

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 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 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) (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: March 26, 2010.

**Lois Rossi,**

*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 180.361, revise the introductory text and the entry for Alfalfa, forage in the table in paragraph (a) to read as follows:

**§ 180.361 Pendimethalin; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the herbicide pendimethalin, including its metabolites and degradates, in or on the commodities. Compliance with the tolerance levels specified in the following table below is to be determined by measuring only pendimethalin, [N- (1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, calculated as the stoichiometric equivalent of pendimethalin, in or on the following commodities:

Commodity	Parts per million
Alfalfa, forage .....	3.5

\* \* \* \* \*

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**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0057; FRL-8818-4]

**Nicosulfuron; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of nicosulfuron in or on cattle, fat; cattle, meat; cattle,

meat byproducts; goat, fat; goat, meat; goat, meat byproducts; grass, forage; grass, hay; horse, fat; horse, meat; horse, meat byproducts; milk; sheep, fat; sheep, meat; and sheep, meat byproducts. E. I. du Pont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes the existing tolerance for residues of nicosulfuron on corn, forage.

**DATES:** This regulation is effective April 7, 2010. Objections and requests for hearings must be received on or before June 7, 2010, 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-2009-0057. All documents in the docket are listed in the docket index available at <http://www.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:** Mindy Ondish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-0723; e-mail address: [ondish.mindy@epa.gov](mailto:ondish.mindy@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 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.gpoaccess.gov/ecfr>. You may also access the OPPTS harmonized test guidelines referenced in this document electronically at <http://www.epa.gov/oppts> and select "Test Methods and Guideline."

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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-2009-0057 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 June 7, 2010.

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-2009-0057, 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 Facility'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 April 8, 2009 (74 FR 15971) (FRL-8407-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7501) by E. I. du Pont de Nemours and Company, P.O. Box 80038, Wilmington, DE 19880-0038. The petition requested that 40 CFR 180.454 be amended by establishing tolerances for residues of the herbicide nicosulfuron, 3-Pyridinecarboxamide, 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethyl-, in or on grass, forage at 0.05 parts per million (ppm); grass, hay at 25.0 ppm; fat (of cattle, goat, hog, horse, and sheep) at 0.05 ppm; meat (of cattle, goat, hog, horse, and sheep) at 0.05 ppm; meat byproducts (of cattle, goat,

hog, horse, and sheep) at 0.05 ppm; milk at 0.05 ppm; and milk, fat at 0.02 ppm. That notice referenced a summary of the petition prepared by E. I. du Pont de Nemours and Company, the registrant, which is available to the public 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 is not establishing the proposed tolerances for hog, fat; hog, meat; hog, meat byproducts; and milk, fat. The proposed tolerance levels for cattle, fat; cattle, meat; goat, fat; goat, meat; horse, fat; horse, meat; milk; sheep, fat; and sheep, meat are being established at 0.01 ppm, not 0.05 ppm. 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 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 tolerances for residues of nicosulfuron and its metabolites and degradates in or on cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.05 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.05 ppm; grass, forage at 9.0 ppm; grass, hay at 25.0 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.05 ppm; milk at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; and sheep, meat

byproducts at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by nicosulfuron 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 "Nicosulfuron Human Health Risk Assessment for the Proposed Use on Grasses," p. 30 in docket ID number EPA-HQ-OPP-2009-0057.

Nicosulfuron has low acute toxicity by oral, dermal, and inhalation routes of exposure. It is a moderate eye irritant and is not a dermal sensitizer. No adverse effects were observed following subchronic or chronic dietary administrations of doses exceeding the limit dose in rats and mice. Chronic dietary administration to dogs produced mild effects (decreased body weight gains in males, increased relative liver and kidney weights) at the limit dose. No findings were reported in dogs following subchronic dosing at comparable dietary levels.

There was no evidence of potential immunotoxicity or neurotoxicity in the submitted studies.

Nicosulfuron was classified by EPA as a "not likely" human carcinogen based on the lack of evidence of carcinogenicity in studies conducted in rats and mice and in the *in vitro* and *in vivo* genotoxicity studies.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a benchmark dose (BMD) approach is sometimes used for

risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 nicosulfuron used for human risk assessment can be found at <http://www.regulations.gov> in document "Nicosulfuron Human Health Risk Assessment for the Proposed Use on Grasses," p. 15 in docket ID number EPA-HQ-OPP-2009-0057.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to nicosulfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing nicosulfuron tolerances in 40 CFR 180.454. EPA assessed dietary exposures from nicosulfuron 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 nicosulfuron; 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 CSFII. As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all existing (corn) and new uses (meat and milk commodities) of nicosulfuron.

