Dated: July 28, 1999.

Joseph J. Angelo,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300894; FRL–6090–2]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in or on cucurbit vegetables (Crop Group 9) at 0.5 parts per million (ppm), tuberous and corm vegetable subgroup at 0.3 ppm, dasheen leaves at 3.5 ppm, and watercress (upland) at 3.5 ppm. The Interregional Research Project Number 4 (IR-4) New Jersey Agricultural Experiment Station 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 August 2, 1999. Objections and requests for hearings must be received by EPA on or before October 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300894], 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–300894], 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300894]. 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: Peg Perreault, 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: Rm. 209, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5417, Perreault.Peg@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 8, 1999 (64 FR 17171) (FRL–6071–2), EPA issued a notice 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 three pesticide petitions (PP 6E4766, 7E4898, and 7E4899) for tolerances by the Interregional Research Project Number 4 (IR-4) New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. This notice included a summary of the petitions prepared by IR-4. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.472(a) 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, all expressed as (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine, in or on cucurbit vegetables (Crop Group 9) at 0.5 parts per million (ppm), tuberous and corm vegetable subgroup at 0.3 ppm, dasheen leaves at 3.5 ppm, and watercress (upland) at 3.5 ppm.

I. Background and Statutory Findings

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).

II. 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 imidacloprid and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety on cucurbit vegetables (Crop Group 9) at 0.5 ppm, tuberous and corm vegetable subgroup at 0.3 ppm, dasheen leaves at 3.5 ppm, and watercress (upland) at 3.5 ppm. 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 in Unit II.A. of the Final rule on Imidacloprid Pesticide Tolerances published in the **Federal Register** on September 18, 1998 (63 FR 49837) (FRL–6027–1).

B. Toxicological Endpoints

The toxicological endpoints for imidacloprid are discussed in Unit II.B. of the Final rule on Imidacloprid Pesticide Tolerances published in the **Federal Register** on September 18, 1998.

C. Exposures and Risks

1. *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, in or on a variety of raw agricultural commodities and meat at 0.3 ppm, milk at 0.1 ppm, poultry at 0.05 ppm, and eggs at 0.02 ppm. Risk assessments were conducted by EPA to assess dietary exposures from imidacloprid as follows.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of crop treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: 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; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information to conduct a chronic dietary exposure analysis for imidacloprid as follows: 6% grapefruits, 3% oranges, 13% other citrus, 19% apples, 2% pears, 11% grapes, 30% eggplants/peppers, 32% head lettuce, 21% cole crops, 15% melons, 10% tomatoes, 6% cotton.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The 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.

i. *Acute exposure and risk.* Acute 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 acute population adjusted dose (aPAD) for imidacloprid is 0.14 mg/kg bwt/day (aPAD = acute RfD/FQPA UF = 0.42 mg/kg bwt/day/3 = 0.14 mg/kg bwt/day). EPA conducted a DEEM (Dietary Exposure Evaluation Model) analysis for acute dietary (food) risk assessment using the Theoretical Maximum Residue Contribution (TMRC), which assumes tolerance level residues and 100% crop-treated (Tier 1). The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 95th percentile) and percentage of aPAD utilized were below EPA's level of concern for the U.S. population and all subgroups, with the highest exposure in the subgroup children, 1-6 yrs (0.062 mg/kg bwt/day, 44% of the aPAD). The results of this analysis indicate that the acute risk from residues of imidacloprid on food is below EPA's level of concern.

ii. *Chronic exposure and risk.* The chronic population adjusted dose (cPAD) for imidacloprid is 0.019 mg/kg bwt/day (cPAD = chronic RfD/FQPA UF = 0.057 mg/kg bwt/day/3 = 0.019 mg/kg bwt/day). EPA conducted a DEEM analysis for chronic dietary (food only) risk assessment using tolerance level residues for imidacloprid and PCT information for some crops. The resulting of cPAD utilized is below EPA's level of concern for the U.S. population and all subgroups, with the highest exposure in the subgroup children, 1-6 yrs. (0.0092 mg/kg/day, 48% of the cPAD). The results of this analysis indicate that the chronic risk from residues of imidacloprid on food is below EPA's level of concern. The chronic risk assessment should be considered partially refined. Further refinement using anticipated residue values and PCT information would result in a lower estimate of chronic exposure.

2. *From drinking water.* There are no Maximum Contaminant Levels (MCLs) or Health Advisory (HA) levels established for residues of imidacloprid in drinking water.

