

Commodity	Parts per million
Goat, meat .....	0.01
Goat, meat byproducts .....	0.03
Grain, aspirated fractions .....	20.0
Grain, cereal, group 15, (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except wheat) .....	3.0
Grain, cereal, forage, fodder and straw, group 16 .....	20
Horse, fat .....	0.05
Horse, meat .....	0.01
Horse, meat byproducts .....	0.03
Milk .....	0.005
Oilseeds, group 20 .....	0.9
Pea and bean, dried shelled except soybean, subgroup 6C .....	0.4
Pea and bean, succulent shelled, subgroup 6B .....	0.5
Peanut .....	0.01
Peanut, refined oil .....	0.02
Plum, prune .....	3.0
Potato, wet peel .....	0.1
Rice, bran .....	4.5
Rice, hulls .....	8.0
Sheep, fat .....	0.05
Sheep, meat .....	0.01
Sheep, meat byproducts .....	0.03
Soybean, hulls .....	0.3
Soybean, seed .....	0.15
Vegetable, foliage of legume, group 7 .....	30
Vegetables, fruiting, group 8 .....	0.7
Vegetable, legume, edible podded, subgroup 6A .....	2.0
Vegetable, tuberous and corn, subgroup 1C .....	0.02
Wheat, bran .....	0.6
Wheat, grain .....	0.3

- (b) Section 18 emergency exemptions. [Reserved]
- (c) Tolerances with regional registrations. [Reserved]
- (d) Indirect or inadvertent residues. [Reserved]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2010-0425; FRL-9341-8]

**Penflufen; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of penflufen in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 14, 2012. Objections and requests for hearings must be received on or before July 13, 2012, 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-2010-0425. 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:** Marianne Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-8043; email address: [lewis.marianne@epa.gov](mailto:lewis.marianne@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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go <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-2010-0425 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 July 13, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0425, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 8, 2010 (75 FR 54631) (FRL-8843-3), 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 0F7711) by Bayer CropScience, 2 T.W. Alexander Drive P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the penflufen, *N*-[2-(1,3-dimethylbutyl)phenyl]-5-fluoro-1,3-dimethyl-1*H*-pyrazole-4-carboxamide, in or on alfalfa, forage; alfalfa, hay; vegetable, tuberous and corm, subgroup 1C; vegetable, legume, group 6; vegetable, foliage of legume, group 7; grain, cereal, group 15, grain, cereal, forage, fodder and straw, group 16; oilseed, group 19; cotton, gin by-products at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Bayer CropScience, 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 made some minor modifications to some commodity definitions for consistency with EPA naming-conventions for those commodities. The reason for these changes is 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 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 penflufen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with penflufen 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. Penflufen is an alkylamide fungicide belonging to the chemical class of carboxamides. The reported pesticidal mode of action is as an inhibitor of mitochondrial respiration by inhibiting succinate dehydrogenase, an enzyme in the electron transport system.

The liver and thyroid are target organs for penflufen. Increased liver weight, alterations in clinical chemistry parameters relevant to effects on the liver, and an increase in the incidence of hepatocellular hypertrophy were consistent findings across species and duration of exposure (28-day, 90-day, and 1- to 2-year exposure periods). The hepatic total cytochrome P-450 content, and benzoxyresorufin (BROD) and pentoxyresorufin (PROD) enzyme activities, were shown to be increased in rats of both sexes following subchronic oral exposure. Additionally, increased incidence of thyroid follicular cell hypertrophy/hyperplasia was observed across studies and species (no data provided on thyroid hormone levels). The liver and thyroid findings were mostly reversible after a 3-month recovery period in the rat. In the rat and mouse, following 104 week/78 week exposure periods at dose levels up to and/or greater than the limit dose, there was no increase in the incidence of liver or thyroid tumors.

Reproductive toxicity was observed in the 2-generation reproduction study in

rats. Delayed sexual maturation was observed in females in both generations, and magnitude of the associated decline in body weight was not considered to be a factor in the delay in sexual maturation. Developmental toxicity was not observed in the rat or rabbit, although the dose levels in both studies were not considered adequate to assess developmental toxicity potential of penflufen. However, there is little concern that new studies would identify a developmental endpoint with a no-observed-adverse-effect-level (NOAEL) lower than the NOAEL selected for risk assessment.

Decreased motor/locomotor activity was observed in both sexes of rats following acute and in female rats following subchronic oral exposure, although neuropathological lesions were not observed in either study.

There are no mutagenicity concerns. Carcinogenicity studies with penflufen found a statistically significant increase in histiocytic sarcomas in male rats; a marginal increase in brain astrocytomas, a fatal tumor, in male rats at the high dose; and ovarian adenomas in female rats at the high dose. Although these three tumors were considered treatment-related, they provided weak evidence of carcinogenicity due to the marginal nature of the tumor responses. There was no evidence of carcinogenicity in male or female mice. Given the weak evidence indicating any potential for carcinogenicity, EPA has determined that quantification of risk using a non-linear approach reference dose (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity, which could result from exposure to penflufen. The NOAEL (38 milligram/kilogram/day (mg/kg/day)) used for establishing the Chronic RfD is approximately 10-fold lower than the dose (approximately 300 mg/kg/day) that induced a marginal tumor response. The EPA has determined that the chronic population adjusted dose is protective of all long-term effects, including potential carcinogenicity.

Specific information on the studies received and the nature of the adverse effects caused by penflufen as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "Penflufen. Human Health Risk Assessment to Support New Uses on Potato (Crop Subgroup 1C), Legume Vegetables (Crop Group 6 and Crop Group 7), Cereal Grains (Crop Group 15 and Crop Group 16), Oilseeds (Crop Group 20), and Alfalfa" in docket ID number EPA-HQ-OPP-2010-0425.

*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 (LOC) 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 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 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 penflufen used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PENFLUFEN 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, including children and women 13–49 years of age).	NOAEL = 50 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day. aPAD = 0.5 mg/kg/day	Acute neurotoxicity study in rats. LOAEL = 100 mg/kg/day based on decreased motor and locomotor activity (39–81% on day of treatment) in females.
Chronic dietary (All populations) .....	NOAEL= 38 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.38 mg/kg/day. cPAD = 0.38 mg/kg/day	Chronic toxicity study in dogs. LOAEL = 357/425 mg/kg/day, based on decreased terminal body weight and body weight gain (females), increased prothrombin time (males), increased alkaline phosphate activity, decreased cholesterol, increased GGT levels, decreased albumin and albumin/globulin ratio, decreased calcium and phosphorus, increased liver weights, increased incidence of focal hepatocellular brown pigment and hepatocellular hypertrophy, and an increased incidence of thyroid follicular cell hypertrophy in both sexes, and in increased incidence of zona glomerulosa vacuolation of the adrenal gland in females.
Cancer (Oral, dermal, inhalation) .....	Quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to penflufen.		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>S</sub> = use of a short-term study for long-term risk assessment. UF<sub>DB</sub> = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. Mg/kg/day = milligrams/kilograms/day.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to penflufen, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from penflufen 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.

Such effects were identified for penflufen. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels

in food, EPA used tolerance-level residues, default dietary exposure evaluation model (DEEM) processing factors for dried potatoes and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EP used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, default DEEM processing factors for dried potatoes and assumed 100 PCT for all commodities.

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 used tolerance-level residues, default DEEM processing factors for dried

potatoes and assumed 100 PCT for all commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a non-linear RfD approach is appropriate for assessing cancer risk to penflufen. Cancer risk was assessed using the same

exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for penflufen. 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 penflufen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of penflufen. 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 penflufen for acute exposures are estimated to be 11.4 parts per billion (ppb) for surface water and 16.6 ppb for ground water. The EDWC of penflufen for chronic exposures for non-cancer assessments are estimated to be 1.8 ppb for surface water and 16.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 16.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 16.6 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).

Penflufen 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 penflufen to share a common mechanism of toxicity with any other substances, and penflufen

does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that penflufen 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.* In the rat multi-generation reproduction study there was slight decrease in litter size, delayed sexual maturation, decreased body weight/gain, decreased brain, spleen, and thymus weights were noted in the offspring. At the same dose level the adults exhibited decreased body weight/gain, alteration in food consumption, decreased thymus weight, and decrease spleen weights. In the rat developmental toxicity study, the maternal findings (decreased body weight gain) at the highest dose tested (HDT) are considered minimal. No adverse effects were observed on the fetuses. In the rabbit developmental toxicity study, the maternal findings (decreased body weight gain) at the HDT are considered minimal. No adverse effects were observed at the HDT.

