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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0417; FRL-9994-93]

Valifenalate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of valifenalate in or on bulb vegetable crop group 3-07, celery, cucurbit vegetables crop group 9, fruiting vegetables crop group 8-10, potato, potato-granules/flakes, and tolerances without U.S. registrations in/on grape; and grape, raisin. FMC Corporation requested these tolerances 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 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-2017-0417, 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: Mike 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-2017-0417 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 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-2017-0417, 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 November 27, 2017 (82 FR 56017) (FRL-9968-5), 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 7F8582) by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide valifenalate, methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alainate, in or on bulb vegetable crop group 3-07 at 0.40 parts per million (ppm); celery at 6.0 ppm; cucurbit vegetable crop group 9 at 0.3 ppm; fruiting vegetable crop group 8-10 at 0.60 ppm; potato at 0.04 ppm; potato-chips at 0.05 ppm; potato-dried pulp at 0.06 ppm; potato-granules/flakes at 0.15 ppm; tomato, wet-peel at 1.8 ppm; and a tolerance without U.S. registration in/on grape at 3.0 ppm. After that notice of that petition was published, the petitioner made some revisions to the petition, so EPA issued another document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), in the *Federal Register* of March 6, 2018 (83 FR 9471) (FRL-9973-27), announcing the new petition requests. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide valifenalate, methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alainate, in or on bulb vegetable crop group 3-07 at 0.40 ppm; celery at 5.0 ppm; cucurbit vegetable crop group 9 at 0.30 ppm; fruiting vegetable crop group 8-10 at 0.50 ppm; potato at 0.01 ppm; tomato, wet-peel at 0.9 ppm; and a tolerance without U.S. registration in/on grape at 5.0 ppm.

Summaries of the petition prepared by FMC Corporation, the registrant, are available in the docket, *http://www.regulations.gov*. Comments were received on both notices of filing.

EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from the petitioner's request in accordance with section 408(d)(4(A)(i). The reasons 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 valifenalate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with valifenalate 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 the thyroid are the main target organs for valifenalate. Following subchronic exposures to dogs, treatment-related effects in the liver were observed including alterations in liver enzyme parameters and histopathological findings as well as increased liver weights. Following chronic exposures, liver effects included increased liver weight (dog, mouse, rat) and histopathological findings (mouse and/or dog). In mice, at 78 weeks there were treatment-related liver adenomas and carcinomas in males and liver adenomas in females. Based on available data demonstrating a non-genotoxic mode of action for the liver tumors, valifenalate has been classified as "not likely to be carcinogenic to humans" at dose levels that do not cause a proliferative response in the liver.

Increases in absolute and relative thyroid weights and follicular cell hypertrophy were observed in the subchronic and chronic dog studies, in the parental animals in the two-generation reproduction study in rats and in the combined chronic toxicity/carcinogenicity study in rats (at 52 weeks). Other effects observed following chronic exposures include decreased prostate and spleen weights in males, decreased ovary weights and lack of corpora lutea in dogs, as well as an increased incidence and severity of pelvic/papillary epithelial hyperplasia in the kidney in rats.

There was no evidence of increased susceptibility to the fetus or offspring in the available developmental and reproduction toxicity studies. There were no developmental or maternal effects seen in either the rat or rabbit studies and no offspring effects were observed in the two-generation reproduction study in rats up to the limit dose of 1,000 milligram/kilogram/day (mg/kg/day). There was also no evidence of neurotoxicity in the database.

Valifenalate is categorized as having low acute lethality via oral, inhalation, and dermal routes of exposure. It is not irritating to the eyes or skin and is not a dermal sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by valifenalate 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 Valifenalate. Human Health Risk Assessment for the Section 3 Registration Action of the New Active Ingredient on Bulb Vegetables, Cucurbits, Fruiting Vegetables, Celery, and Potatoes and Establishment of a Tolerance Without U.S. Registration on Grapes in docket ID number EPA-HQ-OPP-2017-0417.

B. Toxicological Points of Departure/Levels of Concern

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

toxicological endpoints for valifenalate used for human risk assessment is shown in Table 1 of this unit.

Table 1. -- Summary of Toxicological Doses and Endpoints for valifenalate 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)	Endpoint not selected as there are no adverse effects attributable to a single dose observed in the database		
Chronic dietary (All populations)	NOAEL = 22 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.22 mg/kg/day cPAD = 0.22 mg/kg/day	Carcinogenicity - Mouse LOAEL = 97 mg/kg/day based on an increased absolute and relative liver weights, and hepatocyte hypertrophy as well as an increased incidence of macroscopic liver abnormalities (liver masses, pale areas, accentuated lobular patterns, and increased eosinophilic foci) in both sexes and centrilobular vacuolation in males
Cancer (Oral, dermal, inhalation)	"*Not Likely to be Carcinogenic to Humans"* at dose levels that do not cause a proliferative response in the liver.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to valifenalate, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from valifenalate 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 valifenalate; 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 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA; 2003-2008). The chronic analysis assumed 100% crop treated, tolerance-level residues or tolerance-level residues adjusted to account for the residues of concern (ROC) for risk assessment, HED's 2018 default processing factors, and modeled drinking water estimates.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that the chronic assessment will adequately account for all chronic toxicity, including potential carcinogenicity. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for valifenalate. Tolerance level residues 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 valifenalate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of valifenalate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model Ground Water (PRZM GW) and Pesticide Root Zone Model 5 – Variable Volume Water Model (PRZM5-VVWM), the estimated drinking water

