



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0651; FRL-9975-01]

### Clethodim; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of clethodim in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes several previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR-4) 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 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-2016-0651, 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 L. 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](mailto: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](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-2016-0651 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-2016-0651, 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 March 23, 2017 (82 FR 14846) (FRL-9957-99), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8510) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton NJ 08540. The petition requested that 40 CFR 180.458 be amended by establishing tolerances for residues of the herbicide, clethodim, 2-[(1E)-1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on almond, hulls at 0.2 parts per million (ppm); *Brassica*, leafy greens, subgroup 4-16B at 3.0 ppm; leaf petiole vegetable subgroup 22B at 0.60 ppm; leafy greens subgroup 4-16A at 2.0 ppm; nut, tree, group 14-12 at 0.2 ppm; okra at 1.5 ppm; onion, green, subgroup 3-07B at 2.0 ppm; stalk and stem vegetable subgroup 22A at 1.7 ppm; vegetable, *Brassica*, head and stem, group 5-16 at 3.0 ppm; and vegetable, fruiting, group 8-10, except okra at 1.0 ppm. Upon establishment of proposed tolerances above, the Petitioner requests that 40 CFR part 180.458 be amended by removing existing tolerances for residues of clethodim in or on the raw agricultural commodities asparagus at 1.7 ppm; *Brassica*, head and stem, subgroup 5A at 3.0 ppm; *Brassica*, leafy greens, subgroup 5B at 3.0 ppm; leaf petioles subgroup 4B at 0.60 ppm; leafy greens subgroup 4A at 2.0 ppm; onion, green at 2.0 ppm; turnip, greens at 3.0 ppm; and vegetable, fruiting, group 8-10 at 1.0 ppm that are superseded by this final rule. That document referenced a summary of the petition prepared by Valent USA Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's responses to these comments are discussed in Unit IV.C.

Consistent with the authority in FFDCA 408(d)(4)(A)(i), EPA is issuing tolerances that vary from what the petitioner sought. 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 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 clethodim including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clethodim follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their 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 clethodim toxicity database shows relatively low toxicity with the liver being the target organ based on repeated dosing by either oral or dermal routes in rats, mice, and dogs. The observed liver effects are characterized by increased liver weights, clinical chemistry changes, and centrilobular hepatic hypertrophy. Most liver effects that occurred at or below 100 milligrams/kilogram body weight (mg/ kg bw) were considered as adaptive effects and not adverse. Decreased body weight was also a common finding across studies and species. In the 1-year dog oral toxicity study, hematological changes such as increased platelet and leukocyte counts and slight elevation of glucose levels (in dogs only) were also seen.

No developmental effects were present in the rabbits. In the rat developmental toxicity study, reduced fetal body weights and an increase in the incidence of delayed ossification of the lower vertebrae were seen at the dose (350 mg/kg/day) where maternal toxicity (excessive salivation and lacrimation, red nasal discharge) was also observed. No reproductive or offspring effects were seen in the 2-generation rat reproduction study. Therefore, the toxicity data showed no increased susceptibility in the young. The clethodim database also showed no potential for neurotoxicity or immunotoxicity.

Results of rat and mouse carcinogenicity studies did not show treatment-related increases in tumor incidence. Therefore, clethodim is not shown to be genotoxic and is classified as “not likely to be carcinogenic to humans.”

Specific information on the studies received and the nature of the adverse effects caused by clethodim 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 entitled, “**SUBJECT: Clethodim.** Human Health Aggregate Risk Assessment for the Proposed New Uses on Tree Nut Group 14-12; Okra; Crop Group Conversions for *Brassica* Leafy Greens Subgroup 4-16B; Leafy Green Subgroup 4-16A; Leaf

Petiole Vegetable Subgroup 22B; Stalk and Stem Vegetable Subgroup 22A; Vegetable, *Brassica* Head and Stem, Group 5-16; Expansion of Commodity Residue Tolerance to Green Onion Subgroup 3-07B and Response to 6(a)(2) Data Submission” dated March 19, 2018 at 33 - 38 in docket ID number EPA-HQ-OPP-2016-0651.

