2. *Definitions.*

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b. Reporting Agency means the applicable State agency or a local air pollution control agency designated by the State, that will carry out the provisions of § 58.50.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300771; FRL 6051–6]

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 residues of imidacloprid in or on Legume Vegetables (Crop Group 6, 40 CFR 180.41(c)(6)) and Strawberries. 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 legumes and strawberries. This regulation establishes maximum permissible levels for residues of imidacloprid in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on June 30, 2000.

DATES: This regulation is effective January 20, 1999. Objections and requests for hearings must be received by EPA on or before March 22, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300771], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300771], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300771]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9356; e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the insecticide imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine), in or on legume vegetables and strawberries, at 1.0 and 0.1 part per million (ppm), respectively. These tolerances will expire and are revoked on 6/30/00. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New 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 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 FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

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.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Imidacloprid on Legume Vegetables and Strawberries and FFDCA Tolerances

The State of Florida requested a specific exemption for use of imidacloprid on legume vegetables to control the silverleaf whitefly. The state of California also requested a specific exemption for use of imidacloprid on strawberries to control the silverleaf whitefly. Both Florida and California stated that an emergency situation is present due to this recently introduced pest, its devastating effects on many fruit and vegetable crops, and its resistance to registered alternatives. The Applicants state that this pest can have devastating effects on growers' production and revenue. EPA has authorized under FIFRA section 18 the use of imidacloprid on Legume Vegetables and Strawberries for control of silverleaf whitefly in Florida and California, respectively. 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 legume vegetables and strawberries. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address urgent non-routine situations and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on 6/30/00, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on legume vegetables and strawberries 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 legume vegetables and strawberries or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of imidacloprid by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Florida or California to use this pesticide on the respective crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for imidacloprid, contact the Agency's Registration Division at the address provided above.

III. 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 time-limited tolerances for residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, on legume vegetables and strawberries at 1.0 and 0.1 ppm, respectively. EPA's assessment of the dietary exposures and risks associated with establishing the 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 below.

1. *Acute toxicity*. Based on the available acute toxicity data, OPP has determined that the lowest observed effect level (LOEL) of 42 milligrams per kilogram body weight per day (mg/kg/bwt/day) from the neurotoxicity study in rats should be used to assess risk from acute toxicity. There was no observed adverse effect level (NOAEL) in the study. Decreased motor activity in female rats was observed at the LOEL. Using the uncertainty factors (UFs) of 10X for inter- and 10X for intra-species variations, the acute Reference Dose (RfD) is 0.42 mg/kg/day. This risk assessment is required for all population subgroups.

2. *Short - and intermediate - term toxicity.* OPP has determined that available data do not demonstrate that imidacloprid has dermal or inhalation toxicity potential. Therefore, short-term or intermediate-term dermal and inhalation risk assessments, for occupational and residential exposure scenarios, are not required. However, a short-term aggregate risk assessment (oral exposure) is required for hand-to-mouth residential exposure, and the acute toxicological endpoint, as described above, is used for this risk assessment. Incorporating the 3X uncertainty factor, as described below, an MOE of 300 or greater would be acceptable.

3. *Chronic toxicity*. EPA had established the RfD for imidacloprid at 0.057 mg/kg/day. This RfD is based on a standard uncertainty factor (UF) of 100, and the NOAEL of 5.7 mg/kg/day from a combined chronic toxicity/carcinogenicity study in rats, which demonstrated increased number of thyroid lesions in male rats and decreased body weight gains in female rats. For chronic dietary risk assessment, the Agency determined that the FQPA uncertainty factor could be reduced to 3X and should be applied to all population subgroups. This determination is based on the weight-of-the-evidence considerations relating to potential sensitivity and completeness of the data, specifically, in regard to developmental neurotoxicity. This determination is further explained below under section III(D)(v) of this document. Because a developmental neurotoxicity study potentially relates to both acute and chronic effects in both the mother and the fetus, the 3X UF for FQPA is being applied for all population subgroups, and both acute and chronic risk. Therefore, for the purposes of this risk assessment, dietary exposure must not be above 33.3% of the RfD, to make the finding of reasonable certainty of no harm.

4. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified imidacloprid as a ''Group E'' chemical (no evidence of carcinogenicity for

humans) based on the results of carcinogenicity studies in two species. The doses tested are adequate for identifying a cancer risk, and thus, a cancer risk assessment is not required.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.472) for the residues of imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites, in or on a variety of raw agricultural commodities, ranging from 0.02 ppm in/on eggs to 15 ppm in/on raisin waste. Existing meat/milk/poultry tolerances are adequate to cover any secondary residues which may occur as a result of feeding legume products; secondary residues are not expected to occur from strawberries, as they are not a significant livestock feed item. 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 one day or single exposure. An acute dietary risk assessment for imidacloprid is required for all population subgroups. The acute dietary risk assessment used the Theoretical Maximum Residue Contribution (TMRC, tolerance level residues and 100% crop treated); the tolerances used for legumes and strawberries were 1.0 and 0.1 ppm, respectively. The Novigen Dietary Exposure Evaluation Model (DEEM) analysis was used and this 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 99th percentile and percentage of the acute RfD are shown below. Values for the 99th percentile are considered to be conservative as OPP policy dictates exposure estimates from as low as the 95th percentile may be utilized for risk estimates from acute DEEM runs. Thus, these results are viewed as conservative estimates, and refinement using anticipated residue values and percent crop treated information, in conjunction with a Monte Carlo analysis, would result in lower estimates of acute dietary exposure and risk. The subgroups listed in the table below are the U.S. population, and those for infants and children. There are no other subgroups (adult) for which the percentage of the Acute RfD occupied is greater than that occupied by the subgroup U.S. Population (48 states).

Population Subgroup	Exposure @ 99th Percentile (mg/kg bwt/day)	Percent Acute RfD
U.S. Population (48 states)	0.051	12%
Infants (< 1 yr) ..	0.067	16%
Nursing Infants (<1 yr)	0.096	23%
Non-nursing Infants (<1 yr) ...	0.059	14%
Children (1–6 yrs)	0.086	20%
Children (7 – 12 yrs)	0.058	14%

ii. *Chronic exposure and risk.* The endpoint selected for chronic risk assessment is decreased body weight gains in females and increased thyroid lesions observed in males at 7.6 mg/kg/day in a combined chronic toxicity/carcinogenicity study in rats. The NOAEL was 5.7 mg/kg/day. In conducting this chronic dietary (food) risk assessment, EPA used: (1) tolerance level residues for legumes, strawberries, and all other commodities with pending, published, permanent or time-limited imidacloprid tolerances; and, (2) percent crop-treated (%CT) information on some of these crops. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values and additional %CT information would result in a lower estimate of chronic dietary exposure. As discussed above, the FQPA UF of 3X must also be utilized, resulting in an acceptable dietary exposure level not to exceed 33.3% of the chronic RfD for all population subgroups. The Novigen DEEM system was used for this chronic dietary exposure analysis.

The subgroups listed below are: (1) the U.S. Population (48 states); (2) those for infants and children; and, (3) the other subgroups (adult) for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. Population (48 states). The results are summarized below.

Population Subgroup	Exposure (mg/kg bwt/day)	%Chronic RfD
U.S. Population (48 states)	0.0037	6.6%
All Infants (< 1 yr)	0.0053	9.3%
Nursing Infants (<1 yr)	0.0017	3.0%
Non-nursing Infants (<1 yr) ...	0.0068	12%
Children (1–6 yrs)	0.0086	1.5%
Children (7–12 yrs)	0.0054	9.5%
U.S. Population (Autumn & Winter)	0.0038	6.7%
Non-Hispanic Black	0.0038	6.7%
Females (13+ / Nursing)	0.0038	6.7%
Non-Hispanic Others	0.0041	7.2%

