now state: ''Clean Air Act Redesignation and Reclassification, Searles Valley Nonattainment Area; Designation of Coso Junction, Indian Wells Valley, and Trona Nonattainment Areas; California; Determination of Attainment of the PM–10 Standards for the Trona Area; Particulate Matter of 10 microns or less (PM–10).''

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: September 9, 2002.

Wayne Nastri,

Regional Administrator, Region IX.

[FR Doc. 02–23730 Filed 9–18–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0224; FRL–7200–4]

Diflubenzuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) in or on the following raw agricultural commodities: Grass, forage, fodder, and hay group 17 at 6.0 ppm; pepper at 1.0 ppm; stone fruit group 12 (except cherries) at 0.07 ppm; nut, tree, group 14 at 0.06 ppm; almond, hulls at 6.0 ppm; pistachio at 0.06 ppm; cattle, meat byproducts at 0.15 ppm; goat, meat byproducts at 0.15 ppm; hog, meat byproducts at 0.15 ppm; horse, meat byproducts at 0.15 ppm; sheep, meat byproducts at 0.15 ppm. This regulation is increasing the tolerance level for meat byproducts of cattle, goat, hog, horse, and sheep. This regulation is also changing the tolerance on pasture grass to grass, forage, fodder, and hay group 17. Interregional Research Project Number 4 (IR-4), and Uniroyal Chemical Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 19, 2002. Objections and requests for hearings, identified by docket control number OPP–2002–0224, must be received on or before November 18, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–2002–0224 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–8291; e-mail address: kumar.rita@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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

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

2. *In person.* The Agency has established an official record for this action under docket control number OPP–2002–0224. 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 December 14, 2001 (66 FR 64823) (6813–2), 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 pesticide petitions (PP 1E6347 and 1F6235) by Interregional Research Project Number 4 (IR-4), and Uniroyal Chemical Company Inc., 681 US Highway 1 South, North Brunswick, NJ 08902, and Middlebury, CT 06749. This notice included a summary of the petitions prepared by IR-4 and Uniroyal Chemical Company, the registrants. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.377 be amended by establishing a tolerance for the combined residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA), in or on grass, forage, fodder, and hay, group 17 at 6.0 part per million (ppm); pepper at 1.0 ppm; stone fruit group (except cherries) at 0.05 ppm; tree nut group at 0.05 ppm; almond, hulls at 5.0 ppm; pistachio at 0.05 ppm; and meat byproducts at 0.15 ppm.

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 the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) on grass, forage, fodder, and hay group at 6.0 ppm; pepper at 1.0 ppm; stone fruit group (except cherries) at 0.07 ppm; tree nut group at 0.06 ppm; almond hulls at 6.0 ppm; pistachio at 0.06 ppm; cattle, meat byproducts at 0.15 ppm; goat, meat byproducts at 0.15 ppm; hog, meat byproducts at 0.15 ppm; horse, meat byproducts at 0.15 ppm; sheep, meat byproducts at 0.15 ppm.

EPA's assessment of exposures and risks associated with establishing the tolerances 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 diflubenzuron 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 OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL < 8 mg/kg/day LOAEL = 8 mg/kg/day based on increased methemoglobinemia, and signs of hemolytic anemia, erythrocyte destruction in the spleen and liver and regeneration of erythrocytes in the bone marrow.
870.3150	90–Day oral toxicity in nonrodents	NOAEL = 2 mg/kg/day LOAEL = 6.24 mg/kg/day based on methemoglobinemia.
870.3200	21/28–Day dermal toxicity	NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on methemoglobinemia (limit dose).
870.3465	28–Day inhalation toxicity	NOAEL = 20.3 mg/kg/day highest dose tested (HDT) LOAEL was not established.
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 1,000 mg/kg/day (Limit Dose) LOAEL was not established. Developmental NOAEL = 1,000 mg/kg/day (Limit Dose) LOAEL was not established.