concentrations (EDWCs) of valifenalate for acute exposures are estimated to be 2.6 parts per billion (ppb) for surface water and 0.05 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 2.6 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). Valifenalate is not registered for any specific use patterns that would result in residential

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 valifenalate to share a common mechanism of toxicity with any other substances, and valifenalate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that valifenalate 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 Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity studies in rabbits or rats or the reproduction toxicity study in rats.

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

i. The toxicity database for valifenalate is complete.

ii. There is no indication that valifenalate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

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

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues and upper bound drinking water residues. EPA made conservative (protective) assumptions in the

ground and surface water modeling used to assess exposure to valifenalate in drinking water. These assessments will not underestimate the exposure and risks posed by valifenalate.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, valifenalate 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 valifenalate from food and water will utilize 8.6 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for valifenalate.

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). A short-term adverse effect was identified; however, valifenalate is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been

assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for valifenalate.

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

5. *Aggregate cancer risk for U.S. population*. EPA concludes that aggregate cancer risk for valifenalate has been accounted for the chronic risk assessment, which does not present a risk of concern. Therefore, EPA concludes that aggregate exposure to valifenalate does not 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 valifenalate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromotography with tandem mass

spectrometry (LC/MS/MS)) is available to enforce the tolerance expression.

B. International Residue Limits

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

The Codex has not established MRLs for valifenalate in or on the relevant commodities.

C. Response to Comments

The EPA received several comments during the two 30-day comment periods following the publication of the two notices of filing. All the comments were anonymous public comments. Four comments raised issues related to pesticides, while the remainder raised issues unrelated to pesticides, and thus unrelated to this rulemaking. Of the four comments related to pesticides, one expressed concern about farmworker health, which is not an issue relevant to the assessment of the safety of the tolerances under the FFDCA. The three remaining comments expressed general concern about the potential of pesticide residues in food, although none provided any substantive information to take into consideration in EPA's safety assessment. The FFDCA authorizes EPA to establish tolerances that permit certain levels of pesticide residues in or on food when the

Agency can determine that such residues are safe. EPA has made that determination for the tolerances subject to this action; commenters provided no information relevant to that conclusion.

D. Revisions to Petitioned-For Tolerances

Based on available residue data and using the OECD tolerance calculation procedure, EPA is establishing tolerance values for several commodities that vary slightly from what the petition requested. In addition, EPA has determined based on available data that the tolerance requested for tomato, wet peel is not necessary as residues will be covered by the fruiting vegetables crop group tolerance. Finally, EPA is establishing a separate tolerance for grape, raisin and for potato, granules/flakes because the application of processing factors indicates that residues are likely to concentrate in these processed commodities of the raw agricultural commodities on which valifenalate will be used.

V. Conclusion

Therefore, tolerances are established for residues of valifenalate in or on celery at 5 ppm; grape at 5 ppm; grape, raisin at 6 ppm; potato at 0.04 ppm; potato, granules/flakes at 0.09 ppm; vegetable, bulb, group 3-07 at 0.6 ppm; vegetable, cucurbit, group 9 at 0.3 ppm; vegetable, fruiting, group 8-10 at 1 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), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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: June 25, 2019.

Richard Keigwin,

Director, Office of Pesticide Programs, US Environmental Protection Agency.

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. Add § 180.706 to subpart C to read as follows:

§ 180.706 Valifenalate; tolerances for residues.

(a)(1)Tolerances are established for residues of the fungicide valifenalate, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels is to be determined by measuring only valifenalate (methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alainate), in or on the following commodities.

Commodity	Parts per million
Celery	5
Grape[1]	5
Grape, raisin[1]	6
Vegetable, bulb, group 3-07	0.6
Vegetable, cucurbit, group 9	0.3
Vegetable, fruiting, group 8-10	1

[1] As of [*insert date of publication*], valifenalate is not registered in the United States for use on this commodity.

(2) Tolerances are established for residues of the fungicide valifenalate, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels is to be determined by measuring only the sum of valifenalate, methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alainate and valifenalate acid, 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]-amino]propionic acid calculated as the stoichiometric equivalent of valifenalate, in or on the following commodities.

Commodity	Parts per million
Potato	0.04
Potato, granules/flakes	0.09

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

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

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

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[FR Doc. 2019-13990 Filed: 6/28/2019 8:45 am; Publication Date: 7/1/2019]