3. *Conclusion.* The Agency recommends that the 10X FQPA safety factor for the protection of infants and children, be reduced to 1X. The risk assessments conducted for penflufen were based on the most sensitive endpoints in the toxicity database, and the NOAELs selected for risk assessment are considered protective of potential developmental, neurotoxic, and immunotoxic effects for infants and children. Highly conservative exposure estimates were incorporated into the

risk assessment for penflufen. There are no residual uncertainties with regard to pre- and/or postnatal toxicity or neurotoxicity, and exposure; therefore, reduction of the 10X FQPA safety factor for penflufen to 1X is appropriate based on the following findings:

i. The toxicity database for penflufen is complete for consideration of estimated risks for all populations of concern.

ii. Although decreased motor activity was observed following acute oral exposure, no neuropathological lesions were observed and there is little concern for neurotoxicity. There is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is some evidence of qualitative sensitivity of the young (delayed sexual maturation and decreased litter size), the effects are well characterized, and there is a clear NOAEL. The dose level where offspring effects were identified in the reproduction study is comparable to the high dose used in the rat developmental toxicity study where no effects were identified in either the maternal or fetal rat. Since minimal/no effects were observed in the developmental toxicity studies following exposure of the maternal animals to dose levels equal to and greater than those tested in the studies used for risk assessment, there is little concern that new studies would identify a developmental endpoint with a NOAEL lower than the NOAELs selected for risk assessment.

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 penflufen in drinking water. These assessments will not underestimate the exposure and risks posed by penflufen.

#### *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. A highly conservative acute dietary exposure assessment demonstrated that penflufen does not pose an unacceptable aggregate risk.

2. *Chronic risk.* There are no residential uses for penflufen; therefore, the chronic aggregate risk assessment includes exposures from dietary consumption of food and water only. A highly conservative chronic aggregate dietary exposure assessment demonstrated that penflufen does not pose an unacceptable aggregate chronic risk.

3. *Short-term risk.* There are no residential uses of penflufen; therefore a short-term aggregate risk assessment was not conducted for this chemical.

4. *Intermediate-term risk.* There are no residential uses of penflufen; therefore an intermediate-term aggregate risk assessment was not conducted for this chemical.

5. *Aggregate cancer risk for U.S. population.* In a rat carcinogenicity study with penflufen a statistically significant increase in histiocytic sarcomas with a positive trend in male rats only (but in the absence of a dose response and lack of pre-neoplastic lesions) were seen. A marginal increase in brain astrocytomas was also observed in males at the high dose; however, this effect was not dose-related, did not reach statistical significance, and there was no overall trend. In addition, there were no pre-neoplastic lesions, such as glial proliferations, which are a good indicator of chemical tumor induction (*i.e.*, there will be changes in the cells prior to transformation to a neoplasm). The ovarian adenomas observed at the high dose also showed no dose response, no pair-wise significance, no decrease in latency, and there were no pre-neoplastic lesions such as hyperplasia of the epithelial cells of the endometrium. Additionally, there was no evidence of carcinogenicity in male or female mice (at doses that were judged to be adequate to assess the carcinogenic potential), no concern for mutagenicity (*in vivo* or *in vitro*) for the parent molecule or the two metabolites, and there were no other lines of evidence (such as structure-activity relationship). Although these three tumors were considered treatment-related, they provided weak evidence of carcinogenicity due to the marginal nature of the tumor responses and the other factors mentioned in this unit. Given the weak evidence indicating any potential for carcinogenicity, EPA has determined that quantification of risk

using a non-linear approach (*i.e.*, RfD) will adequately account for all chronic toxicity, including carcinogenicity, which could result from exposure to penflufen. The NOAEL (38 mg/kg/day) used for establishing the chronic RfD is approximately 10-fold lower than the dose (approximately 300 mg/kg/day) that induced a marginal tumor response. The EPA has determined that the chronic population adjusted dose is protective of all long-term effects, including potential carcinogenicity.

