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. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

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 a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

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.

List of Subjects in 40 CFR Part 180

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

Dated: November 20, 1996.

Daniel M. Barolo,

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 § 180.368, by adding and reserving paragraph (d) and adding a new paragraph (e) to read as follows:

§ 180.368 Metolachlor; tolerances for residues

* * * * *

(d) [Reserved]

(e) A time-limited tolerance is established for the combined residues (free and bound) of the herbicide metolachlor [2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide] and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerance expires and is automatically revoked on the date specified in the table without further action by EPA.

Commodity	Parts per million	Expiration/Revocation Date
Spinach	0.3	November 15, 1998

[FR Doc. 96–30468 Filed 11–27–96; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300445; FRL–5575–1]

RIN 2070–AB78

Imidacloprid Pesticide Tolerance; Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of the insecticide imidacloprid in or on the raw agricultural commodity garden beets roots and tops and turnip roots and greens 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 garden beet roots and tops and turnip roots and greens in California. This regulation establishes maximum permissible levels for residues of imidacloprid on turnips and beets pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and be revoked automatically without further action by EPA on November 29, 1997.

DATES: This regulation becomes effective November 29, 1996. This regulation expires and is revoked automatically without further action by EPA on November 29, 1997. Objections and requests for hearings must be received by EPA on January 28, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300445], 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 number, [OPP–300445], should 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 Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by

the docket number [OPP–300445]. 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. Additonal information on electronic submission can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Margarita Collantes, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–83427, e-mail: collantes.margarita@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the insecticide imidacloprid, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine in or on garden beet roots at 0.3 part per million (ppm), in or on garden beet tops at 3.5 ppm, in or on turnip roots at 0.3 ppm and in or on turnip greens at 3.5 ppm. These tolerances will expire and be revoked automatically without further action by EPA on November 29, 1997.

I. Background And Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

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 the 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 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 Exemptions for Imidacloprid on Garden Beets and Turnip Greens and FFDCA Tolerances

On August 6, 1966, the California Department of Pesticide Regulations availed of itself the authority to declare the existence of a crisis situation within the State, thereby authorizing use under FIFRA section 18 of imidacloprid on table beets and turnips for control of aphids. California has also requested a specific exemption for this use. Emergency conditions are determined to exist due to the lack of acceptable control with currently registered products and the loss of the insecticide Phosdrin. Under moderate to severe infestation conditions, the aphids are expected to cause serious reductions due to contamination problems at harvest, primarily due to the large number of aphids remaining on the crop. The overall threshold that the market will allow is 2 aphids or less per plant.

As part of its assessment of these applications for crisis declaration and emergency exemptions, EPA assessed the potential risks presented by residues of imidacloprid in or on garden beets (roots and tops) and turnips (roots and greens). 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 tolerances under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for imidacloprid will permit the marketing of garden beets and turnips 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 these tolerances without notice and opportunity for public comment under section 408(e) as provided in section 408(l)(6). Although these tolerances will expire and be revoked automatically without further action by EPA on November 29, 1997, under FFDCA section 408(l)(5), residues of imidacloprid not in excess of the amounts specified in the tolerances remaining in or on garden beet roots and tops and turnip roots and greens 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 these tolerances 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 garden beets and turnips or whether permanent tolerances for imidacloprid for garden beets (roots and tops) and turnips (roots and greens) 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 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). Various studies may be used to determine the RfD although a longterm feeding study in dogs, rats or mice is the type of study typically used for RfD determination. 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 acceptable by EPA.

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 relationship. 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 (MOE) 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 Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Imidacloprid is already registered by EPA for turf pest control. At this time EPA is not in possession of a registration application for imidacloprid on beets and turnips. 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 tolerances for residues of imidacloprid on garden beets and turnip roots at 0.3 ppm and garden beet and turnip tops at 3.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity.* Based on the available chronic toxicity data, the Office of Pesticide Programs (OPP) has established the RfD for imidacloprid at 0.057 milligrams(mg)/kilogram(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 the effect 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 is representative for both maternal and fetal effects.

3. *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 beets and turnips 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 garden beets and turnip roots at 0.3 ppm and garden beets and turnip tops at 3.5 ppm. The TMRC is obtained by multiplying the tolerance level residue for beets and turnips by the average consumption data, which estimates the amount of beets and turnips 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.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources.

Review of terrestrial field dissipation data by the Agency indicates that imidacloprid is persistent and leaches into groundwater. 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. The Agency does not have available data to perform a quantitative drinking water risk assessment for imidacloprid at this time. Previous experience with more persistent and mobile pesticides for which there have been available data to perform quantitative risk assessments have demonstrated that drinking water exposure is typically a small percentage of the total exposure when compared to the total dietary exposure. This observation holds even for pesticides detected in wells and drinking water at levels nearing or exceeding established MCLs. Based on this experience and OPP's best scientific judgement, and considering the low percent of the RfD occupied by dietary exposure estimates (15% RfD for U.S. population), EPA concludes that it is not likely that the potential exposure from residues of imidacloprid in drinking water added to the current dietary exposure will result in an exposure which exceeds the RfD.

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.

3. *Cumulative effects note*. At this time, the Agency has not made a determination that imidacloprid and other substances that may have a common mode of toxicity would have cumulative effects. For purposes of this tolerance only, the Agency is considering only the potential risks of imidacloprid in its aggregate exposure.

C. 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 exposure to imidacloprid will utilize 15% 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. 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. MOE values over 100 do not exceed the Agency's level of concern for acute dietary exposure. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

D. 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 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.

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 12.2 percent for nursing infants, up to 31.0 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 that no harm will result to both females 13+ years and the pre-natal development of infants from aggregate residues of imidacloprid.

3. *Chronic and acute risk determination factors.* FFDCA section 408 provides that EPA shall apply an additional safety factor 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 concludes that a different margin of safety would be appropriate. Taking into account 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. 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. However, 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.

In the case of 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 mg/kg/day from the 2–year rat feeding study which was the basis of the RfD. Therefore the RfD is established at a level which is adequate to assess reproductive pup effects from dietary exposure. In addition, the TRMC estimate (worst case dietary exposure) was used to determine the value for the most highly exposed infant and children subgroup (children 1 to 6 years old). The TRMC value for this age group occupies 31.0% of the RfD.

Both chronic and acute dietary exposure risk assessments assume 100% crop treated and use tolerance level residues for all commodities (TMRC estimate). 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 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.

If an additional safety factor were deemed appropriate when considered in conjunction with a refined exposure estimate it is unlikely that the dietary risk will exceed 100 percent of the RfD and likely that the acute MOE would be greater than the currently calculated value should. Therefore, EPA concludes that there is a 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 Codex maximum residue levels established for residues of imidacloprid on sugar beets, sugar beet tops, turnip roots or turnip greens (tops). 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, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of imidacloprid in beet and turnip roots at 0.3 ppm and beet and turnip tops at 3.5 ppm. These tolerances will expire and be automatically revoked without further action by EPA on November 29, 1997.

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 January 28, 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–300445]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 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.

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.

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. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

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.

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.

List of Subjects In 40 CFR Part 180

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

Dated: November 20, 1996.

Daniel M. Barolo,

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 by revising the section heading and by adding paragraph (d) to to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

(d) Time-limited tolerances are established for residues of the insecticide imidacloprid 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. Each tolerance expires and is automatically revoked on the date specified in the table without further action by EPA.

Commodity	Parts per million	Expiration/Revocation Date
Beet roots	0.3	November 29, 1997
Beet tops	3.5	November 29, 1997
Turnip roots	0.3	November 29, 1997
Turnip tops	3.5	November 29, 1997

* * * * *

[FR Doc. 96–30469 Filed 11–27–96; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300446; FRL–5574–9]

RIN 2070-AC78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the insecticide tebufenozide in or on the raw agricultural commodity peppers in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of tebufenozide on peppers in Georgia and New Mexico. This regulation establishes maximum permissible levels for residues of tebufenozide on peppers pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This tolerance will expire and be revoked automatically without further action by EPA on November 30, 1997.

DATES: This regulation becomes effective November 29, 1996. This regulation expires and is revoked automatically without further action by EPA on November 30, 1997. Objections and requests for hearings must be received by EPA on January 28, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300446], 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–300446], should 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 Hwy., Arlington, VA. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300446]. 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: Margarita Collantes, Registration Division (7505W), 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) 308-8347, e-mail: collantes.margarita@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the insecticide tebufenozide (benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2(4-ethylbenzoyl)hydrazide) in or on peppers at 0.5 part per million (ppm). This tolerance will expire and be revoked automatically without further action by EPA on November 30, 1997.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

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