Nicosulfuron; Pesticide Tolerances

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0035; FRL-9912-31]

Rimsulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of rimsulfuron in or on sorghum, grain, forage; sorghum, grain, grain; and sorghum, grain, stover. E.I. du Pont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 30, 2015. Objections and requests for hearings must be received on or before December 29, 2015, 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0035, 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. To access the Office of Chemical Safety and Pollution Prevention (OCSPP) test guidelines referenced in this document electronically, please go to http://www.epa.gov/ocspp and select ``Test Methods and Guidelines.''

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-2013-0035 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 December 29, 2015. 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-2013-0035, 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 July 19, 2013 (78 FR 43115) (FRL-9392-9), 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 2F8131) by E.I. du Pont de Nemours and Company, 1007 Market Street, Wilmington, DE 19898. The petition requested that 40 CFR 180.478 be amended by establishing tolerances for residues of the herbicide rimsulfuron, N-((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)-3-(ethylsulfonyl)-2-pyridinesulfonamide, in or on sorghum, forage; sorghum, grain; and sorghum, stover at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed commodity definitions. EPA has also revised the chemical name nomenclature for rimsulfuron in the tolerance expression. The reasons for these changes are explained in Unit IV.C.

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 rimsulfuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with rimsulfuron 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.

Rimsulfuron has low acute toxicity by oral, dermal, and inhalation routes of exposure. It is moderately irritating to the eye, non-irritating to the skin, and is not a skin sensitizer. In subchronic and chronic toxicity studies in rats, toxic effects included decreased body weight, decreased body weight gain, increased relative liver and absolute kidney weights, and diuresis. In the subchronic study in mice, increased red blood cell and hemoglobin, and decreased body weight gain and food efficiency were observed. In the chronic study in mice, decreased body weight, increased incidences of dilation and cysts in the glandular stomach, and degeneration of the testicular artery and tunica albuginea were observed. In the subchronic study in dogs, diuresis was indicated by urinary volume, platelet concentration, and kidney weights accompanied by decreased urinary osmolality. In the chronic study in dogs, increased absolute liver and kidney weights, increased seminiferous tubule degeneration, and increased number of spermatid giant cells present in epididymides in males were observed. In both sexes, decreases in mean body

weights and body weight gain, and increases in serum cholesterol levels, alkaline phosphatase activity, absolute liver weight, relative liver, and relative kidney weights were observed.

In the developmental toxicity study in rats, no toxicity was seen at the highest dose tested. In the developmental toxicity study in rabbits (in which both maternal and fetal death were observed), and in the 2-generation reproduction toxicity study in rats (in which decreases in body weight gain were observed in both parents and offspring), developmental and offspring effects were seen in the presence of maternal/systemic toxicity at the same dose levels.

In the acute and subchronic neurotoxicity studies, no evidence of neurotoxicity was observed. In the immunotoxicity study, no evidence of immunosuppression was observed. In the mutagenicity studies, no evidence of clastogenicity or mutagenicity was observed. Rimsulfuron is classified as ``Not Likely to be Carcinogenic to Humans'' based on lack of evidence of carcinogenicity in rats and mice studies.

Specific information on the studies received and the nature of the adverse effects caused by rimsulfuron 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 document ``Rimsulfuron. Human Health Risk Assessment for Proposed Section 3 Use on Acetolactase Synthase (ALS) Tolerant Grain Sorghum'' at pp. 27-32 in docket ID number EPA-HQ-OPP-2013-0035.

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 the NOAEL and the LOAEL are identified. 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 rimsulfuron used for human risk assessment is shown in Table 1 of this unit.

Table 1--Summary of Toxicological Doses and Endpoints for Rimsulfuron for Use in Human Health Risk Assessment

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	No endpoint attributable to a single dose identified.		
Chronic dietary (All populations)	NOAEL = 11.8 mg/kg/day UFA = 10x..... UFH = 10x..... FQPA SF = 1x.....	Chronic RfD = 0.118 mg/kg/day. cPAD = 0.118 mg/kg/ day	Combined Chronic/Carcinogenicity--Rat. LOAEL = 121 mg/kg/day in males; 568 mg/kg/day in females . (NOAEL = 163 mg/kg/day in females), based on decreased body weight gains and liver effects.

FQPA SF = Food Quality Protection Act Safety Factor.

LOAEL =lowest-observed-adverse-effect-level. mg/kg/day =milligram/kilogram/day.

NOAEL = no-observed-adverse-effect-level. cPAD = chronic population adjusted dose.

RfD= reference dose. UF = uncertainty factor.

UFA = extrapolation from animal to human (interspecies). UFH =potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to rimsulfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing rimsulfuron tolerances in 40 CFR 180.478. EPA assessed dietary exposures from rimsulfuron 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 rimsulfuron; 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's 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed that rimsulfuron residues were present at tolerance levels in all commodities for which tolerances have been established or proposed, and that 100% of those crops were treated with rimsulfuron.

iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that rimsulfuron does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for rimsulfuron. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for rimsulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of rimsulfuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www.epa.gov/oppefed1/models/water/index.htm.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM-GW), the estimated drinking water concentrations (EDWCs) of rimsulfuron for chronic exposures for non-cancer assessments are estimated to be 0.38 parts per billion (ppb) for surface water and 19.7 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 19.7 ppb was used to assess the contribution to drinking water.

3. From non-dietary exposure. The term ``residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Rimsulfuron 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 rimsulfuron to share a common mechanism of toxicity with any other substances, and rimsulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that rimsulfuron 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 Federal Quality Protection Act Safety Factor (FQPA 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. In the developmental toxicity study in rats, no developmental toxicity was seen at the highest dose tested. In the developmental toxicity study in rabbits and in the 2-generation reproductive study in rats, developmental and offspring toxicity were seen only in the presence of maternal/systemic toxicity. Consequently, there is no evidence of quantitative or qualitative increased susceptibility following pre- and/or postnatal exposures.

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 toxicity database for rimsulfuron is complete.

ii. There is no indication that rimsulfuron is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional Uncertainty Factor (UF) to account for neurotoxicity.

iii. There is no evidence that rimsulfuron 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. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to rimsulfuron in drinking water. These assessments will not underestimate the exposure and risks posed by rimsulfuron.

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

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and no acute dietary endpoint was selected. Therefore, rimsulfuron 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 rimsulfuron from food and water will utilize 1.4% of the cPAD for all infants less than 1-year old, the population group receiving the greatest exposure. There are no residential uses for rimsulfuron.

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).

Because there are no residential uses, no short- or intermediate-term aggregate risk assessments were conducted.

4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, rimsulfuron is not expected to pose a cancer risk to humans.

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 rimsulfuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method DuPont-32277, a high performance liquid chromatography with tandem mass spectroscopy (HPLC/MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

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 not established MRLs for rimsulfuron.

C. Revisions to Petitioned-For Tolerances

The Agency is revising the proposed commodity definitions of ``sorghum, forage'' to ``sorghum, grain, forage''; ``sorghum, grain'' to ``sorghum, grain, grain''; and ``sorghum, stover'' to ``sorghum, grain, stover''. The tolerance expression is revised to reflect the preferred chemical name for rimsulfuron using CAS nomenclature.

V. Conclusion

Therefore, tolerances are established for residues of rimsulfuron, N-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide, in or on sorghum, grain, forage; sorghum, grain, grain; and sorghum, grain, stover at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 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 FFDCA section 408(d), such as the tolerances 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 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 final rule. In addition, this final 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) (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 of 1995 (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: October 21, 2015.

G. Jeffrey Herndon,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

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PART 180--[AMENDED]

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

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

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2. In Sec. 180.478, revise paragraph (a) and add alphabetically the following commodities to the table in paragraph (a) to read as follows:

Sec. 180.478 Rimsulfuron; tolerances for residues.

(a) General. Tolerances are established for residues of the herbicide rimsulfuron, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only rimsulfuron, N-[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide.