

pesticides. Furthermore, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change EPA's previous analysis.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop

an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### VI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: June 26, 2002.

**James Jones,**

*Acting Director, Office of Pesticide Programs.*

Therefore, 40 CFR part 180 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), 346(a) and 371.

#### § 180.220 [Amended]

2. Section 180.220 is amended by removing the "(N)" designation wherever it appears in the "Parts per million" column in the table under paragraph (a)(1), and by removing the entries for "Orchardgrass" and "Orchardgrass, hay" from the table in paragraph (a)(2).

#### § 180.230 [Removed]

3. Section 180.230 is removed.

4. Section 180.239 is revised to read as follows:

#### § 180.239 Phosphamidon; tolerances for residues.

(a) *General.* Tolerances (expressed as phosphamidon) for residues of the insecticide phosphamidon (2-chloro-2-diethylcarbamoyl-1-methylvinyl dimethyl phosphate) including all of its related cholinesterase-inhibiting compounds in or on raw agricultural commodities are established as follows:

Commodity	Parts per million	Expiration/Revocation Date
Apple .....	1.0	12/31/02

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

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

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

#### § 180.240 [Removed]

5. Section 180.240 is removed.

#### § 180.241 [Amended]

6. Section 180.241 is amended by removing the word "cottonseed."

#### § 180.305 [Removed]

7. Section 180.305 is removed.

#### § 180.338 [Removed]

8. Section 180.338 is removed.

#### § 180.413 [Amended]

9. Section 180.413 is amended by removing the entry for "cottonseed" from the table in paragraph (a)(1).

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-2002-0129; FRL-7185-7]

RIN 2070-XXXX

#### Clethodim; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for the residues of clethodim in or on alfalfa forage; alfalfa hay; dry bean; Brassica, leafy greens, subgroup

5B; peanut; peanut hay; peanut meal; peppermint tops; spearmint tops; spinach; and turnip greens. The Interregional Research Project Number 4 (IR4) and Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective July 17, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0129, must be received on or before September 16, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0129 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. General Information**

##### *A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person

listed under **FOR FURTHER INFORMATION CONTACT**.

##### *B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations", "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0129. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

#### **II. Background and Statutory Findings**

In the **Federal Register** of April 17, 2002 (67 FR 18890) (FRL-6830-9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170), announcing the filing of pesticide petitions (PP 1E6351, 2E6394, and

2E6396) by IR4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390, and pesticide petitions (PP 5F4440 and 5F4572) by Valent U.S.A. Corporation, 1333 North California Boulevard, Suite 600, Walnut Creek, CA 94596-8025. This notice included a summary of the petitions prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing. The petitions requested that 40 CFR 180.458 be amended by establishing tolerances for residues of the herbicide clethodim, (E)-(±)-2-1-(3-chloro-2-propenyl)oxyiminopropyl-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 Brassica, leafy greens, subgroup 5B at 3.0 part per million (ppm), turnip greens at 3.0 ppm, peppermint and spearmint tops at 5.0 ppm, and spinach at 2.0 ppm.

The petitions also requested that 40 CFR 180.458 be amended by replacing existing timelimited tolerances, with permanent tolerances for residues of the herbicide clethodim, (E)-(±)-2-1-(3-chloro-2-propenyl)oxyiminopropyl-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 alfalfa forage at 6.0 ppm, alfalfa hay at 10 ppm, dry bean at 2.0 ppm, peanut at 3.0 ppm, peanut hay at 3.0 ppm, and peanut meal at 5.0 ppm.

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) 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) 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....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

### III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2), for tolerances for residues of clethodim on alfalfa forage at 6.0 ppm, alfalfa hay at 10 ppm, dry bean at 2.5 ppm, Brassica, leafy greens, subgroup at 3.0, peanut at 3.0 ppm, peanut hay at 3.0, peanut meal at 5.0, and turnip tops at 3.0 ppm, peppermint and spearmint tops at 5.0 ppm, and spinach at 2.0 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

#### 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 nature of the toxic effects caused by clethodim is discussed in Unit III.A. of the **Federal Register** of March 14, 2001 (66 FR 14829) (FRL-6770-8).

#### B. Toxicological Endpoints

A summary of the toxicological endpoints for clethodim used for human risk assessment is discussed in Unit III.B of the **Federal Register** of March 14, 2001 (66 FR 14829) (FRL-6770-8). Chronic, and short-term, intermediate-term, and long-term aggregate risk assessments are appropriate for clethodim and were performed by EPA.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.458) for the residues of clethodim, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to

assess dietary exposures from clethodim in food as follows:

i. *Acute Exposure.* Acute dietary 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 one day or single exposure. An endpoint was not identified for acute dietary exposure and risk assessment because no effects were observed in oral toxicity studies including developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, an acute dietary exposure assessment was not performed.

ii. *Chronic Exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Chronic analysis used tolerance level residues for all crops and livestock commodities. The projected % crop treated data (2% for lettuce, broccoli and cauliflower, 15% cabbage, and 1% for brussels sprouts), and the weighted average % crop treated data (3% for cotton, 8% for onions, 3% for peanuts, 4% for soybeans, 15% for sugar beets, and 1% for tomatoes) were used for the analysis; 100% crop treated (CT) data were assumed for the leafy Brassica greens, turnip greens, dry bean, peanuts, and the other crops for the analysis. DEEM default concentration factors were used for all commodities. The analysis is considered Tier 2 because percent of crop treated information was used.

iii. *Cancer.* Clethodim has been classified as a group E carcinogen. Therefore, a cancer risk assessment was not performed.

iv. *Anticipated residue and percent crop treated information.*

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant sub-population group; and Condition 3, if 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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows.

