

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301114; FRL-6777-6]

RIN 2070-AB78

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of imidacloprid in or on edible podded beans, succulent shelled beans, turnip greens, cilantro, sweet corn, field corn, leaf petiole vegetable subgroup, and the citrus fruits group. The Interregional Research Project Number 4 (IR-4) and the Bayer Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 10, 2001. Objections and requests for hearings, identified by docket control number OPP-301114, must be received by EPA on or before June 11, 2001.

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 VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301114 in the subject line on the first page of your response.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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:

| Categories | NAICS codes | Examples of potentially affected entities |
|------------|-------------------|------------------------------------------------------------|
| Industry | 111 112 311 | Crop production Animal production Food manufacturing |

| Categories | NAICS codes | Examples of potentially affected entities |
|------------|-------------|-------------------------------------------|
| | 32532 | Pesticide manufacturing |

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," "Regulations and Proposed Rules," 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/>. 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.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301114. 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

In the **Federal Register** of July 5, 2000 (65 FR 41455) (FRL-6590-6), and February 11, 2000 (65 FR 7008) (FRL-6487-9) EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of pesticide petitions (PP) for tolerances by IR-4, Technology Centre of New Jersey, 681 US Highway #1 South, North Brunswick, NJ 08902-3390, and Bayer Corporation, 8400 Hawthorn Road, POB 4913, Kansas City, MO 64120-0013. These notices included summaries of these petitions prepared by Bayer Corporation, the registrant. There were no comments received in response to the notices of filing.

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

1. PP 0E6101 proposes the establishment of a tolerance for edible podded beans at 1.0 part per million (ppm).
 2. PP 0E6104 proposes the establishment of a tolerance for succulent shelled beans at 1.0 ppm.
 3. PP 0E6156 proposes the establishment of a tolerance for turnip greens at 3.5 ppm.
 4. PP 9E6041 proposes the establishment of a tolerance for cilantro at 3.5 ppm.
 5. PP 0E6106 proposes the establishment of tolerances for sweet corn grain at 0.05 ppm, sweet corn forage at 0.10 ppm, and sweet corn stover at 0.20 ppm.
 6. PP 6F4682 proposes the establishment of tolerances for field corn grain at 0.05 ppm, field corn forage at 0.10 ppm, and field corn fodder at 0.20 ppm.
 7. PP 8F4940 proposes the establishment of tolerances for leaf petiole vegetable subgroup at 6.0 ppm, citrus fruits group at 0.7 ppm, and citrus dried pulp at 5.0 ppm.
- 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....”

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).

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of imidacloprid on edible podded beans at 1.0 ppm, succulent shelled beans at 1.0 ppm, turnip greens at 3.5 ppm, cilantro at 3.5 ppm, sweet corn grain at 0.05 ppm, sweet corn forage at 0.10 ppm, sweet corn fodder at 0.20 ppm, field corn grain at 0.05 ppm, field corn forage at 0.10 ppm, field corn fodder at 0.20 ppm, leaf

petiole vegetable subgroup at 6.0 ppm, citrus fruits group at 0.7 ppm, and citrus dried pulp at 5.0 ppm. EPA’s assessment of exposures and risks associated with establishing these tolerances follow.

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 Unit II. A. in the **Federal Register** of March 25, 1998 (FRL-5776-5).

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 intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided

by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor 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 Safety Factor.

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 x 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 the following Table 1:

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

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute Dietary general population including infants and children | (NOAEL was not established) LOAEL = 42 mg/kg/day UF = 100 Acute RfD = 0.42 mg/kg/day | FQPA SF = 3X aPAD = acute RfD FQPA SF = 0.14 mg/kg/day | Acute RfD = 0.42 mg/kg bwt/day LOAEL = 42 mg/kg bwt/day based on decreased motor activity in female rats; additional 3x FQPA factor for all population subgroups to account for neurotoxicity, structure-activity concerns and lack of a NOAEL. aPAD = RfD /3 = 0.14 mg/kg bwt/day. |

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

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|----------------------------------------------------------|-------------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chronic Dietary all populations | NOAEL= 5.7 mg/kg/day UF = 100 Chronic RfD = 0.057 mg/kg/day | FQPA SF = 3X cPAD = chronic RfD FQPA SF = 0.019 mg/kg/day | Chronic RfD = 0.057 mg/kg bwt/day; NOAEL = 5.7 mg/kg bwt/day based on increased number of thyroid lesions at the LOAEL of 16.9/24.9 mg/kg bwt/day (males and females, respectively); additional 3x FQPA factor for all population subgroups. |
| Short-Intermediate-Long Term Dermal (Residential) | N/A | N/A | Dermal endpoints were not identified due to demonstrated absence of toxicity. |
| Short-Intermediate-Long Term Inhalation (Residential) | N/A | N/A | Inhalation endpoints were not identified due to demonstrated absence of toxicity. |
| Cancer (oral, dermal, inhalation) | N/A | N/A | No evidence of carcinogenicity. |

