responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. 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: September 24, 2004.

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), 346a and 371.

■ 2. In § 180.910 the table is amended by revising the entry for ''sodium thiosulfate'' to read as two separate entries and inserting them alphabetically as follows:

§ 180.910 Inert ingredients used pre- and post-harvest.; exemptions from the requirement of a tolerance.

* * *

Inert Ingredients	Limits	Uses
* * * * * * *		
Thiosulfuric acid, disodium salt, anhydrous. (CAS Reg. No 7772–98–7)		Dechlorinator, reducing agent
Thiosulfuric acid, disodium salt, pentahydrate. (CAS Reg. No. 10102–17–7)		Dechlorinator, reducing agent
* * * * * * *		

[FR Doc. 04–21933 Filed 9–30–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0272; FRL–7681–5]

Forchlorfenuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of forchlorfenuron, *N*-(2-chloro-4-pyridinyl)-*N*′-phenylurea in or on grapes and kiwifruit. Siemer & Associates, Inc. on behalf of 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).

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0272. 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: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: 703–308–6742; e-mail address:*mcneilly.dennis@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), e.g., agricultural workers; greehouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 Related Information?

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 May 16, 2003 (68 FR 26607–26611) (FRL–7303–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6550) by Siemer & Associates, 4672 W. Jennifer, Suite 103, Fresno, California 93722. The petition requested that 40 CFR 180.569 be amended by establishing a tolerance for residues of the plant growth regulator forchlorfenuron, *N*-(2-chloro-4-pyridinyl)-*N*′-phenylurea, in or on grapes, raisins and kiwifruit at 0.03 parts per million (ppm). That notice included a summary of the petition prepared by Siemer & Associates, Inc., the registrant. The proposed uses are the first section 3 tolerances for this new active ingredient. Time-limited tolerances are currently in effect (69 FR 48799–48805, Aug 11, 2004) for residues of forchlorfenuron in or on grapes, kiwifruit, apples, blueberries, cranberries, figs, pears, plums (fresh), olives and almonds. These time-limited tolerances were established in conjunction with the granting of an Experimental Use Permit (EUP) originally issued on May 21, 2001. The time-limited tolerances were first established in the **Federal Register** on May 7, 2001 (66 FR 22930–22936 (FRL 6781–4)). Agency review of the submitted residue studies indicate that higher tolerances are required for raisins at 0.06 ppm and kiwifruit at 0.04 ppm. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of 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 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 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 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 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 FFDCA, for a tolerance for residues of forchlorfenuron, *N*-(2-chloro-4-pyridinyl)-*N*′-phenylurea on grapes at 0.03 ppm; raisins at 0.06 ppm; and kiwifruit at 0.04 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, 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 is 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- rat ..	NOAEL = M ≥ 400, F = 84 milligrams/kilogram/day (mg/kg/day) LOAEL = M = not determined, F = 428: decrease BW gain and food efficiency mg/kg/day
870.3150	90 day oral toxicity -dogs	NOAEL = M = 16.8, F = 19.1 mg/kg/day LOAEL = M = 162.4, F = 188.7; decreases (≥ 10%) in BW gain, FC and food efficiency mg/kg/day
870.3700	Developmental tox-rat	Maternal NOAEL = 200 mg/kg/day Maternal LOAEL = 400 mg/kg/day based on increased incidence of alopecia: decrease in BW and BW gains Developmental NOAEL = 200 mg/kg/day Developmental LOAEL = 400 mg/kg/day based on decreased mean fetal BW
870.3700	Developmental tox - non-rodent.	Maternal NOAEL = ≥100 mg/kg/day Maternal LOAEL = not determined Developmental NOAEL = ≥100 mg/kg/day Developmental LOAEL = not determined

