on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

National Technology Transfer Advancement Act

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under Section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 13, 2007. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* Section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: May 18, 2007.

Gary Gulezian,

Acting Regional Administrator, Region 5.

■ For the reasons stated in the preamble, part 52, chapter I, of title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart P—Indiana

■ 2. Section 52.770 is amended by adding paragraph (c) (179) to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

(179) On July 17, 2006, Indiana submitted final adopted revisions, which add 326 IAC 8–1–6 (3)(B) and (C), to its VOC rules for new facilities in 326 IAC 8–1–6 as a requested revision to the Indiana state implementation plan. EPA is approving these revisions, which exempt boat manufacturers subject to NESHAPS for boat manufacturing, or reinforced plastics composites manufacturers subject to NESHAPS for reinforced composites production facilities, from the requirement to do a best available control technology analysis provided they comply with the applicable NESHAPS.

(i) Incorporation by reference.

(A) Indiana Administrative Code Title 326: Air Pollution Control Board, Article 8: Volatile Organic Compound Rules, Rule 1: General Provisions, Section 6: New facilities; general reduction requirements. Final adopted by the Air Pollution Control Board on March 1, 2006. Filed with the Secretary of State on May 25, 2006, and became effective June 23, 2006. Published in the Indiana Register on July 1, 2006 (29 IR 3350).

[FR Doc. E7–11290 Filed 6–12–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0559; FRL–8133–2]

Diuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for diuron in or on cactus (with regional restrictions for use); spearmint, tops; peppermint, tops; and fish–freshwater finfish, farm raised. Interregional Research Project Number 4 (IR–4) and the Catfish Farmers of America requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 13, 2007. Objections and requests for hearings must be received on or before August 13, 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–2006–0559. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. 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 Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility 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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2006–0559 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 as required by 40 CFR part 178 on or before August 13, 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 this copy, identified by docket ID number EPA–HQ–OPP–2006–0559, 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 Bldg.), 2777 S. Crystal Dr., 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 Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of July 26, 2006 (71 FR 42390) (FRL–8079–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filings of a pesticide petitions (PP 2E6438, 6E3390 and 6F4680) by Interregional Research Project Number 4 (IR-4), 681 Highway 1 South, North Brunswick, NJ 08902 and the Catfish Farmers of America, 1100 Hwy. 82 East, Suite 202, Indianola, MS 38751. The petitions requested that 40 CFR 180.106 be amended by establishing tolerances for residues of the herbicide diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea in or on cactus, prickly pear at 0.05 part per million (ppm) (6E3390), mint at 1.5 ppm (2E6438) and freshwater finfish, farm raised at 2.0 ppm (6F4680). That notice referenced a summary of the petitions prepared by Dupont, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments received on the notice of filing are discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has recommended certain changes to the petitions including:

1. Revised tolerance levels for certain commodities;
2. A revised tolerance expression to be applied to all new uses; and
3. Revised commodity terms for some commodities.

The reasons for these changes are explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerance for combined residues of diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea and its metabolites convertible to 3,4-dichloroaniline on cactus at 0.05 ppm, spearmint, tops at 1.5 ppm, peppermint, tops at 1.5 ppm and fish - freshwater finfish, farm raised at 2.0 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 adverse effects caused by diuron 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.regulations.gov*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2006–0059. Additional information regarding this chemical can also be found in the docket for the reregistration eligibility decision (RED) for diuron identified as EPA–HQ–OPP–2002–0249.

Diuron has low acute toxicity (Toxicity Category 3-4) by the oral, dermal, or inhalation exposure routes. Diuron is not an eye or skin irritant, and not a skin sensitizer. The primary target organs are the hematopoietic system, the bladder, and renal pelvis. Erythrocyte damage resulted in hemolytic anemia and compensatory hematopoiesis, which were manifested as significantly decreased erythrocyte counts, hemoglobin levels, and hematocrit, and increased mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), abnormal erythrocyte forms, reticulocyte counts, and leukocyte count. Consistent observations of erythrocytic regeneration were seen in chronic toxicity studies in rats, mice and dogs. Gross pathology findings in chronic rat and mouse studies showed increased incidences of urinary bladder edema and wall thickening at high doses. Microscopic evaluation showed dose-related increases in the severity of epithelial focal hyperplasia of the urinary bladder and renal pelvis in both sexes. The available data did not reveal any developmental or reproductive toxicity. The Carcinogenicity Peer Review Committee (CPRC) characterized diuron as a ''known/likely'' human carcinogen based on urinary bladder carcinomas in both sexes of the Wistar rat, kidney carcinomas in the male rat, and mammary gland carcinomas in the female NMRI mouse. Diuron was not mutagenic in bacteria or in cultured mammalian cells and no indication of DNA damage in primary rat hepatocytes was observed. There were marginal statistically significant increases in cells with structural aberrations in a Sprague Dawley rat *in vivo* bone marrow chromosomal aberration assay. However, the levels of aberrations were within historical control range and assessed negative.

The Metabolism Assessment Review Committee (MARC) recommended that a separate dietary cancer assessment be conducted for N'-(3-chlorophenyl)-N,N-dimethyl urea (MCPDMU), a potential residue of concern in drinking water, but not found in food (in plant or animal metabolism studies). The MARC raised concerns for MCPDMU based on an analogous compound, N'-(4-chlorophenyl)-N,N-dimethyl urea (monuron). With the exception of the position of the chlorine, the structures are identical. There are cancer concerns for monuron but the target organs are different than those affected by diuron. In the absence of the data needed for a more comprehensive evaluation of MCPDMU, the carcinogenic risk assessment was conducted using the Q_1* of monuron.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (''aPAD'') and chronic population adjusted dose (''cPAD''). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (''MOE'') called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for diruon used for human risk assessment can be found at *www.regulations.gov* in document Diuron. Updated Aggregate Risk Assessment to Support Permanent Tolerances for Residues in Prickly Pear Cactus, Peppermint Tops, Spearmint Tops, and Freshwater Finfish, Farm-Raised at page 4 in Docket ID EPA–HQ–OPP–2006–0059.

There are no adverse effects attributed to a single exposure identified in any available studies for diuron. In addition, diuron has low acute toxicity and no developmental or neurotoxic concerns. Therefore, no acute dietary endpoint was chosen and no acute dietary risk assessment was conducted. Also, no systemic toxicity was observed following repeated dermal dosing up to 1,200 mg/kg/day. Therefore, no short- or intermediate-term dermal endpoints were chosen either. The short-term incidental oral and the inhalation endpoints are based on decreased maternal body weight and food consumption observed in a rabbit developmental toxicity study [No Observable Adverse Effect Level (NOAEL) = 10 mg/kg/day]. The intermediate-term incidental oral and intermediate-term inhalation endpoints are based on hematological effects observed at 10 mg/kg at 6 months in the chronic rat study. The NOAEL is 1 mg/kg/day. The chronic dietary, and long-term dermal and inhalation endpoints are based on hemolytic anemia and compensatory hematopoiesis [Lowest Observable Adverse Effect Level (LOAEL) = 1.0 mg/kg/day]. Since the dose and endpoint for establishing the chronic dietary reference Dose (RfD) is a LOAEL and a NOAEL was not established, a total uncertainty factor (UF) of 1,000 was applied (a UF of 100 to account for both interspecies extrapolation and intra-species

variability and an UF of 10 since the 10X FQPA safety factor has been retained to protect infants and children). A low dose linear extrapolation model with a Q_1* of 1.91 x 10^{-2} (mg/kg/day)$^{-1}$was applied to the animal data for the quantification of human risk to diuron, based on the urinary bladder carcinomas in the rat.

