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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0559; FRL-9952-22]

Penflufen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of penflufen in or on vegetable, bulb, group 3-07; beet, sugar, roots; and beet, sugar, tops. Interregional Research Project Number 4 (IR-4) requested the tolerance associated with pesticide petition number (PP#) 5E8382, and Bayer CropScience requested the tolerances associated with PP# 5F8379, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2015-0559, 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How Can I Get Electronic Access to Other Related Information?

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0559 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2015-0559, 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 October 21, 2015 (80 FR 63731) (FRL-9935-29), 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# 5E8382) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Princeton, NJ 08540. The petition requested that 40 CFR 180.664 be amended by establishing tolerances for residues of the fungicide penflufen, (1*H*-Pyrazole-4-carboxamide, *N*-[2-(1,3-dimethylbutyl)phenyl]-5-

fluoro-1,3-dimethyl-), in or on onion, bulb, 3-07A at 0.01 parts per million (ppm); and onion, green, 3-07B at 0.015 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket EPA-HQ-OPP-2015-0559-0002 at *http://www.regulations.gov*.

In the **Federal Register** of July 20, 2016 (81 FR 47150) (FRL-9948-45), 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# 5F8379) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.664 be amended by establishing tolerances for residues of the fungicide penflufen, (1*H*-Pyrazole-4-carboxamide, *N*-[2-(1,3-dimethylbutyl)phenyl]-5-fluoro-1,3-dimethyl-), in or on beet, sugar, roots at 0.01 ppm and beet, sugar, tops at 0.01 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket EPA-HQ-OPP-2015-0559-0006 at *http://www.regulations.gov*.

Five comments were received in response to the notices of filing. EPA's responses to these comments are discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the petitioned-for tolerances for subgroups 3-07A and 3-07B since the Agency has determined that a crop group tolerance for vegetable, bulb, group 3-07 is more appropriate. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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.

The liver and thyroid are target organs for penflufen. No evidence of quantitative or qualitative susceptibility was seen in developmental toxicity studies (rats and rabbits). Developmental toxicity was not observed in the rat or rabbit studies, although the studies did not test up to the limit dose. However, new studies are not expected to identify developmental endpoints with points of departure (PODs) lower than those determined in the current studies. In the reproductive study, decreased pup weight, delayed vaginal patency, and decreased brain, spleen, and thymus weights were seen in the presence of limited maternal effects (body weight changes), suggesting qualitative sensitivity. However, concern for the sensitivity is low since the effects are well characterized, and there is a clear NOAEL for the effects seen. Decreased motor and locomotor activity were observed in both sexes of rats following acute oral exposure and in female rats following subchronic oral exposure; neuropathological lesions were not observed in either study.

Penflufen is classified as having "suggestive evidence of carcinogenicity." 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) was 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 of carcinogenicity (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 above. 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, based on limited evidence for carcinogenicity (histiocytic sarcomas) in male rats. There is no mutagenicity concern for penflufen. The risk assessments conducted for penflufen are based on the most sensitive endpoints in the toxicity database and are protective of all effects observed in the toxicology database.

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 Bulb Vegetables (Crop Group 3-07) and Sugar Beets.” in pages 8-12 in docket ID number EPA-HQ-OPP-2015-0559.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for penflufen used for human risk assessment is discussed in Unit III.B. of the final rule published in the Federal Register of May 14, 2012 (77 FR 28278) (FRL-9341-8).

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 as well as all existing penflufen tolerances in 40 CFR 180.664. 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 the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues, default processing factors, and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, Version 3.16 software with 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA used tolerance-level residues, default processing factors, and 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 nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer 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 determined that quantification of risk using a non-linear approach (i.e., cRfD) will adequately account for all chronic toxicity, including carcinogenicity, which could result from exposure to penflufen. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

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

2. *Dietary exposure from drinking water*.

In drinking water, the residue of concern is penflufen parent and its degradates, penflufen-hydroxybutyl (Pen-3HB) and penflufen-pyrazolyl-AAP (AAP). 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Based on the Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW) models, the estimated drinking water concentrations (EDWCs) of penflufen for acute exposures are estimated to be 5.09 parts per billion (ppb) for surface water and 123 ppb for ground water. The EDWCs of penflufen for chronic exposures for non-cancer assessments are estimated to be 3.95 ppb for surface water and 84.8 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 123 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 84.8 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 website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

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*. No evidence of quantitative or qualitative susceptibility was seen in developmental toxicity studies in rats and rabbits. In the rat and rabbit developmental toxicity studies, maternal findings were limited to decreased body

weight gain at the highest doses tested (HDT). No adverse effects were observed in rat or rabbit fetuses. In the rat multi-generation reproduction study, a slight decrease in litter size, delayed sexual maturation, decreased body weight and weight gain, and decreased brain, spleen, and thymus weights were noted in the offspring animals in the presence of less pronounced maternal toxicity (decreased body weight and weight gain, alteration in food consumption, decreased thymus weight, and decreased spleen weights) suggesting qualitative susceptibility.