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

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 1,000 mg/kg/day (Limit Dose) LOAEL was not established. Developmental NOAEL = 1,000 mg/kg/day (Limit Dose) LOAEL was not established.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL < 36 mg/kg/day (LDT) LOAEL = 36 mg/kg/day based on dose-related decreased hematocrit, hemoglobin concentration, red blood cell count and an increase in percent methemoglobin, changes in cell morphology and brown pigment in Kupffer cells. Reproductive NOAEL> 4254 mg/kg/day (HDT) LOAEL was not established. Offspring NOAEL = 427 mg/kg/day LOAEL = 4254 mg/kg/day based on Significant decrease in F-1 pup weights on day 4, 8 and 21 of lactation.
870.4100	Chronic toxicity dogs	NOAEL = 2 mg/kg/day LOAEL = 10 mg/kg/day based on methemoglobinemia and sulfhemoglobinemia.
870.4200	Carcinogenicity rats	NOAEL was not established LOAEL = 7.8 mg/kg/day based on histological evidence of erythrocyte destruction and compensatory regeneration. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 2.4 mg/kg/day LOAEL = 12 mg/kg/day based on increased methemoglobin and sulfhemoglobin levels. No evidence of carcinogenicity
870.5100	Gene Mutation	*Salmonella* strains TA98, TA100, TA1535, TA1537 and TA1538 exposed to diflubenzuron in DMSO at doses of 0 to 1,000 µg/plate both in the presence and absence of S9 did not induce mutations.
870.5375	Cytogenetics	Chinese hamster ovary cells *in vitro* exposure to diflubenzuron in DMSO at dose levels of 200 to 250 µg/mL both in the presence and absence of S9 did not induce an increase in chromosomal aberrations.
870.5550	Other Effects	In the UDS assay primary rat hepatocytes exposed to diflubenzuron in DMSO at dose levels of 0.1 to 333 µg/mL did not induce unscheduled DNA syntheses.
870.7485	Metabolism and pharmacokinetics	[^{14}C-anilino]-diflubenzuron was completely absorbed and 87% of radioactivity was recovered in the urine and feces as parent, diflubenzuron by 96 hours post-dosing. Diflubenzuron did not metabolize to 4-chloroaniline (CPA), or chlorophenylurea (CPU); the former was associated with methemoglobin formation and tumor formation in rats and mice in the NTP study. [U-^{14}C-phenyl]-chlorophenylurea (CPU) was completely absorbed and 91% of the dose was eliminated in urine and feces by 144 hours. Unmetabolized CPU was not identified in urine or feces. Most of urinary/fecal metabolites were sulfate or glucuronide conjugates of CPU.
870.7600	Dermal penetration	Dermal application of ^{14}C) diflubenzuron at either 0.005 or 0.05 mg/cm.sq. resulted in less than 0.5% absorption at any dose level after 1, 4 or 10 hours of exposure.
N/A	Special studies	In acute oral toxicity study in rats CPA at 62 mg/kg caused significant increase in methemoglobinemia while CPU at 200 mg/kg did not cause methemoglobinemia.

B. Toxicological Endpoints

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

The FQPA Safety Factor Committee (SFC) recommended that the FQPA safety factor used in human health risk assessments (as required by FQPA of August 3, 1996) be removed (reduced to 1x) in assessing the risk posed by this chemical. Consequently, the current cRfD and cPAD values are equivalent (0.02 mg/kg/day). This decision was based on the following:

1. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure;

2. A developmental neurotoxicity study (DNT) with diflubenzuron is not required;

3. Food and drinking water exposure assessments will not underestimate the potential exposure for infants and children; and

4. There are currently no registered or proposed residential (non-occupational) uses of diflubenzuron. Although there are no registered homeowner uses, there

is potential for professional applications to outdoor residential and recreational areas to control mosquitos, moths, and other insects. However, the potential for post-application residential exposures are expected to be limited. Due to the low dermal absorption rate (0.5%) of diflubenzuron, and since it is only applied to the tree canopy, minimal bystander contact is expected.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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 diflubenzuron and its metabolites used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIFLUBENZURON AND ITS METABOLITES FOR USE IN HUMAN RISK ASSESSMENT[1].

