ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 97

[FRL–9942–27–OAR]

Allocations of Cross-State Air Pollution Rule Allowances From New Unit Set-Asides for the 2015 Compliance Year

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of data availability (NODA).

SUMMARY: The Environmental Protection Agency (EPA) is providing notice of emission allowance allocations to certain units under the new unit set-aside (NUSA) provisions of the Cross-State Air Pollution Rule (CSAPR) federal implementation plans (FIPs). EPA has completed final calculations for the second round of NUSA allowance allocations for the 2015 compliance year of the CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 Trading Programs. EPA has posted spreadsheets showing the second-round 2015 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances to new units as well as the allocations to existing units of the remaining CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances not allocated to new units in either round of the 2015 NUSA allocation process. EPA will record the allocated CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances in sources' Allowance Management System (AMS) accounts by February 15, 2016.

DATES: February 12, 2016.

FOR FURTHER INFORMATION CONTACT: Questions concerning this action should be addressed to Robert Miller at (202) 343–9077 or *miller.robertl@epa.gov* or to Kenon Smith at (202) 343–9164 or *smith.kenon@epa.gov.*

SUPPLEMENTARY INFORMATION: Under the CSAPR FIPs, a portion of each state budget for each of the four CSAPR trading programs is reserved as a NUSA from which allowances are allocated to eligible units through an annual one- or two-round process. EPA has described the CSAPR NUSA allocation process in five NODAs previously published in the **Federal Register** (80 FR 30988, June 1, 2015; 80 FR 44882, July 28, 2015; 80 FR 55061, September 14, 2015; 80 FR 69883, November 12, 2015; 80 FR 77591, December 15, 2015). In the most recent of these previous NODAs, EPA provided notice of preliminary lists of new units eligible for second-round 2015 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances and provided an opportunity for the public to submit objections.

EPA received no objections to the preliminary lists of new units eligible for second-round 2015 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, or SO_2 Group 2 allowances whose availability was announced in the December 15 NODA. EPA is therefore making second-round 2015 NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances to the new units identified on these lists in accordance with the procedures set forth in 40 CFR 97.412(a)(9) and (12), 97.612(a)(9) and (12), and 97.712(a)(9) and (12).

As described in the December 15 NODA, any allowances remaining in the CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 NUSAs for a given state and control period after the second round of NUSA allocations to new units is completed are to be allocated to the existing units in the state according to the procedures set forth in 40 CFR 97.412(a)(10) and (12), 97.612(a)(10) and (12), and 97.712(a)(10) and (12). EPA has determined that CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances do remain in the NUSAs for a number of states following completion of second-round 2015 NUSA allocations; accordingly, EPA is allocating these allowances to existing units. The NUSA allowances are generally allocated to the existing units in proportion to the allocations previously made to the existing units under 40 CFR 97.411(a)(1), 97.611(a)(1), and 97.711(a)(1), adjusted for rounding.

Under 40 CFR 97.412(b)(10), 97.612(b)(10), and 97.712(b)(10), any allowances remaining in the CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 Indian country NUSAs for a given state and control period after the second round of Indian country NUSA allocations to new units are added to the NUSA for that state or are made available for allocation by the state pursuant to an approved SIP revision. No new units eligible for allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances from any 2015 Indian country NUSA have been identified, and no state has an approved SIP revision governing allocation of 2015 CSAPR allowances. The Indian country NUSA allowances are therefore being added to the NUSAs for the respective states and are included in the pools of allowances that are being allocated to existing units under 40 CFR 97.412(b)(10) and (12), 97.612(b)(10) and (12), and 97.712(b)(10) and (12).

The final unit-by-unit data and allowance allocation calculations are set forth in Excel spreadsheets titled ''CSAPR_NUSA_2015_NOx_Annual_2nd_Round_Final_Data_New_Units'', ''CSAPR_NUSA_2015_SO_2_2nd_Round_Final_Data_New_Units'', ''CSAPR_NUSA_2015_NOx_Annual_2nd_Round_Final_Data_Existing_Units'', and ''CSAPR_NUSA_2015_SO_2_2nd_Round_Final_Data_Existing_Units'', available on EPA's Web site at *http://www.epa.gov/crossstaterule/actions.html.*

Pursuant to CSAPR's allowance recordation timing requirements, the allocated NUSA allowances will be recorded in sources' AMS accounts by February 15, 2016. EPA notes that an allocation or lack of allocation of allowances to a given unit does not constitute a determination that CSAPR does or does not apply to the unit. EPA also notes that NUSA allocations of CSAPR NO_X Annual, SO_2 Group 1, and SO_2 Group 2 allowances are subject to potential correction if a unit to which NUSA allowances have been allocated for a given compliance year is not actually an affected unit as of January 1 of the compliance year.[1]

(Authority: 40 CFR 97.411(b), 97.611(b), and 97.711(b).)

