Commodity	Parts per million	Expiration/ Revocation Date
Almonds, nutmeat	0.05	none
Almond, hulls	0.70	12/31/05
Banana	0.20	none
Cattle, fat	0.05	none
Cattle, mbyp	0.05	none
Cattle, liver	0.05	none
Citrus fruit	2.0	none
Citrus, oil	60	none
Citrus, dried pulp	6.0	none
Cotton, gin byproducts	15	12/31/05
Cotton, undelinted seed	0.40	12/31/05
Goats, fat	0.05	none
Goats, mbyp	0.05	none
Goats, liver	0.05	none
Grape	0.40	none
Grape, raisin	0.60	none
Hogs, fat	0.05	none
Hogs, mbyp	0.05	none
Hogs, liver	0.05	none
Horses, fat	0.05	none
Horses, mbyp	0.05	none
Horses, liver	0.05	none
* * * * * * *		
Milk	0.01	none
Sheep, fat	0.05	none
Sheep, mbyp	0.05	none
Sheep, liver	0.05	none
Tomato	0.40	12/31/05
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(b) *Section 18 emergency exemption.* [Reserved]

[FR Doc. 01–22281 Filed 9–4–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301165; FRL–6798–6]

RIN 2070–AB78

Pyriproxyfen; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of pyriproxyfen in or on succulent beans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on succulent beans. This regulation establishes a maximum permissible level for residues of pyriproxyfen in this food commodity. The tolerance will expire and is revoked on June 30, 2003.

DATES: This regulation is effective September 5, 2001. Objections and requests for hearings, identified by docket control number OPP–301165, must be received by EPA on or before November 5, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301165 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9367; and e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301165. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the insect growth regulator pyriproxyfen, [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine], in or on succulent beans at 0.10 part per million (ppm). This tolerance will expire and is revoked on June 30, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (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 the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Pyriproxyfen on Succulent Beans and FFDCA Tolerances

The silverleaf whitefly (SLW) is a relatively new pest, and has caused severe economic damage to various commodities nationwide. The larval instars and adults feed on the sap of bean plants, resulting in honeydew production which serves as a medium for fungal disease development, which hampers photosynthesis and renders pods unmarketable. Additionally, in late 1992, bean golden mosaic virus (BGMV) was first detected, although it's distribution was limited for several years. This virus is transmitted by the SLW. Recently, BGMV has become a more serious problem, believed to be the result of season-long build-up of the disease. This shift is a significant new development making BGMV a major pest in legume production in Florida. This trend is expected to continue unless an effective insecticide is available to control the SLW. EPA has authorized under FIFRA section 18 the use of pyriproxyfen on succulent beans for control of silverleaf whitefly in Florida. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of pyriproxyfen in or on succulent beans. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on June 30, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on succulent beans after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. 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.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether pyriproxyfen meets EPA's registration requirements for use on succulent beans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of pyriproxyfen by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Florida to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for pyriproxyfen, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of pyriproxyfen and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of pyriproxyfen in or on succulent beans at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is

retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for pyriproxyfen used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIPROXYFEN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF[1]	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute dietary all populations	not applicable	not applicable	There were no effects that could be attributed to a single exposure (dose) in oral toxicity studies including the developmental toxicity studies in rats and rabbits.
Chronic dietary all populations	NOAEL= 35.1 mg/kg/day UF = 100 Chronic RfD = 0.35 mg/kg/day	FQPA SF = 1 cPAD = 0.35 1 = 0.35 mg/kg/day	Combined/chronic toxicity - rat LOAEL = 182.7 mg/kg/day based on decreased weight gain in female rats.
Short-term dermal and inhalation (1-7 days) and intermediate-term dermal and inhalation (1 week - several months) (Occupational/Residential)	not applicable	not applicable	
Long-term dermal (several months - lifetime)[2] (Occupational/Residential)	35.1 mg/kg/day	LOC for MOE = 100 (Residential)	Combined/chronic toxicity - rat LOAEL = 182.7 mg/kg/day based on decreased weight gain in female rats.
Long-term inhalation (several months - lifetime)[2] (Occupational/Residential)	35.1 mg/kg/day	LOC for MOE = 100 (Residential)	Combined/chronic toxicity - rat LOAEL = 182.7 mg/kg/day based on decreased weight gain in female rats.
Cancer (oral, dermal, inhalation)	''Group E'' human carcinogen	not applicable	There is no evidence of carcinogenic potential. Therefore, a cancer risk assessment is not required.

