of section 107(d)(1)(B) of the Clean Air Act (42 U.S.C. 7407(d)(1)(B)), the Administrator shall defer until April 15, 2008 the effective date of a nonattainment designation of any area subject to a compact that does not meet (or that contributes to ambient air quality in a nearby area that does not meet) the 8-hour ozone national ambient air quality standard if the Administrator determines that the area subject to a compact has met the requirements in paragraphs (e)(2)(i) through (iii) of this section. The Administrator shall defer until July 1, 2007 the effective date of a nonattainment designation of the Denver area.

* * * * *

(ii) * * *

(B) Prior to expiration of the deferred effective date on April 15, 2008, if the Administrator determines that an area or the State subject to a compact has not met either requirement in paragraphs (e)(2)(iv) and (v) of this section, the nonattainment designation shall become effective as of the deferred effective date, unless EPA takes affirmative rulemaking action to further extend the deadline.

(C) If the Administrator determines that an area subject to a compact and/or State has not met any requirement in paragraphs (e)(2)(iv) through (vi) of this section, the nonattainment designation shall become effective as of the deferred effective date, unless EPA takes affirmative rulemaking action to further extend the deadline.

* * * * *

■ 3. In § 81.306, the table entitled ''Colorado-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.306 Colorado.

* * * * *

Colorado-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until July 1, 2007.

* * * * *

■ 4. In § 81.311, the table entitled ''Georgia-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.311 Georgia.

Georgia-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

[2] Effective date of nonattainment designation for Denver EAC is extended to July 1, 2007.

■ 5. In § 81.321, the table entitled ''Maryland-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.321 Maryland.

* * * * *

Maryland-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

■ 6. In § 81.334, the table entitled ''North Carolina-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.334 North Carolina.

* * * * *

North Carolina-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

■ 7. In § 81.341, the table entitled ''South Carolina-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.341 South Carolina.

* * * * *

South Carolina-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

■ 8. In § 81.343, the table entitled ''Tennessee-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.343 Tennessee.

* * * * *

Tennessee-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

■ 9. In § 81.344, the table entitled ''Texas-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.344 Texas.

* * * * *

Texas-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

■ 10. In § 81.347, the table entitled ''Virginia-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.347 Virginia.

* * * * *

Virginia-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

■ 11. In § 81.349, the table entitled ''West Virginia-Ozone (8–Hour Standard)'' is amended by revising footnote 2 to read as follows:

§ 81.349 West Virginia.

* * * * *

West Virginia-Ozone (8–Hour Standard)

* * * * *

[2] Early Action Compact Area, effective date deferred until April 15, 2008.

* * * * *

[FR Doc. E6–20221 Filed 11–28–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0181; FRL–8103–8]

Diflubenzuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of diflubenzuron and its metabolites 4-chlorophenylurea and 4-chloroaniline in or on brassica, leafy greens subgroup 5B, turnip greens, peanut, peanut hay, peanut oil, barley grain, barley hay, barley straw, oat grain, oat forage, oat hay, oat straw, wheat grain, wheat forage, wheat hay, wheat straw, aspirated grain fractions, and pummelo. The Interregional Research Project #4 requested these tolerances 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 November 29, 2006. Objections and requests for hearings must be received on or before January 29, 2007, and must be filed in accordance with the instructions provided in 40 CFR part

178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0181. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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; greenhouse, 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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.epa.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0181 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 January 29, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0181, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of April 12, 2006 (71 FR 18742) (FRL–7773–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 5E6965, PP 5E6966, and PP 5E6967) by Interregional Project Number 4, 681 Highway 1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.377 be amended by establishing tolerances for residues of diflubenzuron, (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide and metabolites convertible to p-chloroaniline expressed as diflubenzuron in or on the raw agricultural commodities barley grain, oat grain, wheat grain at 0.06 ppm; forage of barley, oat and wheat at 5.0 ppm; hay of barley, oat and wheat at 2.0 ppm; straw of barley, oat and wheat at 2.0 ppm; aspirated grain fractions of barley, oat and wheat at 3.0 ppm; and pummelo at 0.5 ppm (PP 5E6965), brassica, leafy greens subgroup 5B and turnip greens at 8.0 ppm, eggplant and okra at 1.0 ppm (PP 5E6966), and peanut at 0.2 ppm (PP 5E6967). That notice included a summary of the petition prepared by IR-4. There were no comments received in response to the notice of filing.