EPA's Drinking Water Assessment for Imidacloprid indicates that 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, EPA has required the submission of the results of two prospective ground water monitoring studies; however, results from these studies are not yet available. Therefore, EPA has calculated estimated concentrations of imidacloprid in surface and ground waters.

i. *Acute exposure and risk.* For acute exposure analysis, the estimated concentrations of imidacloprid in surface and ground water were calculated based on an application rate of 0.5 lbs ai/acre/year. The estimated concentrations in surface and ground water are 4.1 and 1.1 µg/L (ppb), respectively. Estimated acute drinking water levels of comparison (DWLOCs) for imidaloprid range from 780 µg/L for children (1-6 years old) to 3,900 µg/L for the U.S. population (male). The estimated acute concentrations of imidacloprid in surface and ground water are less than the acute DWLOCs for imidacloprid. Therefore, taking into account the currently registered uses and the uses proposed in this action, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of acute aggregate human health risk at this time.

ii. *Chronic exposure and risk.* For chronic exposure analysis, the estimated concentrations of imidacloprid in surface and ground water were calculated based on an application rate

of 0.5 lbs ai/acre/year. The estimated concentrations in surface and ground water are 0.1 and 1.1 µg/L parts per billion (ppb), respectively. Estimated chronic drinking water levels of comparison (DWLOCs) for imidacloprid range from 98 µg/L for children (1-6 years old) to 490 µg/L for the population subgroup males. The estimated chronic concentrations of imidacloprid in surface and ground water are less than the chronic DWLOCs for imidacloprid. Therefore, taking into account the currently registered uses and the uses proposed in this action, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of chronic aggregate human health risk at this time.

iii. *Short-term exposure and risk*. For purposes of risk assessment, the estimated maximum chronic exposure of imidacloprid from surface and ground waters (1.1 µg/L), were used for comparison to the DWLOCs for the short-term endpoint.

The DWLOC for short-term exposure to imidacloprid was calculated relative to the aPAD which was utilized for estimating risk for short-term oral exposure to imidacloprid. To calculate the DWLOC for short-term exposure relative to an acute toxicity endpoint, the sum of chronic dietary food exposure and oral exposure to imidacloprid from home garden, turf, and pet uses was subtracted from the aPAD to obtain the acceptable short-term exposure to imidacloprid in drinking water (highest chronic food exposure = 0.0092 mg/kg/day, oral exposure from home garden and turf uses = 0.072 mg/kg bwt/day and, oral exposure from pet uses = 0.058 mg/kg bwt/day). DWLOCs were then calculated using default body weights and drinking water consumption figures. The estimated chronic concentrations of imidacloprid in surface and ground water are less than the short-term DWLOCs for imidacloprid. Therefore, taking into account the currently registered uses and the uses proposed in this action, EPA concludes with reasonable certainty that residues of imidacloprid in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of short-term 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), tobacco, golf courses, walkways, recreational areas, household or domestic dwellings (indoor/outdoor), and pets (cats and dogs). Available data do not demonstrate that imidacloprid has either dermal or inhalation toxicity potential; therefore, non-dietary dermal and inhalation exposure assessments are not required. Since available 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, there is the potential for residential exposure via incidental non-dietary ingestion from treated lawns and gardens and incidental non-dietary ingestion by toddlers of pesticide residues on pets from hand-to-mouth transfer. Therefore, an increase in short-term aggregate risk is anticipated from residential exposure via incidental non-dietary ingestion and residential exposure.

The product Premise, a termiticide, is also registered for residential use. Premise may be applied only by PCOs and only to inaccessible areas of homes or other buildings; therefore, oral exposure to children is not expected. There is potential for inhalation exposure. However, an inhalation endpoint has not been established, and data from EPA's environmental fate one-liner data base indicates that imidacloprid has a low vapor pressure (6.9×10^{-9} torr). Therefore, inhalation exposure due to residential use is not expected to pose a risk.

Short-term exposure and risk from residential uses of imidacloprid are discussed in detail in Unit II.C.3. of the Final rule on Imidacloprid Pesticide Tolerances published in the **Federal Register** on September 18, 1998. In summary, the residential exposure scenarios examined include the following postapplication short-term oral exposure scenarios for toddlers:

- Incidental non-dietary ingestion of residues on lawns from hand-to-mouth transfer.
- Ingestion of pesticide-treated turfgrass.
- Incidental ingestion of soil from treated gardens.
- Incidental ingestion of pesticide residues on pets from hand-to-mouth transfer.