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 penflufen is complete.

ii. There is no concern for neurotoxicity and no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Although clinical signs were observed in acute and subchronic neurotoxicity studies with penflufen, there is a clear NOAEL for the effects seen and the endpoints and PODs selected for risk assessment are protective. The NOAELs used for risk assessment are 2x lower than where clinical signs were observed.

iii. Although there is some evidence of qualitative sensitivity of the young in the reproduction study, the effects are well characterized, and there is a clear NOAEL for effects seen. Also, the current risk assessments are based on the most sensitive endpoints derived from studies with NOAELs 5x lower than the doses at which offspring effects

were observed in the reproductive toxicity study. Thus, the PODs selected for risk assessment are protective of potential offspring effects.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to penflufen will occupy 4.2% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to penflufen from food and water will utilize 1.2% of the cPAD for all infants (<2 year old) the population group receiving the greatest exposure. There are no residential uses for penflufen.

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

4. *Aggregate cancer risk for U.S. population*. EPA assessed cancer risk using a non-linear approach (i.e., RfD) since it adequately accounts for all chronic toxicity, including carcinogenicity, that could result from exposure to penflufen. As the chronic dietary endpoint and dose are protective of potential cancer effects, penflufen is not expected to pose an aggregate cancer risk.

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 penflufen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography and triple stage quadrupole mass spectrometry (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 a MRL for penflufen.

C. Response to Comments

One comment was received in response to the Notice of Filing for PP# 5E8382. The commenter was opposing the use and sale of penflufen in the United States. The

Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. EPA has found that there is a reasonable certainty of no harm to humans after considering the toxicological studies and the exposure levels of humans to penflufen.

Three comments were received in response to the Notice of Filing for PP# 5F8379. One comment was in support of the Proposed Rule, while two comments were opposing any tolerance level above 0.00 ppm for any pesticides used in the US. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. In addition, both commenters indicated that IR-4 and Rutgers University are profiteering. The IR-4 program was created by Congress in 1963 in order to assist minor crop growers in the process of obtaining pesticide registrations. IR-4 National Coordinating Headquarters is located at Rutgers University in New Jersey and receives the majority (90%) of its funding from the USDA. It is the only publicly funded program that conducts research and submits petitions for tolerances. IR-4 operates in collaboration with USDA, the Land Grant University System, the agrochemical industry, commodity associations, and EPA. IR-4 identifies needs, prioritizes accordingly, and conducts

research. The majority (over 80%) of IR-4's research is conducted on reduced-risk chemicals. Under the Pesticide Registration Improvement Act (PRIA), IR-4 works in cooperation with the registrant to request an exemption for the registration services. The exemption may be granted if the application is solely associated by simultaneous submission with a tolerance petition in connection with IR-4 and if it is in the public interest. This fee exemption serves as an incentive to pursue registration of minor uses supported by the IR-4 program. In addition to the work done in pesticide registration, IR-4 develops risk mitigation measures for existing registered products. Therefore, IR-4 and Rutgers University are not profiteering from registering pesticides.

A comment was submitted by the Environmental Health Program of the Center for Biological Diversity and was primarily concerned about environmental risks and Agency compliance with any relevant obligations under the Endangered Species Act. This comment is not relevant to the Agency's evaluation of safety of the penflufen tolerances; section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

D. Revisions to Petitioned-For Tolerances

Based on review of the data supporting the petitions, EPA has revised the petitioned-for tolerance on onion, green, subgroup 3-07B. Both representative commodities for crop group 3-07 were submitted for the new uses, which included different tolerances proposed for crop subgroup 3-07A and 3-07B. Although the petitioner requested separate tolerances (based on the Organization for Economic Cooperation and Development (OECD) calculation procedure), EPA has decided to

establish a tolerance for crop group 3-07 at the level of qualification (LOQ) of the enforcement method (0.01 ppm), because maximum residues from crop subgroup 3-07A and subgroup 3-07B representative commodities were within a five-fold difference of each other, and because with residues in the field trials all less than the LOQ, the OECD calculation procedure stipulates that the LOQ is the appropriate tolerance level. Therefore, a single tolerance on the crop group vegetable, bulb, group 3-07 is appropriate.

V. Conclusion

Therefore, tolerances are established for residues of penflufen, in or on vegetable, bulb, group 3-07 at 0.01 ppm; beet, sugar, roots at 0.01 ppm; and beet, sugar, tops at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive

Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as

described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 30, 2016,

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.664, alphabetically add entries for "beet, sugar, roots", "beet, sugar, tops", and "vegetable, bulb, group 3-07" to the table in paragraph (a) to read as follows:

§ 180.664 Penflufen; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Beet, sugar, roots	0.01 ppm
Beet, sugar, tops	0.01 ppm
* * * * * * *	
Vegetable, bulb, group 3-07	0.01 ppm
* * * * * * *	

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[FR Doc. 2016-25293 Filed: 10/18/2016 8:45 am; Publication Date: 10/19/2016]