26, 1996 notice. Today's notice also makes two other technical corrections to conform with the intent of the September 17, 1996 final rule.

DATES: Effective date of this document: December 26, 1996.

Effective date for amended definition of ''principal limit'' in § 206.3: May 1, 1997.

FOR FURTHER INFORMATION CONTACT: Mark W. Holman, Acting Director, Home Mortgage Insurance Division, Office of Insured Single Family Housing, Room number 9270, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–2121; TTY (202) 708–4594. (These are not toll-free telephone numbers.)

SUPPLEMENTARY INFORMATION: The September 17, 1996 final rule issued by the Department delayed the effective date for the amendment to the definition of ''principal limit'' in § 206.3 until January 5, 1997. The December 26, 1996 document further delayed the effective date for the definition of ''principal limit'' in § 206.3, until May 1, 1997, but inadvertently neglected to change the date references within the definition in two places. The correct date references of May 1, 1997 are being substituted through this correction notice. This notice also corrects the definition of ''principal limit,'' as it was set forth in the September 17, 1996 final rule by changing ''unless'' in the fifth sentence to ''if'' so that the definition clearly applies the changed method of calculating principal limit to mortgages executed on or after May 1, 1997, as was intended by the September 17, 1996 final rule. In addition, this notice corrects the sixth sentence of the definition of ''principal limit,'' as it was set forth in the September 17, 1996 final rule to add the words ''each month'' after ''increases'' and the words ''one-twelfth of'' after ''rate equal to.''

Accordingly, in FR Doc. 96–23717, on page 49032, the definition of ''principal limit'' in § 206.3, as set forth in the final rule published on September 17, 1996, at 61 FR 49030, is corrected to read as follows:

§ 206.3 Definitions.

* * * * *

Principal limit means the maximum disbursement that could be received in any month under a mortgage, assuming that no other disbursements are made, taking into account the age of the youngest mortgagor, the mortgage interest rate, and the maximum claim amount. Mortgagors over the age of 95 will be treated as though they are 95 for purposes of calculating the principal limit. The principal limit is used to calculate payments to a mortgagor. It is calculated for the first month that a mortgage could be outstanding using factors provided by the Secretary. It increases each month thereafter at a rate equal to one-twelfth of the mortgage interest rate in effect at that time, plus one-twelfth of one-half percent per annum, if the mortgage was executed on or after May 1, 1997. If the mortgage was executed before May 1, 1997, the principal limit increases each month at a rate equal to one-twelfth of the expected average mortgage interest rate plus one-twelfth of one-half percent per annum. The principal limit may decrease because of insurance or condemnation proceeds applied to the mortgage balance under § 209.209(b) of this chapter.

* * * * *

Dated: March 13, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 97–6860 Filed 3–18–97; 8:45 am]

BILLING CODE 4210–27–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300460; FRL–5594–2]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the pesticide imidacloprid in or on the raw agricultural commodity crop group, cucurbits (Crop Group 9 cucumbers, melons, and squash) in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of imidacloprid on cucurbits in Texas and California. This regulation establishes maximum permissible levels for residues of imidacloprid in these foods. This tolerance will expire on March 31, 1998.

DATES: This regulation becomes effective March 19, 1997. The entry in the table expires on March 31, 1998. Objections and requests for hearings must be received by EPA on or before May 19, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300460], 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–300460], must also be 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 objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Highway., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Such 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 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–300460]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–8791, e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the pesticide imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine), in or on cucurbits, at 0.2 part per million (ppm). This tolerance will expire and be revoked automatically without further action by EPA on March 31, 1998.

I. Background and Statutory Authority

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

New section 408(b)(2)(A)(i) 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, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemption for Imidacloprid on Cucurbits and FFDCA Tolerances

The Texas Department of Agriculture and the California Department of Pesticide Regulation availed themselves of the authority to declare the existence of a crisis situation within their states, on January 27, and February 5, 1997, respectively, thereby authorizing use under FIFRA section 18 of imidacloprid on cucurbits to control white flies. The States of Texas and California have also requested specific exemptions for this use of imidacloprid. Texas and California stated that an emergency situation was present due to this recently introduced pest, its devastating effects on the cucurbit crop, and its resistance to registered alternatives. Texas and California state that this pest can have devastating effects on growers' production and revenue. After having reviewed their submission, EPA concurs that an emergency condition exists.

As part of its assessment of these crisis declarations, EPA assessed the potential risks presented by residues of imidacloprid in or on cucurbits. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. This tolerance for imidacloprid will permit the marketing of cucurbits treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e) as provided for in section 408(l)(6). Although this tolerance will expire and be revoked automatically without further action by EPA on March 31, 1998, under FFDCA section 408(l)(5), residues of imidacloprid not in excess of the amount specified in the tolerance remaining in or on cucurbits after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. 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.

EPA has not made any decisions about whether imidacloprid meets the requirements for registration under FIFRA section 3 for use on cucurbits, or whether a permanent tolerance for imidacloprid for cucurbits would be appropriate. This action by EPA does not serve as a basis for registration of imidacloprid by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than Texas and California to use this product on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for imidacloprid, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose-response relationship can be determined, which provides a dose that

causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight-of-the-evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure-activity relationships. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low-dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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 assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a 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.

IV. Aggregate Risk Assessments, Cumulative Risk Discussion, 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. Imidacloprid is registered by EPA for use on turf, as a termiticide, and for flea control on pets. At this time EPA is not in possession of a registration application for imidacloprid on cucurbits. However, based on information submitted to the Agency, 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 the time-limited tolerance for residues of imidacloprid on cucurbits at 0.2 ppm. EPA's assessment of the dietary exposures and risks associated with establishing this tolerance follows.

A. Toxicological Profile

1. *Chronic toxicity.* Based on the available chronic toxicity data, the EPA's Office of Pesticide Programs (OPP) has established the RfD for imidacloprid at 0.057 milligrams/kilogram/day (mg/kg/day). The RfD for imidacloprid is based on a 2–year feeding study in rats with a NOEL of 5.7 mg/kg/day and an uncertainty factor of 100. An increase in thyroid lesions in males was observed at the Lowest Effect Level (LEL) at 16.9 mg/kg/day.

2. *Acute toxicity.* Based on the available acute toxicity data, OPP has determined that the NOEL of 24 mg/kg/day from the developmental toxicity study in rabbits should be used to assess risk from acute toxicity. Maternal effects observed at the 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. The population subgroup of concern for this risk assessment is females 13+ years and older. This subgroup takes into account both maternal and fetal effects.

3. *Short- and intermediate-term toxicity.* OPP has determined that available data do not demonstrate that imidacloprid has dermal or inhalation toxicity potential. Therefore, short-term or intermediate-term dermal and inhalation risk assessments, for occupational and residential exposure scenarios, are not required.

4. *Carcinogenicity.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified imidacloprid as a ''Group E'' chemical (no evidence of carcinogenicity for humans) based on the results of carcinogenicity studies in two species. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment would not be appropriate.

B. Aggregate Exposure

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 raw agricultural 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. There are no livestock feed items associated with these section 18 requests, so no additional livestock dietary burden will result from this section 18 registration. Therefore, existing meat/milk/poultry tolerances are adequate.

In conducting this exposure assessment, EPA has made very conservative assumptions — 100% of cucurbits and all other commodities having imidacloprid tolerances will contain imidacloprid tolerance 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.

1. *Chronic exposure.* Given the emergency nature of this request for the use of imidacloprid and the resulting need for a timely analysis and risk assessment, EPA has utilized the TMRC to estimate chronic dietary exposure

from the tolerances for imidacloprid on cucurbits at 0.2 ppm. The TMRC is obtained by multiplying the tolerance level residue for cucurbits by the average consumption data, which estimate the amount of cucurbits eaten by various population subgroups. This calculation is performed as well for every food having existing imidacloprid tolerances. The risk assessment is therefore considered to be overestimated. The Agency has extensive experience refining chronic dietary risk assessments for a broad range of pesticide chemicals. It is OPP's experience that when the chronic dietary risk assessment is refined using anticipated residue contribution (ARC) estimates derived from anticipated residue levels and percent crop treated data, the percent of the RfD occupied by the ARC is generally in the range of an order of magnitude lower than the percent of the RfD occupied by the unrefined TMRC. A similar decrease in estimated exposure to imidacloprid is expected once more refined data is received based on ARCs for imidacloprid on some crops.

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).

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.

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. 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 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.

2. *Acute exposure.* EPA has not estimated non-occupational exposures other than dietary for imidacloprid. Acceptable, reliable data are not currently available with which to assess acute risk. Imidacloprid is registered for turf pest control. While dietary and residential scenarios could possibly occur in a single day, imidacloprid would rarely be present on both the food eaten and the lawn on that single day. Even assuming this were the case, it is yet more unlikely that residues would be present at tolerance level on all food eaten that day for which imidacloprid tolerances exist, as is assumed in the acute dietary risk analysis, and on the lawn that same day. Because the acute dietary exposure estimate assumes tolerance level residues and 100% crop treated for all crops evaluated, it is a large over-estimate of exposure and it is considered to be protective of any acute exposure scenario.

C. Cumulative Exposure to Substances with Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' 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.

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).

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.

D. Determination of Safety for U.S. Population

1. *Chronic risk.* Using the conservative exposure assumptions described above, and 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 percent 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 Margin of Exposure (MOE) value is 480. This MOE does not exceed the Agency's level of concern for acute dietary exposure.

E. 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 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. 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 the 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 rat reproduction study, the maternal (systemic) NOEL was 55 mg/kg/day (the highest dose tested). The reproductive/developmental NOEL (effect on the pup) was 8 mg/kg/day, based on decreased pup body weight during lactation in both generations at the LOEL of 19 mg/kg/day.

In the 2-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 infants and children subgroup (children 1 to 6 years old) occupies 31.0% 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 percent for nursing infants, up to 32 percent for children 1 to 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.* 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 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.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (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.

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.

It is unlikely that the dietary risk will exceed 100 percent of the RfD or that the acute MOE would be greater 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.

V. Other Considerations

The metabolism of imidacloprid in plants and animals is adequately understood for the purposes of these tolerances. There are no Mexican, Canadian, or Codex maximum residue levels established for residues of imidacloprid on cucurbits. There is a practical analytical method for detecting and measuring levels of imidacloprid in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources 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 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of imidacloprid in/on cucurbits at 0.2 ppm. This tolerance will expire on March 31, 1998.

VII. Objections and Hearing Requests

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

Any person may, by May 19, 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 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 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.

VIII. Public Docket

A record has been established for this rulemaking under docket number [OPP–300460]. 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 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 Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

The official record for this rulemaking, as well as the public version, as described above, 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 Virginia 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.

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by 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) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: February 28, 1997.

Peter Caulkins,

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. In § 180.472, in paragraph (d), by adding alphabetically the following entry to the table:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	* *	
Vegetables, Cucurbits	0.2	March 31, 1998

* * * * *

[FR Doc. 97–6654 Filed 3–18–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, 27, and 97

[GN Docket No. 96–228; DA 97–548]

The Wireless Communications Service (''WCS'')

AGENCY: Federal Communications Commission

ACTION: Final rule; petitions for reconsideration.

SUMMARY: On March 13, 1997, the Wireless Telecommunications Bureau of the Federal Communications Commission released a Public Notice establishing an expedited pleading cycle for oppositions and replies to oppositions to two petitions for reconsideration of the Commission's Report and Order establishing rules and policies for a new Wireless Communications Service (''WCS'') in the 2305–2320 and 2345–2360 MHz bands. The Public Notice summarizes the petitions for reconsideration and announces that oppositions to the petitions for reconsideration are due on or before March 21, 1997, and that replies to oppositions to the petitions for reconsideration are due on or before March 25, 1997.

DATES: Oppositions are due on or before March 21, 1997. Replies to oppositions are due on or before March 25, 1997.

FOR FURTHER INFORMATION CONTACT: Josh Roland or Matthew Moses, Wireless Telecommunications Bureau, (202) 418–0660.

SUPPLEMENTARY INFORMATION: This is a summary of the Public Notice released on March 13, 1997. The complete Public Notice is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., 20554, and also may be purchased from the Commission's copy contractor, International transcription Services, (202) 857–3800, 2100 M Street, N.W., Washington, D.C. 20037. The complete Public Notice is also available on the Commission's Internet home page (http://www.fcc.gov).

Summary of the Public Notice

Expedited Pleading Cycle Established for Oppositions and Replies to Oppositions to Petitions for Reconsideration Filed by the Wireless Cable Association International, Inc. and by PACS Providers Forum and DigiVox Corporation

March 13, 1997.

Oppositions Due: March 21, 1997.

Replies to Oppositions Due: March 25, 1997.

The Federal Communications Commission has received two petitions for reconsideration of the Commission's *Report and Order* reallocating the frequencies at 2305–2320 and 2345–2360 MHz and establishing auction and service rules for the Wireless Communications Service (''WCS''). See *Amendment of the Commission's Rules to Establish Part 27, the Wireless Communications Service,''* GN Docket No. 96–228, Report and Order, FCC 97–50, 62 FR 9636 (March 3, 1997) (*''WCS Report and Order''*). The Commission's action in adopting these rules was taken in response to the Congressional mandate expressed in Section 3001 of the Omnibus Consolidated Appropriations Act, 1997, that the Commission reallocate and assign the use of these frequencies by means of competitive bidding commencing no later than April 15, 1997. See Omnibus Consolidated Appropriations Act, 1997, Public Law 104–208, 110 Stat. 3009 (1996).

On March 10, 1997, the Wireless Cable Association International, Inc. (''WCA'') filed a ''Petition for Expedited Reconsideration'' of the WCS Report and Order. WCA requests that the Commission reconsider its decision not to impose any technical restrictions on WCS licensees designed to prevent interference with Multipoint Distribution Service (''MDS'') and Instructional Television Fixed Service (''ITFS'') operations in the 2150–2162 and 2500–2690 MHz bands. WCA states that it is necessary to limit WCS radiated power to 20 watts EIRP in order to avoid blanketing interference which could adversely effect MDS and ITFS operations throughout the United States. Interested parties should address the appropriateness of the proposed power limitation and its potential effect on prospective WCS operations. In addition, it would be useful to have commenters' views on whether a different power limit than that proposed by WCA would be more appropriate, and alternatively on whether and in what circumstances, in the absence of a specific power limit, a WCS licensee should be required to take remedial action if blanketing interference to MDS or ITFS reception is demonstrated.

On March 11, 1997, PACS Providers Forum (''PPF'') and DigiVox Corporation (''DigiVox'') jointly filed a ''Petition for Expedited Reconsideration'' of the WCS Report and Order urging the Commission to reconsider the out-of-band emission limits adopted for WCS. Specifically, PPF and DigiVox argue that the out-of-band emission limits for WCS are unnecessarily stringent, and that lower limits would permit a greater number of potential uses for the WCS spectrum while at the same time protecting satellite DARS operations in adjacent spectrum. In addition to requesting lower out-of-band emission limits generally, PPF and DigiVox propose that the Commission adopt additional operating parameters for certain operations in the WCS A and B blocks, such as Personal Access Communications Systems (''PACS''). Commenters are requested to address whether lower out-of-band emission limits would adequately protect satellite DARS operations from interference caused by WCS operations, and whether requiring low-power services such as PACS to employ the proposed parameters when operating in WCS spectrum would mitigate the need for the out-of-band emission limits adopted in the WCS Report and Order.

In an effort to rapidly resolve these matters given the statutory deadline of April 15, 1997, for commencement of