*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 clethodim used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of May 6, 2016 (81 FR 27339) (FRL-9945-68).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to clethodim, EPA considered exposure under the petitioned-for tolerances as well as all existing clethodim tolerances in 40 CFR 180.458. EPA assessed dietary exposures from clethodim 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 clethodim. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID), Version 3.16, which incorporates 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 conducted unrefined acute dietary analyses assuming tolerance levels for all commodities and 100 percent crop-treated (PCT). DEEM version 7.81 default processing factors were assumed, except where tolerances were established for processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used DEEM–FCID, Version 3.16, which incorporates 2003–2008 food consumption data from the USDA’s NHANES/WWEIA. As to residue levels in food, EPA conducted unrefined chronic dietary analyses assuming tolerance levels for all commodities and 100 PCT. DEEM version 7.81 default processing factors were assumed, except where tolerances were established for processed commodities.

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

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for clethodim. Tolerance-level residues and 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 clethodim in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of clethodim. 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>.

Surface and ground water contamination may occur from clethodim as well as its sulfoxide and sulfone degradates. Exposure from water contamination is primarily associated with clethodim sulfone and clethodim sulfoxide rather than parent clethodim based on greater persistence and mobility of these degradates. Thus, the exposure assessments were based on the total toxic residue rather than parent only.

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of clethodim for acute exposures are estimated to be 330 parts per billion (ppb) for surface water and 1,430 ppb for ground water. For chronic exposures for non-cancer assessments EDWCs are estimated to be 137 ppb for surface water and 1,150 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

1,430 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1,150 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).

Clethodim is currently registered for the following uses that could result in residential exposures: In and around ornamental plant beds, landscaped area, trees, and ground covers (mulch). EPA assessed residential exposure using the following assumptions:

In a reassessment of existing residential uses of clethodim conducted to reflect updates to EPA’s 2012 Residential SOPs along with policy changes for body weight assumptions, the Agency assessed short-term residential handler (adult only) inhalation exposure. There is potential residential dermal post-application exposure from the existing use of clethodim on ornamentals. However, since there is no adverse systemic hazard via the dermal route of exposure, and there is no incidental oral exposure expected from clethodim use on ornamental plants, a residential post-application assessment has not been conducted. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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 clethodim to share a common mechanism of toxicity with any other substances, and clethodim does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that clethodim 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on 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.* There is no evidence of increased susceptibility of fetuses as compared to maternal animals following *in utero* and/or postnatal exposure to clethodim in the developmental toxicity studies in rats or rabbits, and no increased sensitivity in pups as compared to adults in the 2-generation rat reproduction toxicity study. There are no residual uncertainties concerning prenatal and postnatal toxicity.

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 clethodim is complete and sufficient for selecting toxicity endpoints and PODs for assessing risks.

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

iii. There is no evidence that clethodim results in increased susceptibility of fetuses as compared to maternal animals following *in utero* and/or postnatal exposure to clethodim in the prenatal developmental toxicity studies in rats or rabbits, and no increased sensitivity in pups as compared to adults in the 2-generation rat reproduction toxicity study. In the rat developmental study, reduced ossification seen at the same dose that resulted in maternal toxicity is considered secondary to reduced maternal body weight, and is not considered qualitative susceptibility.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were determined 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 clethodim in drinking water. Post application exposure of children and incidental oral exposures to toddlers are expected to be negligible. All exposure estimates are based on conservative assumptions that will not underestimate the exposure and risks posed by clethodim.

#### *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. The acute aggregate risk is equivalent to the acute dietary risk.

Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to clethodim will occupy 29% of the aPAD, at the 95<sup>th</sup> percentile of exposure 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 clethodim from food and water will utilize 30% of the cPAD for all infants (<1 year old) the population group receiving the greatest exposure. There are no chronic residential exposure scenarios. Therefore, the chronic aggregate risk would be equivalent to the chronic dietary exposure (food and drinking water) estimate.