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF** and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary all populations	Not Applicable	Not Applicable	No appropriate endpoint attributable to single exposure was available in oral studies. Therefore, a risk assessment is not required.
Chronic Dietary (All populations)	NOAEL= 2 mg/kg/day UF = 100 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD/FQPA SF = 0.02 mg/kg/day	Chronic Toxicity Study - Dog LOAEL = 10 mg/kg/day based on methemoglobinemia and sulfhemoglobinemia
Short- and Intermediate- Term Incidental Oral (1 day–6 months) (Residential)	Not applicable	Not applicable	These endpoints were not evaluated. There are no registered uses of diflubenzuron which result in significant residential exposure.
Short- Term Dermal (1–30 days) (Occupational)	NOAEL = 500 mg/kg/day	LOC for MOE = 100	21-Day dermal rat LOAEL = 1,000 mg/kg/day based on methemoglobinemia
Intermediate-Term Dermal (1–6 months) (Occupational)	NOAEL = 2 mg/kg/day	LOC for MOE = 100	13 - week oral dog LOAEL = 6.4 mg/kg/day based on methemoglobinemia
Long- Term Dermal (Longer than 6 months) (Occupational)	NOAEL = 2 mg/kg/day	LOC for MOE = 100	Chronic Toxicity Study - Dog LOAEL = 10 mg/kg/day based on methemoglobinemia and sulfhemoglobinemia
Short- Term Inhalation (1–30 days) (Occupational)	NOAEL = 20.30[2] mg/kg/day	LOC for MOE = 100	28–day Inhalation Toxicity Study - Rat/21–day Inhalation Toxicity Study - Rat LOAEL = 0.12 mg/L based on methemoglobinemia (21–day study)
Intermediate-Term Inhalation (1–6 months) (Occupational)	NOAEL = 20.30[2] mg/kg/day	LOC for MOE = 100	28–day Inhalation Toxicity Study - Rat/21–day Inhalation Toxicity Study - Rat LOAEL = 0.12 mg/L based on methemoglobinemia (21–day study)
Long - Term Inhalation (Longer than 6 months) (Occupational)	NOAEL = 2 mg/kg/day	LOC for MOE = 100 (Occupational)	Chronic Toxicity Study - Dog LOAEL = 10 mg/kg/day based on methemoglobinemia and sulfhemoglobinemia
Cancer (Oral, dermal, inhalation)	Diflubenzuron Not Required	Not Applicable	Acceptable oral rat and mouse carcinogenicity studies; no evidence of carcinogenic or mutagenic potential. Group E evidence of non-carcinogenicity for humans.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIFLUBENZURON AND ITS METABOLITES FOR USE IN HUMAN RISK ASSESSMENT[1].—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF** and LOC for Risk Assessment	Study and Toxicological Effects
Cancer (Oral, dermal, inhalation)	PCA Group B2 probably human carcinogen Q1* 1.12 x 1^{-1} $(mg/kg/day)^{-1}$	Not Applicable	NTP Oral mouse study
Cancer (Oral, dermal, inhalation)	CPU Q_1* based on monuron a structural analog and the Q_1*1.52 x 10^{-2}	Not Applicable	NTP Oral rat study

[1]UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, cPAD = chronic population adjusted dose, RfD = reference dose, MOE = margin of exposure, LOC = level of concern.
[2]Conversion from mg/L to oral dose (mg/kg/day)
* 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.* Tolerances have been established (40 CFR 180.377) for the combined residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide and its metabolites, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from diflubenzuron and its metabolites 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. Acute doses and endpoints were not selected for the general U.S. population (including infants and children) or the females 13–50 years old population subgroup for diflubenzuron; therefore, an acute dietary exposure analysis was not performed.

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

For the chronic analysis, anticipated residue (AR) information based on field trial data and percent crop treated (%CT) information for some commodities were used. Dietary exposure estimates for representative population subgroups are presented in Table 3. Chronic exposure estimates are expressed in mg/kg bw/day and as a percent of the cPAD. The chronic dietary risk assessment also indicates that for all included commodities, the chronic dietary risk estimates are below Agency's level of concern (<100% cPAD) for the general U.S. population (<1.0% of the cPAD) and all population subgroups. The chronic dietary exposure estimate for the highest exposed population subgroup (all infants (<1 year old)) is 5.5% of the cPAD.

TABLE 3.—RESULTS OF CHRONIC DIETARY EXPOSURE ANALYSIS.

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
U.S. Population (Total)	0.02	0.000153	< 1.0
All Infants (> 1 year old)	0.02	0.001109	5.5
Children 1–6 years old	0.02	0.000248	1.2
Children 7–12 years old	0.02	0.000199	1.0
Females 13–50 years old	0.02	0.000112	< 1.0
Males 13–19 years old	0.02	0.000065	< 1.0
Males 20+ years old	0.02	0.000124	< 1.0
Seniors 55+ years old	0.02	0.000144	< 1.0

iii. *Cancer.* In 1995, based on the available evidence, which included carcinogenicity studies in rats and mice, and battery of negative mutagenicity studies, diflubenzuron was classified as Group E, evidence of non-carcinogenicity for humans. Rat metabolism data generated at this time also indicated that diflubenzuron was metabolized to PCA and CPU and estimated to be about 2% of *in vivo* conversion.

At that time, EPA also considered the carcinogenicity of PCA, a known diflubenzuron metabolite, that was tested by the NTP in 1989 for carcinogenicity in rats and mice as a hydrochloride form. In rats treated with PCA, a treatment-related increased incidence of uncommon sarcomas of the spleen was observed in males and included fibrosarcomas, hemangiosarcomas, and osteosarcomas, many of which metastasized to other sites. In addition, in treated females, one fibrosarcoma and one osteosarcoma were also observed. Furthermore, there

was a marginally-increased incidence of pheochromocytomas in the adrenal glands in both males and females at the HDT. In mice treated with PCA, a treatment-related increased incidence of combined hepatocellular adenomas/carcinomas was observed in males. The increase in combined tumors was primarily due to a dose-related increase in hepatocellular carcinomas. Many of these tumors metastasized to the lungs. An increased incidence of hemangiosarcomas in the spleen and/or liver of the male mice was also observed at the HDT. The incidence was higher than the historical control mean for male mice. There was no evidence of a carcinogenic response in female mice. On this basis PCA was classified as a Group B2, probable human carcinogen.

Recently submitted tier 2 rat metabolism data indicate that diflubenzuron does not metabolize to PCA or CPU nor is CPU converted to PCA. The Agency concluded that a 2% *in vivo* conversion factor for diflubenzuron to PCA or CPU should be dropped. It was recommended that non-carcinogenic risk assessment should include parent, CPU and PCA; and cancer risk for CPU and PCA should be assessed individually.

The Q_1* (estimated unit risk) for PCA, based on male mouse liver adenoma and/or carcinoma combined tumor rates was calculated to be 1.12×10^{-1} (mg/kg/day)$^{-1}$ in human equivalents.

CPU is structurally related to monuron (N,N-dimethyl-CPU), a compound producing tumors of the kidney and liver in male rats. Given that there is no accepted mechanism of carcinogenicity for monuron and that CPU is major metabolite of monuron in rats, a Q_1* was calculated for monuron and applied to CPU. The most potent Q_1* for monuron, based on male rat liver neoplastic nodule and/or carcinoma combined tumor rats, was calculated to be 1.52×10^{-2} (mg/kg/day)$^{-1}$ in human equivalents. Although CPU is structurally related to monuron, there is no need to assess aggregate or cumulative risk scenarios using monuron because monuron is no longer a registered pesticide active ingredient.

a. *Cancer risk from consumption of PCA and CPU*. Based on the submitted metabolism studies, there are two possible sources for dietary exposure to PCA and CPU: Residues in plants/fungi (mushrooms) and residues in animal commodities (milk and liver).

b. *Mushrooms/Milk/Liver*. EPA used results from metabolism studies to determine the percent of the total radioactive residue (TRR) present as PCA+CPU in mushrooms, milk and liver. For milk and liver, ARs were calculated from the results of the ruminant feeding study using tolerance level residues in livestock feed items and adjusting for percent crop treated. The total levels of PCA+CPU were estimated by multiplying the ratio of (PCA+CPU)/Diflubenzuron by the diflubenzuron consumption (from DEEM). The U.S. population exposure to PCA and CPU is given in Table 4 as follows.

TABLE 4.—DIETARY CANCER EXPOSURE (TO PCA AND CPU).

Commodity	(PCA+CPU)/ Diflubenzuron Ratio	Diflubenzuron Consumption mg/kg/day	PCA+CPU Consumption mg/kg/day	CPU/(PCA+CPU) Ratio	PCA Consumption mg/kg/day	CPU Consumption mg/kg/day
Mushrooms	3.45	0.0000018	0.0000062	0.33[1]	0.0000042	0.00000205
Milk	1.33	0.0000003	0.0000004	1.02	0	0.0000004
Liver	0.21	0.0000008	0.00000017	0.97	5×10^{-9}	0.00000016
Total			0.0000068		0.0000042	0.0000026

[1]Worst case ratio.
Overall U.S. exposure to PCA (Table 4): 0.0000042 mg/kg/day
Carcinogenic Risk: 4.7×10^{-7} (0.0000042 mg/kg/day x 0.112 (mg/kg/day)$^{-1}$)
Overall U.S. exposure to CPU (Table 4): 0.0000026 mg/kg/day
Carcinogenic Risk: 3.9×10^{-87} (0.0000026 mg/kg/day x 0.0152 (mg/kg/day)$^{-1}$)

The Agency does not consider the cancer dietary risk from either PCA or CPU to exceed the Agency's level of concern (generally, in the range of 10^{-6}).

iv. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows.

Dietary exposure estimates were based on the following percent crop treated (PCT) estimates: Grass, 1%; grapefruit, 8%; mushrooms, 31%; oranges, 2%; tangerines, 4%; cottonseed oil and meal, 2%; soybean, 1%; cattle bolus, 5%, walnuts 50%. Other commodities were assumed to be 100 percent treated. Anticipated residue levels for diflubenzuron were calculated in livestock, citrus and mushroom commodities. Anticipated residue estimates for diflubenzuron were not calculated for other raw agricultural commodities. Percent crop treated data were utilized where available.

The Agency believes that the three conditions listed above regarding percent crop treated information have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which diflubenzuron may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) 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 diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA).

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. 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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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 screen for sorting out pesticides for which it is highly 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 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 diflubenzuron they are further discussed in the aggregate risk sections.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of diflubenzuron and CPU are estimated to be 0.99 ppb (diflubenzuron) and 8.81 ppb (CPU) for surface water and 0.0023 ppb (diflubenzuron) and 0.065 ppb (CPU) for ground water. PCA is not a significant metabolite in the environment.

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). Although there are no registered homeowner uses for diflubenzuron, there is potential for professional applications to outdoor residential and recreational areas to control mosquitos, moths, and other insects. However, due to the low dermal absorption rate (0.05%) and extremely low dermal and inhalation toxicity, exposure through these uses is expected to be insignificant, and residential post-application exposure was not quantitatively evaluated.

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

EPA does not have, at this time, available data to determine whether diflubenzuron 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, diflubenzuron 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 diflubenzuron 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.*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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. Based on the developmental and reproductive toxicity studies summarized in Table 1, there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for diflubenzuron and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the developmental and reproductive data available, EPA determined that the 10X safety factor to protect infants and children (as required by FQPA) should be removed. This decision was based on the following:

i. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure;

ii. A developmental neurotoxicity study (DNT) with diflubenzuron is not required;

iii. Food and drinking water exposure assessments will not underestimate the potential exposure for infants and children; and

iv. There are currently no registered or proposed residential (non-occupational) uses of diflubenzuron for homeowners. Although there are no registered homeowner uses, there is potential for professional applications to outdoor residential and recreational areas to control mosquitos, moths, and other insects. However, the potential for post-application residential exposures are expected to be limited. Due to the low dermal absorption rate (0.5%) of diflubenzuron, and since it is only applied to the tree canopy to control gypsy moths and mosquitoes, minimal bystander contact is expected.

Recently, EPA has received objections to a tolerance it established for residues of diflubenzuron in or on pears. The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children.

NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has initiated a public comment period on them in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL–7167–7), which ends on September 17, 2002. Although that proceeding remains ongoing, prior to acting on this current tolerance action, EPA reviewed the diflubenzuron-specific objections raised by NRDC and has addressed them below.

NRDC claims datagaps include missing residue chemistry and toxicology data for two diflubenzuron metabolites, deemed necessary by EPA to justify an unconditional registration.

EPA determined that the toxicology database for diflubenzuron is complete for assessment of increased susceptibility to infants and children as required by the Food Quality Protection Act (FQPA) . There are no data gaps for the assessment of the effects of diflubenzuron following *in utero* and/or postnatal exposure. There was no evidence that diflubenzuron targets the nervous system; neither clinical signs indicative of neurotoxicity nor neuropathology were seen in any of the acute, subchronic or chronic studies. There are reliable data that indicate there are (residual) concerns for pre- and/or post-natal toxicity. There was no evidence (quantitative or qualitative) of increased susceptibility following *in utero* exposure to rats or rabbits or to postnatal exposure to rats. In the prenatal developmental toxicity studies in rats and rabbits, no developmental toxicity was seen at the Limit Dose (1,000 mg/kg/day) and in the two-generation reproduction study in rats toxicity in the offspring was manifested as decreased body weight at approximately 4,000 mg/kg/day (4 times the Limit Dose). Based on the lack of evidence of neurotoxic potential and increased susceptibility, EPA determined that a developmental neurotoxicity study in rats was not required.