2. *From drinking water.* There is no established Maximum Contaminant Level or Health Advisory Levels for imidacloprid in drinking water. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency uses models designed for use for ecological assessment, which are not ideal tools for use in drinking water risk assessment, as they could overestimate actual drinking water concentrations. Thus, these models are considered a coarse screening tool for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern. For surface water, the Agency used PRZM1 (Pesticide Root Zone Model - simulates the transport of a pesticide off the agricultural field) and EXAMS (Exposure Analysis Modeling System - simulates fate and transport of a pesticide in surface water) models which are used to produce estimates of pesticide concentrations in a farm pond. For ground water the Agency used SCI-GROW (Screening Concentration In Ground Water) model to estimate the concentration of imidacloprid residues in ground water. SCI-GROW is a prototype model for estimating ''worst case'' ground water concentrations of pesticides. SCI-GROW is biased in that studies where the pesticide is not detected in ground water are not included in the data set. Thus, it is not expected that SCI-GROW estimates would be exceeded.

In the absence of monitoring data for pesticides, 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, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to imidacloprid they are further discussed in the aggregate risk sections below.

i. *Acute exposure.* EPA used estimated concentrations of imidacloprid in surface and ground water for acute exposure analysis of 4.1 and 1.1 milligram/Liter (µg/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/A/year). For purposes of risk assessment, the estimated maximum concentration of 4.1 ppb was used. The calculated acute DWLOCs ranged from 440 ppb for Nursing Infants <1 yr. old, to 3,100 ppb for the U.S. population - Males.

ii. *Short-term exposure.* For purposes of risk assessment, the estimated maximum chronic exposure of imidacloprid from surface and ground waters of 1.1 µg/L is used for comparison to the back-calculated human health DWLOCs for the short-term endpoint. The DWLOC for short-term exposure for the population subgroup of concern, Children 1 – 6 yrs. old was calculated to be 600 ppb.

iii. *Chronic exposure.* EPA used estimated concentrations of imidacloprid in surface and ground water for chronic exposure analysis of 0.1 and 1.1 µg/L (ppb), respectively. These estimated concentrations of imidacloprid in surface and ground water are based upon an application rate of 0.5 lbs ai/A/year. The calculated chronic DWLOCs ranged from 100 ppb for Children 1 – 6 yrs. old, to 540 ppb for the U.S. population - Males.

iv. *Conclusions concerning residues in drinking water.* The estimated concentrations of imidacloprid in surface and ground water are considerably less than the Agency's DWLOCs for imidacloprid in drinking water as a contribution to acute, short-term, and chronic aggregate exposure. Therefore, taking into account the present uses, including those under emergency exemptions, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water would not result in an unacceptable estimate of acute, short-term, or chronic aggregate human health risk at this time.

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, et al.), tobacco, golf courses, walkways, recreational areas, bathrooms, household or domestic dwellings (indoor/outdoor), cats/dogs, and wood protection treatment to buildings. Available data do not demonstrate that imidacloprid has either dermal or inhalation toxicity potential, therefore, occupational/ residential risk assessments are not required. Since data show no toxicity from short term exposure via the dermal or inhalation route, the Agency feels there is no contribution to toxicity from these routes of exposure, and no increase in aggregate risk is anticipated from this exposure. However, oral exposure due to the registered residential uses may result, in particular for Children (1–6 years old). Post-application exposure scenarios for children include: incidental non-dietary ingestion of residues on lawn from hand-to-mouth transfer; ingestion of pesticide-treated turfgrass; incidental ingestion of soil from treated gardens; and incidental ingestion of pesticide residues on pets from hand-to-mouth transfer. These exposures are considered to be short-term oral exposures, and thus a residential short-term risk assessment via the oral route is required.

Incidental ingestion of pesticide residues on pets from hand-to mouth transfer may occur during the same period as the exposures from the turf and home garden uses. However, children's exposures from pet and turf uses are not expected to both occur at the high-end level. Therefore, these exposures were considered in separate estimates of risk. For Children (1 – 6 years), the residential exposure from the home garden and turf uses was estimated to be 0.072 mg/kg bwt/day and the residential exposure from the pet use was estimated to be 0.058 mg/ kg bwt/day.

4. *Cumulative exposure to substances with 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.'' An explanation of the current Agency approach to assessment of pesticides with a common mechanism of toxicity may be found in the Final Rule in Bifenthrin Pesticide Tolerances (**Federal Register**, November 26, 1997, 62 FR 62961–62970).

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. Imidacloprid is the sole member to date of the new chloronicotinyl class of pesticides.

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

1. *Acute risk.* Acute dietary risk was estimated using the conservative TMRC assumptions, as explained above. There was no refinement using anticipated residue values and percent crop-treated information in conjunction with Monte Carlo analysis which would result in much lower estimates of acute dietary exposure. For the most highly exposed subgroup, (Nursing Infants <1 Year) dietary esposure was estimated to utilize 23% of the acute RfD. Since an additional 3-fold uncertainty factor is used, in accordance with FQPA requirements, for imidacloprid an acceptable acute dietary exposure (food plus water) is 33.3% or less of the acute RfD.

For the purposes of this risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters of 4.1 µg/L is used for comparison to the human health DWLOCs for the acute endpoint. Despite the potential for exposure to imidacloprid in drinking water, after calculating DWLOCs and comparing them to these conservative model estimates of concentrations of imidacloprid for surface and ground water, EPA does not expect the aggregate exposure to exceed 33.3% of the acute RfD. Under current guidelines, non-dietary uses of imidacloprid do not constitute an acute exposure scenario. Therefore, EPA concludes that there is a reasonable certainty that no harm will

result to infants, children, or adults from acute aggregate (food and water) exposure to imidacloprid residues.

Dermal and inhalation exposure endpoints were not selected due to the demonstrated absence of toxicity; thus, there is no residential component for assessing chronic aggregate exposure and risk.

The refined assumptions described above were used, and thus this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values and additional %CT information would result in a lower estimate of chronic dietary exposure. EPA has estimated that the chronic exposure to imidacloprid from food for the most highly exposed adult population subgroup (Non-Hispanic Other Than Black or White) will utilize 7.2% of the Chronic RfD, and for the most highly exposed population subgroup that includes children (Children, 1–6 years old), dietary exposure will utilize 15% of the Chronic RfD, as shown previously. For imidacloprid, it was determined that an acceptable chronic dietary exposure (food plus water) of 33.3% or less of the Chronic RfD is needed to protect the safety of all population subgroups (due to the FQPA 3-fold uncertainty factor).

For purposes of chronic risk assessment, the estimated maximum concentration for imidacloprid in surface and ground waters (which is 1.1 µg/L) is used for comparison to the human health drinking water levels of comparison (DWLOCs) for the chronic (non-cancer) endpoint. Despite the potential for exposure to imidacloprid in drinking water, after calculating DWLOCs and comparing them to these conservative model estimates of concentrations of imidacloprid for surface and ground water, EPA does not expect the aggregate exposure to exceed 33.3% of the chronic RfD. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants, children, or adults from chronic aggregate (food and water) exposure to imidacloprid residues.

2. *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. Thus, this risk assessment is not required.

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. These exposures were considered in separate estimates of risk. These risk estimates are discussed below in the section on aggregate risks and determination of safety for infants and children.

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

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

D. 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 pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species 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 the rat developmental study, the maternal (systemic) NOAEL was 30 mg/kg/day, based on decreased weight gain at the LOEL of 100 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day based on increased wavy ribs at the LOEL of 100 mg/kg/day. In the rabbit developmental study, the maternal (systemic) NOAEL was 24 mg/kg/day, based on decreased body weight, increased resorptions and abortions, and death at the LOEL of 72 mg/kg/day. The developmental (fetal) NOAEL was 24 mg/kg/day, based on decreased body weight and increased skeletal anomalies at the LOEL of 72 mg/kg/day.