Tolerances were later amended by IR-4 as follows: Barley, hay at 3.0 ppm; barley, straw at 1.8 ppm; oat forage at 7.0 ppm; oat hay at 6.0 ppm; oat straw at 3.5 ppm; wheat, forage at 7.0 ppm, wheat, hay at 6.0 ppm, wheat, straw at 3.5 ppm; grain, aspirated fractions at 11 ppm (PP 5E6965); brassica, leafy greens, subgroup 5B and turnip greens at 9.0 ppm (PP 5E6966); peanut at 0.10 ppm; peanut, hay at 55 ppm; peanut, refined oil at 0.20 ppm (PP 5E6967).

In addition, the proposed tolerance for barley, forage (PP 5E6965) was deleted by IR-4 because this is not a raw agricultural commodity (RAC) of barley. Also, the proposed tolerances for eggplant and okra (PP 5E6966) were withdrawn by IR-4 because the Agency concluded that there are insufficient data to establish tolerances for

diflubenzuron residues in or on these commodities at this time.

EPA is also deleting several established tolerances in § 180.377 (b) that are no longer needed as a result of this action. The tolerance deletions under § 180.377 (b) are time-limited tolerances established under section 18 emergency exemptions that are superceded by the establishment of general tolerances for diflubenzuron and its metabolites under § 180.377 (a)(2).

The revisions to § 180.377 (b) are as follows:

1. Delete the time-limited tolerance for barley, grain at 0.05 ppm. A tolerance for barley, grain at 0.06 ppm is established by this action under § 180.377(a)(2).

2. Delete the time-limited tolerance for barley, hay at 1.0 ppm. A tolerance for barley, hay at 3.0 ppm is established by this action under § 180.377(a)(2).

3. Delete the time-limited tolerance for barley, straw at 0.50 ppm. A tolerance for barley, straw at 1.8 ppm is established by this action under § 180.377 (a)(2).

4. Delete the time-limited tolerance for wheat, grain at 0.05 ppm. A tolerance for wheat, grain at 0.06 ppm is established by this action under § 180.377(a)(2).

5. Delete the time-limited tolerance for wheat, hay at 1.0 ppm. A tolerance for wheat, hay at 6.0 ppm is established by this action under § 180.377(a)(2).

6. Delete the time-limited tolerance for wheat, straw at 0.50 ppm. A tolerance for wheat, straw at 3.5 ppm is established by this action under § 180.377 (a)(2).

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 the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

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(a)(2) of FFDCA, for tolerances for combined residues of diflubenzuron, (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide and its metabolites 4-chlorophenylurea and 4-chloroaniline in or on the raw agricultural commodities barley, grain at 0.06 ppm; barley, hay at 3.0 ppm; barley, straw at 1.8 ppm; oat, grain at 0.06 ppm; oat forage at 7.0 ppm; oat hay at 6.0 ppm; oat straw at 3.5 ppm; wheat, grain at 0.06 ppm; wheat, forage at 7.0 ppm, wheat, hay at 6.0 ppm, wheat, straw at 3.5 ppm; grain, aspirated fractions at 11 ppm; pummelo at 0.50 ppm; brassica, leafy greens, subgroup 5B at 9.0 ppm; turnip greens at 9.0 ppm; peanut at 0.10 ppm; peanut, hay at 55 ppm; peanut, refined oil at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by diflubenzuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.epa.gov/fedrgstr/EPA-PEST/2002/September/Day-19/p23818.htm* (67 FR 59006).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for diflubenzuron used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 19, 2002 (67 FR 59006) (FRL–7200–4).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances for residues of diflubenzuron are established under 40 CFR 180.377. Tolerances listed in 40 CFR 180.377(a)(1) are expressed in terms of diflubenzuron per se. Under this section, tolerances of 0.05-6.0 ppm are established for residues in/on eggs; milk; fat and meat of cattle, goat, hog, horse, poultry, and sheep; poultry meat byproducts; cottonseed; mushroom; grapefruit, orange (sweet); tangerine; soybean hulls; and globe artichoke. Tolerances listed in 40 CFR 180.377(a)(2) are expressed in terms of the combined residues of diflubenzuron and its metabolites 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA). Under this section, tolerances of 0.02-6.0 ppm are established for residues in/on rice grain; tree nuts (group 14); pistachios; fruit, stone (group 12) except cherry; meat byproducts of cattle, goat, hog, horse, and sheep; pear; rice straw; pepper; and almond hulls. Time-limited tolerances listed in 40 CFR 180.377(b) are expressed in terms of the combined residues of diflubenzuron and its metabolites CPU and PCA, expressed as the parent diflubenzuron, in connection with use of the pesticide under Section 18 Emergency Exemptions granted by EPA. Risk assessments were conducted by EPA to assess dietary exposures from diflubenzuron in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The diflubenzuron toxicology studies indicated no possibility of such an effect for either 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-FCID™) 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: For the chronic analysis a Tier 1 chronic dietary-exposure assessment was conducted using the established/recommended tolerances for all food commodities, 100% CT information for all proposed and existing uses, and DEEM(™) Version 7.81 default processing factors for some processed commodities.

iii. *Cancer*. The Agency has classified diflubenzuron as ''Group E,'' evidence of non-carcinogenicity for humans, based on lack of evidence of carcinogenicity in rats and mice. There are also two metabolites of diflubenzuron; PCA and CPU. PCA tested positive for splenic tumors in male rats and hepatocellular adenomas/carcinomas in male mice in a National Toxicology Program (NTP) study. Therefore, EPA classified PCA as a ''Group B2'' probable human carcinogen. The Agency determined for those commodities that contained PCA and CPU, the Q1* of PCA should be used to calculate the cancer risk from the sum of these two metabolites.

Based on the submitted metabolism studies, there are two possible sources for dietary exposure to PCA and CPU: residues in mushrooms and residues in milk and liver. Because human exposure to PCA and CPU will not be affected by the proposed new uses, and EPA has previously concluded that exposure to these compounds is safe, therefore, the cancer dietary risk from PCA and CPU will not be addressed in this document. For a detailed discussion on the exposure and risks to PCA and CPU, please refer to the September, 2002 **Federal Register** document titled Diflubenzuron; Pesticide Tolerances (September 19, 2002, FR 67 59006); *http://www.epa.gov/fedrgstr/EPA-PEST/2002/September/Day-19/p23818.htm*.

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 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. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentrations in Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of diflubenzuron and the major degradate CPU for chronic exposures are estimated to be 2.76 ppb for surface water and 0.208 ppb for ground water.Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™, Version 2.03). For chronic dietary risk assessment, the annual average concentration of 2.76 ppb was used to assess the contribution to drinking 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).

Although there are no registered homeowner uses, there are registered uses for professional applications to outdoor residential and recreational areas to control mosquitoes, moths, and other insects. However, the potential for post-application residential exposure is 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.

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 diflubenzuron and any other substances and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website 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 data base 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*. Based on the developmental and reproductive toxicity studies, there is no indication of increased susceptibility of rats or rabbits to *in utero* or postnatal exposure.

3. *Conclusion*. Based on the reliable data available on diflubenzuron, EPA determined that the additional FQPA 10X safety factor to protect infants and children was not needed. This decision was based on the following:

i. There is a complete toxicity data base for diflubenzuron

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

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

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

v. 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 mosquitoes, 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.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but 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. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at *http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf*.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs. The risk assessment for diflubenzuron used in this tolerance document uses this approach of incorporating water exposure directly into the dietary exposure analysis.

1. *Acute risk*. Because there were no toxic effects attributable to a single dose of diflubenzuron, it is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to diflubenzuron from food and water will utilize 11% of the cPAD for the U.S. population, 12% of the cPAD for all infants less than 1 year old, and 37% of the cPAD for children 1-2 years old. There are no residential uses for diflubenzuron that result in chronic residential exposure to diflubenzuron. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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 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).