The Agency believes that it has sufficient data for the metabolites, PCA and CPU because the rate of metabolism of diflubenzuron to PCA or CPU in plants, ruminants, and the environment is low and, thus, exposure to these metabolites will be minimal. Adequate data are available to assess the cancer risks for both PCA and CPU. Even using the most conservative cancer risk assessment model, which is the low dose linear model, risk is negligible. EPA's experience is that a risk assessment using a low dose linear cancer assessment will be the most sensitive risk endpoint indicating that additional hazard testing for these metabolites will not lead to a more protective regulatory decision.

NRDC also claims that by relying on anticipated residue estimates for diflubenzuron on certain crops EPA vastly underestimates dietary exposure. This underestimation occurs, according to NRDC because EPA does not take into account that a significant number of consumers buy produce at farm stands. Even assuming that exposure as a result of purchases at farm stands constitute more than a negligible exposure, NRDC's claims here are inaccurate. Anticipated residues are based on data from crop field trials using application rates and procedures that will produce maximum residues under the currently-approved pesticide label at the time of harvest. As such, they are likely to overstate not understate residue levels of crops at farm stands.

Finally, NRDC asserts that EPA has underestimated aggregate exposure to diflubenzuron because EPA concluded that application of diflubenzuron to tree canopies would result in negligible residential exposure to diflubenzuron. After review, however, EPA reaffirms that these potential exposures are expected to be limited. The label states that ''applications should be made during periods of minimal use.'' and requires users to ''Notify persons using recreational facilities or living in the area to be sprayed before application.'' Diflubenzuron is only applied by commercial applicators to the tree canopy for control of gypsy moths and mosquitoes. Generally applied by helicopter, these sprays are not aerosols or ultra low volume sprays designed as space sprays, but are rather directed to the tree canopy and designed to impinge on the tree tops where they would be effective in pest control. The sprays designed for application to tree canopies utilize much larger droplet sizes which are essentially nonrespirable; therefore, minimal inhalation exposure to bystanders is expected. Additionally, due to a low dermal absorption rate (0.5%), the potential for dermal exposure to bystanders is expected to be minimal.

In any event, EPA would note that the results of the chronic dietary analysis indicated that the estimated chronic dietary risk associated with the proposed use of diflubenzuron was well below the Agency's level of concern for the general U.S. population. In fact, the highest exposed population subgroup (all infants < 1 years of age) is 5.5% of the PAD. The PAD is the Population Adjusted Dose, which is the Reference Dose (RfD) divided by the FQPA Safety Factor. The Agency's level of concern is for exposures in excess of 100% of the PAD. An acute dietary exposure risk assessment was not conducted since no hazard was identified for any population, including infants and children, following a single exposure to diflubenzuron (i.e., no hazard was

identified, therefore, quantification of risk is not required).

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

When EECs for surface water and groundwater 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*. There is no risk from acute dietary exposure (1 day) to diflubenzuron as there is no toxic endpoint identified.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to diflubenzuron and its metabolite CPU from food will utilize 1% of the cPAD for the U.S. population, 5.5% of the cPAD for infants and 1.2% of the cPAD for children 1–6 years old. Based on the use pattern, chronic residential exposure to residues of diflubenzuron is not expected. In addition, there is potential for chronic dietary exposure to diflubenzuron and its metabolite CPU 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 Table 5 below.

For the chronic analysis, ARs and %CT information for some commodities were used (Tier 3). The results of the chronic analysis for diflubenzuron indicate that the estimated chronic dietary risk associated with the proposed use of diflubenzuron is below HED's level of concern. The EECs generated by EFED are less than HED's DWLOCs. Thus, chronic non-cancer aggregate risk estimates are below HED's level of concern. Table 5 summarizes the chronic non-cancer aggregate exposure to diflubenzuron residues.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO DIFLUBENZURON AND CPU

Scenario/Population Subgroup	cPAD, mg/kg/day	%cPAD (Food)	Ground Water EEC, ppb	Surface Water EEC[1], ppb	Chronic DWLOC[2], ppb
U.S. population	0.02	<1.0	0.067	9.8	700
All infants (<1 year old)	0.02	5.5	0.067	9.8	190
Children (1–6 years old)	0.02	1.2	0.067	9.8	200
Children (7–1 2 years old)	0.02	1.0	0.067	9.8	200
Females (13–50 years old)	0.02	<1.0	0.067	9.8	700
Males (13–19 years old)	0.02	<1.0	0.067	9.8	700
Males (20+ years old)	0.02	< 1.0	0.067	9.8	700
Seniors (55+ years old)	0.02	< 1.0	0.067	9.8	700

[1] EECs for diflubenzuron + CPU resulting from the worst-case water exposure estimate scenario (peppers).
[2] The chronic DWLOCs were calculated as follows:
DWLOC (µg/L) = maximumwater exposure (mg/kg/day)/consumption (L/day) x 0.001 mg/µg x body weight(kg)

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). Diflubenzuron is not registered for use on any sites that would result in substantial residential exposure. Therefore, a short-term aggregate risk assessment was not performed.

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). Based on the use pattern, intermediate-term exposure to diflubenzuron would not be expected. Therefore, an intermediate-term aggregate risk assessment was not performed.

5. *Aggregate cancer risk for U.S. population*. As discussed in the Exposure Assessment in Unit. III.C. of this document, CPU is the only metabolite of concern for aggregate cancer risk that is likely to be found in drinking water. For the chronic analysis, ARs and %CT information for some

commodities were used (Tier 3). The results of the cancer analysis indicate that the estimated cancer dietary risk from CPU associated with the proposed use of diflubenzuron is below the Agency's level of concern. Based on a negligible risk in the range of 1-3 x 10^{-6}, the DWLOCs were calculated to be in the range of 2.2-6.8 µg/L. The EECs for surface water (8.81 µg/L) slightly exceed the DWLOCs.

Since PCA is not found in drinking water, the aggregate cancer risk for PCA is the risk calculated for food only (4.7 x 10^{-7}).

The Agency used a screening level model designed to estimate pesticide concentrations in surface water. Although the cancer DWLOC is exceeded by the EEC for CPU on peppers, a number of factors lead the Agency to believe that the actual lifetime exposure through drinking water from the metabolite CPU will be less than the cancer DWLOC. An explanation is provided below:

i. The dietary risk for CPU is minimal from mushrooms, milk, and liver. Therefore, the dietary risk from CPU occurs mostly from exposure that results from its formation in the environment and leaching into the surface water as a result of field application.

ii. The PRZM/EXAMS model does not consider the impact of processing (mixing, dilution, or treatment) of raw water for distribution of drinking water and removal of pesticides from source water.

iii. In the absence of reliable monitoring data, a default percent crop area (PCA) factor is applied to the PRZM/EXAMS modeling. Although the DWLOC is exceeded for peppers, the PCA factor of 87% that was used in the assessment is likely to be higher than the actual factor that would be appropriate for peppers in an agricultural watershed.

iv. To address the uncertainties caused by the absence of reliable monitoring data, the applicant has agreed to conduct edge-of-field runoff studies for peppers to monitor the actual concentrations of CPU in surface water. These data, albeit still relevant solely for estimation of residues in raw water and thus still likely to overestimate residues in actual drinking water, are likely to lower the upper bound risk estimate considerably.

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 diflubenzuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods are available for the analysis of diflubenzuron, PCA, and CPU in crops. Three enforcement methods for diflubenzuron are published in the Pesticide Analytical Method Volume II (PAM II) as Methods I, II, and III. Method II is a GC/ECD method that can separately determine residues of diflubenzuron, CPU, and PCA in eggs, milk, and livestock tissues. All three methods have undergone a successful petition method validation (PMV) and are acceptable for enforcement purposes. Individual analyte methods for CPU (limit of quantitation (LOQ) of 0.001 ppm) and PCA (LOQ of 0.005 ppm) have been successfully validated by the Analytical Chemistry Branch (ACB).

Multiresidue Method (MRM). The FDA PESTDATA database dated 1/94 (PAM Vol. I, Appendix II) contains no information on diflubenzuron recovery using MRM PAM, Vol. I Sections 302, 303, and 304. However, the registrant has submitted Multiresidue testing data that the Agency has forwarded to the FDA. Also, the results of MRM testing of PCA and CPU have been submitted and forwarded to FDA. Neither PCA nor CPU were adequately recovered by any protocols.

B. International Residue Limits

There are no Codex proposals, Canadian, or Mexican limits for residues of diflubenzuron on rice. A compatibility issue is not relevant to the proposed tolerances.

C. Conditions

Environmental fate. Edge of field monitoring study for peppers.