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects.	Parental/Systemic NOAEL = M = 11/13, F= 13/15 mg/kg/day Parental/Systemic LOAEL = 144–202 mg/kg/day based on decreased FC in F_0 and F_1 M; clinical signs of toxicity and lower BW in F_1 M and F and growth retardation in F_1 and F_2 pups Reproductive NOAEL = M = 144/168, F = 169/202 mg/kg/day Reproductive LOAEL = 544–926 mg/kg/day based on increased pup mortality (F_{1a}, F_{1b} and F_{2a}), emaciation in F_{1b}, and decrease in F_2 pups/litter
870.4300	Chronic carcinogenicity rat	NOAEL = M = 7, F = 9 mg/kg/day LOAEL = M = 93, F = 122 mg/kg/day based on Reduced BW and BW gain and FC; kidney toxicity (M = suppurative inflammation, F = non-suppurative interstitial nephritis) No evidence of carcinogenicity
870.4100	1-year feeding study-dogs	NOAEL (in mg/kg/day): M = 87, F = 91 LOAEL (in mg/kg/day): M = 195, F = 246, decreases in BW, BW gains and FC
870.4200	18–month carcinogenicity study-mice.	NOAEL (in mg/kg/day): M = 10.0, F = 9.9 LOAEL (in mg/kg/day): M = 991.4, F = 1001.8, decreases in BW and BW gains in M and F Not carcinogenic
870.7485	Metabolism study-rat	Recovery of 97% (M and F) by 168 hours. Absorbed dose 72–84%. Urine 62–74%. Feces 16–28%. Biliary excretion, 20–23% in bile. Urine and feces, elimination half-life 13.1–16.2 hours. Analyses identified parent and six metabolites in excreta. Parent not in urine and 1–2% in feces. Major metabolite forchlorfenuron-sulfate in urine of males (84%) and females (57%). Hydroxy forchlorfenuron (2 isomers) <4% in urine; predominant metabolite in feces (11% males and 18% females). Other metabolites: hydroxy forchlorfenuron-sulfate, methoxy forchlorfenuron-sulfate, forchlorfenuron glucuronide and dihydroxy forchlorfenuron (each <5%). Metabolism of forchlorfenuron in rats: conjugation with sulfate at phenyl ring before (major pathway), conjugation with glucuronide at phenyl ring, methylation of hydroxy group of hydroxy forchlorfenuron-sulfate and hydroxylation of both chloropyridinyl and phenyl rings.
870.5375	*In vitro* mammalian cytogenetics assay in Chinese Hamster CHO-KI cells 10, 20, 40, and 80 μg/mL ± S9 activation.	No increase in chromosomal aberrations over background ± S9
870.5550	Unscheduled DNA synthesis in primary rat hepatocytes/mammalian cell cultures 0.1 to 30 7μg/mL.	No increase in unscheduled DNA synthesis
870.5265	*Salmonella*/mammalian activation gene mutation assay. 10–1000 μg/plate +S9 ..... 2–200 μg/plate -S9	Evidence of a positive response in tester strain TA1535 in absence of S9 at 50, 100, and 200 μg/plate
870.5265	Salmonella/mammalian activation gene mutation assay. 10–1,000 μg/plate +S9 .... 2–200 μg/plate -S9	Evidence of induced mutany colonies over background in tester strain TA1535 in absence of S9

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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,''

EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety factor.

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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FORCHLORFENURON FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose(mg/kg/day)	Endpoint	Study
Acute Dietary	NOAEL - assumed to be 100 UF = 100	aPAD = 1.0 mg/kg/day	Rabbit developmental study
Chronic Dietary	NOAEL = 7.0	Decreases in body weight, body weight gain and food consumption as well as effects on the kidney at the LOEAL of 93 and 122 mg/ kg/day for males and females, respectively.	2–year rat feeding study
	UF = 100 FQPA = 1x	Chronic RfD = 0.07 mg/kg/day Chronic Population-Adjusted Dose (cPAD) = 0.07 mg/kg/day; apply to all population subgroups.	NA
Short-Term (Dermal)	NOAEL = 200	Decreases in maternal body weights and body weight gains as well as a decrease in mean fetal body weights.	developmental rat study
Intermediate-Term (Dermal)	NOAEL = 87	Based on decreases in body weight, bw gain, and food consumption.	1–Year feeding study in dogs
Long-Term (Dermal)	NA	Based on the limited use, long-term exposure is not expected anda risk assessment not conducted	NA
Short-Term (Inhalation)	NOAEL = 200	Same as short-term dermal	developmental rat study
Intermediate-Term (Inhalation)	NOAEL = 87	Same as intermediate-term dermal	1–Year feeding study in dogs

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FORCHLORFENURON FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose(mg/kg/day)	Endpoint	Study
Long-Term (Inhalation)	NA	Based on the limited use, long-term exposure is not expected anda risk assessment not conducted	NA
Cancer	NA	Not likely to be a human carcinogen	NA

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*— i. *Acute exposure*. In conducting this acute dietary risk assessment the Lifeline Model Version 2.0 and the Dietary Exposure Evaluation Model (DEEM™, Version 2.03) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 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 acute exposure assessments: Tolerance-level residues and 100% crop treated assumptions were used. DEEM (Version 7.81) default processing factors were used to modify the tolerance values for processed commodities for which separate tolerances are not being established.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Lifeline Model Version 2.0 and the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 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: A conservative chronic dietary exposure analysis was performed for the general U.S. population and various population subgroups. Tolerance-level residues and 100% crop treated assumptions were used. The 1-in-10-year average surface water concentration from the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM-EXAMS) Model was used as a point estimate for drinking water in the dietary analyses.

iii. *Cancer*. A quantitative cancer dietary exposure assessment is not needed for forchlorfenuron since it is not a carcinogen.