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

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 and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, in or on a variety of raw agricultural commodities. Tolerances, which also include time-limited tolerances, have also been established 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 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 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumption was made for the acute exposure assessment: Tolerance level residues for imidacloprid were used, and a Tier 1 analysis for 100% crop-treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992–

nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessment: Tolerance level residues for imidacloprid were used, and percent crop-treated information for some crops.

iii. *Cancer.* Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans. Therefore, a cancer risk assessment was not conducted.

iv. *Anticipated residue and percent crop treated information.* 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; 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 crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows:

The Agency used PCT information to conduct a routine chronic dietary exposure analysis for imidacloprid

based on likely maximum percent crop treated as follows: 19% apples, 21% brassica leafy vegetables, 15% christophine, 15% crenshaws, 15% melons, 15% watermelon, 15% wintermelon, 13% citrus citron, 6% cotton, 30% eggplant, 6% grapefruit, 11% grapes, 13% kumquats, 13% lemons, 32% lettuce-head varieties, 13% limes, 3% oranges, 30% paprika, 2% pears, 3% peppers, 13% tangelos, 13% tangerines, and 10% tomatoes. Other commodities were assumed to be 100% treated.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute

dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which imidacloprid may be applied in a particular area.

2. *Dietary exposure from drinking water.* 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. However, estimates of imidacloprid's residue concentration in surface and ground waters has been provided by EPA water models.

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 Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond

scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a water shed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health 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 below.

Based on the GENEEC and SCI-GROW models the EECs of imidacloprid for acute exposures are estimated to be 17.4 parts per billion (ppb) for surface water and 1.4 ppb for ground water. The EECs for chronic exposures are estimated to be 15.8 ppb for surface water and 1.4 ppb for ground water.

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

Imidacloprid is currently registered for use on the following residential non-dietary sites: Turf, home garden and pet uses. Dermal and inhalation short- and intermediate-term risk assessments were not conducted for imidacloprid as dermal and inhalation exposure endpoints were not identified due to the demonstrated absence of toxicity. Short- and intermediate term oral exposures are not expected for adult population subgroups. A short-term aggregate risk assessment is required for hand-to-

mouth (oral) exposure for children. The risk assessment was conducted using the following residential exposure assumptions: (oral exposure) hand to mouth exposure for children from home garden, turf, and pet uses.

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 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. Safety Factor for Infants and Children

1. *In general.* FFDC 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 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 margin of exposure (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.* 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 (**Federal Register** September 18, 1998, Unit II. A.). 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 did not identify any increased sensitivity of rats to *in utero* or postnatal exposure.

3. *Conclusion.* Based on the clinical signs of neurological toxicity in the acute toxicity studies and the requirement for a developmental neurotoxicity study, EPA concluded that a FQPA safety factor of 3x is appropriate for this risk assessment. The safety factor of 10x was reduced to 3x because there was no qualitative or quantitative evidence of increased susceptibility of fetuses or offspring exposed to imidacloprid in the prenatal developmental toxicity studies in rats and rabbits, or in the 2-generation reproduction toxicity study in rats.

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: 2L/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 23% of the aPAD for the U.S. population, 18% of the aPAD for females 13 years and older, 35% of the aPAD for all infants < 1 year old and 46% of the aPAD for children 1-6 years old. 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 the following Table 2:

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

| Population Subgroup | aPAD (mg/kg) | % aPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Acute DWLOC (ppb) |
|-----------------------------|--------------|---------------|-------------------------|------------------------|-------------------|
| U.S. Population (48 states) | 0.14 | 23 | 17.4 | 1.4 | 3900 |
| All infants (<1 yr) | 0.14 | 35 | 17.4 | 1.4 | 900 |
| Children (1-6 yrs old) | 0.14 | 46 | 17.4 | 1.4 | 760 |
| Females (13-50 yrs old) | 0.14 | 18 | 17.4 | 1.4 | 3600 |

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 24% of the cPAD for the U.S. population, 38% of the cPAD for all infants <1 years old and 51% of the

cPAD for children 1-6 years old]. 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 the following Table 3:

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

| Population Subgroup | cPAD (mg/kg/day) | % cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|-----------------------------|------------------|---------------|-------------------------|------------------------|---------------------|
| U.S. Population (48 states) | 0.019 | 24 | 15.8 | 1.4 | 490 |
| All infants (<1 yr) | 0.019 | 38 | 15.8 | 1.4 | 120 |
| Children (1-6 yrs old) | 0.019 | 51 | 15.8 | 1.4 | 92 |
| Females (13-50 yrs old) | 0.019 | 18 | 15.8 | 1.4 | 450 |

3. *Short-term risk.* Dermal and inhalation exposure endpoints were not identified due to the absence of toxicity. As a result, dermal and inhalation short term risk assessments are not required for imidacloprid. Subsequently, short term oral exposures are not expected for adult population subgroups. However, EPA has identified potential short-term oral exposures to children for these uses.

Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water

(considered to be a background exposure level).

Imidacloprid is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term oral exposures for children.

Using the exposure assumption described in this unit for short-term exposure, EPA has concluded that food and residential exposures aggregated result an aggregate MOE of 350 for children 1-6 years old (hand to mouth).

This aggregate MOE does 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 the following Table 4:

TABLE 4.—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) |
|----------------------|------------------------------------|----------------------------------|-------------------------|------------------------|------------------------|
| Children 1-6 yrs old | 350 | 300 | 17.4 | 1.4 | 200 |

4. *Aggregate cancer risk for U.S. population.* Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans. Accordingly, EPA does not consider imidacloprid to pose a cancer risk.

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 the regulated imidacloprid residues in plant commodities (Bayer GC/MS Method 00200 and Bayer HPLC-UV Confirmatory Method 00357). EPA concludes that these methods are suitable for enforcement purposes on the subject commodities.

B. International Residue Limits

There are no established Codex, Canadian, or Mexican maximum residue limits for imidacloprid in/on succulent shelled beans, turnip greens, celery, citrus, and cilantro; thus, international harmonization is not an issue.

C. Conditions

Edible podded beans and succulent shelled beans have been made conditional for a period of three years to allow time to submit data on shelled dried beans to complete the crop group for bean tolerances.

V. Conclusion

Therefore, these tolerances are established for the combined residues of imidacloprid, (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, in or on edible podded beans at 1.0 ppm, succulent shelled beans at 1.0 ppm, turnip greens at 3.5 ppm, cilantro at 3.5 ppm, sweet corn grain at 0.05 ppm, sweet corn forage at 0.10 ppm, sweet corn fodder at 0.20 ppm, field corn grain at 0.05 ppm, field corn forage at 0.10 ppm, field corn fodder at 0.20 ppm, leaf petiole vegetable subgroup at 6.0 ppm, citrus fruits group at 0.7 ppm, and citrus dried pulp at 5.0 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 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-301114 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 June 11, 2001.

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 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.2. Mail your copies, identified by docket control number OPP-301114, 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 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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). 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. 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 record keeping requirements.

Dated: March 28, 2001.

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. Section 180.472 is amended by revising "corn, field, fodder," "corn, field, forage," and "corn, field, grain" and alphabetically adding the remaining commodities to the table in paragraph (a) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

| Commodity | Parts per million | Expiration/Revocation Date |
|-----------------------------------|-------------------|----------------------------|
| Beans, edible, podded | 1.0 | None |
| Beans, succulent, shelled | 1.0 | None |
| Cilantro | 3.5 | None |
| Citrus, dried pulp | 5.0 | None |
| Citrus, fruits, group | 0.7 | None |
| Corn, field, fodder | 0.20 | None |
| Corn, field, forage | 0.10 | None |
| Corn, field, grain | 0.05 | None |
| Corn, sweet, forage | 0.10 | None |
| Corn, sweet, (K+CWHR) | 0.05 | None |
| Corn, sweet, stover | 0.20 | None |
| Greens, turnip | 3.5 | None |
| Vegetable, leaf petiole, subgroup | 6.0 | None |

* * * * *

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BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301109; FRL-6773-2]

RIN 2070-AB78

Fenpyroximate; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of fenpyroximate benzoic acid, 4-[[[(E)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[(Z)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-, 1,1-dimethylethyl ester] in or on wine grapes and hops. Nihon Nohyaku requested this tolerance under the

Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act (FQPA) of 1996. The tolerance will expire April 12, 2004.

DATES: This regulation is effective April 10, 2001. Objections and requests for hearings, identified by docket control number OPP-301109, must be received by EPA on or before June 11, 2001.

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 VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301109 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Melody Banks, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5413; and e-mail address: banks.melody@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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:

| Categories | NAICS codes | Examples of potentially affected entities |
|------------|----------------------------|---------------------------------------------------------------------------------------|
| Industry | 111 112 311 32532 | Crop production Animal production Food manufacturing Pesticide manufacturing |

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