As discussed in Unit III.A., a separate dietary cancer assessment was conducted for N'-(3-chlorophenyl)-N,N-dimethyl urea (MCPDMU), a potential residue of concern in drinking water, but not found in food. A low dose linear extrapolation model with a Q_1* of 1.52 x 10^{-2} (mg/kg/day)$^{-1}$ was applied to the animal data for the quantification of human risk, based on male rat liver neoplastic nodule and/or carcinoma combined tumor rates.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to diuron, EPA considered exposure under the petitioned-for tolerances as well as all existing diuron tolerances in (40 CFR 180.106). EPA assessed dietary exposures from diuron and its metabolites convertible to 3,4-dichloroaniline 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 one-day or single exposure.

No such effects were identified in the toxicological studies for diuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, the EPA analyses incorporated tolerance level residues for some commodities as well as anticipated residues (ARs) for other commodities, based on a combination of average field trial data and USDA/Pesticide Data Program (PDP) monitoring data. The chronic exposure estimates were further refined with percent crop treated (PCT) information for some crops. In some cases, DEEM(TM) (ver. 7.78) default processing factors were used, but empirical processing factors were used when available.

iii. *Cancer.* —a. *Diuron.* In conducting the cancer dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, the EPA analyses incorporated tolerance level residues for some commodities as well as anticipated residues (ARs) for other commodities, based on a combination of average field trial data and USDA PDP monitoring data. The cancer exposure estimates were further refined with PCT information for some crops. In some cases, DEEM(TM) (ver. 7.78) default processing factors were used, but empirical processing factors were used when available.

b. *MCPDMU.* EPA has identified MCPDMU as a potential residue of concern of diuron that may be found in drinking water but not found in food. In the absence of a metabolism study in fish, based on potential concern for residues of the drinking water, EPA conducted an assessment based on a worst-case dietary exposure analysis for the degradate MCPDMU, including residues in drinking water and a conservative estimate of potential residues in fish. EPA estimated the MCPDMU drinking water residue value of 1 ppb, based on monitoring data and assumed 25% (i.e., 0.5 ppm) of the residue in fish could be attributed to the degradate. This is a conservative assumption of a 500-fold accumulation of the degradate in fish, whereas acceptable metabolism studies in rat, ruminants and poultry indicate the majority of the residue in animals consists of dichlorinated and hydroxy metabolites; further, the rat metabolism study indicates diuron residues do not bioaccumulate. Therefore, the assumption that 25% of the tolerance-level residue in fish is comprised of the MCPDMU degradate is considered to be conservative.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) of FFDCA 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. For the present action, EPA will issue such data call-ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

a. 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;

b. The exposure estimate does not underestimate exposure for any significant subpopulation group; and

c. 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 PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

1% alfalfa, 1% almonds, 10% apples, 5% artichokes, 55% asparagus, 1% barley, 50% blackberries, 30% blueberries, 1% corn, 25% cotton, 20% filberts, 10% grapes, 45% grapefruit, 15% lemon, 50% limes, 20% Macadamia nut, 5% oats, 15% olives, 50% oranges, 10% peaches, 10% pears, 5% pecans, 90% mint, 1% pistachios, 30% raspberries, 15% sugarcane, 30% tangerines, 15% walnuts, and 1%wheat.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

There are existing tolerances for residues of diuron on peppermint, hay at 2 ppm. However, the EPA has determined the preferred commodity term should be peppermint, tops. Therefore, the PCT estimates used for mint are based on the existing registration and are not projections.

The Agency believes that the three conditions listed in Unit III.C.iv. 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. 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 diuron may be applied in a particular area.

2. *Dietary exposure from drinking water*. The drinking water exposure assessment conducted in conjunction with the 2003 RED noted that surface water monitoring data resulted in diuron residues less than 1 parts per billion (ppb) (*http://www.regulations.gov*, document 0006 - Docket ID EPA–HQ–OPP–2002–0249). For ground water, modeling results indicted that residues of diuron and degradates would be at most 0.6 ppb for long-term exposure assessment. For the current assessment, EPA used PDP monitoring data from 2003 and 2004, in which 1,072 samples of raw and treated water were analyzed for diuron residues. Residues were detected in 12 samples, ranging from 27 to 267 parts per trillion (ppt), with an average of 20.2 ppt (0.020 ppb). For chronic dietary risk assessment, the water concentration of value 0.020 ppb was used to access the contribution to drinking water. These estimates of drinking water concentrations were directly entered into the dietary exposure model.

