there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **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: April 16, 1997.

Stephen L. Johnson,

Acting Director, 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. By adding § 180.504 as follows:

§ 180.504 Fenoxycarb; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the insecticide fenoxycarb, ethyl(2-[4-phenoxyphenoxy]ethyl) carbamate, in or on the following commodity:

Commodity	Parts per million	Expiration/ Revocation Date
Pears	0.1	April 30, 1998

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–10749 Filed 4–24–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300468; FRL–5599–5]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document extends the effective date for the established time-limited tolerance for residues of the insecticide imidacloprid and its metabolites resulting from crop rotational practices in or on the food commodities of the cucurbit vegetables crop group. The Interregional Research Project (IR–4) requested this time extension under the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1966.

DATES: This regulation is effective April 25, 1997. Submit written objections and hearing requests on or before June 24, 1997.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP–300468; PP–5E4598], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Room 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 should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the objections and hearing requests to: Crystal Mall #2, Rm. 1132, 1921 Jefferson Davis Highway, Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP 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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document control number [OPP–300468; PP–5E4598]. 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. Additional information on electronic submissions can be found in Unit III. of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection

Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Crystal Station #1, Sixth Floor, 2800 Jefferson Davis Highway, Arlington, VA, 703–308–8783, e-mail: jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 22, 1997, FRL–5583–3 (62 FR 3288), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, announcing the filing of an amendment to pesticide petition (PP–5E4598) for tolerance by the Interregional Research Project No. 4 (IR–4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. That notice included a summary of the petition prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing. The amended petition requested that 40 CFR 180.472 be amended by extending the effective date to expire on December 31, 1997, for the time-limited tolerance established for the indirect or inadvertent 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, resulting from crop rotational practices in or on the food commodities in the cucurbit vegetables crop group at 0.2 parts per million (ppm).

This tolerance will not support registration for imidacloprid on cucurbit vegetables. EPA will not consider applications for section 3 or section 24(c) registration for use of imidacloprid on cucurbit vegetables based on this time-limited tolerance. The tolerance will allow growers to produce cucurbit vegetables in rotation with crops that are treated in accordance with registered uses of imidacloprid. Imidacloprid registrations prohibit growers from planting crops that lack an imidacloprid tolerance on ground treated with the insecticide within a 12-month period. Crop rotational studies indicate that plant back crops grown in fields treated with imidacloprid may contain measurable amounts of the pesticide residue, if the rotational crop is planted within 12 months of application of the pesticide. In some areas, however, it is a common practice for growers to plant back cucurbit vegetables (melons, squash, and cucumbers) in fields that have been used to produce tomatoes and peppers. Imidacloprid is registered and tolerances are established for the fruiting vegetables crop group (including tomatoes and peppers).

IR–4 has submitted PP–6E4766, which proposes a permanent tolerance for residues of imidacloprid and its metabolites in or on the cucurbit vegetables crop group at 0.5 ppm. Although PP–6E4766 proposes a tolerance in support of registration for use of imidacloprid on cucurbit vegetables, the proposed tolerance, if established, will be adequate to cover indirect or inadvertent residues on cucurbits resulting from registered uses of imidacloprid. EPA's evaluation of PP–6E4766 was not completed in time to establish a permanent tolerance, prior to the December 31, 1996, expiration date for the time-limited tolerance. Therefore, EPA is extending the effective date for the time-limited tolerance for imidacloprid to expire December 31, 1997, to allow EPA additional time to review IR–4's petition for permanent tolerance for residues of imidacloprid on cucurbit vegetables.

In addition to the new tolerance being established, since for purposes of establishing tolerances the Food Quality Protection Act (FQPA), Pub. L. 104–170, has eliminated all distinctions between raw and processed food, EPA is combining the tolerances that now appear in § § 185.900 and 186.900 with the tolerances in § 180.472 and is eliminating § § 185.900 and 186.900

I. Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

A. Method of Determining Risks

1. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The theoretical maximum residue contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumption that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the reference dose (RfD) or poses a lifetime cancer risk that is greater than approximately 1 in 1 million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances and that the total acreages for all crops with established tolerances are seldom treated with the pesticide.

