but not later than August 18, 2006. If your onshore or offshore facility becomes operational after August 16, 2002, through August 18, 2006, and could reasonably be expected to have a discharge as described in § 112.1(b), you must prepare a Plan on or before August 18, 2006, and fully implement it as soon as possible, but not later than August 18, 2006.

(b) If you are the owner or operator of an onshore or offshore facility that becomes operational after August 18, 2006, and could reasonably be expected to have a discharge as described in § 112.1(b), you must prepare and implement a Plan before you begin operations.

(c) If you are the owner or operator of an onshore or offshore mobile facility, such as an onshore drilling or workover rig, barge mounted offshore drilling or workover rig, or portable fueling facility, you must prepare, implement, and maintain a facility Plan as required by this section. You must maintain your Plan, but must amend and implement it, if necessary to ensure compliance with this part, on or before August 18, 2006. If your onshore or offshore mobile facility becomes operational after August 18, 2006, and could reasonably be expected to have a discharge as described in § 112.1(b), you must prepare and implement a Plan before you begin operations. This provision does not require that you prepare a new Plan each time you move the facility to a new site. The Plan may be a general Plan. When you move the mobile or portable facility, you must locate and install it using the discharge prevention practices outlined in the Plan for the facility. The Plan is applicable only while the facility is in a fixed (non-transportation) operating mode.

* * * * *

[FR Doc. 04–18370 Filed 8–10–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0145; FRL–7362–1]

Forchlorfenuron; N-(2-chloro-4-pyridinyl)-N'-phenylurea; Time-LimitedPesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues 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 and Associates Incorporated, agent for KIM-C1, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerance will expire on May 31, 2006.

DATES: This regulation is effective August 11, 2004. Objections and requests for hearings must be received on or before October 12, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0145. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Cynthia Giles-Parker, Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7740; e-mail address: *giles-parker.cynthia@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 entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other RelatedInformation?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of April 7, 2004 (69 FR 18375)(FRL–7349–9), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7G4906) by KIM-C1, LLC, c/o Siemer and Associates, Inc., 4672 West Jennifer Street, Suite 103, Fresno, CA 93722. This notice included a summary of the petition prepared by KIM-C1, the registrant.

The petition requested that 40 CFR 180.569 be amended by establishing an extension of a time-limited tolerance for residues of the fungicide forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea, in or on the raw agricultural commodities almonds, apples, blueberries, figs, grapes, kiwi fruit, pears, and plums at 0.01 parts per million (ppm). The tolerance will expire on May 31, 2006.

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

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

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 of the FFDCA 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) of the FFDCA, 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) of the FFDCA, for a tolerance for residues of forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea on the raw agricultural commodities almonds, apples, blueberries, figs, grapes, kiwi fruit, pears, and plums 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 forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea are discussed in Table 1 of this unit 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 OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rats	NOAEL = M*400; F* = 84milligrams/kilogram/day (mg/kg/day); LOAEL = M* = not determined, F = 428mg/kg/day based on decrease body weight, body weight gainand food efficiency.
870.3150	90–Day oral toxicity in dogs	NOAEL = M = 16.8; F = 19.1 mg/kg/day LOAEL = M = 162.4; F = 188.7 mg/kg/daybased on decreases (10%) in body weight gain, FC andfood efficiency.
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 200 mg/kg/day Maternal LOAEL = 400 mg/kg/day based on increased incidence of alopecia; decrease body weight and body weight gains Developmental NOAEL = 200 mg/kg/day Development LOAEL = 400 mg/kg/day based on decreased mean fetal body weight
870.3700	Prenatal developmental in non-rodents	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = not determined Developmental NOAEL = 100 mg/kg/day Development LOAEL = not determined
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = M 11/13; F13/15 effects mg/kg/day Parental/Systemic LOAEL = 144-202mg/kg/day based on decreased FC F0 and F1;clinical signs of toxicity and lower body weight in F1Mand F and growth retardation in F1 and F2 pups Reproductive NOAEL = M144/168; F = 169/202 mg/kg/day Reproductive LOAEL = 544-926 mg/kg/day based on increased pup mortality (F1a, F1b and F2a), emaciation in F1b, and decrease in F1 pups litter
870.4300	Chronic carcinogenicity rat	NOAEL = M = 7; F = 9 mg/kg/day LOAEL = M = 93; F = 122 mg/kg/day basedon reduced body weight and body weight gain and FC; kidney toxicity(M = suppurative inflammation, F = non-suppurative interstitialnephritis. No evidence of carcinogenicity

*M = Male; F = Female; FC = Food Consumption

B. 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 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 (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine 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 forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea used for human risk assessment is shown in Table 2 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary	.....	None	.....
Chronic dietary (all populations)	NOAEL= 7 mg/kg/day UF = 100 Chronic RfD =0.07 mg/kg/day	FQPA SF = 10X cPAD = 0.007mg/kg/day. Applyto all populationsubgroups	2-Year rat feeding study LOAEL = M = 93; F = 122mg/kg/day based on decreasesin body weight, body weightgain and food consumption aswell as effects on the kidney
Short-term dermal (1 to 7 days)	NOAEL= 200 mg/kg/day (dermal absorption rate= 100%)	LOC is MOE = 1,000 (residentialexposures)	Developmental rat study (oral);decreases in maternal bodyweights and body weight gainsas well as decrease in mean fetalbody weights
Intermediate-term dermal (1 week to several months)	NOAEL = 17 mg/kg/day (dermalabsorption rate = 100%)	LOC is MOE = 1,000 (residentialexposures)	90–Day feeding study in dogs(oral); based on decreases inbody weight gain and food consumption
Long-term dermal (several months tolifetime)	None	None	.....
Short-term inhalation (1 to 7 days)	NOAEL= 200mg/kg/day (inhalationabsorption rate = 100%)	LOC = same asshort term dermal	Developmental rat study (oral);decreases in maternal bodyweights and body weight gainsas well as decrease in mean fetalbody weights
Intermediate-term inhalation (1 week to several months)	NOAEL = 17 mg/kg/day (inhalation absorption rate= 100%)	LOC for MOE = same asintermediate-term dermal	90–Day feeding study in dogs (oral):Based on decreases in body weight gain and foodconsumption
Long-term inhalation (several months to lifetime)	None	None	.....
Cancer	.....	Not yet classified	.....

*The reference to the FQPA SF 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.* Temporary tolerances were previously established (40 CFR 180.569) for the residues of forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from forchlorfenuron; *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 1 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™) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture 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 concerns 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 lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for forchlorfenuron; *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 forchlorfenuron; *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 Screening Concentrations in Groundwater (SCI-GROW), which predicts pesticide concentrations in ground water. 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 incorporates 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 forchlorfenuron; *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 estimated EECs of forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea for acute 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).

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

EPA does not have, at this time, available data to determine whether forchlorfenuron; *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, forchlorfenuron; *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 forclorfenuron: *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) (FRL–5754–7).

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA 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 bases 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 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 database for forchlorfenuron; *N*-(2-chloro-pyridinyl)-*N*'-phenylurea, 71049–EUP–2, to support the extension of this EUP and time-limited tolerances. The available data suggest there is no increased qualitative or quantitative susceptibility based on the results of developmental and reproduction studies, no evidence of neurotoxicity and therefore no need to require a developmental neurotoxicity study. In addition, data used to evaluate exposure are adequate, and conservative assumptions were used to evaluate aggregate exposure through food and drinking water; therefore, exposure has not been underestimated. However, for the purposes of the experimental use permit only (and associated time-limited tolerances), the FQPA safety factor has been retained (10X) as a default for all population groups, pending final review of data submitted to support permanent tolerances for several crops.

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 (i.e., 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 water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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 endpoint was identified.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to forchlorfenuron; *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 forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea that result in chronic residential exposure to forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea. In addition, there is potential for chronic dietary exposure to forchlorfenuron; *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 FORCHLORFENURON; 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	0.007	0.3	4.7	26	240
Females (13 to 50 years)	0.007	0.1	4.7	26	210
Non-nursing infants	0.007	1.5	4.7	26	70
Non-hispanic	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). Forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risks are the sum of the risks from food and water, which do not exceed the Agency's level of concern.

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

Forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*'-phenylurea is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risks are the sum of the risks 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 endpoint has 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 forchlorfenuron; *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 procedure using ultraviolet detection (HPLC/UV) which measures parent forchlorfenuron; *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 tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue levels for forchlorfenuron; *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 forchlorfenuron; *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 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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 sections 408 and 409 of the FFDCA. 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 ID number OPP–2004–0145 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 October 12, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0145, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 section 408(d) of the FFDCA, 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 section 408(n)(4) of the FFDCA. 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. Congressional Review Act

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: July 29, 2004.

Betty Shackleford,

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), 346a and 371.

■ 2. Section 180.569 is amended by revising the table in paragraph (a) to read as follows:

§ 180.569 Forchlorfenuron; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/revocation date
Almond	0.01	05/31/06
Apple	0.01	05/31/06
Blueberry	0.01	05/31/06
Cranberry	0.01	05/31/06
Fig	0.01	05/31/06
Grape	0.01	05/31/06
Kiwifruit ...	0.01	05/31/06
Olive	0.01	05/31/06
Pear	0.01	05/31/06
Plum (fresh) ..	0.01	05/31/06

* * * * *

[FR Doc. 04–18383 Filed 8–10–04; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2004–18794]

RIN 2127–AF75

Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices and Associated Equipment

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This document amends the Federal lighting standard for motor vehicle turn signal lamps, stop lamps, taillamps, and parking lamps to increase compatibility with the requirements of the Economic Commission for Europe (ECE) and to improve visibility of these lamps. Manufacturers will be permitted to comply with either the existing requirements or the new requirements for a period of between seven to 10 years, depending on vehicle type, at which time they will be required to comply with the new requirements. This action completes rulemaking that implemented the grant of a petition for rulemaking submitted by the Groupe de Travail Bruxelles 1952.

DATES: *Effective date:* The final rule is effective September 10, 2004. Petitions for reconsideration. Petitions for reconsideration of the final rule must be received not later than September 27, 2004.

ADDRESSES: Any petitions for reconsideration should refer to the docket number of this document and be submitted to: Administrator, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590.