V. Conclusion

Therefore, the tolerance is established for combined residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA), in or on the following raw agricultural commodities: Grass, forage, fodder, and hay group at 6.0 ppm; pepper at 1.0 ppm; stone fruit group (except cherries) at 0.07 ppm; tree nut group at 0.06 ppm; almond hulls at 6.0 ppm; pistachio at 0.06 ppm; cattle, meat byproducts at 0.15 ppm; goat, meat byproducts at 0.15 ppm; hog, meat byproducts at 0.15 ppm; horse, meat byproducts at 0.15 ppm; sheep, meat byproducts at 0.15 ppm. The tolerances for pasture grass and walnut will be deleted, concomitant with the establishment of the tree nut group and grass, forage, fodder, and hay group tolerances.

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 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–2002–0224 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 18, 2002.

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 (1900C), 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. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit 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–2002–0224, 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) 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 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.*, 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 11, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.377 is amended as follows:

i. By removing the entries for ''Cattle, meat byproducts''; ''Goat, meat byproducts''; ''Hog, meat byproducts''; ''Horse, meat byproducts''; ''Sheep, meat byproducts''; and ''Walnut'' from the table in paragraph (a)(1);

ii. By alphabetically adding the entries for ''Almond, hulls''; ''Cattle, meat byproducts''; ''Fruit, stone, group 12, except cherries''; ''Goat, meat byproducts''; ''Grass, fodder, forage, and hay, group 17''; ''Hog, meat byproducts''; ''Horse, meat byproducts''; ''Nut, tree, group 14''; ''Pepper''; ''Pistachio''; and ''Sheep, meat byproducts'' to the table in paragraph (a)(2); and

iii. By removing the text from paragraph (c) and reserving paragraph (c) with the heading.

The additions and revisions read as follows:

§ 180.377 Diflubenzuron; tolerances for residues.

(a) *General.* (1) * * *

(2) * * *

Commodity	Parts per million
Almond , hulls	6.0
Cattle, meat byproducts	0.15
Fruit, stone, group 12, except cherries	0.07
Goat, meat byproducts	0.15
Grass, forage, fodder, and hay, group 17	6.0
Hog, meat byproducts	0.15
Horse, meat byproducts	0.15
Nut, tree, group 14	0.06
* * *	* *
Pepper	1.0
Pistachio	0.06
* * *	* *
Sheep, meat byproducts	0.15

* * * * *

[FR Doc. 02–23818 Filed 9–18–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7377–4]

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

AGENCY: Environmental Protection Agency.

ACTION: Direct final notice of deletion of the Basic Microelectronics, Incorporated (BMI)-Textron Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 is publishing a direct final notice of deletion of the BMI-Textron Superfund Site (Site), located in Lake Park, West Palm Beach County, Florida, from the National Priorities List (NPL).

The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Florida, through the Florida Department of Environmental Protection (FDEP (formerly FDER)) because EPA has determined all appropriate response actions under CERCLA have been completed and, therefore, further remedial action pursuant to CERCLA is not appropriate.

DATES: This direct final deletion will be effective November 18, 2002, unless EPA receives adverse comments by October 21, 2002. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public the deletion will not take effect.

ADDRESSES: Comments may be mailed to: Jan Martin, Remedial Project Manager (RPM), U.S. EPA, Region 4 (4WD–SSMB), 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562–8593, *martin.jan@epa.gov.*

Information Repositories: Comprehensive information about the Site is available for viewing and copying at the Site information repositories located at:

U.S. EPA Record Center, 61 Forsyth Street, SW., Atlanta, Georgia 30365, Phone: (404) 562–8190, Hours: 8 a.m. to 5 p.m., Monday through Friday (By Appointment Only).

Lake Park Library, 529 Park Avenue, Lake Park, Florida 30403, Phone: (561) 881–3330, Hours: 9 a.m. to 8:30 p.m., Monday and Tuesday, 9 a.m. to 5:30 p.m., Wednesday through Friday, 9:30 a.m. to 2 p.m., Saturday.

FOR FURTHER INFORMATION CONTACT: Jan Martin, Remedial Project Manager (RPM), U.S. EPA, Region 4 (4WD–SSMB), 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562–8593, *martin.jan@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 4 is publishing this direct final notice of deletion of the BMI-Textron Superfund Site (Site) from the NPL. The EPA identifies sites that appear to present a significant risk to public health or the environment and maintains the NPL as the list of those sites. As described in the § 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions if conditions at a deleted site warrant such action.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective November 18, 2002, unless EPA receives adverse comments by October 21, 2002, on this document.