Dated: February 1, 2016.

Reid P. Harvey,

Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0672; FRL–9939–59]

Diflubenzuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of diflubenzuron in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 12, 2016. Objections and requests for hearings must be received on or before April 12, 2016, and must be filed in accordance with the

[1] *See* 40 CFR 97.411(c), 97.611(c), and 97.711(c).

instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0672, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, 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–2014–0672 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 12, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0672, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL–9921–94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8306) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.377 be amended by: (1) Establishing tolerances in for the combined residues of the insecticide diflubenzuron *N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) and its metabolites 4-chlorophenlyurea and 4-chloroaniline, in or on the raw agricultural commodities carrot, roots at 0.2 ppm; peach subgroup 12–12B at 0.5 ppm; plum subgroup 12–12C at 0.5 ppm; plum, prune, dried at 0.5 ppm; nut, tree group 14–12 at 0.2 ppm; pepper/eggplant subgroup 8–10 B at 1.0 ppm, and cottonseed subgroup 20C at 0.2 ppm; (2) upon the approval of these tolerances, removing established tolerances in or on fruit, stone, group 12, except cherry at 0.07 ppm; nut, tree, group 14 at 0.06 ppm; pistachio at 0.06 ppm; pepper at 1.0 ppm; and cotton, undelinted seed at 0.2 ppm; (3) establishing regional tolerances for the combined residues of diflubenzuron and its metabolites 4-chlorophenlyurea and 4-chloroaniline in or on the raw agricultural commodities alfalfa, forage at 6 ppm; alfalfa, hay at 20 ppm; and alfalfa, seed at 0.9 ppm; and (4) modifying the existing tolerances in or on the following raw agricultural commodities: Egg from 0.05 to 0.15 ppm; poultry, fat from 0.05 to 0.15 ppm; and poultry, meat byproducts from 0.05 to 0.06 ppm. That document referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. A second notice of filing for the same petition (PP 4E8306) and same uses was inadvertently published in the **Federal Register** on December 2, 2015 (80 FR 75449) (FRL–9939–55). This notice of filing contained the same information as the previously published notice of filing. Comments were received in response to both notices of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for diflubenzuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with diflubenzuron 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.

For diflubenzuron, the hemopoietic system is the target site with effects including increased sulfhemoglobin and/or methemoglobin levels in rat and dog studies. In subchronic and chronic feeding studies, the primary endpoint of concern was methemoglobinemia and/or sulfhemoglobinemia. These effects were evident in both sexes of mice, rats, and dogs and were produced by more than one route of administration in rats (*i.e.,* oral, dermal and inhalation). The general consequence of methemoglobinemia and/or sulfhemoglobinemia is the impairment of the oxygen transportation capacity of the blood, which is generally known to be caused by aromatic amines in both humans and animals. Degradates of diflubenzuron with aromatic amines, CPU (4-chlorophenylurea) and PCA (4-chloroaniline), are also included in the diflubenzuron non-cancer risk assessment. Monuron, an analog of CPU, does not affect methemoglobin formation but does produce tumors in the liver and kidneys of male rats. The non-cancer toxicities of CPU and PCA are understood. PCA is similar in potency to diflubenzuron on methemoglobin formation, while CPU is less toxic than PCA. Therefore, the non-cancer assessment will include diflubenzuron, CPU and PCA, and additional toxicity studies are not required on CPU and PCA.

The toxicity data provide no indication of an increased susceptibility to rats or to rabbits from *in utero* or postnatal exposure to diflubenzuron. Developmental and reproduction studies in rats and rabbits indicate a very low hazard potential for adverse effects. Developmental studies were tested at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day) without apparent effects in both dams and the fetuses. The reproduction study indicated that effects in offspring occurred at doses that were higher than the doses producing effects in parents. The requirements for acute and subchronic neurotoxicity studies were waived because there are no clear signs of neurotoxicity following subchronic or chronic dosing in multiple species in the diflubenzuron database. The toxicity profile of diflubenzuron shows that the principal toxic effects are the formation of methemoglobinemia and/or sulfhemoglobinemia in the blood. An immunotoxicity study has been reviewed and immunotoxicity was not observed above the limit dose.

The Agency concluded that diflubenzuron is not carcinogenic in humans based on lack of evidence of carcinogenicity in rats and mice. PCA, a plant metabolite of diflubenzuron, tested positive for splenic tumors in male rats and hepatocellular adenomas/carcinomas in male mice in a National Toxicology Program (NTP) study.

Therefore, EPA has classified PCA as a probable human carcinogen. CPU is the major degradate found in water and is a significant metabolite in milk. CPU is structurally related to monuron (*N,N*dimethyl-CPU), a compound producing tumors of the kidney and liver in male rats. EPA has assumed CPU is a probable human carcinogen as well. However, based on methemoglobinemia observed only at high doses of monuron, a compound similar to CPU and PCA, the non-carcinogenic risk assessment will include diflubenzuron, CPU, and PCA.

Specific information on the studies received and the nature of the adverse 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.regulations.gov* in the document titled ''Diflubenzuron: Human Health Risk Assessment for an Amended Section 3 Registration for Carrot, Peach Subgroup 12–12B, Plum Subgroup 12–12C, Pepper/Eggplant Subgroup 8–10B, Cottonseed Subgroup 20C, Alfalfa (Regional Restrictions) and R175 Crop Group Conversion for Tree Nut Group 14–12'' on page 45 in docket ID number EPA–HQ–OPP–2014–0672.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. 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/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for diflubenzuron used for human risk assessment is discussed in Table 1 in Unit III.B. of the final rule published in the **Federal Register** of January 31, 2014 (79 FR 5294) (FRL–9904–27).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to diflubenzuron, EPA considered exposure under the petitioned-for tolerances as well as all existing diflubenzuron tolerances in 40 CFR 180.377. EPA assessed 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. No such effects were identified in the toxicological studies for diflubenzuron; 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 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, ''What We Eat in America'' (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA used the assumption that diflubenzuron residues are present in most commodities at tolerance levels (including tolerances previously established as well as those established in this action) and that 100% of all crops are treated. Average field trial residues were assumed for grapefruit, lemon, and orange. Tolerances include residues of diflubenzuron, PCA, and CPU.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that diflubenzuron does not pose a cancer risk to humans. However, the metabolites CPU and PCA are considered probable carcinogens and have Q*s assigned to them. Individual cancer dietary exposure analyses were conducted for each metabolite. For PCA, average percent crop treated (PCT) was used for some commodities. One-half the Limit of Quantitation (LOQ) was used for estimating PCA residues on the majority of crops because most crops did not contain detectable residues of PCA. Average field trial residue was used for mushrooms. The CPU cancer dietary analysis focused on CPU residues in milk because metabolism studies indicate that diflubenzuron metabolizes to CPU in milk. EPA assumed that 100% of milk commodities contained CPU at ½ the LOQ. One-half the LOQ was used since detectable residues of CPU were not found in the feeding study.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of 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 require pursuant to FFDCA section 408(f)(1) 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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

- Condition 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 the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition 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 FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the cancer dietary exposure analysis, the Agency estimated the PCT for existing uses as follows:

Soybeans (1%), peppers (2.5%), oranges (10%), tangerines (10%), grapefruit (25%), pear (5%), apricot (10%), peach (5%), almond, (10%), pecan (2.5%), rice (2.5%), wheat (1%), cotton (1%), artichoke (45%), peanut (10%), lemon (1%), plum (5%), and walnut (2.5%).

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 Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, 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 b and c, 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 reliable information on the regional consumption of food to which diflubenzuron may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for diflubenzuron and CPU in drinking water. PCA is only a minor metabolite in the environment and residues are not expected to be present in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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*.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

Based on the Surface Water Concentration Calculator model (SWCC) for surface water the Estimated Drinking Water Concentration (EDWC) of 1.3 microgram/Liter (µg/L) (including diflubenzuron and CPU) was used to assess chronic non-cancer dietary risk. Based on the Pesticide Root Zone Model-Groundwater (PRZM–GW) model for ground water the cancer risk for CPU was assessed using the EDWC of 8.02 µg/L.

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).

Diflubenzuron is not registered for any specific use patterns that would result in residential exposure.

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

requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found diflubenzuron to share a common mechanism of toxicity with 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 assumed that diflubenzuron does not have 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 EPA's Web site at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Based on the available developmental toxicity studies in rats and rabbits and the reproduction study, there is no increased susceptibility to fetuses exposed *in utero.* There was no indication of abnormalities in fetal development in the developmental toxicity studies in either rats or rabbits at the maternal limit doses of 1,000 mg/kg/day. In addition, there was no evidence of sensitivity following pre- and/or post-natal exposure in a two-generation reproduction study in rats.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicological database for diflubenzuron is adequate for risk assessment. The non-cancer toxicity of CPU and PCA is well understood. CPU is less toxic and does not affect methemoglobin. PCA does cause methemoglobin formation but is similar in potency to diflubenzuron. Therefore, assuming equal toxicity of CPU and PCA to diflubenzuron is health protective, additional toxicity studies are not required on the metabolites.

ii. There are no clear signs of neurotoxicity following subchronic or chronic dosing in multiple species in the diflubenzuron database; therefore, there is no need for any neurotoxicity studies.

iii. There is no evidence that diflubenzuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. The dietary exposure assessment uses conservative assumptions which will not underestimate dietary exposure and EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to diflubenzuron in drinking water. These assessments will not underestimate the exposure and risks posed by diflubenzuron.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, diflubenzuron 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 chronic exposure to diflubenzuron from food and water will utilize 39% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for diflubenzuron.

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

Short- and intermediate-term adverse effects were identified; however, diflubenzuron is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for diflubenzuron.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, diflubenzuron is not expected to pose a cancer risk to humans. However, the metabolites CPU and PCA are considered probable carcinogens and have Q*s assigned to them. Individual cancer dietary exposure analyses were conducted for each metabolite. The cancer assessment for PCA includes food only (it is not expected to be present in drinking water). The cancer assessment for CPU includes milk and water only. For PCA, the cancer dietary exposure estimate for the U.S. population is 1.3×10^{-6}. For CPU, the cancer dietary exposure estimate for the U.S. population is 2.8×10^{-6}.

EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}.

Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Although the PCA and CPU exposure risk assessment are refined, they retain significant conservatism in that residues in food

were estimated at ½ LOQ even though no residues were detected in field trials and feeding studies, and for some commodities EPA assumed 100 PCT. Accordingly, EPA has concluded the cancer risk for all existing diflubenzuron uses, and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus negligible.

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 diflubenzuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement analytical methods are available for the enforcement of tolerances for residues of diflubenzuron and its metabolites in crop and livestock commodities. Three enforcement methods for diflubenzuron are published in PAM, Vol. II as Methods I, II, and III. Method I is a GC/ECD method that determines diflubenzuron in plants as derivatized 4-chloroaniline (PCA). Method II is a GC/ECD method that can separately determine residues of diflubenzuron, 4-chlorophenylurea (CPU) and PCA in eggs, milk, and livestock tissues, each as derivatized PCA. Method III is an HPLC/UV method that determines diflubenzuron per se in eggs, milk, and livestock tissues. All three methods have undergone successful Agency validations.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for diflubenzuron in or on peach and nectarine at 0.5 ppm which is the same as the tolerance in the United States for the peach subgroup 12–12B at 0.50 ppm; a tolerance on plums at 0.5 ppm which is the same as the U.S. tolerance for the plum subgroup 12–12C at 0.5 ppm; and a tolerance on tree nuts at 0.2 ppm which is the same as the U.S. tolerance for the tree nut group 14–12 at 0.20 ppm, and which was raised to harmonize with Codex.

The Codex has established MRLs for diflubenzuron on chili peppers at 3 ppm, dried chili peppers at 20 ppm, and sweet peppers at 0.7 ppm which are different from the tolerances established in the U.S. for diflubenzuron on the pepper/eggplant subgroup 8–10B at 1.0 ppm. The pepper/eggplant subgroup 8–10B covers both bell and non-bell peppers and the Codex MRLs split them out into two separate tolerances which the U.S. does not do because the petition was for the entire subgroup. Based on the residue data submitted and reviewed for this action, it would not be appropriate for the U.S. tolerance to harmonize with either the chili pepper MRL of 3 ppm or the sweet pepper MRL of 0.7 ppm. Also, in regards to the dried chili pepper MRL, this is not expected to be an issue since the U.S. does not set tolerances on dried fruits and vegetables, but instead the processed food is considered to be the whole processed commodity after compensating for or reconstituting the commodity's normal moisture content.

C. Response to Comments

One comment was received in response to the February 11, 2015 Notice of Filing, however, it related to a different chemical than diflubenzuron and therefore is not relevant to this action. Two comments were received in response to the December 2, 2015 Notice of Filing. One commenter opposed residues of this pesticide on food and argued that EPA should deny the petition. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. The second comment stated that ''without long term studies of its effects on the environment and the toxic effects on aquatic invertebrates, then there should be a slight reduction in ppm of diflubenzuron used on crops.'' This comment is not relevant to the Agency's evaluation of safety of the diflubenzuron tolerances; section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

D. Revisions to Petitioned-For Tolerances

Based on an evaluation of the residue data, the Agency modified the levels at which tolerances were proposed for the existing tolerances for egg, poultry fat, and poultry meat byproducts. In addition, the Agency determined that a separate tolerance is not required for the commodity ''plum, prune, dried'' since residues are not found to concentrate on prunes. Lastly, some of the tolerances levels were modified to reflect the correct significant figures.

V. Conclusion

Therefore, tolerances are established, modified and removed for residues of diflubenzuron *N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) and its metabolites 4-chlorophenlyurea and 4-chloroaniline, as follows:

Under 180.377(a)(1) a tolerance is established for the cottonseed subgroup 20C at 0.20 ppm; existing tolerances are changed for egg to 0.07 ppm; poultry, fat to 0.10 ppm; and poultry, meat byproducts to 0.08 ppm; and the existing tolerance for cotton, undelinted seed at 0.2 ppm is removed as unnecessary.

Under 180.377(a)(2), tolerances are established in or on the raw agricultural commodities carrot, roots at 0.20 ppm; peach subgroup 12–12B at 0.50 ppm; plum subgroup 12–12C at 0.50 ppm; nut, tree group 14–12 at 0.20 ppm; the pepper/eggplant subgroup 8–10 B at 1.0 ppm; and the following existing tolerances are removed as unnecessary: Fruit, stone, group 12, except cherry at 0.07 ppm; nut, tree, group 14 at 0.06 ppm; pistachio at 0.06 ppm; and pepper at 1.0 ppm.

Under 180.377(c) regional tolerances are established for the combined residues of diflubenzuron and its metabolites 4-chlorophenlyurea and 4-chloroaniline in or on the raw agricultural commodities alfalfa, forage at 6 ppm; alfalfa, hay at 20 ppm; and alfalfa, seed at 0.9 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''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 action 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action 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 FFDCA section 408(n)(4). 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 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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**. This action 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: February 3, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.377:

■ a. Remove the entries in the table in paragraph (a)(1) for ''Cotton, undelinted seed,'' ''Egg,'' ''Poultry, fat,'' and ''Poultry, meat byproducts.''

■ b. Add alphabetically the entries for ''Cottonseed subgroup 20C,'' ''Egg,'' ''Poultry, fat,'' and ''Poultry, meat byproducts'' to the table in paragraph (a)(1).

■ c. Remove the entries in the table in paragraph (a)(2) for ''Fruit, stone, group 12, except cherry,'' ''Nut, tree, group 14,'' ''Pepper,'' and ''Pistachio.''

■ d. Add alphabetically the entries for ''Carrot, roots,'' ''Peach subgroup 12–12B,'' ''Pepper/Eggplant subgroup 8–10B,'' ''Plum subgroup 12–12C,'' and ''Nut, tree, group 14–12'' to the table in paragraph (a)(2).

■ e. Revise paragraph (c).

The additions and revision read as follows:

§ 180.377 Diflubenzuron; tolerances for residues.

(a) General (1) * * *

Commodity	Parts per million
* * * * *	
Cottonseed subgroup 20C	0.20
Egg	0.07
* * * * *	
Poultry, fat	0.10
Poultry, meat byproducts	0.08
* * * * *	

(2) * * *

Commodity	Parts per million
* * * * *	
Carrot, roots	0.20
* * * * *	
Peach subgroup 12–12B	0.50
* * * * *	
Pepper/Eggplant subgroup 8–10B	1.0
* * * * *	
Plum Subgroup 12–12C	0.50
Nut, tree, group 14–12	0.20
* * * * *	

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(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for residues of the insecticide diflubenzuron (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide), in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of diflubenzuron (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide), 4-chlorophenylyurea and 4-chloroaniline, calculated as the stoichiometric equivalent of diflubenzuron, in or on the commodity.

Commodity	Parts per million
Alfalfa, forage	6.0
Alfalfa, hay	20
Alfalfa, seed	0.90

* * * * *

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