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 penflufen residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method involves extraction of samples with acetonitrile/water, cleanup using solid phase extraction, and analysis of penflufen by liquid chromatography/mass spectrometry (LC/MS/MS) (EL-002-P09-03).

##### 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 U.N. 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 a MRL for penflufen.

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

Some minor modifications to commodity definitions initially submitted were made to be consistent with the updated EPA naming-conventions for commodities.

#### V. Conclusion

Therefore, tolerances are established for residues of penflufen, in or on alfalfa, forage; alfalfa, hay; vegetable, tuberous and corm, subgroup 1C; vegetable, legume, group 6; vegetable, foliage of legume, group 7; grain, cereal, group 15, grain, cereal, forage, fodder and straw, group 16; oilseed, group 19; cotton, gin by-products at 0.01 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) (Pub. L. 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 3, 2012.

**Steven Bradbury,**

*Director, 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 180.664 is added to subpart C to read as follows:

#### § 180.664 Penflufen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide penflufen, including its metabolites and degradates, in or on the following commodities listed in the table. Compliance with the tolerance levels

specified in the table is to be determined by measuring only penflufen *N*-[2-(1,3-dimethylbutyl)phenyl]-5-fluoro-1,3-dimethyl-1*H*-pyrazole-4-carboxamide, in or on the following commodities.

Commodity	Parts per million
Alfalfa, forage .....	0.01
Alfalfa, hay .....	0.01
Cotton, gin by-products .....	0.01
Grain cereal, forage, fodder and straw, group 16 .....	0.01
Grain, cereal, group 15 .....	0.01
Oilseed, group 20 .....	0.01
Vegetable, foliage of legume, group 7 .....	0.01
Vegetable, legume, group 6 .....	0.01
Vegetable, tuberous and corm subgroup 1C .....	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

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

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

[FR Doc. 2012-11629 Filed 5-11-12; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 799

[EPA-HQ-OPPT-2005-0033; FRL-9350-2]

RIN 2070-AD16

### Withdrawal of Revocation of TSCA Section 4 Testing Requirements for One High Production Volume Chemical Substance

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

**ACTION:** Final rule.

**SUMMARY:** In the **Federal Register** issue of March 16, 2012, EPA published a direct final rule revoking certain testing requirements promulgated under the Toxic Substances Control Act (TSCA) for 10 chemical substances, including benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- (CAS No. 1324-76-1), also known as C.I. Pigment Blue 61. EPA received an adverse comment regarding C.I. Pigment Blue 61. This document withdraws the revocation of testing requirements for C.I. Pigment Blue 61 as described in the March 16, 2012 direct final rule. In withdrawing the revocation, this document also restores the original testing requirements as currently shown in the Code of Federal Regulations

(CFR). Elsewhere in today's **Federal Register**, EPA is publishing a proposed rule revoking the same testing requirements for C.I. Pigment Blue 61 that were published in the March 16, 2012 direct final rule.

**DATES:** This final rule is effective May 15, 2012.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Catherine Roman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-8157; email address: [roman.catherine@epa.gov](mailto:roman.catherine@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Does this action apply to me?

A list of potentially affected entities is provided in the **Federal Register** issue of March 16, 2012 (77 FR 15609) (FRL-9335-6). If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

#### II. What rule is being withdrawn?

In the March 16, 2012 **Federal Register**, EPA issued a revocation of some or all of the TSCA section 4 testing requirements for 10 chemical substances by direct final rule. In accordance with the procedures described in the March 16, 2012 **Federal Register** document, EPA is withdrawing the revocation of certain testing requirements for C.I. Pigment Blue 61 and also restoring the original testing requirements found in the CFR, because the Agency received an adverse comment concerning this chemical substance. The final rule revoking testing requirements for the other 9 chemical substances described in the March 16, 2012 **Federal Register** document is otherwise unaffected by the withdrawal of the revocation for C.I. Pigment Blue 61. Elsewhere in today's **Federal Register**, EPA is proposing a rule to revoke certain test rule requirements for C.I. Pigment Blue 61.

The docket identification (ID) number for the test rule concerning this chemical substance was established at EPA-HQ-OPPT-2005-0033. That docket includes information considered by the Agency in developing those rules and the adverse comment.