[1]UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, LOC = level of concern, MOE = margin of exposure.

[2]Appropriate route-to-route extrapolation should be performed for these risk assessments. Exposure values using absorption factors of 10% for dermal and 100% for inhalation (default value) should be converted to equivalent oral doses and compared to the oral NOAEL.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.510) for the combined residues of pyriproxyfen, in or on a variety of raw agricultural commodities. Section 18 emergency exemptions for use in/on cotton, citrus, almonds, and stone fruits have been approved. Section 3 permanent tolerances have been granted for cotton, citrus fruits, pome fruits, tree nuts, fruiting vegetables, and all foods in food handling establishments. Risk assessments were conducted by EPA to assess dietary exposures from pyriproxyfen in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The acute dietary assessment is not required for pyriproxyfen because there were no effects that could be attributed to a single exposure (dose) in oral toxicity studies including the developmental toxicity studies in rats and rabbits.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992–nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

Tolerance level residues and 100% crop treated.

iii. *Cancer*. Pyriproxyfen has been classified as a Group E carcinogen; there is no evidence of carcinogenic potential. Therefore, a cancer risk assessment is not required.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyriproxyfen in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of pyriproxyfen.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to pyriproxyfen they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of pyriproxyfen for chronic exposures are estimated to be 0.11 ppb for surface water and 0.006 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyriproxyfen is currently registered for use on the following residential non-dietary sites: Residential (indoor, non-food) products for flea and tick control. Formulations include contact sprays, emulsifiable concentrates, and impregnated materials (pet collars). With the exception of the pet collar uses, consumer use of pyriproxyfen typically results in short-term, intermittent exposures. Hence, chronic residential postapplication exposure and risk assessments were conducted to estimate the potential risks from pet collar uses.

The risk assessment was conducted using the following assumptions: Application rate of 0.58 mg ai/day (product label), average body weight for a 1 to 6 year old child of 10 kg, the active ingredient dissipates uniformly through 365 days (the label instructs to change the collar once a year), and 1% of the active ingredient is available for dermal and inhalation exposure per day. The assessment also assumes an absorption rate of 100%. This is a conservative assumption since the dermal absorption was estimated to be 10%.

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

EPA does not have, at this time, available data to determine whether pyriproxyfen 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, pyriproxyfen 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 pyriproxyfen has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies*. In the developmental study in rats, the maternal (systemic) NOAEL was 100 mg/kg/day, based on decreased body weight, body weight gain, food consumption and increased water consumption at the LOAEL of 300 mg/kg/day. The developmental (fetal) NOAEL was 300 mg/kg/day, based on increased skeletal variations and unspecified visceral variations at the LOAEL of 1,000 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 100 mg/kg/day, based on abortions, soft stools, emaciation, decreased activity and bradypnea at the LOAEL of 300 mg/kg/day. The developmental (pup) NOAEL was 300 mg/kg/day, based on decreased viable litters at the LOAEL of 1,000 mg/kg/day.

3. *Reproductive toxicity study*. In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was 87/96 mg/kg/day for M/F, based on decreased body weights, body weight gains, and increased liver weight associated with histopathological findings in the liver at the LOAEL of 453/498 mg/kg/day for M/F. The developmental (pup) NOAEL was 87/96 mg/kg/day, based on decreased body weight on lactation days 14 and 21 at the LOAEL of 453/498 mg/kg/day. The

reproductive NOAEL was 453/498 mg/kg/day HDT.