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). Clethodim is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to clethodim.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in a short-

term aggregate risk estimate for adults ages 20 to 49 is a MOE of 2,100. Because EPA's level of concern for clethodim is a MOE of 100 or below, this MOE is not of concern.

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).

Intermediate-term exposure is not expected for the residential exposure pathway. Therefore, the intermediate-term aggregate exposure would be equivalent to the chronic dietary exposure estimate.

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

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 clethodim residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate analytical methods are available for enforcing clethodim tolerances in/on the proposed/registered plant commodities. Samples were analyzed for residues of clethodim and metabolites containing the 2-cyclohexen-1-one moiety using the gas chromatography/mass spectroscopy (GC/MS) Method YARL-0602D, adapted from Method RM-26B-3 entitled, "The Determination of Clethodim Residues in Crops, Chicken and Beef Tissues, Milk and Eggs" (revision dated January 20, 1994). The method converts residues of clethodim and metabolites to clethodim sulfoxide (CSO) and clethodim 5 hydroxy sulfoxide (5-OH CSO<sub>2</sub>), which are

determined as their dimethyl esters (DME and DME-OH, respectively). Method RM-26B-3 is the enforcement method for tolerances for clethodim including its metabolites and degradates.

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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs for clethodim and its metabolites in or on the crops associated with this action.

#### *C. Response to Comments*

The Agency received four comments on the notice of filing (NOF) for this petition. While none of the commenters mentioned any specific concerns with the clethodim tolerances noticed in the NOF, two comments generally opposed the use of chemicals or pesticides in or food and two comments generally urged the Agency to ensure protection of the environment

and human health by reviewing science and determining whether use of pesticide is safe for human consumption.

The Agency recognizes that some individuals believe that certain pesticides are “toxic chemicals” that should not be permitted in our food; however, no new information demonstrating toxicity or exposure of clethodim that EPA could use to evaluate the safety of the pesticide was provided by commenters. 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. When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency, as is required by section 408 of FFDCA, estimates the risk of the potential exposure to these residues. The Agency has conducted that risk assessment, which includes the consideration of long-term animal studies with clethodim, and concluded that there is a reasonable certainty that no harm will result from aggregate human exposure to clethodim and that, accordingly, the use of clethodim on petitioned-for food commodities is “safe.”

#### *D. Revisions to Petitioned-For Tolerances*

In accordance with its standard practice to provide greater precision about the levels of residues that are permitted by a tolerance, EPA is adding an additional significant figure to the petitioned-for tolerance values for Almond hulls and Nut, tree, group 14-12. This is to avoid the situation where residues may be higher than the tolerance level, but as a result of rounding would be considered non-violative (for example, Almond tolerance proposed at 0.2 ppm was established at 0.20 ppm, to avoid an observed hypothetical tolerance at 0.24 ppm being rounded to 0.2 ppm).

#### *E. International Trade Considerations*

In this final rule, EPA is establishing a crop subgroup tolerance for subgroup 22A (stalk and stem vegetable) at 1.7 ppm. This subgroup includes the commodity kohlrabi, for which a tolerance is currently set at 3.0 ppm, as one of the commodities in the currently established tolerance for *Brassica*, head and stem subgroup 5A. Setting a new tolerance at 1.7 ppm on kohlrabi as part of subgroup 22A has a potentially trade restrictive effect on the import of kohlrabi. In the 2016 crop grouping rule, kohlrabi was moved to the stalk and stem vegetable subgroup 22A. See 81 FR 26471 (May 3, 2016).

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to promptly publish this action with the WTO. In addition, EPA is allowing the existing kohlrabi tolerance to remain in effect for six months following publication of this rule in order to provide a six-month reasonable interval for producers in exporting countries to adapt the modified tolerances. Before that date, residues of clethodim in or on kohlrabi will be permitted at the current tolerance levels; after that date, residues will need to be in compliance with the new tolerance levels.