2. *Dietary exposure from drinking water*. The Agency usesthe FQPA Index Reservoir Screening Tool (FIRST) or the PRZM/EXAMS, to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency has generally not used estimated environmental drinking water concentrations (EDWCs), which are the model estimates of a pesticide's concentration in water. EDWCs derived from these models are used 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 they are further discussed in the aggregate risk Unit III. E. below.

As EPA has gathered more information regarding pesticide residues in drinking water and drinking water consumption amounts, it has been working toward refining the screening-level DWLOC approach to conducting aggregate risk assessments that combine exposures across all pathways. As a first step in this process, EPA has begun using the chronic and cancer EDWCs directly in chronic and cancer dietary exposure assessments to calculate aggregate dietaryfood + water risk. This is done by using the relevant PRZM-EXAMS value as a residue for water (all sources) in the dietary exposure assessment. The principal advantage of this approach is that the actual individual body weight and water consumption data from the Continuing Survey of Food Intake by Individuals (CSFII) are used, rather than assumed weights and water consumption for broad age groups.

Accordingly, the 1-in-10-year average surface water concentration from the PRZM-EXAMS Model was used as a point estimate for drinking water in the chronic dietary analysis. Estimated concentrations in drinking water were not included in the acute analysis. Instead, the maximum allowable exposure from drinking water was calculated by subtracting the exposure in food from the total allowable exposure. The maximum allowable exposure from drinking water is converted to the maximum allowable drinking water concentration, or DWLOCs. These values are then compared to the estimated drinking water concentrations.

Based on the PRZM/EXAMS and SCI-GROW models, the EDWCs of forchlorfenuron for chronic exposures are estimated to be 0.32 parts per billion (ppb) for surface water and 0.003 ppb for ground water. Based on the PRZM/EXAMS and SCI-GROW models, the EDWCs of forchlorfenuron for acute exposures are estimated to be 0.54 ppb for surface water and 0.003 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).

Forchlorfenuron is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to forchlorfenuron and any other substances and forchlorfenuron 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 forchlorfenuron 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 policy statements released by EPA's Office of Pesticide Programs (OPP) concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of 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 database on toxicity and exposure unless EPA determines based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is a lack of increased qualitative or quantitative susceptibility in developmental or reproductive studies. There are no concerns and no residual uncertainties with regard to pre-and/or postnatal toxicity.

3. *Conclusion*. As indicated, available data do not show any increased susceptibility to the young from exposure to forchlorfenuron and there are no residual uncertainties regarding pre- or post-natal toxicity. There is an adequate toxicity database for forchlorfenuron. As there was no evidence of neurotoxicity, it is not necessary to require a developmental neurotoxicity study. In addition, data used to evaluate exposure are adequate, and conservative assumptions are being used to evaluate aggregate exposure through food and drinking water. As a result, exposures are probably considerably overestimated. Accordingly, EPA concludes it has reliable data supporting removal of the additional FQPA 10-fold safety factor for the protection of infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency either calculates DWLOCs which are used as a point of comparison against EDWCs or uses the EDWCs directly in the aggregate exposure assessment. 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 EPA's 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. As explained above, however, EPA is beginning to use EDWCs directly in estimating aggregate exposure in chronic and cancer assessment.

When EDWCs for surface water and ground water are less than the calculated DWLOCs, 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*. From the Lifeline Model, the U.S. population and all population subgroups had risk estimates that were below 1% of the acute population adjusted dose (aPAD) from exposure to forchlorfenuron in food. The most highly exposed population subgroup was children 1–2 years old, which had a risk estimate of 0.08% of the aPAD. The general U.S. population utilized 0.02% of the aPAD. In addition, there is potential for acute dietary exposure to forchlorfenuron in drinking water. After calculating DWLOCs and comparing them to the EDWCs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FORCHLORFENURON

Population Subgroup	% aPAD (Food)	Surface Water EDWCs (ppb)	Ground Water EDWCs (ppb)	Acute DWLOC (ppb)
U.S. Population	0.000157	0.54	0.003	35,000
All Infants	0.000526	0.54	0.003	10,000
Children 1–2 years	0.000846	0.54	0.003	10,000
Children 3–5 years	0.000557	0.54	0.003	10,000
Children 6–12 years	0.000217	0.54	0.003	10,000
Youth 13–19 years	0.000089	0.54	0.003	30,000
Adults 20–49 years	0.000101	0.54	0.003	35,000
Adults 50+ years	0.000105	0.54	0.003	35,000
Females 13–49	0.000112	0.54	0.003	30,000

[1] Maximum Allowable Water Exposure = PAD - sum of all quantifiable exposures.
[2] Drinking Water Level of Comparison = Maximum Allowable Water Exposure x Body Weight (10 kg infants and children, 60 kg females, 70 kg all others) x 1,000 μg/mg ÷ Consumption (1 L/day infants and children, 2 L/day all others).