4. *Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for pyriproxyfen is complete with respect to current data requirements. There are no prenatal or postnatal toxicity comparisons for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study.

5. *Conclusion.* Based on the above, the Agency concludes that reliable data support use of a 100-fold margin of exposure/uncertainty factor, rather than the standard 1,000-fold margin/factor, to protect infants and children.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to pyriproxyfen in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of pyriproxyfen on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* The acute dietary assessment is not required for pyriproxyfen because there were no effects that could be attributed to a single exposure (dose) in oral toxicity studies including the developmental toxicity studies in rats and rabbits.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyriproxyfen from food will utilize 0.9% of the cPAD for the U.S. population, 1.6% of the cPAD for all infants <1 year old and 2.6% of the cPAD for children 1-6 years old. Chronic residential exposure to pyriproxyfen from pet collars is estimated to increase total pyriproxyfen exposure to infants and children only marginally. In addition, despite the potential for chronic dietary exposure to pyriproxyfen in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of pyriproxyfen in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRIPROXYFEN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population all seasons	0.35	0.9	0.11	0.006	12000
All infants (<1 year)	0.35	1.6	0.11	0.006	3400
Children (1-6 years)	0.35	2.6	0.11	0.006	3400
Children (7-12 years)	0.35	1.5	0.11	0.006	3400
Females (13-50 years)	0.35	0.7	0.11	0.006	10000
Males (13-19 years)	0.35	0.9	0.11	0.006	12000
Males (20+ years)	0.35	0.6	0.11	0.006	12000
Seniors (55+)	0.35	0.6	0.11	0.006	12000

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term residential exposure assessment is not required for pyriproxyfen due to the lack of significant toxicological effects observed.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term residential exposure assessment is not required for pyriproxyfen due to the lack of significant toxicological effects observed.

5. *Aggregate cancer risk for U.S. population.* Pyriproxyfen has been classified as a Group E carcinogen; there is no evidence of carcinogenic potential.

Therefore, a cancer risk assessment is not required.

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

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for pyriproxyfen on succulent beans.

VI. Conclusion

Therefore, the tolerance is established for combined residues of pyriproxyfen in or on succulent beans at 0.10 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301165 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 5, 2001.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301165, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any

unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 21, 2001.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.510 is amended by alphabetically adding the commodity bean, succulent to the table in paragraph (b) to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *		
Bean, succulent	0.10	6/30/03
* * * * *		

* * * * *

[FR Doc. 01–22282 Filed 9–4–01; 8:45am]
BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2100–F]

RIN 0938–AK89

Medicaid Program; Modification of the Medicaid Upper Payment Limit Transition Period for Inpatient Hospital Services, Outpatient Hospital Services, Nursing Facility Services, Intermediate Care Facility Services for the Mentally Retarded, and Clinic Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule modifies the Medicaid upper payment (UPL) limit provisions by establishing a new transition period for States that submitted plan amendments before March 13, 2001 that do not comply with the new UPLs effective on that date (but do comply with the prior UPLs) and were approved on or after January 22, 2001. This new transition period applies to payments for inpatient hospital services, outpatient hospital services, nursing facility services, intermediate care facility services for the mentally retarded, and clinic services.

EFFECTIVE DATE: November 5, 2001.

FOR FURTHER INFORMATION CONTACT:

Robert Weaver, (410) 786–5914—Nursing facility services and intermediate care facility services for the mentally retarded

Marge Lee, (410) 786–4361—Inpatient and outpatient hospital services and clinic services

SUPPLEMENTARY INFORMATION:

I. Background

In the final rule published on January 12, 2001 in the **Federal Register** (66 FR 3148), we specified transition periods for those States with State plan amendments (SPAs) approved before the final rule effective date of March 13, 2001. In our March 13, 2001 letter to State Medicaid Directors, we clarified that state plan amendments submitted on or after the effective date of that final rule would be subject to the new requirements of that final rule. We further explained that we would disapprove any state plan amendment that is submitted on or after that date, including modification to existing state plans, that does not conform with the new upper payment limitations.