2. The RfD is assumed to be the exposure at or below which daily aggregate exposure over a lifetime will not pose an appreciable risk to human health. To assure the adequacy of the RfD, the Agency uses an uncertainty factor in deriving it. The factor is usually 100, based on the assumption that certain segments of the human population could be as much as 100 times more sensitive than the species represented by the toxicology data. The aggregate daily exposure to a pesticide residue at or below the RfD (expressed as l00% of the RfD) is generally considered acceptable by EPA.

3. Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. If the pesticide is determined to be a human carcinogen, the toxicological endpoint must be determined based on the nature of the carcinogenic response and a knowledge of its mode of action. The Agency uses a weight of evidence approach in classifying the potential of the pesticide as a human carcinogen.

4. In addition to assessing long-term, chronic exposure to pesticide residues in food, the Agency also evaluates single day or single event, acute exposure. Acute dietary exposure to residues of a pesticide in a food commodity is estimated by multiplying individual, single-day consumption estimates of that food by the tolerance level or the anticipated pesticide residue level. Each individual's daily exposure to a pesticide is the sum of the food commodities that individual consumed on that given day multiplied by the residue assumed to be present on each food commodity consumed. Using this

method, a distribution of possible daily exposures for a given population is established.

5. From this distribution, an upper-end estimate of exposure is chosen and compared to the most sensitive no-observed-effect level (NOEL) from studies relating to the toxicological effect of acute concern (usually developmental toxicity or neurotoxicity) to derive a margin of exposure (MOE). The MOE is a measure of the level of safety that exists between the estimated exposure to a highly exposed individual and the level below which effects were observed in the available toxicological studies. As with chronic exposure estimates, residue and percent of crop treated refinements are incorporated to derive a more accurate exposure estimate when risks calculated using ''worst case'' assumptions exceed risk levels of concern

B. Toxicological Study Summaries

The toxicological data considered in support of the tolerance include:

1. A 1-year chronic feeding study in dogs fed diets containing 0, 200, 500, or 1,250/2,500 ppm (average intake was 0, 6.1, 15, or 41/72 milligrams (mg)/kilogram (kg)/day) with a NOEL of 1,250 based on increased plasma cholesterol and liver cytochrome P–450 levels in dogs at the 2,500 ppm dose level. The high dose was increased to 2,500 ppm (72 mg/kg/day) from week 17 onward due to lack of toxicity at the 1,250-dose level.

2. A 2-year feeding/carcinogenicity study in rats fed diets containing 0, 100, 300, 900, or 1,800 ppm with a NOEL for chronic effects at 100 ppm (5.7 mg/kg/day in males, 7.6 mg/kg/day in females) that included decreased body weight gain in females at 300 ppm (24.9 mg/kg/day) and above, and increased thyroid lesions in males at 300 ppm (16.9 mg/kg/day) and above, and in females at 900 ppm (73 mg/kg/day) and above. There were no apparent carcinogenic effects under the conditions of the study.

3. A 2-year carcinogenicity study in mice fed diets containing 0, 100, 330, 1,000, or 2,000 ppm with a NOEL of 1,000 ppm (208 mg/kg/day in males, 274 mg/kg/day in females) based on decreased food consumption and decreased water intake at the 2,000 ppm dose level. There were no apparent carcinogenic effects observed under the conditions of this study.

4. A three-generation reproduction study with rats fed diets containing 0, 100, 250, or 700 ppm with a reproductive NOEL of 100 ppm (equivalent to 8 mg/kg/day based on decreased pup body weight observed at the 250 ppm dose level).