The drinking water exposure assessment conducted in conjunction with the 2003 RED noted that surface water monitoring data resulted in diuron residues less than 1 ppb. For ground water, modeling results indicated that residues of diuron and degradates would be at most 0.6 ppb for long-term exposure assessment. The analysis in the RED noted that the potential for residues in drinking water sources is more likely to occur from run-off to surface water, and the ground water sources of drinking water are likely to be less vulnerable to contamination with diuron. The RED cited numerous monitoring studies from areas known for high diuron usage. The drinking water risks in the RED were calculated from diuron residues in a Florida surface water monitoring study in which the highest residue found was 1.2 ppb, but the 90^{th} and 95^{th} percentile residues were both less than the limit of detection in the study, which ranged from 0.2 to 0.4 ppb. For the current assessment, drinking water residues were estimated from PDP monitoring data from 2003 and 2004, in which 1,072 samples of raw and treated water were analyzed for diuron residues. Residues were detected in 12 samples, ranging from 27 to 267 ppt, with an average detected residue of 20.2 ppt (0.02 ppb). This average of detected residues was considered to be more appropriate for estimating cancer risk from drinking water than a high-end estimate of surface water residues from the Florida monitoring data. However, the 2 sets of monitoring data support the conclusion that potential residues in surface water are much less than 1 ppb.

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).

In conjunction with the RED, the agency concluded that all registered uses were eligible for reregistration, provided labeling requirements and mitigation measures were observed. This included voluntary cancellation of uses allowing application to home lawns. Currently, all registered labels for diuron no longer allow applications to home lawns. As a result the current uses registered that could result in non-occupational, non-dietary exposures are diuron added to paints and stains and residential ponds and aquariums.

Exposures of concern to diuron resulting from residential uses is expected to be negligible. The existing residential uses for diuron result in only short-term exposures, generally less than 7 days. No short-term dermal endpoints have been identified for diuron. A short-term incidental oral endpoint was identified. However, all residential uses to home lawns have been cancelled so incidental oral exposures are not expected. Inhalation endpoints have been identified for diuron. However, diuron has a low vapor pressure (2×10^{-7} mm Hg@30°C) and therefore, absorption by the inhalation route is likely to be low. Potential residential handler exposures from applying paints and stains containing diuron were assessed in the 2003 RED. Conservative assumptions included 2 days of painting per year for 50 years of a 70 year lifetime. However, based on information gathered through the RED process it was determined that less than 1% of paint sold contains diuron, and that such paints would likely only be used in rooms subject to high moisture (e.g., bathrooms). Therefore, lifetime exposure to home applicators of diuron-containing products is likely to negligible. Postapplication inhalation exposure resulting from the use of diuron in residential ponds and aquariums is also expected to be minimal based on the extremely high dilution rate. Therefore, an exposure assessment was not conducted for non-occupational, non-dietary exposures.

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

Based on available data, EPA has previously concluded that diuron, propanil and linuron, all of which contain 3,4 dichloroaniline (3,4-DCA) in their structures, do not share a common mechanism of toxicity. (Additional information regarding this conclusion can be found in the docket for the RED for diuron identified as EPA–HQ–OPP–2002–0249.)

Propanil readily metabolizes to 3,4-DCA, but neither diuron nor linuron metabolize to 3,4–DCA in plant or animal metabolism studies. EPA previously recommended against aggregating residues of 3,4 DCA for the propanil and diuron risk assessments. The following considerations support the recommendation:

- 3,4-DCA is a significant residue of concern for propanil, but is not a residue of concern per se for diuron;
- The analytical method for quantifying residues of concern from applications of diuron converts all residues to 3,4-DCA as a technical convenience. However, 3,4-DCA is not a significant residue in diuron plant and animal metabolism or hydrolysis studies. Therefore, the agency determined that all residues hydrolyzable to 3,4-DCA would be included in the tolerance expression for

diuron, because no validated enforcement method is available for quantification for the actual residues of concern for diuron.

• Propanil and its metabolite 3,4-DCA were found to induce methemoglobinemia, the endpoint of concern for propanil. Diuron has not been shown to cause this effect. Diuron induces hemolytic anemia and compensatory hematopoiesis, which are mechanistically different from methemoglobinemia.

• Linuron and diuron metabolism studies show that both chemicals metabolize to DCPU and DCPMU. However, for reasons that are yet unknown, these chemicals do not induce the same toxic effects in mammals. Submitted data indicate that diuron is primarily (though not exclusively) metabolized by the hydroxylation of the urea group in either the methyl or the amino position and conjugated. Linuron, on the other hand, appears to be primarily ring-hydroxylated and conjugated. The methoxy group is removed, followed by the methyl group, with ring hydroxylation. Unlike linuron, hydroxylation of the phenyl ring is not a major metabolite pathway of diuron and, both methyl groups are lost.

• Methemoglobinemia is the dominant toxic effect of concern for linuron. As mentioned above, diuron does not induce methemoglobinemia. Mechanistic and reproductive studies show that linuron, and to some extent propanil, is an androgen receptor antagonist and that linuron induces testicular abnormalities in rodents. Studies with diuron showed no indications of any endocrine effects and no developmental or reproductive effects.

• Although the mechanisms of action for the differing effects induced by the two ureas, diuron and linuron, are not entirely known, there is sufficient cause to believe that exposures from the two compounds should not be cumulated.

• The estimated dietary cancer risk for diuron did not include residues from linuron and propanil since it was recognized that the target organs for tumor induction for diuron are different from those for linuron and propanil, and data were available which indicated that the mechanism of action may be different for diuron.

For the purposes of this tolerance action, therefore, EPA has not assumed that diuron 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 (''10X'') 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is an acceptable developmental toxicity study in rabbits and an acceptable 2-generation reproduction study in rats. A developmental toxicity study in rats was classified as unacceptable due to deficiencies in analytical data on the sample analysis; however, the EPA considers the developmental toxicity study in rats adequate for the FQPA susceptibility assessment based on the observation that the developmental toxicity NOAEL was higher than the maternal NOAEL. The EPA has also concluded that a developmental neurotoxicity (DNT) study is not required.

There is no indication of increased susceptibility to young exposed to diuron in the available studies. In the developmental toxicity study in rabbits, there were no developmental effects at the highest dose tested. In the developmental toxicity study in rabbits and in the 2-generation rat reproduction study, developmental/offspring effects were observed only at maternally/parentally toxic dose levels.

There are no neurotoxic signs in any of the submitted subchronic or chronic studies.

3. *Conclusion*. The chronic dietary endpoint for diuron used in risk assessment is based on a LOAEL of 1 mg/kg/day from the chronic toxicity/carcinogenicity study in rats. EPA has retained the 10X FQPA safety factor for diuron because of reliance on a LOAEL in the rat chronic toxicity study and because the data in that study or other studies did not show that a smaller factor would be safe. EPA has determined that reliable data show that it would be safe for infants and children provided the FQPA safety factor of 10X is retained and no additional safety factors are needed. That decision is based on the following findings:

i. There are no uncertainties with the toxicology database other than with regard to the lack of a NOAEL in the rat chronic toxicity study. The only outstanding toxicity data requirement for diuron is a 28–day inhalation study which is required to address the concern for inhalation exposure to workers during the application of diuron. Occupational exposures are not considered under section 408 of FFDCA. Postapplication inhalation exposure resulting from the indoor use of diuron in paints is expected to be minimal because of the low vapor pressure of diuron, and because diuron-treated paint is only likely to be used in rooms where high humidity is expected (e.g... a bathroom), and would rarely be used in the entire house based on the use pattern. Additionally, based on information gathered through the RED process it was determined that less than 1% of paint sold contains diuron. As a result, non-occupational exposure to diuron via inhalation is not expected to occur with infants and children. Therefore, the 28–day inhalation study will not change the endpoints used in risk assessment to address the potential risks to infants and children.