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. It should be noted that these exposures are very conservative estimates since EPA utilized the Draft Standard Operating Procedures for Residential Exposure Assessments (dated December 18, 1997) to estimate these exposures. In the absence of data, it was estimated that 20% of the application rate is retained on pets and that 1% of the available residues are transferred to the skin of individuals who have contact with treated animals. The actual values may be different. A study to quantify dislodgeable residue for toddler's hand from pets treated with these types of products is required. The submission of this study is a condition of the registration of imidacloprid.

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

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from ground or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor and/or outdoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. *Acute risk.* Using the conservative TMRC exposure assumptions and taking into account the completeness and reliability of the toxicity data, EPA has estimated the acute exposure to imidacloprid from food for the most highly exposed population subgroup (children 1 - 6 yrs) will utilize 44% of the aPAD. It was determined that an acceptable acute dietary exposure (food plus water) of 100% or less of the aPAD is needed to protect the safety of all population subgroups.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD for adults. The maximum estimated concentration of Imidacloprid in surface and ground water for acute exposure is very small compared to the DWLOC. Under current EPA guidelines, non-dietary uses of imidacloprid do not constitute an acute exposure scenario.

2. *Chronic risk.* Using the partially refined exposure assumptions described in this unit and taking into account the completeness and reliability of the toxicity data, EPA has estimated the chronic exposure to imidacloprid from food for the most highly exposed population subgroup (children, 1-6 years old) will utilize 48% of the cPAD. It was determined that an acceptable chronic dietary exposure (food plus water) of 100% or less of the cPAD is needed to protect the safety of all population subgroups.

Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD. The maximum estimated concentration of Imidacloprid in surface and ground water for chronic exposure is very small compared to the DWLOC. The registered non-dietary uses of imidacloprid do not constitute a chronic exposure scenario.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Dermal and inhalation short- and intermediate-term risks are not expected 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.

Since imidacloprid is registered for use on turf, home gardens and pets, EPA has identified potential short-term oral exposures to children for these uses. A short-term oral endpoint was not identified for imidacloprid. If an oral endpoint is needed for short-term risk assessment (for incorporation of food, water, or oral hand-to-mouth type exposures into an aggregate risk assessment), the acute oral endpoint (LOAEL = 42 mg/kg bwt/day) is used to incorporate the oral component into aggregate risk. The short-term aggregate exposure and risk were calculated (chronic dietary exposure (food only) plus residential exposure (hand-to-mouth from turf, garden, and pet uses) for children age 1-6, resulting in a total MOE of 302 (the acceptable MOE for imidacloprid is 300). Potential short-term exposure from drinking water is at a level below EPA's level of concern. It should also be pointed out that this short-term aggregate risk assessment is a very conservative assessment due to the fact that all exposures are conservative estimates, with the chronic food exposure derived from assuming all residues at the tolerance level and some PCT, and the residential exposures from lawn, garden, and pet uses derived from the Draft Standard Operating Procedures for Residential Exposure Assessment (December 18, 1997) where several conservative assumptions were made including assuming 100% of residue on hands of toddlers is ingested. In addition, the aggregation routes are conservative by assuming children eat treated grass, soil, and have hand-to-mouth transfer from treated pets all on the same day.

4. *Aggregate cancer risk for U.S. population.* Imidacloprid has been classified as a Group E chemical, no evidence of carcinogenicity for humans.

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

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

1. *Safety factor for infants and children*— i. *In general.* The determination of the 3X safety factor to account for the potential for increased sensitivity of infants and children to residues of imidacloprid is discussed in Unit II.E.1.i. of the Final rule on Imidacloprid Pesticide Tolerances published in the **Federal Register** on September 18, 1998.

ii. *Developmental toxicity studies.* Developmental toxicity is discussed in Units II.A.4. and II.E.1. of the **Federal Register** document published on September 18, 1998.

iii. *Reproductive toxicity study.* Reproductive toxicity is discussed in Units II.A.5. and II.E.1. of the **Federal Register** document published on September 18, 1998.

iv. *Prenatal and postnatal sensitivity.* Prenatal and postnatal sensitivity is discussed in Unit II.E.1. of the **Federal Register** document published on September 18, 1998.

v. *Conclusion.* The toxicology data base for imidacloprid is complete with respect to core requirements; however, a developmental neurotoxicity study (Guideline No. 83-6) is required. Exposure data are estimated based on data that reasonably accounts for potential exposures; however, a study to quantify dislodgeable residues on toddler's hands from pets treated with imidacloprid is required.