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/day for males and 0, 8.0, 20.5, or 57.4 mg/kg/day for females). For parental/systemic/reproductive toxicity, the NOAEL was 250 ppm (18.3 mg/kg/day) and the LOEL was 750 ppm (52 mg/kg/day), based on decreases in body weight in both sexes in both generations.

iv. *Pre- and post-natal 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. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure 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.

v. *Conclusion*. Although developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, no increased sensitivity in pups as compared to adults was seen in the 2-generation reproduction toxicity study in rats, and the toxicology data base is complete as to core requirements, the Agency determined that the additional safety factor for the protection of infants and children will be retained but reduced to 3X based on the following weight-of-the-evidence considerations

relating to potential sensitivity and completeness of the data:

a. There is concern for structure activity relationship. Imidacloprid, a chloronicotinyl compound, is an analog to nicotine and studies in the published literature suggests that nicotine, when administered causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed *in utero*.

b. There is evidence that imidacloprid administration causes neurotoxicity following a single oral dose in the acute study and alterations in brain weight in rats in the 2–year carcinogenicity study.

c. The concern for structure activity relationship along with the evidence of neurotoxicity dictates the need for a developmental neurotoxicity study for assessment of potential alterations on functional development.

Because a developmental neurotoxicity study potentially relates to both acute and chronic effects in both the mother and the fetus, the UF for FQPA is being applied for all population subgroups, and for both acute and chronic risk. Therefore, for the purposes of this risk assessment, dietary exposure must not be above 33.3% of the RfD, to make the finding of reasonable certainty of no harm.

2. *Acute risk*. More detail on the acute risk assessments are given above. EPA used the conservative exposure assumptions described above, and estimated acute exposure to imidacloprid from food will utilize 23% of the acute RfD for the most highly exposed population subgroup that includes children (Non-nursing Infants <1 yr. old). All other population subgroups have acute risk estimates below this level. It was determined that an acceptable acute dietary exposure (food plus water) for imidacloprid is 33.3% or less of the acute RfD, and the estimated exposures for all population subgroups at the 99th percentile are less than this level. Despite potential for exposure to imidacloprid via drinking water, EPA does not expect the aggregate exposure to exceed 33.3% of the acute RfD. Under current EPA guidelines, the registered non-dietary uses of imidacloprid do not constitute an acute exposure scenario. Therefore, EPA concludes that there is reasonable certainty that no harm will result to infants and children from acute aggregate exposure to imidacloprid residues.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to imidacloprid from food will utilize 15% of the RfD for the most highly exposed population subgroup, Children (1–6 years old). 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. However, as discussed previously, a 3X UF in accordance with FQPA is also required. Thus, for the purposes of this risk assessment, dietary exposure must not be above 33.3% of the RfD, to make the finding of reasonable certainty of no harm. Despite the potential for exposure to imidacloprid in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 33.3% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to imidacloprid residues.

4. *Short- or intermediate-term risk*. 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 exposures are not expected for adult population subgroups. Thus, this risk assessment is not required.

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. These exposures could occur through the following routes: incidental ingestion of residues on lawns from hand-to-mouth transfer; ingestion of pesticide-treated turfgrass; incidental ingestion of soil from treated gardens; and, incidental ingestion of pesticide residues on pets from hand-to-mouth transfer. These exposures are considered to be short-term oral exposures. Incidental ingestion of pesticide residues on pets from hand-to-mouth transfer may occur during the same period as the exposures from the turf and home garden uses. However, it is extremely unlikely that children's exposures from pet and turf/garden uses would both occur at the high-end level. Therefore, these exposures are considered in two separate estimates of risk.