2. *Chronic risk.* The U.S. population and all population subgroups had risk estimates that were below 1% of the chronic population adjusted dose (cPAD) from exposure to forchlorfenuron in food. The most highly exposed population subgroup was children 1–2 years old, which had a risk estimate of 0.3% of the cPAD. There are no residential uses for forchlorfenuron that result in chronic residential exposure to forchlorfenuron. Based on the use pattern, chronic residential exposure to residues of forchlorfenuron is not expected. However, there is potential for chronic dietary exposure to forchlorfenuron in drinking water. The Agency does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

Chronic (non-cancer) aggregate risk is the sum of exposures resulting from chronic dietary food + chronic drinking water + chronic residential uses. Forchlorfenuron has no registered or proposed residential uses. Therefore, this risk assessment is the aggregate of chronic food and chronic drinking water exposures only. As stated above, the drinking water EDWCs were included in the dietary exposure analysis. As a result, the aggregate risk assessment is equivalent to the dietary analysis, the results of which are reported in Table 4 below. The results of the DEEM-FCID analysis were comparable to those of the Lifeline analysis. In the DEEM-FCID analysis, the general U.S. population and all population subgroups used <1% of the cPAD.

TABLE 4—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON–CANCER) EXPOSURE TO FORCHLORFENURON

Population Subgroup	Exposure (mg/kg/day)		%cPAD	
	Lifeline	DEEM–FCID	Lifeline	DEEM–FCID
General U.S. Population	0.000032	0.000040	<1.0	<1.0
All Infants (<1 year old)	0.000122	0.000142	<1.0	<1.0
Children 1–2 years old	0.000217	0.000230	<1.0	<1.0
Children 3–5 years old	0.000140	0.000140	<1.0	<1.0
Children 6–12 years old	0.000047	0.000053	<1.0	<1.0
Youth 13–19 years old	0.000017	0.000021	<1.0	<1.0
Adults 20–49 years old	0.000019	0.000023	<1.0	<1.0
Adults 50+ years old	0.000020	0.000026	<1.0	<1.0
Females 13–49 years old	0.000021	0.000025	<1.0	<1.0

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

Forchlorfenuron 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*. Forchlorfenuron was classified as not likely to be a human carcinogen, and therefore forchlorfenuron is not expected to pose a cancer risk.

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 residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The proposed enforcement method is a high performance liquid chromatography with ultra violet detection HPLC/UV procedure that measures parent forchlorfenuron. The method, including the confirmatory Mass spectrometry with mass spectrometry (MS/MS) analysis, has been adequately validated. The Analytical Chemistry Branch of BEAD performed a tolerance method validation (TMV) trial on the enforcement method using grapes. For grapes, the laboratory reported a limit of quantitation of 0.010 ppm and a limit of detection of 0.002 ppm.

An enforcement method for the regulable residue in animal commodities is not required for section 3 registrations on grapes and kiwifruit.

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 MRLs for forchlorfenuron.

C. Conditions

Conditions of registration are discussed in the Notice of Registration.

V. Conclusion

Therefore, tolerances are established for residues of forchlorfenuron, *N*-(2-chloro-4-pyridinyl)-*N*′-phenylurea, in or on grapes at 0.03 ppm; raisins at 0.06 ppm; and kiwifruit at 0.04 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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) of FFDCA, as was provided in the old sections 408 and 409 of 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–2004–0272 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 29, 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–2004–0272, 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 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 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 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: September 21, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.569 is amended by redesignating paragraph (a) as paragraph (a)(2), by removing the entries for grape and kiwifruit from the table in newly designated paragraph (a)(2), and by adding new paragraph (a)(1) to read as follows:

§ 180.569 Forchlorfenuron; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the plant growth regulator forchlorfenuron; *N*-(2-chloro-4-pyridinyl)-*N*′phenyl urea in or on the following commodities:

Commodity	Parts per million
Grape	0.03
Grape, raisin	0.06
Kiwifruit	0.04

* * * * *

[FR Doc. 04–21932 Filed 9–29–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7821–8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Final rule; Notice of deletion of the Love Canal Superfund site from the National Priorities List.

SUMMARY: The United States Environmental Protection Agency (EPA) Region II Office announces the deletion of the Love Canal Superfund site (Love Canal site) from the National Priorities List (NPL). The Love Canal site is located in the City of Niagara Falls, Niagara County, New York. The NPL constitutes appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300, which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended.

EPA and the State of New York, through the Department of Environmental Conservation (NYSDEC), have determined that all appropriate response actions have been