2. *Acute risk.* Aggregate acute risks for the entire U.S. population and for population subgroups, including infants and children, are discussed in Unit II.D.1. of this preamble.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to imidacloprid from food will utilize 31% of the cPAD for all infants (< 1 year old), 9.2% of the cPAD for nursing infants (<1 year old), 40% of the cPAD for non-nursing infants (<1 year old), 48% of the cPAD for children 1-6 years old, and 10% of the cPAD for children 7-12 years old. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to imidacloprid in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk.* Aggregate short- and intermediate-term risks for the entire U.S. population and for population subgroups, including infants and children are discussed in Unit II.D.3. of this preamble.

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

III. Other Considerations

A. Metabolism in Plants and Animals.

Data concerning the metabolism of imidacloprid in apples, potatoes, tomatoes, eggplant, cottonseed, field corn, ruminants and poultry have previously been submitted. 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 PAM II. In the interim, these methods are available from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703–305–5229).

Bayer Corporation has previously submitted adequate multiresidue method (MRM) recovery data for imidacloprid and its olefin, hydroxy, guanidine, and 6-chloronicotininc acid metabolites through FDA's Protocols A through E. imidacloprid and its metabolites were not recoverable by these methods. These data have been forwarded to FDA and we expect them to be published in the Pesticide Analytical Manual (PAM), Vol I, Appendix I in a future update. Additional MRM recovery data are not required.

C. Magnitude of Residues

The crop field trial data support the proposed tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety.

D. International Residue Limits

There are no established CODEX, Canadian or Mexican residue limits for imidacloprid in/on the cucurbit vegetable crop group, tuberous and corm vegetable subgroup, dasheen leaves, and upland watercress. Thus, harmonization of the proposed tolerances with CODEX, Canada and Mexico is not an issue for these petitions.

E. Rotational Crop Restrictions

Data concerning the metabolism of imidacloprid in confined rotational crops was previously submitted. The nature of the residue in rotational crops is adequately understood and is nearly identical to that identified in the primary crops. The residue of concern in rotational crops is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as parent. Treated areas may be replanted with any crop specified on an imidacloprid label, or any crop for which a tolerance exists for imidacloprid, as soon as practical following the last application, with the exception of cereals, legumes, and safflower, which have a 30-day plant-back restriction. A 12-month plant-back restriction must be observed for crops not listed on an imidacloprid label and for crops for which no tolerances for imidacloprid have been established.

IV. Conclusion

Therefore, tolerances are established for combined residues of Imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in cucurbit vegetables (Crop Group 9) at 0.5 ppm, tuberous and corm vegetable subgroup at 0.3 ppm, dasheen leaves at 3.5 ppm, and upland watercress at 3.5 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation 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 October 1, 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 under the ''ADDRESSES'' section (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 regulation. 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). 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 tolerance objection fee waivers, contact James Tompkins, 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: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300894] (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 Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

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 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: July 19, 1999.

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), (346a) and 371.

2. In § 180.472(a), by alphabetically adding the following commodities to the table to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/ RevocationDate
* *	*	* *
Dasheen, leaves	3.5	None
* *	*	* *
Vegetable, cucurbit, group	0.5	None
Vegetable, tuberous and corm, subgroup	0.3	None
Watercress, upland	3.5	None
* *	*	* *

* * * * *

[FR Doc. 99–19595 Filed 7–30–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300901; FRL–6092–9]

RIN 2070–AB78

Pyriproxyfen; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for combined residues of the insecticide pyriproxyfen and its metabolites in or on tomatoes at 0.1 part per million (ppm) for an additional 2–year period. This tolerance will expire and is revoked on July 31, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on tomatoes. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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 FIFRA section 18.

DATES: This regulation becomes effective August 2, 1999. Objections and requests for hearings must be received by EPA, on or before October 1, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300901], 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–300901], 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, Crystal Mall #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@epa.gov. Copies of electronic 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 electronic objections and hearing requests must be identified by the docket control number [OPP–300901]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, 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: Rm. 280, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367; e-mail: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of May 13, 1998 (62 FR 26466) (FRL–5788–2), which announced that on its own initiative under 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) it established a time-limited tolerance for the residues of pyriproxyfen in or on tomatoes at 0.1 ppm, with an expiration date of July 31, 1999. EPA established the tolerance because 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 FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of pyriproxyfen on tomatoes for this year's growing season due to the continuing emergency situation with whiteflies. A recently introduced strain or species of whitefly has caused extensive damage over the past several years to various vegetable crops in southern areas of the U.S., including tomatoes. This pest has demonstrated resistance to available materials and is expected to cause significant economic losses if not adequately controlled. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of pyriproxyfen on tomatoes for control of whiteflies in tomatoes.

EPA assessed the potential risks presented by residues of pyriproxyfen in or on tomatoes. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of May 13, 1998 (62 FR 26466). Based on those data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 2–year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on July 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on tomatoes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.