iii. *Cancer.* Based on the lack of evidence of carcinogenicity observed in the 2-year rat and 18-month mouse carcinogenicity studies and a lack of evidence of mutagenicity in the *in vitro* and *in vivo* genotoxicity studies, EPA does not expect nicosulfuron to pose a cancer risk to humans. Therefore, an exposure assessment for evaluating cancer risk is not needed for this chemical.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for nicosulfuron. 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 nicosulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of nicosulfuron. 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of nicosulfuron for chronic exposures for non-cancer assessments are estimated to be 0.685 ppb for surface water and 0.056 ppb for ground water. EDWCs of nicosulfuron for acute exposures and chronic exposures for cancer assessments are not relevant to this dietary exposure assessment as explained in unit III.C.1.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.685 ppb was used to assess the contribution to drinking water. The surface water value was used in the chronic, non-cancer dietary risk assessment since it was higher than the ground water value and, therefore, more protective.

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).

Nicosulfuron 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 nicosulfuron to share a common mechanism of toxicity with any other substances, and nicosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that nicosulfuron 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 website 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 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 in rats, no developmental toxicity was seen at the highest dose tested (6,000 mg/kg/day). In the developmental study in rabbits, developmental toxicity (decreased fetal body weight, post-implantation loss) occurred at the same dose (500 mg/kg/day) as the dose (500 mg/kg/day) resulting in maternal toxicity (abortions, clinical signs, decreased body weight gain, post-implantation loss). In the 2-generation reproductive toxicity study in rats, F2a offspring effects (decreased litter size at birth, decreased pup weights at postpartum day 14 through 21) also occurred at the same dose (1265 mg/kg/day) as the dose (1265 mg/kg/

day) resulting in parental toxicity (decreased body weight gain in F1 females during the last week of gestation). Consequently, there is no quantitative or qualitative evidence of increased susceptibility following pre- and/or postnatal exposure to nicosulfuron.

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 nicosulfuron is adequate to assess potential pre- and/or postnatal toxicity. In accordance with 40 CFR part 158 Toxicology Data Requirements, an immunotoxicity study (870.7800), and acute and subchronic neurotoxicity studies (870.6200) are required for nicosulfuron. Despite the absence of specific immunotoxicity and neurotoxicity studies, EPA has evaluated the available toxicity data and has determined that there is no evidence that nicosulfuron either causes neurotoxic effects or targets the immune system, and, therefore, EPA does not expect that these studies will result in a lower NOAEL than the NOAEL currently used in assessing nicosulfuron risk.

ii. There is no indication that nicosulfuron is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that nicosulfuron 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 significant residual uncertainties identified in the exposure databases for nicosulfuron. Additional storage stability studies are required for residues of nicosulfuron in grass forage and hay, and in livestock tissues. However, as explained in this Unit, EPA does not expect these studies to have a measurable impact on exposure estimates for nicosulfuron.

a. Data must be submitted on the stability of nicosulfuron and its metabolite in grass forage and hay stored frozen for intervals of up to 9.6 and 12.4 months, respectively. Interim data are available showing that residues of nicosulfuron in grass hay and forage are stable when stored frozen up to 3 months. Additionally, storage stability data are available for corn, a related crop, which indicate that nicosulfuron residues are stable when stored frozen up to 12 months. Based on these data,

EPA expects nicosulfuron to be stable in grass forage and hay stored frozen for the required 9.6 and 12.4 month intervals but is requiring submission of the final study reports as confirmation.

b. Data must also be submitted on the stability of nicosulfuron and its metabolite in livestock tissues stored frozen up to 9.4 months. Despite the absence of data, EPA has assumed that nicosulfuron is stable in frozen livestock tissues, based on data for similar sulfonylurea (SU) pesticides, such as prosulfuron, where studies have shown residues to be stable for up to 25 months. In addition, EPA notes that dietary exposure to nicosulfuron is low (< 1% of the cPAD for all population subgroups), and that the contribution of residues in livestock to overall dietary exposure to nicosulfuron is minor, accounting for only 2.5% of total exposure for children 1-2 years old, the population subgroup with the highest estimated dietary exposure to nicosulfuron. Therefore, any adjustments in livestock residue estimates that might be necessary following submission of the required storage stability data would have little impact on overall dietary exposure estimates.

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 nicosulfuron in drinking water. There are no residential uses for nicosulfuron; therefore, residential exposure is not expected. These assessments will not underestimate the exposure and risks posed by nicosulfuron.

#### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute 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, nicosulfuron 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 nicosulfuron from food and water will utilize <1% of the cPAD for the general population and all population subgroups, including children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for nicosulfuron.

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

Nicosulfuron is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to nicosulfuron through food and water and will not be greater than the chronic aggregate risk.

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

Nicosulfuron is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to nicosulfuron through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on a lack of evidence for carcinogenicity in mice and rats following long-term dietary administration and lack of evidence for mutagenicity in a battery of genotoxicity studies, nicosulfuron is not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to nicosulfuron residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography with tandem mass spectrometric (HPLC/MS/MS) detection method) 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; e-mail address: *residuemethods@epa.gov*.

##### B. International Residue Limits

There are currently no established Codex or Mexican maximum residue limits (MRLs) for residues of nicosulfuron. Canadian MRLs are established on blueberries and corn, and are expressed in terms of nicosulfuron. There are no Canadian MRLs established on the grass and livestock commodities associated with this petition.

##### C. Revisions to Petitioned-For Tolerances

EPA is not establishing the proposed tolerances for hog, fat; hog, meat; and hog, meat byproducts because there are no swine feed items associated with the proposed use on grasses, and the dietary burden to swine resulting from registered use on corn is low enough that there is no reasonable expectation of finite residues in hog commodities. The proposed tolerance for milk fat is not being established because residues did not concentrate in cream and thus the tolerance for milk will be sufficient to cover residues in milk fat from legal uses of nicosulfuron. The proposed tolerances for cattle, fat; cattle, meat; goat, fat; goat, meat; horse, fat; horse, meat; milk; sheep, fat; and sheep, meat were lowered from 0.05 ppm to the level of quantitation (LOQ) at 0.01 ppm, since the maximum adjusted residue for meat and fat was at 0.008 ppm.

EPA has also revised the tolerance expression for all existing and new nicosulfuron tolerances. The revised tolerance expression makes clear that the tolerances cover "residues of nicosulfuron, including its metabolites and degradates" and that compliance with the tolerance levels will be determined by measuring only nicosulfuron, 3-Pyridinecarboxamide, 2-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethyl-. EPA has determined that it is reasonable to make this change in the tolerance expression final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

Finally, EPA is removing the redundant and obsolete tolerance for residues of nicosulfuron on "corn, forage" at 0.1 ppm. "Corn, forage" is an

obsolete commodity term that has been replaced by the terms "corn, field, forage" and "corn, sweet, forage." Since there are existing tolerances for residues of nicosulfuron on "corn, field, forage" and "corn, sweet, forage" at 0.1 ppm, the tolerance on "corn, forage" at the same level is unnecessary. EPA is making this change final without prior proposal and opportunity for comment because it merely corrects a redundancy in the nicosulfuron tolerances and has no substantive effect on them.

#### V. Conclusion

Therefore, tolerances are established for residues of nicosulfuron, including its metabolites and degradates, in or on cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.05 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.05 ppm; grass, forage at 9.0 ppm; grass, hay at 25.0 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.05 ppm; milk at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts at 0.05 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 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 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 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) (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: March 26, 2010.

**Lois Rossi,**

*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 180.454 is revised to read as follows:

**§ 180.454 Nicosulfuron; tolerances for residues.**

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

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.05
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Corn, pop, grain	0.1
Corn, pop, stover	0.1
Corn, sweet, forage	0.1

Commodity	Parts per million
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, sweet, stover	0.1
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.05
Grass, forage	9.0
Grass, hay	25.0
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.05
Milk	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table [below] are established for residues of the herbicide nicosulfuron, 3-Pyridinecarboxamide, 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethyl-, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/Revocation Date
Bermuda grass, forage	10	12/31/11
Bermuda grass, hay	25	12/31/11

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2010-7745 Filed 4-6-10; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2009-0141; FRL-8808-9]

#### Aminopyralid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of aminopyralid, including its metabolites and degradates, in or on corn, field, forage; corn, field, grain; and corn, field, stover. Dow AgroSciences requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 7, 2010. Objections and requests for hearings must be received on or before June 7, 2010, 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-2009-0141. All documents in the docket are listed in the docket index available at <http://www.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:** Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: [stanton.susan@epa.gov](mailto:stanton.susan@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 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 cite at <http://www.gpoaccess.gov/ecfr>. To access the OPP's harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods & Guidelines" on the left-side navigation menu.

###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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-2009-0141 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 June 7, 2010.

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-2009-0141, 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 Facility'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 May 6, 2009 (74 FR 20947) (FRL-8412-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7455) by Dow AgroSciences, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.610 be amended by establishing tolerances for combined residues of the herbicide aminopyralid, 4-amino-3,6-dichloro-2-pyridinecarboxylic acid, and its glucose conjugate, expressed as total parent, in or on corn, forage at 0.30 parts per million (ppm); corn, grain at 0.20 ppm; and corn, stover at 0.20 ppm. That notice referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were