5. A developmental toxicity study in rats given gavage doses at 0, 10, 30, or 100 mg/kg/day during gestation days 6 to 16 with a NOEL for developmental toxicity at 30 mg/kg/day based on increased wavy ribs observed at the 100 mg/kg/day dose level.

6. A developmental toxicity study in rabbits given gavage doses at 0.8, 24, or 72 mg/kg/day during gestation days 6 through 19 with a NOEL for developmental toxicity at 24 mg/kg/day based on decreased body weight and increased skeletal abnormalities observed at the 72 mg/kg/day dose level.

7. Imidacloprid was negative for mutagenic effects in all but 2 of 23 mutagenic assays. Imidacloprid tested positive for chromosome abberations in an *in vitro* cytogenic study with human lymphocytes for the detection of induced clastogenic effects, and for genotoxicity in an *in vitro* cytogenetic assay measuring sister chromatid exchange in Chinese hamster ovary cells.

C. Toxicological Endpoints

1. *Dietary*—i. *Chronic toxicity.* The RfD for imidacloprid is established at 0.057 mg/kg/day. The RfD is established based on a 2-year feeding/carcinogenicity study in rats with a NOEL of 5.7 mg/kg/day and an uncertainty factor of 100. The lowest-observed-effect level (LOEL) of 16.9 mg/kg/day is based on increased thyroid lesions in males.

ii. *Acute toxicity.* EPA has determined that an NOEL of 24 mg/kg/day from a developmental toxicity study in rabbits should be used to assess acute toxicity. A decrease in body weight, an increases in resorptions, abortions, and skeletal abnormalities were observed at the LOEL of 72 mg/kg/day. The population of concern for this risk assessment are females 13+ years old.

iii. *Cancer risk.* Using its Guidelines for Carcinogen Risk Assessment published in the **Federal Register** on September 24, 1986 (51 FR 33992), EPA has classified imidacloprid as a Group E carcinogen (''no evidence of carcinogenicity for humans''—based on the results of carcinogencity studies in two species). The doses tested are adequate for identifying a cancer risk. Thus, cancer risk assessments are not appropriate for imidacloprid.

2. *Non-Dietary—Short- and intermediate-term risk.* No effects were observed at the highest dose tested (0.191 mg/liter (L)) in a 28-day inhalation study in rats and no systemic toxicity was observed at dose levels up to 1,000 mg/kg/day in a 21-day dermal toxicity study in rabbits.

D. Aggregate Exposures and Risks

1. *From food and feed uses.* i. Tolerances have been established (40 CFR 180.472) for the combined residues of imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) and its metabolites containing 6-chloropyridinyl moiety expressed in or on certain food commodities ranging from 0.02 ppm in eggs to 3.5 ppm in Brassica vegetable crop group (cabbage, chinese cabbage, and kale) and head and leaf lettuce.

ii. In conducting this exposure assessment, EPA has made very conservative assumptions—100% of cucurbits and all other commodities having imidacloprid tolerances will contain imidacloprid tolerances residues and those residues would be at the level of the tolerance—which result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

iii. The existing imidacloprid tolerances (published, pending, and including the current time-limited tolerance for cucurbits) result in a TMRC that is equivalent to the following percentages of the RfD:

U.S Population	16%
Nursing Infants	12%
Non-Nursing Infants (<1 year old).	31%
Children (1–6 years old)	32%
Children (7–12 years old)	24%

2. *From drinking water.* i. 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 groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

ii. Based on the available studies used in EPA's assessment of environmental risk, imidacloprid is persistent and could potentially leach into groundwater, and run off to surface water under certain environmental conditions. There is no established maximum concentration level (MCL) for residues of imidacloprid in drinking water. No drinking water health advisories have been issued for imidacloprid. The ''Pesticides in

Groundwater Database'' (EPA 734–12–92–001, September 1992) has no information concerning imidacloprid.

iii. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. A more detailed description of this analysis is included in the docket for this rulemaking. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all well below the level that would cause imidacloprid to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with imidacloprid in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary uses.* i. Imidacloprid is currently registered for use on the following non-food sites: turf, ornamentals, buildings for termite control, and cats and dogs for flea control.

ii. A residential exposure and risk assessment for imidacloprid use on turfgrass was recently conducted by EPA in conjunction with the reregistration of imidacloprid. Dermal and inhalation exposures were measured using volunteers who performed a choreographed exercise routine on a turf plot treated with imidacloprid at the maximum registered rate. Dermal levels were measured using whole body dosimetry. Using the NOEL of 1,000 mg/kg/day from the dermal toxicity study in rabbits, an MOE corresponding to an upper bound risk of 7,587 was calculated for 10 year old and 6,858 for 5 year old children. Inhalation levels were measured using quartz microfiber filters connected by polyvinylchloride tubing to portable air sampling pumps. Specific toxicological endpoints of concern for inhalation exposure have not been identified by EPA. However, in the rat sub-acute inhalation study (28-day study in which rats were exposed 6 hours/day, 5 days a week for 4 weeks) the no-observable-effect concentration (NOEC) for imidacloprid was 5.5 mg/m^3. This NOEC is approximately 800 times the concentration recorded in the immediate vicinity of the volunteers during the performance of their exercise routine. The analysis concluded that ''...risks to children are negligible from imidacloprid-treated turf as soon as the spray has dried.''

iii. An exposure and risk assessment for the termiticide use of imidacloprid was also conducted by EPA. Conservative estimates of maximum air concentrations to which humans could be exposed and continuous exposure (24 hours per day) were assumed in calculating MOEs. Adult exposure was calculated at 1.24×10^{-5} mg/kg/day and infant exposure at 3.3×10^{-5} mg/kg/day. As noted above, specific toxicological endpoints of concern for inhalation exposure have not been identified by EPA. For calculating MOEs, the sub-acute rat inhalation study was used which had a NOEL of 0.191 mg/L, the highest dose tested (corresponding to 43.08 mg/kg/day). Based on the exposures and using this NOEL, MOEs of 3.4×10^6 and 1.3×10^6 were calculated for adults and children, respectively.

4. *Cumulative exposure to substances with common mechanism of toxicity.* i. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

ii. Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

iii. 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. For the purposes of this tolerance action, therefore, EPA has not assumed that imidacloprid has a common mechanism of toxicity with other substances.

E. Determination of Safety for U.S. Population

1. *Chronic risk.* Using the conservative exposure assumptions described above, taking into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate dietary exposure to imidacloprid will utilize 16% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to imidacloprid in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will

result from aggregate exposure to imidacloprid residues.

2. *Acute risk.* For the population subgroup of concern, females 13+ and older (accounts for both maternal and fetal exposure), the calculated MOE value is 480. This MOE does not exceed the Agency's level of concern for acute dietary exposure.

F. Determination of Safety For Infants and Children

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 two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure to female test animals. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

In the rat developmental study, the maternal (systemic) NOEL was 30 mg/kg/day, based on decreased weight gain at the LOEL of 100 mg/kg/day. The developmental (fetal) NOEL 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) NOEL 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) NOEL was 24 mg/kg/day, based on decreased body weight and increased skeletal anomalies at the LOEL of 72 mg/kg/day.

In the rat developmental study, the developmental (fetus) and maternal (mother) NOELs occur at the same dose level, 24 mg/kg/day. The same response is seen in the rabbit developmental study with the developmental (fetus) and maternal (mother) NOELs occurring at same dose level of 30 mg/kg/day. This suggests that there are no special prenatal sensitivities for unborn children in the absence of maternal toxicity. However, a detailed analysis of the developmental studies indicates that the skeletal findings (wavy ribs and other anomalies) in both the rat and rabbit fetuses are severe malformations which occurred in the presence of slight toxicity (decreases of body weight) in the maternal animals. Additionally, in rabbits, there were resorptions and abortions which can be attributed to acute maternal exposure. This information has been interpreted by the Toxicology Endpoint Selection Committee (TESC) as indicating a potential acute dietary risk for pre-natally exposed infants.

In the two-generation rat reproduction study, the maternal NOEL is 55 mg/kg/day and the NOEL for decreased pup body weight during lactation is 8 mg/kg/day with the LOEL at 19 mg/kg/day. This study shows that adverse postnatal development of pups occurs at levels (19 mg/kg/day) which are lower than the NOEL for the parental animals (55 mg/kg/day). Therefore, the pups are more sensitive to the effects of imidacloprid than parental animals. The pup NOEL of 8 mg/kg/day in the reproduction study is 1.4 times greater than the NOEL of 5.7 from the 2-year rat feeding study which was the basis of the RfD. The TMRC value for the most highly exposed infant and children subgroup (children 1–6 years old) occupies 32% of the RfD.

1. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of imidacloprid ranges from 12% for nursing infants, up to 32% for children 1–6 years old. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to imidacloprid residues.

2. *Acute risk.* i. At present, the acute dietary MOE for females 13+ years old (accounts for both maternal and fetal exposure) is 480. This MOE calculation was based on the developmental NOEL in rabbits of 24 mg/kg/day. Maternal effects observed at the lowest-effect level (LEL) of 72 mg/kg/day included decreased body weight and increased resorptions and abortions. Fetal effects observed at the LEL of 72 mg/kg/day included an increase in skeletal abnormalities. This risk assessment also assumed 100% crop treated with tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. The large acute dietary MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

ii. FFDCA section 408 provides that EPA shall apply an additional tenfold MOE (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 MOE (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard MOE (usually 100x for combined inter- and intra-species variability) and not the additional tenfold MOE 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. Based on current toxicological data requirements, the database for imidacloprid relative to pre- (provided by rat and rabbit developmental studies) and post-natal (provided by the rat reproduction study) toxicity is complete. Further, as noted above, the acute dietary MOE for women 13+ years or older is 480. This large MOE demonstrates that the prenatal exposure to infants is not a toxicological concern at this time, and the additional uncertainty factor is not needed to protect the safety of infants and children.

iii. Both chronic and acute dietary exposure risk assessments assume 100% crop treated and use tolerance level residues for all commodities. Refinement of these dietary risk assessments by using percent crop treated and anticipated residue data would greatly reduce dietary exposure. Therefore, both of these risk assessments are also an over-estimate of dietary risk. Consideration of anticipated residues and percent crop treated would likely result in an anticipated residue contribution (ARC) which would occupy a percent of the RfD that is likely to be significantly lower than the currently calculated TMRC value. Additionally, the acute dietary MOE would be greater than the current MOE. This provides an adequate safety factor for children during the prenatal and postnatal development.

iv. It is unlikely that the dietary risk will exceed 100% of the RfD or that the acute MOE would be less than the currently calculated value if, in the future, an additional safety factor is deemed appropriate, when considered in conjunction with a refined exposure estimate. Therefore, EPA concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to imidacloprid residues.

G. Other Considerations

1. *Endocrine effects.* An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however, no evidence of such effects were reported in the

chronic toxicology studies described above. There were no observed pathology of the endocrine organs in these studies. There is no evidence at this time that imidocloprid causes endocrine effects.

2. *Metabolism in plants and animals.* The metabolism of imidacloprid in plants and animals is adequately understood for the purposes of these tolerances. The residues of concern in plants and animals are combined residues of imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety, all calculated as imidacloprid (as stated in 40 CFR 180.472). Adequate methods are available for the determination of the regulated imidacloprid residues.