A short-term oral endpoint was not identified for imidacloprid. According to current Agency 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 (Acute RfD = 0.42 mg/kg bwt/day) will be used to incorporate the oral component into aggregate risk. Short-term aggregate exposure is defined by EPA to be average food and water exposure (chronic) plus residential exposure. The short-term risk estimates for the population subgroup (Children, 1–6 yrs. old) is summarized below. This subgroup was chosen because it has the highest chronic food exposure and because toddlers have the highest exposure from the residential uses.

The table below aggregates the dietary exposure (food only) and residential exposures from the two different routes (hand-to-mouth from turf and home garden use; and hand-to-mouth from pet use) for the population subgroup Children 1–6 yrs. old.

IMIDACLOPRID: SHORT-TERM AGGREGATE EXPOSURE AND RISK FOR CHILDREN (1–6 YRS. OLD)

Exposure Scenario	Chronic Food Exposure (mg/kg bwt/day)	Residential Exposure (mg/kg bwt/day)	Total Exposure (mg/kg bwt/day)	Margin of Exposure (MOE)
Turf & Garden Use	0.0086	0.072	0.081	520
Pet Use	0.0086	0.058	0.067	630

As the table indicates, the total MOEs are 520 and 630, for turf/garden and pet uses, respectively, both of which are higher than 300, the determined acceptable MOE for imidacloprid. Additionally, potential short-term exposure from drinking water is at a level well below EPA's level of concern. EPA concludes the short-term aggregate risk to the highest exposed population subgroup (Children, 1 – 6 Yrs. Old) from home garden, turf, and pet uses of imidacloprid does not exceed EPA's level of concern.

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of imidacloprid residues in plants and 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 methods are available for determination of the regulated imidacloprid residue in plant (Bayer GC/MS Method 00200 and Bayer HPLC-UV Confirmatory Method 00357) and animal (Bayer GC/MS Method 00191) commodities. These methods have successfully completed EPA Tolerance Method Validation, and are awaiting publication in Pesticide Analytical Manual II (PAM II). In the interim, these methods are available from Calvin Furlow, EPA, OPP, IRSD, PIRIB.

C. Magnitude of Residues

Residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent, are not expected to exceed 0.1 ppm in/on strawberries, and 1.0 ppm in/on legume vegetables.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for imidacloprid on legumes or strawberries. International compatibility is thus not an issue.

E. Rotational Crop Restrictions

EPA previously concluded that field crop rotational studies with three crop groups (small grains, root crops, and leafy vegetables) supported a 12-month plant-back restriction. However, EPA recently recommended in favor of granting tolerances for inadvertent residues of imidacloprid in/on the following crop groups: cereal grains, forage, fodder, and straw of cereal grains, legume vegetables and the foliage of legume vegetables; and on sweet corn, soybeans, and safflower. EPA recommended a 30–day plant back interval be observed fore these crops. Therefore, the following rotation restriction is adequate for this section 18 use: Any crops may be planted back 12 months following imidacloprid applications, except for the following: crops having imidacloprid tolerances, sweet corn, soybeans, and safflower; and the commodities of the crop groups Cereal grains and Legume vegetables. These aforementioned crops may be rotated 30-days after the last imidacloprid treatment; except for crops with imidacloprid tolerances, which may be rotated at any time.

V. Conclusion

Therefore, the time-limited tolerances are established for residues of imidacloprid in/on legume vegetables at 1.0 ppm, and strawberry at 0.1 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by March 22, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300771] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes time-limited tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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 the rule in the **Federal Register**. This 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: December 23, 1998.

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. 346a 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) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	* *	*
Legume Vegetables.	0.1	6/30/00
Strawberry	1.0	6/30/00
* *	* *	*

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 185

Tolerances for Pesticides in Food

CFR Correction

In Title 40 of the Code of Federal Regulations, parts 150 to 189, revised as of July 1, 1998, on page 533, § 185.5000 was incorrectly published. The text, with the correctly revised table and reinstated effective date note, reads as follows: