Dated: May 1, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

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

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

■ 2. Section 180.527 is amended as follows:
■ i. By revising the section heading;
■ ii. By revising paragraph (a);
■ iii. By removing the text of paragraph (b) and reserving with heading;
■ iv. By revising the introductory text of paragraph (c) and adding commodities to the table; and
■ v. By revising the introductory text of paragraph (d).

The amendments read as follows:

§ 180.527 Flufenacet, N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide and its metabolites containing the 4-fluoro-N-methylethyl benzenamine tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the herbicide flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following commodities.

Commodity	Parts per million
Cattle, kidney	0.05
Corn, field, forage	0.4
Corn, field, grain ...	0.05
Corn, field, stover	0.4
Corn, sweet, forage	0.45
Corn, sweet, kernel plus cob with husks removed ..	0.05
Corn, sweet, stover	0.30
Goat, kidney	0.05
Hog, kidney	0.05
Horse, kidney	0.05
Sheep, kidney	0.05
Soybean, seed	0.1
Wheat, bran	0.80
Wheat, forage	6.0
Wheat, grain	0.60
Wheat, hay	1.2
Wheat, straw	0.35

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

(c) *Tolerances with regional registrations.* Tolerances are established for combined residues of flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1, 3, 4-thiadiazol-2-yl] oxy]acetamide, and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety, with regional registration.

Commodity	Parts per million
Grass, forage	7.0
Grass, hay	0.4

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the herbicide flufenacet, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following raw agricultural commodities when present therein as a result of application of flufenacet to the growing crops in paragraph (a) of this section.

* * * * *

[FR Doc. E7–8936 Filed 5–8–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0535; FRL–8127–2]

Clethodim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of clethodim and certain of its metabolites in or on asparagus; flax, seed; herb, subgroup 19A; hop, dried cones; leafy greens subgroup 4A; safflower, meal; safflower, seed; sesame, seed; and vegetable, legume, group 6, except soybean. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 9, 2007. Objections and requests for hearings must be received on or before July 9, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0535. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*,or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to

assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, 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–2005–0535 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before July 9, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2005–0535, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

II. Petition for Tolerance

In the **Federal Register** of April 21, 2006 (71 FR 20669) (FRL–8056–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 3E6555, 5E6977, 4E6836, 5E6978, and 4F6895) by the Interregional Research Project #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 a tolerance for combined residues of the herbicide clethodim, (E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexene-1-one moiety in or on flax, seed at 0.5 parts per million (ppm) (PP 3E6555); herb, subgroup 19A at 10.0 ppm (4E6836); asparagus at 2.0 ppm and hop, dried cones at 0.5 ppm (5E6977); leafy greens subgroup 4A at 2.0 ppm (5E6978); and sesame, seed at 0.40 ppm; vegetable, legume, group 6 at 3.0 ppm; safflower, meal at 10.0 ppm; and safflower, seed at 5.0 ppm (4F6895). That notice referenced a summary of the petitions prepared by Valent U.S.A. Corporation, 133 N. California Blvd., Walnut Creek, CA 94596, the registrant, which is available to the public in the docket, *http://www.regulations.gov*.

There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has recommended certain changes to the petitions including:

- Revised tolerance levels for certain commodities, and:
- A specific tolerance expression to be applied to all new uses in an effort to harmonize tolerances with Codex Maxium Residue Limits. The reasons for these changes are explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 the 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 the 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. . . .'' These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in 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 the petitioned for tolerances for combined residues of clethodim on flax, seed at 0.6 ppm; herb, subgroup 19A at 12.0 ppm (4E6836); asparagus at 1.7 ppm and hop, dried cones at 0.5 ppm; leafy greens subgroup 4A at 2.0 ppm (5E6978); and sesame, seed at 0.35 ppm; vegetable, legume (except soybean), group 6 at 3.5 ppm; safflower, meal at 10.0 ppm; and safflower, seed at 5.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. 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*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as ''Clethodim: Human Health Risk Assessment for Proposed Uses on Herb Sugbroup 19A, Leafy Greens.....and Flax seed, dated 03/07/2007'' in that docket.

Additionally, clethodim toxicological data are discussed in the final rule published in the **Federal Register** of March 14, 2001(66 FR 14829) (FRL–6770–8).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which NOAELs are observed in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL of concern identified is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for clethodim used for human risk assessment can be found at *www.regulations.gov* in document ''Clethodim: Human Health Risk Assessment for Proposed Uses on Herb Sugbroup 19A, Leafy Greens.....and Flax seed, dated 03/07/2007'' at page 14 in Docket ID EPA–HQ–OPP–2005–0535.

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. No such effects were identified in the toxicological studies for clethodim; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary (food and water) exposure assessment, EPA used the food consumption data from the U.S. Department of Agriculture's (USDA) Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) from 1994-1996 and 1998. The chronic dietary exposure assessment was based on the assumption of tolerance-level residues for existing and proposed tolerances; and incorporated percent crop treated (PCT) information for certain registered uses.

iii. *Cancer*. Clethodim was negative for carcinogenicity in feeding studies in rats and mice and was classified as ''not likely'' to be a human carcinogen. Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

a. The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue;

b. The exposure estimate does not underestimate exposure for any significant subpopulation group; and

c. Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Commodity	Percent of Crop Treated (Weighted Average)
Beets	1
Broccoli	10
Cabbage	1
Cantaloupes	1
Carrots	10
Celery	5
Cotton	1
Cucumbers	1
Dry beans	5
Lettuce	1
Onions	10
Peanuts	5

Commodity	Percent of Crop Treated (Weighted Average)
Potatoes	5
Pumpkins	5
Soybeans	5
Squash	5
Strawberries	1
Sugar beets	45
Sunflowers	20
Sweet potatoes	1
Tomatoes	1
Watermelons	5

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from sources as discussed above including Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which clethodim may be applied in a particular area.

2. *Dietary exposure from drinking water.*The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for clethodim in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of clethodim. 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*.

Surface water and ground water contamination may occur from the sulfoxide and sulfone degradates of clethodim, as well as from parent clethodim. However, the risk of water contamination is primarily associated with clethodim sulfone and clethodim sulfoxide rather than parent clethodim based on greater persistence and mobility for these degradates. Parent clethodim may move from the treated field to surface water or ground water through run-off or leaching which occurs shortly after application (e.g. rainfall). Also, the sulphoxide and sulphone degradates may migrate by runoff or leaching for longer periods of time since they are more persistent. All residues of clethodim (parent and degradates) are very mobile in soil.

The only significant routes of dissipation of clethodim are microbial degradation in soil and movement by leaching or runoff. Parent clethodim is moderately persistent to hydrolysis at pH 5 with half-lives of 26-42 days and stable at pH 7 and 9 with half-lives greater than 300 days. Even though acceptable water and soil photolysis studies show half-lives of 1.5 to 9.3 days, this may not be an important route of dissipation because of suspended sediment and shading. Photolysis is only an important route of dissipation in shallow, well-mixed surface water with no shading. The half-lives in aerobic soil are 2-3 days for parent clethodim, and 30-38 days for total toxic residues (parent + sulphoxide + sulphone). The sulphoxide and sulphone metabolites are more persistent than parent clethodim and are formed in significant quantities in soil. All residues of clethodim (parent and metabolites) are very mobile in soil with five out of six soil desorption coefficients (Kd) less than one. The field dissipation studies show that parent clethodim was only found at levels at or near the quantitation limit of 0.02 ppm, which is consistent with the rapid degradation in soil. Clethodim sulphoxide had an apparent half-life of 2.5 to 3.7 days, indicating that movement from the treated field may have been an important route of dissipation.

In surface water, parent clethodim may move from the treated field to surface water or ground water through run-off or leaching which occurs shortly after application (e.g. rainfall). Also, the sulphoxide and sulphone degradates may migrate by runoff or leaching for longer periods of time since they are

more persistent. All residues of clethodim (parent and degradates) are very mobile in soil.

In ground water, parent clethodim is mobile, but has a short metabolic half-life in soil under aerobic conditions. Therefore, parent compound should not be a ground water concern in most environments. While it is expected that parent clethodim can be transformed to sulphoxide or sulphone products quickly by soil metabolism ($t_{\frac{1}{2}}$ = 1 - 3 days), it may be more persistent since it is leached below the more biologically active top soil. In such instances (i.e., leaching rainfall shortly after application) parent clethodim concentrations may be higher than estimated and correspondingly, the concentration of the degradates sulphoxide and sulphone would be lower. In the event that parent clethodim did reach ground water, the available routes of disappearance would be dilution, some metabolism to persistent degradates, and slow hydrolysis with the rate depending on the pH of the ground water. Estimates are provided for both parent clethodim and total toxic clethodim (parent + sulphoxide + sulphone).

Based on the (FQPA Index Reservoir Screening Tool (FIRST)) model, Tier 1 surface water concentrations for parent clethodim and total toxic residues (parent + sulphoxide + sulphone) were estimated in drinking water. These estimates are based on a maximum application rate of 0.5 lb ai/acre per year (2 applications). The peak FIRST estimated environmental concentration (EEC) for clethodim and it's degradates, sulphoxide and sulphone for acute exposures are estimated to be 38.9 parts per billion (ppb) for surface water. The EECs for chronic exposures are estimated to be 7.6 ppb for surface water. For drinking water derived from ground water, the Screening Concentration in Ground water (SCI-GROW) model estimates a total toxic clethodim concentration of 1.39 ug/L sources were not included, as the EEC's for this water source are minimal in comparison to surface 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 38.9 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 7.6 ppb was used to access 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).

Although clethodim is registered for use in non-crop areas and for commercial use on ornamentals, no residential exposure is expected from these uses because these uses are clearly intended for commercial and institutional applications on commercially grown ornamentals and not for ornamentals in a residential setting. Therefore, non-occupational exposure assessment of clethodim was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to clethodim and 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 not assumed that clethodim has 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://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional (10X) tenfold 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 data based 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence of susceptibility following *in utero* and/or postnatal exposure to clethodim in the developmental toxicity studies in rats or rabbits, and in the 2-generation rat reproduction study.

There are no residual uncertainties concerning pre- and postnatal toxicity and no neurotoxicity concerns.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity data base for clethodim is complete.

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

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

iv. There are no residual uncertainties identified in the exposure databases. The dietary (food and drinking water) exposure assessment will not underestimate the potential exposure for infants, children, and/or women of childbearing age. There is no potential for residential exposure.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure MOE called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk.* There were no effects observed in oral toxicity studies including developmental toxicity studies in rats and rabbits that could be attributable to a single dose (exposure).

Therefore, clethodim 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 exposure to clethodim from food and water will utilize 29% of the cPAD for the general U.S. population group and 84% of the cPAD for children 1-2 years old, the subpopulation group with greatest exposure. There are no residential uses for clethodim that result in chronic residential exposure to clethodim.

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

Clethodim is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water which do not exceed the Agency's level of concern.

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

Clethodim is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Clethodim is classified as a ''not likely'' to be carcinogenic in humans based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in the rat. Therefore, 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

For plants, adequate methodology is available for enforcement of the proposed tolerances through the use of FDA Multiresidue Methods. The analytical method used to assay clethodim residues in/on commodities that are the subject of this action was RM-26B-3 (a modification of RM-26B-2) or RE 45601 (also adapted from Valent (the registrant) method RM-26B), which was validated for the analyses of residues of clethodim sulfoxide and its metabolite (5-hydroxy clethodim sulfone) in/on green onions, leaf lettuce, and cabbage. Samples were analyzed for combined clethodim residues (dimethylester sulfone (DME) and 5-hydroxy dimethylester sulfone (DME-OH)) by gas chromatography with flame photometric detection in the sulfur mode (GC/FPD-S). In the analytical results, DME and DME-OH were reported as clethodim equivalents. Only one crop, hops, dried cones, had residues below the limit of quantitation (LOQ) <0.50 ppm) for combined total residues of clethodim (DME and DME-OH). The concurrent recoveries of clethodim (DME and DME-OH) for the submitted trials were generally within the accepted range of 70-120%. An exception was the concurrent recovery of DME-OH in succulent pea at 62%. There is no reason to believe that the residues of clethodim were unstable, or that the analytical method was not reliable under the conditions of these studies.

For livestock, Analytical Method RM-26B-3 (a modification of RM-26B-2) has been successfully validated for use with livestock commodities and has been submitted to the FDA for publication in PAM II.

IR-4 (petitioner) has previously submitted data describing the testing of clethodim and its metabolites through FDA Multiresidue Methods. These data, which have been forwarded to FDA for review indicate that adequate recoveries of clethodim, clethodim sulphoxide, and 5-OH clethodim sulphone have been obtained under FDA's multiresidue protocols.

Accordingly, EPA concludes that Adequate enforcement methodology (GC/FPD-S) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently Codex MRLs established for clethodim and its metabolites containing 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on bean, dry at 2 ppm; beans, except broad bean and soya bean at 0.5 ppm; field peas (dry) at 2 ppm; and soya bean (dry) at 10 ppm. Based on newly submitted field trial data, the Agency is establishing a new crop group tolerance, i.e., on vegetables, legume, group (crop group 6), except soybean. Because the Agency is establishing the tolerances on legume vegetables as a crop group, it cannot harmonize the crop group tolerance with the varying Codex MRLs for individual legume vegetables.

There are established Canadian MRLs for clethodim residues and its metabolites containing the 2-cyclohex-1-enone moiety on soybean at 10.0 ppm, beans, 0.5, chickpea at 0.5 ppm; lentils at 0.5 ppm; pea, dry at 0.5 ppm and flax seed at 0.3 ppm. In addition, Mexican MRLs are established for clethodim on bean, kidney at 2.0 ppm and soya bean at 10 ppm. Harmonization with Canadian and Mexican MRLs is not possible based on the MRL calculations of the newly submitted data.

V. Conclusion

The Agency has revised the proposed tolerance expression to make it consistent with the existing tolerance expression in 40 CFR 180.458 (a)(3). Clethodim is defined as the combined residues of clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones. In addition, the Agency revised tolerance levels proposed by IR-4 for certain commodities to reflect tolerance levels supported by current data bases.

Therefore, tolerances are established for the combined residues of the herbicide clethodim, (E)-(±)-2-[1-[[(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)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones in or on flax, seed at 0.6 ppm; herb, subgroup 19A at 12.0 ppm; asparagus at 1.7 ppm; hop, dried cones at 0.5 ppm; leafy greens subgroup 4A at 2.0 ppm; and sesame, seed at 0.35 ppm; vegetable, legume group 6, except soybean at 3.5 ppm; safflower, meal at 10.0 ppm; and safflower, seed at 5.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not

subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: May 1, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.458 is amended by alphabetically adding the following commodities to the table in paragraph (a)(3) to read as follows:

§ 180.458 Clethodim; tolerances for residues.

(a) * * *

(3) * * *

Commodity	Parts per million
Asparagus	1.7
* * * * *	
Flax seed	0.6
* * * * *	
Herb subgroup 19A	12.0
* * * * *	
Hop, dried cones	0.5
* * * * *	
Leafy greens subgroup 4A	2.0
* * * * *	
Safflower, meal	10.0
Safflower, seed	5.0
Sesame, seed	0.35
* * * * *	
Vegetable, legume group 6, except soybean	3.5

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