3. *Analytical method.* There is a practical analytical method for detecting and measuring levels of imidocloprid and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in this tolerance. The proposed analytical method for determining residues is Bayer method 00200 for imidacloprid residues on plants and Bayer method 00191 for imidacloprid residues in animal tissues and milk. Copies of these methods have been forwarded to Food and Drug Administration (FDA) for publication in PAM Volume II. Both of these methods are common moiety GC-MS methods. EPA has provided information on this method to FDA. Because of the long lead time from establishing these tolerances to publication, the enforcement methodology is being made available in the interim to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1130A, 1921 Jefferson Davis Highway, Arlington, VA, 703– 305–5937.

4. *International tolerances.* There are no Mexican, Canadian, or Codex Alimentarius Commission (Codex) maximum residue levels and/or tolerances established for residues of imidacloprid on cucurbits.

II. 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 FFDCA section 408(e) and (1)(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 governs 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 June 24, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) 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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) 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 ''Confidential Business Information'' (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.

III. Public Record

A record has been established for this rulemaking under document control number [OPP–300468; PP–5E4598]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operation Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

IV. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, l993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 180, 185, and 186

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

Dated: April 16, 1997.

Stephen L. Johnson,

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. Section 180.472 is revised to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) *General.* Tolerances are established permitting the 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 the following food commodities:

Commodities	Parts per million	Expiration/ Revocation date
Apples	0.5	None
Apples, pomace (wet)	3.0	None
Barley, forage	1.5	November 28, 1998
Barley, grain	0.05	November 28, 1998
Barley, straw	0.2	November 28, 1998
Beet roots	0.3	November 29, 1997
Beet tops	3.5	November 29, 1997
Beets, sugar (roots)	0.05	August 24, 1998
Beets, sugar (tops)	0.1	August 24, 1998
Beets, sugar, molasses	0.3	August 24, 1998
Brassica vegetables crop group	3.5	None
Canola	0.05	None
Cattle, fat	0.3	None
Cattle, mbyp	0.3	None
Cattle, meat	0.3	None
Cotton, gin by-products	4.0	None
Cottonseed	6.0	None
Cottonseed meal	8.0	None
Eggs	0.02	None
Fruiting vegetables crop group	1.0	None
Goats, fat	0.3	None
Goats, mbyp	0.3	None
Goats, meat	0.3	None
Grape, juice	1.5	None
Grape, pomace (wet or dried)	5.0	None
Grape, raisin	1.5	None
Grape, raisin waste	15.0	None
Grapes	1.0	None
Hogs, fat	0.3	None
Hogs, mbyp	0.3	None
Hogs, meat	0.3	None
Hops, dried	6.0	None
Horses, fat	0.3	None
Horses, mbyp	0.3	None
Horses, meat	0.3	None
Leafy greens subgroup	3.5	None
Lettuce, head and leaf	3.5	None
Mango	0.2	None
Milk	0.1	None
Pome fruits crop group	0.6	None
Potato, chip	0.4	None
Potato, waste	0.9	None
Potatoes	0.3	None
Poultry, fat	0.05	None
Poultry, mbyp	0.05	None
Poultry, meat	0.05	None
Sheep, fat	0.3	None
Sheep, mbyp	0.3	None
Sheep, meat	0.3	None
Sorghum, forage	0.1	November 17, 1997
Sorghum, straw	0.1	November 17, 1997
Sorghum, grain	0.05	November 17, 1997
Tomato, paste	6.0	None
Tomato, pomace (wet or dried)	4.0	None
Tomato, puree	3.0	None
Turnip roots	0.3	November 29, 1997
Turnip tops	3.5	November 29, 1997
Wheat, forage	7.0	August 24, 1998
Wheat, grain	0.05	August 24, 1998
Wheat, straw	0.3	August 24, 1998

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent 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, when present therein as a result of the application of the pesticide to growing crops listed in this section and other non-food crops as follows:

Commodities	Parts per million	Expiration/ Revocation date
Vegetables, cucurbit	0.2	December 31, 1997

PART 185—[AMENDED]

1. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.900 [Removed]

2. Section 185.900 is removed.

PART 186—[AMENDED]

1. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.900 [Removed]

2. Section 186.900 is removed.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5814–8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.