ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301122; FRL–6781–4]

RIN 2070–AB78

Forchlorfenuron; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance forresidues of Forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea in or on almond, apple, blueberry, cranberry, fig, grapes, kiwifruit, olive, pear, and plums (fresh). Siemer & Associates Incorporated, agent for KIM-C1, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire on April 1, 2004.

DATES: This regulation is effective May 7, 2001. Objections and requests for hearings, identified by docket control number OPP–301122 must be received by EPA on or before July 6, 2001.

ADDRESSES: Written objections and hearing requests may besubmitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301122 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–305–7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 ''**FederalRegister**—Environmental Documents.'' You can also godirectly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/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–301122. 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, Crystal 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

In the **Federal Register** of July 28, 1998 (63 FR 40273)(FRL–5799–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 7G4906) for tolerance by KIM-C1, LLC, 6333 East Liberty Avenue, Fresno, California 93727. This notice included a summary of the petition prepared by KIM-C1, the registrant.

The petition requested that 40 CFR part 180 be amended by establishing a time-limited tolerance for residues of the plant growth regulator *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea, in or on almond, apple, blueberry, cranberry, fig, grapes, kiwifruit, olive, pear, and plums (fresh) at 0.01 part per million (ppm). The tolerance will expire on April 1, 2004.

One comment was received in response to the Notice of Filing. The comment was received on December 7, 2000 as a letter dated December 1, 2000 from Mr. Robert Bianco, Desert Grape Growers League of California. The League requested that the Agency reduce the number of table grape acres, investigate allegations regarding taste, and that the Experimental Use Permit be crop destruct. In response to the first issue, it is noted that the registrant has subsequently submitted a revised testing program that incorporates a reduced number of table grape acres. Regarding the issue of requiring a crop destruct condition on the grapes treated in the Experimental Use Permit due to a difference in taste of the harvested grapes, the Agency has determined that requiring a crop destruct condition may be imposed only in response to concerns relating to human health.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea on almond, apple, blueberry, cranberry, fig, grapes, kiwifruit, olive, pear, and plums (fresh) at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHERTOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL = M*≥400; F*=84 mg/kg/day; LOAEL = M*=not determined, F=428 mg/kg/day based on decrease BW*, BW gain & food efficiency.
870.3150	90–Day oral toxicity in non-rodents	NOAEL = M=1608; F=19.1 mg/kg/day; LOAEL = M=162.4; F=188.7 mg/kg/day based on decreases (≥10%) in BW gain, FC & food efficiency.
870.3700a	Prenatal developmental in rodents	Maternal NOAEL = 200 mg/kg/day; LOAEL = 400 mg/kg/day based on increased incidence of alopecia; decrease in BW & BW gains. Developmental NOAEL = 200 mg/kg/day; LOAEL = 400 mg/kg/day based on decreased mean fetalBW.
870.3700b	Prenatal developmental in nonrodents	Maternal NOAEL = ≥100 mg/kg/day; LOAEL = not determined. Developmental NOAEL = ≥100 mg/kg/day; LOAEL = not determined.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = M=11/13;F=13/15 mg/kg/day; LOAEL = 144–202 mg/kg/day based on decreasedFC F0 & F1; clinical signs of toxicity & lower BW in F1M& F and growth retardation in F1 & F2 pups. Reproductive NOAEL = M144/168; F=169/202 mg/kg/day; LOAEL = 544–926 mg/kg/day based on increased pup mortality (F1a, F1b and F2a), emaciation in F1b, anddecrease in F1 pups litter.
870.4300	Carcinogenicity mice	NOAEL = M=7; F=9 mg/kg/day; LOAEL = M=93; F=122 mg/kg/day based on reduced BW & BW gain & FC; kidney toxicity (M=suppurative inflammation, F = non-suppurative interstitial nephritis. no evidence of carcinogenicity.

*M=Male; F=Female; BW=Body Weight; FC=Food Consumption

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from thetoxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). 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 intraspecies 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 todetermine the 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 1×10^{-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 *N*-(2-chloro-4-pyridinyl)-*N'*-phenylurea used for human risk assessment is shown in the following Table 2:

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR N-(2-CHLORO-4-PYRIDINYL)-*N'*-PHENYLUREA FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF (mg/kg/day)	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary		None	
Chronic Dietary	NOAEL = 7.0	Decreases in body weight, body weight gain and food consumption as well as effects on the kidney at the LOAEL of 93 and 122 mg/kg/day for males and females, respectively. The risk assessment is required..	2–year rat feeding study
	UF = 100; FQPA = 10X	Chronic RfD=0.07 mg/kg/day cPAD=0.007 mg/kg/day Apply to all population subgroups.	
Short-Term Dermal	NOAEL=200	Decreases in maternal body weights and body weight gains as well as decrease in mean fetal body weights..	developmental rat study
Intermediate-Term Dermal	NOAEL=17	Based on decreases in body weight gain and food consumption..	90–day feeding study in dogs
Long-Term Dermal		None	
Short-Term Inhalation	NOAEL=200	Same as short-term dermal.	developmental rat study
Intermediate-Term Inhalation	NOAEL=17	Same as intermediate-term dermal..	90–day feeding study in dogs
Long-Term Inhalation		None	
Cancer		Not yet classified	

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Risk assessments were conducted by EPA to assess dietary exposures from *N*-(2-chloro-4-pyridinyl)-*N'*-phenylurea 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 one day or single exposure. An acute exposure assessment is unnecessary because no toxicological endpoint was selected.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysisevaluated 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: This chronic dietary DEEM® analysis was a Tier 1 (assumptions: time-limited tolerance level residues of the subject commodities and 100% crop treated). The DEEM® default concentration factors were used for the processed commodities of all the subject crops. The resulting dietary food exposures occupy 1.5% of the cPAD for the most highly exposed population subgroup, non-nursing infants. These results should be viewed as conservative (health protective) risk estimates. Refinements such as the use of percent crop-treated information (this is a limited acreage EUP use) and/or anticipated residue values would yield lower estimates of chronic dietary exposure.

iii. *Cancer.* No concern for cancer risks were identified. Data from available studies do not indicate a treatment-related tumor problem and cancer risk endpoints have not been identified.

2. *Dietary exposure from drinking water.* The Agency lackssufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for *N*-(2-chloro-4-pyridinyl)-*N'*-phenylurea 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 *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea.

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 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 *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea for acute and chronic exposures are estimated to be 4.7 parts per billion (ppb) (peak and 56–day average) for surface water and 26 ppb (acute and chronic) 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).

N-(2-Chloro-4-pyridinyl)-*N′*-phenylurea is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanismof 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 *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea 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, *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea 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 *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children—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. *Conclusion*. There is an adequate toxicity databasefor *N*-(2-chloro-pyridinyl)-*N′*-phenylurea for this EUP and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. For the purposes of the experimental use permit only, the FQPA safety factor will be retained (10X) and applied to all groups for assessing chronic dietary risk.

E. 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 + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking waterconsumption, 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 groundwater are less than the calculated DWLOCs, the Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to the pesticide 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 residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Not applicable; no acute dietary endpointwas identified.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea from food will utilize 0.3% of the cPAD for the U.S. population, 1.5% of the cPAD for non-nursing infants and 1.0% of the cPAD for children (1–6 years). There are no residential uses for *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea that result in chronic residential exposure to *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea. In addition, there is potential for chronic dietary exposure to *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO N-(2-CHLORO-4-PYRIDINYL)-N′-PHENYLUREA

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population (total)	0.007	0.3	4.7	26	240
Females (13–50 years)	0.007	0.1	4.7	26	210
Infants/Children	0.007	0.4-1.5	4.7	26	70
Other	0.007	0.3	4.7	26	240

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).

N-(2-Chloro-4-pyridinyl)-*N′*-phenylurea is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-termaggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

N-(2-Chloro-4-pyridinyl)-*N′*-phenylurea is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. No concern for cancer risks were identified. Data from available studies do not indicate a treatment-related tumor problem and cancer risk endpoints have not been identified.

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 *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Plants*. The proposed enforcement method is a high performance liquid chromatography using ultraviolet detection (HPLC/UV) procedure which measures parent *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea. For the purpose of the Experimental Use Permit, the method has been adequately validated. The limit of quantitation (LOQ) is 0.01 ppm and the limit of detection is 0.003 ppm.

2. *Animals*. Depending on the results of a ruminant metabolism study, an enforcement method for the regulated residue in animal commodities may be required to support a Section 3 registration with permanent tolerances.

Adequate enforcement methodology is available to enforce the toleranceexpression. 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 IRLs for *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea.

C. Conditions

There are no conditions for the registration.

V. Conclusion

Therefore, the time-limited tolerance is established for residues of *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea in or on almond, apple, blueberry, cranberry, fig, grapes, kiwifruit, olive, pear, and plums (fresh) at 0.01 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any personmay 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–301122 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 July 6, 2001.

1. *Filing the request*. Your objection must specify thespecific 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 orrequest 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 inthe 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 VI.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 docket control number OPP–301122, 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) inresponse to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).Nor does it require any special considerations 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 petition under FFDCA section 408(d), such as the tolerance 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.''

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, asadded 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 recordkeepingrequirements.

Dated: April 30, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. Section 180.569 is added to read as follows:

§ 180.569 Forchlorfenuron; tolerances for residues.

(a) *General.* Time-limited tolerances are established forresidues of the plant growth regulator forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N′*-phenylurea in or on the food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Almond	0.01	4/1/04
Apple	0.01	4/1/04
Blueberry ..	0.01	4/1/04
Cranberry ..	0.01	4/1/04
Fig	0.01	4/1/04
Grape	0.01	4/1/04
Kiwifruit	0.01	4/1/04
Olive	0.01	4/1/04
Pear	0.01	4/1/04
Plum (fresh).	0.01	4/1/04

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

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

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

[FR Doc. 01–11414 Filed 5–4–01; 8:45 am]

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7761]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATES: The effective date of each community's suspension is the third date (''Susp.'') listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Donna M. Dannels, Division Director, Policy and Assessment Division, Mitigation Directorate, 500 C Street, S.W., Room 411, Washington, D.C. 20472, (202) 646–3098.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*, unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Associate Director finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because