exposed population subgroup (children 1–6 years old) will utilize 45% of the aPAD. It was determined that an acceptable acute dietary exposure (food plus water) of 100% or less of the aPAD is needed to protect the safety of all population subgroups. Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD for children 1–6 years old. The maximum concentration of imidacloprid in surface and ground water for acute exposure is very small (4.1 µg/L) compared to the DWEC of 800 µg/L.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to imidacloprid from food will utilize 51% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD for children 1–6 years old. The maximum concentration of imidacloprid in surface and ground water for acute exposure is very small (1.1 µg/L) compared to the DWEC of 90 µg/L.

4. *Short- and intermediate-term risk.* As noted earlier in this document, dermal and inhalation short- and intermediate-term risk assessments are not required for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. Short- and intermediate-term oral exposure are not expected for adult population subgroups. However, since imidacloprid is registered for use on turf, home gardens and pets, EPA has identified potential short-term oral exposures to children for these uses.

A short-term oral endpoint was not identified for imidacloprid. According to current EPA policy, if an oral

endpoint is needed for short-term risk assessment (for incorporation of food, water, or oral hand-to-mouth type exposures into an aggregate risk assessment), the acute oral endpoint (LOAEL = 42 mg/kg bwt/day) will be used to incorporate the oral component into aggregate risk.

The margin of exposure for chronic dietary exposure (food only) and residential exposure (hand-to-mouth from turf, garden, and pet uses) for children ages 1–6 was calculated to be 300. The safe level for imidacloprid is 300.

Potential short-term exposure from drinking water is at a level below the Agency's level of concern with the DWLOC (2 µg/L) being greater than the DWEC of 1.1 µg/L.

The Agency concludes the short-term aggregate risk to the highest exposed population subgroup (children 1–6 years old) from home garden, turf, and pet uses of imidacloprid does not exceed EPA's level of concern.

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

V. Other Considerations

A. Metabolism in Plants and Animals

The nature of imidacloprid residues in plants and in animals is adequately understood. The residue of concern is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, as specified in 40 CFR 180.472.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Crop field trials on peaches have been submitted, and the highest residues of imidacloprid were found to be 0.77 ppm. For the purposes of this section 18, the Agency will translate the peach residue data to all stone fruit and tolerances will be set at 1.0 ppm.

The only processed commodity associated with stone fruit is prunes, as plums can be processed into prunes. Since no processing study was submitted, a default factor of 3.4 was

used, and therefore, the tolerance on prunes will be set at 3.5 ppm.

D. International Residue Limits

There are no Codex, Canadian, or Mexican Maximum Residue Limits for imidacloprid on sweet corn. Thus, harmonization is not an issue for these time-limited tolerances.

E. Rotational Crop Restrictions

The rotational crop restrictions follow the original section 3 labels. In addition, there is little concern over rotational crops for this section 18 as stone fruit are rarely rotated to other crops.

VI. Conclusion

Therefore, the tolerances are established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, in or on stone fruit at 1.0 ppm and prunes at 3.5 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP-301004 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 7, 2000.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260-4865.

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.

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.

3. *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 Unit I.B.2. Mail your copies, identified by the docket control number OPP-301004, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format 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. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408. 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). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with*

Indian Tribal Governments (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 petition under FFDCA section 408, 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 FFDCA section 408(n)(4).

IX. Submission to Congress and the Comptroller General

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: May 25, 2000.

James Jones,

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. In §180.472, by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* * * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	*	*
Prunes	3.5	12/31/01
* * *	*	*
Stone fruit, crop group 12	1.0	12/31/01
* * *	*	*

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