The State Medicaid Directors letter did not address the amendments pending CMS approval. After reviewing the legal and policy issues involved, the Administration now believes that each State's pending amendment should be reviewed under the criteria in place when it was submitted, and, for those submitted before March 13, 2001, the criteria before the January 12, 2001 final rule rather than applying the provisions of that rule. However, the Administration is also committed to phasing out the UPL loophole and assuring that tax dollars are spent properly. Absent modification of the UPL transition provisions, approval of these State plan amendments could trigger a 2-year transition period through September 30, 2002, which would have greater budget implications than anticipated.

II. Provisions of the Proposed Rule

On April 3, 2001, we published a proposed rule in the **Federal Register** (66 FR 17657) proposing to create a separate UPL transition period for State plan amendments that were submitted to us before March 13, 2001 but were approved on or after January 22, 2001. We proposed that these State plan amendments would qualify for a transition period that would end on the later of March 13, 2001 or 1 year after the approved effective date of each State plan amendment. With respect to pending UPL plans that are expansions of previously approved plans, we proposed that the separate transition period would only apply to the portion of spending under the pending plan that is above the amount that was previously approved.

The proposed rule did not include those State plan amendments that were actively (not deemed) approved after January 12, 2001 based on their compliance with the final rule of January 12, 2001. Because these amendments comply with the January 12, 2001 final rule, the amendments are not subject to the transition periods specified in the January 12, 2001 final rule. Also, as noted in the State Medicaid Directors letter of March 13, 2001, any State plan amendments submitted on or after March 13, 2001 would be reviewed and acted upon under the January 12, 2001 final rule. We would also treat any material change submitted on or after March 13, 2001 to a State plan amendment pending on that date as a new State plan amendment. We would not be able to approve such a submission under the UPL requirements in effect, and it would not be eligible for the new transition period.

III. Analysis of and Responses to Public Comments

We received 7 timely comments in response to the April 3, 2001 proposed rule. The majority of the comments were from State agencies, and associations representing hospitals, health care systems, and providers of long-term care, assisted living, and nursing facilities. We reviewed each comment and grouped like or related comments. The comments and our responses are summarized below.

Comment: Several commenters requested either this regulation be withdrawn or that State plan amendments submitted prior to March 13, 2001 and approved after January 22, 2001 receive the transition period as defined in the January 12, 2001 final UPL rule. Several of these commenters felt the rule was a retroactive application of policy. Two commenters pointed out that the impact on one State would be to reduce its transition period from September 30, 2002 to September 30, 2001. Another commenter felt it was unfair to change the rules in mid-stream on States that had submitted amendments prior to January 12, 2001. If we decline to withdraw this proposal, one commenter asked that States submitting plan amendments on or before January 12, 2001 be allowed to exceed the newly established payment limits until September 30, 2002, the rationale being that States did not receive official word until the rule was published on January 12, 2001.

Response: We do not agree with the request to withdraw this rule or to extend the full two-year transition period to States with pending (unapproved) amendments as of January 12, 2001 but we have altered the timing of the new transition period to ensure that it will not apply retroactively to any payments that may already have been made.

We note that States had clear and sufficient notice of an impending change in the UPL rules, and should have had no reasonable expectation of favorable treatment for unapproved amendments after the publication of the final rule. Therefore, the proposed shorter transition reflected an approach to balance our interest in curtailing the use of inappropriate Federal Medicaid funds with the States concerns about a shift in federal rules. When the final UPL regulation was issued on January 12, 2001, we did not state that pending State plan amendments would be approved. Thus, we do not believe