The tolerance level is appropriate based on available data and residue levels resulting from registered use patterns. The tolerance levels are not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. None of the other tolerance actions taken in this rulemaking restrict permissible pesticide residues below currently allowed levels in the United States.

Any commodities listed in the regulatory text of this document that are treated with the pesticides subject to this final rule, and that are in the channels of trade following the expiration of the tolerance, shall be subject to FFDCA section 408(1)(5). Under this unit, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA.

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates that the pesticide was applied to such food.

## V. Conclusion

Therefore, tolerances are established for residues of the herbicide clethodim, 2-[[[(1E)-1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on Almond, hulls at 0.20 ppm; *Brassica*, Leafy, greens, subgroup 4-16B at 3.0 ppm; Leaf petiole vegetable subgroup 22B at 0.60 ppm; Leafy greens subgroup 4-16A at 2.0 ppm; Nut, tree, group 14-12 at 0.20 ppm; Okra 1.5 ppm; Onion, green, subgroup 3-07B at 2.0 ppm; Stalk and stem vegetable subgroup 22A at 1.7 ppm; Vegetable, *Brassica*, head and stem, group 5-16 at 3.0 ppm; and Vegetable, fruiting, group 8-10, except okra at 1.0 ppm. In addition, established tolerances in or on “Asparagus”; “*Brassica*, head and stem, subgroup 5A”; “*Brassica*, leafy greens, subgroup 5B”; “Leaf petioles subgroup 4B”; “Leafy greens subgroup 4A”; “Onion, green”; “Turnip, greens”; and “Vegetable, fruiting, group 8-10” are removed as they are superseded by this final tolerance rule. To minimize the potential for trade irritation, the Agency is allowing the existing tolerance for kohlrabi to remain in place for six months by adding an expiration date of six months following publication of this rule to each individual tolerance. Since kohlrabi is currently contained within

the existing subgroup 5A tolerance, which is being removed by this action, the Agency is listing kohlrabi as a separate tolerance at 3.0 ppm to remain in effect for a six-month period.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDC 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) ); or 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 FFDC 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 FFDC 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: March 19, 2018.

Michael L. Goodis,  
*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 § 180.458:

a. Remove the entries for “Asparagus”; “*Brassica*, head and stem, subgroup 5A”; “*Brassica*, leafy greens, subgroup 5B”; “Leaf petioles subgroup 4B”; “Leafy greens subgroup 4A”; “Onion, green”; “Turnip, greens”; and “Vegetable, fruiting, group 8-10”; from the table in paragraph (a).

b. Add alphabetically the entries to the table in paragraph (a) “Almond, hulls”; “*Brassica*, Leafy, greens, subgroup 4-16B”; “Kohlrabi”; “Leaf petiole vegetable subgroup 22B”; “Leafy greens subgroup 4-16A”; “Nut, tree, group 14-12”; “Okra”; “Onion, green, subgroup 3-07B”; “Stalk and stem vegetable subgroup 22A”; “Vegetable, *Brassica*, head and stem, group 5-16”; and “Vegetable, fruiting, group 8-10, except okra”.

c. Add footnote 1 to the table in paragraph (a).

The additions and revisions read as follows:

**§ 180.458 Clethodim; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	* * *
Almond, hulls	0.20
* * *	* * *
<i>Brassica</i> , leafy, greens, subgroup 4-16B	3.0
* * *	* * *
Kohlrabi <sup>1</sup>	3.0
Leaf petiole vegetable subgroup 22B	0.60
Leafy greens subgroup 4-16A	2.0

* * * * *	
Nut, tree, group 14-12	0.20
Okra	1.5
* * * * *	
Onion, green, subgroup 3-07B	2.0
* * * * *	
Stalk and stem vegetable subgroup 22A	1.7
* * * * *	
Vegetable, <i>brassica</i> , head and stem, group 5-16	3.0
Vegetable, fruiting, group 8-10, except okra	1.0
* * * * *	

<sup>1</sup> This tolerance expires on October 12, 2018.

\* \* \* \* \*