The developmental toxicity study in rats is classified as unacceptable due to deficiencies in analyses of the test material and dosing solutions. However, the EPA has not required the study be repeated since it is considered adequate for the FQPA susceptibility assessment based on the observation that the developmental toxicity NOAEL was higher than the maternal NOAEL, and because maternal and developmental toxicity were well-defined at their respective LOAELs. Finally, the rabbit is considered to be the more sensitive species than the rat for developmental toxicity, and the rabbit developmental study is acceptable. The chronic toxicity study in dogs has also been classified as unacceptable due to the purity of the test material, as well as potential problems with stability and homogeneity issues related to the test material. However, the EPA determined that a repeated chronic dog study is not required; similar effects were observed in rats and dogs, but the effects in the

rat occurred at lower doses and the rat NOAEL serves as the dose for risk assessment. Therefore, the EPA concluded that a new chronic dog study would not change the endpoint chosen for risk assessment.

The data base as a whole is adequate for pre- and post-natal toxicity evaluation.

ii. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure. There is no indication of increased susceptibility to young exposed to diuron in the available studies. In the developmental toxicity study in rabbits, there were no developmental effects at the highest dose tested. In the developmental toxicity study in rabbits and in the 2-generation rat reproduction study, developmental/offspring effects were observed only at maternally/parentally toxic dose levels.

iii. There are no neurotoxic signs in any of the submitted subchronic or chronic studies. A developmental neurotoxicity study (DNT) for diuron is not required.

iv. There are no residual uncertainties identified in the exposure databases. The dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children. The dietary food exposure assessments were performed based on reliable field trial data where tolerance level residues for some commodities as well as anticipated residues (ARs) for other commodities, based on a combination of average field trial data and USDA/PDP monitoring data. Average PCT values were assumed for chronic dietary assessment for some crops and 100 PCT treated were assumed for the remaining uses. Drinking water estimates were based on monitoring studies and USDA/PDP monitoring data. EPA expects any residential exposure from use of diuron to be negligible. The EPA is confident that these assessments will not underestimate the exposure and risks posed by diuron.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (''aPAD'') and chronic population adjusted dose (''cPAD''). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (''MOE'') called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk*. As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13-50 years old. No acute risk is expected from exposure to diuron.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to diruon from food and water will utilize 19% of the cPAD for the population group children 1-2 years old, the subpopulation group with greatest exposure. There are no residential uses for diuron that result in chronic residential exposure to diuron.

3. *Short-term risk and Intermediate risk*. Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The current uses registered that could result in non-occupational, non-dietary exposures are from diuron added to paints and stains as well as applications to residential ponds and aquariums. However, EPA expects any residential exposure from use of diuron to be negligible. Therefore, no short-term and intermediate-term risk is expected from exposure to diuron as a result of non-occupation, non-dietary exposures.

4. *Aggregate cancer risk for U.S. population*. Using the exposure assumptions described in this unit for cancer for diuron, EPA has concluded that exposure to diruon from food and water will result in a cancer risk estimate of 1.4×10^{-6} for the general U.S. population. This risk estimate is within the range of 1 in 1 million that EPA considers negligible risk for cancer. EPA has generally concluded that computed cancer risks as high as 3 in 1 million fall within this risk range.

Using the exposure assumptions described in this unit for cancer for the degradate MCPDMU, EPA has concluded that exposure to MCPDMU from fish and water will result in a cancer risk estimate of 5.9×10^{7}, which is not of concern.

5. *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, or to infants and children from aggregate exposure to diuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography) is available to enforce the tolerance expression. The principle of the determination is the hydrolysis of diuron and its metabolites by alkaline reflux to 3,4-dichloroanaline (3,4-DCA), followed by a distillation of the aniline into an acid solution. The acid distillate is made alkaline with concentrated base and subsequently extracted into an organic solvent (hexane) and analyzed by gas chromatography. With the modified method, recoveries exceeded 70% and the limit of quantitation (LOQ) is 0.01. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian, or Mexican tolerances or maximum residue limits for diuron in cactus; spearmint, tops; peppermint, tops; and fish - freshwater finfish, farm raised. Therefore, harmonization with international tolerances is not an issue for this action.

C. Response to Comments

Several comments were received from a private citizen objecting to establishment of tolerances. The Agency has received similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** of June 30, 2005 (70 FR 37686; FRL–7718–3); January 7, 2005 (70 FR 1354; FRL–7691–4); and October 29, 2004 (69 FR 63096; FRL–7681–9) for the Agency's response to these objections. In addition, the commenter noted several adverse effects seen in animal toxicology studies with diruon and claims because of these effects no tolerance should be approved. EPA has found, however, that there is a reasonable certainty of no harm to humans after considering these toxicological studies and the exposure levels of humans to diruon.

The EPA also received an additional comment in support of this action.

V. Conclusion

Upon completing review of the current diuron database, the Agency concluded that the tolerance expression proposed in the Notice of Filing should be changed to include metabolites hydrolyzable to 3,4-dichloroaniline (3,4-DCA). This determination is based on

the results of the reviewed plant and animal metabolism studies.

Currently, there are existing tolerances for residues of diuron on peppermint, hay at 2 ppm. The petitioner proposed tolerances be established on mint at 1.5 ppm. The EPA has determined that the preferred commodity terms are spearmint, tops and peppermint, tops and based on the residue field trial data the appropriate tolerance level for spearmint and peppermint should be 1.5 ppm. The EPA has also determined the preferred commodity terms should be cactus and fish - freshwater finfish, farm raised.

Therefore, these tolerances are established for combined residues of diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea and its metabolites convertible to 3,4-dichloroaniline on cactus at 0.05 ppm, spearmint, tops at 1.5 ppm, peppermint, tops at 1.5 ppm and fish - freshwater finfish, farm raised at 2.0 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: May 31, 2007.

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 180.106 is amended by redesignating the text in paragraph (a) as (a)(1); by adding paragraph (a)(2); and by adding text to paragraph (c) to read as follows:

§ 180.106 Diuron; tolerances for residues.

(a) (1) * * *

(2) Tolerances are established for the combined residues of the herbicide diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea and its metabolites convertible to 3,4-dichloroaniline, in or on the following raw agricultural commodities:

Commodity	Parts per million
Fish - freshwater finfish, farm raised	2.0
Peppermint, tops	1.5
Spearmint, tops	1.5

* * * * *

(c) *Tolerances with regional registrations*. Tolerances with a regional registration as defined in § 180.1(n) are established for the combined residues of the herbicide diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea and its metabolites convertible to 3,4-dichloroaniline) in or on the raw agricultural commodities:

Commodity	Parts per million
Cactus	0.05

* * * * *

[FR Doc. E7–11205 Filed 6–12–07; 8:45 am]

BILLING CODE 6560–50–S

AGENCY FOR INTERNATIONAL DEVELOPMENT

48 CFR Parts 719 and 752

RIN 0412–AA58

Mentor-Protégé Program

AGENCY: U.S. Agency for International Development (USAID).

ACTION: Final Rule.

SUMMARY: The United States Agency for International Development (USAID) is issuing this final rule to amend its acquisition regulations to formally encourage USAID prime contractors to assist small business, including veteran-owned small business, service-disabled veteran-owned small business, HUBZone, small socially and