Diflubenzuron 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*. Based on the available evidence, which included adequate carcinogenicity studies in rats and mice, and battery of negative mutagenicity studies, diflubenzuron has been classified as ''Group E,'' evidence of non-carcinogenicity for humans, by the Agency.

As noted in Unit III.C.1.iii. of this document, the Agency has concluded that human exposure to PCA and CPU (metabolites of diflubenzuron) will not be affected by the proposed new uses. EPA has previously found aggregate exposure to these compounds to be safe. (September 19, 2002, 67 FR 59006); *http://www.epa.gov/fedrgstr/EPA-PEST/2002/September/Day-19/p23818.htm*

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

There are adequate enforcement methods, published in the Pesticide Analytical Manual (PAM, Vol. II), for determining diflubenzuron residues of concern. In addition, a new analytical methodology for plant commodities was successfully validated by an independent laboratory as well as by Agency chemists at the Analytical Chemistry Branch (ACB)/Biological and Economics Analysis Division (BEAD) in conjunction with the approved rice petition (PP#8F4925). The new methods were forwarded to the Food and Drug Administration (FDA) for publication in PAM Vol. II as Roman Numeral Methods. These methods can separately determine residues of diflubenzuron by gas chromatography/electron-capture detection (GC/ECD), CPU by GC/ECD, and PCA by GC/mass spectrometry (MS). The reported limit of quantitation (LOQ) for diflubenzuron in/on rice grain, straw, and bran is 0.01 ppm, and is 0.05 ppm in/on rice hull. In rice straw, the LOQ for CPU is 0.01 ppm and 0.005 ppm for PCA.

B. International Residue Limits

The Codex Alimentarius has established maximum residue limits (MRL), expressed in terms of diflubenzuron per se, for many commodities including: apple (5 ppm), citrus fruits (0.5 ppm), edible offal (mammalian) (0.1 ppm), eggs (0.05 ppm), meat (from mammals other than marine mammals) (0.1 ppm), milks (0.02 ppm), mushrooms (0.3 ppm), pear (5 ppm), pome fruits (5 ppm), poultry meat (0.05 ppm), rice (0.01 ppm), and rice straw and fodder (dry) 0.7 ppm). As the U.S. residue definition includes CPU and PCA, compatibility is not possible with the proposed tolerances.

V. Conclusion

Therefore, tolerances are established for combined residues of diflubenzuron, (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide and its metabolites 4-chlorophenylurea and 4-chloroaniline in or on the raw agricultural commodities barley, grain at 0.06 ppm; barley, hay at 3.0 ppm; barley, straw at 1.8 ppm; oat, grain at 0.06 ppm; oat forage at 7.0 ppm; oat hay at 6.0 ppm; oat straw at 3.5 ppm; wheat, grain at 0.06 ppm; wheat, forage at 7.0 ppm, wheat, hay at 6.0 ppm, wheat, straw at 3.5 ppm; grain, aspirated fractions at 11 ppm; pummelo at 0.50 ppm; brassica, leafy greens, subgroup 5B

at 9.0 ppm; turnip greens at 9.0 ppm; peanut at 0.10 ppm; peanut, hay at 55 ppm; peanut, refined oil at 0.20 ppm.

VI. 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.

VII. 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: November 16, 2006.

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. Section 180.377 is amended by alphabetically adding commodities to the table in paragraph (a)(2) and removing from the table in paragraph (b), the commodities ''barley, grain''; ''barley, hay''; barley, straw''; ''wheat, grain''; ''wheat, hay''; and ''wheat, straw'' to read as follows:

§ 180.377 Diflubenzuron; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * *	*
Barley, grain	0.06
Barley, hay	3.0
Barley, straw	1.8
Brassica, leafy greens, subgroup 5B	9.0
* * * *	*
Grain, aspirated fractions	11
* * * *	*
Oat, forage	7.0
Oat, grain	0.06
Oat, hay	6.0
Oat, straw	3.5
Peanut	0.10
Peanut, hay	55
Peanut, refined oil	0.20
* * * *	*
Pummelo	0.50
* * * *	*
Turnip greens	9.0
Wheat, forage	7.0
Wheat, grain	0.06
Wheat, hay	6.0
Wheat, straw	3.5

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