2% for lettuce, broccoli and cauliflower; 15% cabbage, and 1% for brussels sprouts; (weighted average PCT) 3% for cotton, 8% for onions, 3% for peanuts, 4% for soybeans, 15% for sugar beets, and 1% for tomatoes.

The Agency believes that the three conditions listed III.C.1.iv have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. 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 sub-populations is taken into account through EPA's computer-based model for evaluating the exposure of significant sub-populations 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 sub-population 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 exposure 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 physical characteristics of clethodim.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCIGROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a % RfD or % PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from

residential uses. Since DWLOCs address total aggregate exposure to clethodim they are further discussed in the aggregate risk sections III.E.

**Summary:** Surface 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 the degradates. The drinking water estimates are based on a maximum application rate of 0.5 pounds of active ingredient per acre per year.

**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 sulfoxide and sulfone 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. Tier 1 surface water concentrations for parent clethodim and total toxic residues (parent + sulfoxide + sulfone) estimations are as follows:

Based on the FIRST model, the estimated environmental concentrations (EECs) of clethodim for acute exposure are estimated to be 38.9 parts per billion (ppb), and for chronic exposure the EECs are estimated to be 7.6 ppb for surface water.

**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 be transformed to sulfoxide or sulfoxone products quickly by soil metabolism ( $t_{1/2}$  = 1 to 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. 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. The estimation for both parent clethodim and total toxic clethodim (parent + sulfoxide+sulfone) is as follows: Based on the SCIGROW model, the EEC for ground water is 0.49 ppb.

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 use on the following noncrop sites: rights of way such as railroads, highways, roads, dividers, medians, pipelines, public utility lines, pumping stations, transformer stations and substations, around airports, electric utilities, commercial buildings, manufacturing plants, storage yards, rail yards, fence lines, parkways, greenhouse benches, and around golf courses (not on golf courses). It is possible that the public could be exposed to clethodim residues in these noncrop areas.

Homeowner use of clethodim is not prohibited on the label, therefore the Agency assumes clethodim products are available for use by untrained applicators. A residential handler assessment was performed to determine the risk potential to homeowners. The following assumptions were made in conducting the assessment: clethodim would be applied by low pressure handwand (spot treatment); the highest label rate of 1.3 ounces per gallon was used; five gallons of spray are used; applicators mix, load and apply; and short sleeved shirt and short pants are worn by homeowners.

Clethodim is typically used to control unwanted weeds of all types (grass and broadleaf) through spot treatment, usually resulting in a small treated area. Broadcast treatment is not expected. It is unlikely that adults and children would be exposed to treated areas which would most likely consist of a single spot. Therefore, a non-occupational post-application exposure assessment was not performed.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether clethodim has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

#### *D. Safety Factor for Infants and Children*

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional 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 base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to in utero exposure to clethodim.

3. *Conclusion.* There is a complete toxicity data base for clethodim and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to in utero and/or postnatal exposure; a developmental neurotoxicity study is

not required; and the dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children.

#### *E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, shortterm, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* An endpoint was not identified for acute dietary exposure and risk assessment because no effects were observed in oral toxicity studies including developmental toxicity studies in rats or 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 will utilize 33% of the cPAD for the U.S. population, 26% of the cPAD for females 1350 years old and 66% of the cPAD for children (16 years old). Based the use pattern, chronic residential exposure to residues of clethodim is not expected. In addition, there is potential for chronic dietary exposure to clethodim in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NONCANCER) EXPOSURE TO CLETHODIM

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population 0.01 33 7.6 0.49 201	Females (13-50 years old) 0.01 26 7.6 0.49 220	Children (1- 6 years old) 0.01 66 7.6 0.49 34			

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

Clethodim is currently registered for use that could result in short-term

residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for clethodim.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food

and residential exposures aggregated resulted in an aggregate MOE of 29,000 for males (13 to 19 years old). The dietary exposure of all adult population subgroups is comparable to that of the subgroup with the highest exposure (males 13 to 19 years old). This

aggregate MOE does not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of clethodim in

ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown

below in Table 2. Additionally, no incidental oral exposure is anticipated for infants and children, since postapplication exposure is not expected.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CLETHODIM

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb) Ground Water EEC (ppb)	ShortTerm DWLOC (ppb)	
US Population	29,000	100	7.6	0.49	30,000

#### 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). Intermediate-term oral, dermal and inhalation aggregate risks are made up of exposures from these routes of exposure.

Although, clethodim is currently registered for use(s) that could result in intermediate-term residential exposure dermal, inhalation and incidental oral exposures were not calculated because neither handler nor post-application intermediate-term exposure for these routes of exposure are expected. Therefore, no intermediate-term risk is expected from these routes of exposure.

5. *Aggregate cancer risk for U.S. population.* Clethodim was negative for carcinogenicity in feeding studies in rats and mice and is classified as "not likely" to be a human carcinogen.

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, and to infants and children from aggregate exposure to clethodim residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate methods are available for enforcement of tolerances for clethodim and its metabolites in/on Brassica, leafy greens, subgroup, turnip greens, and other commodities (including livestock). Analytical Method RM26B3 (a modification of RM26B2) has been successfully validated for use with many commodities including livestock commodities and has been submitted to the FDA for publication in PAM II.

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be

requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, Environmental Protection Agency, 701 Mapes Road, Fort George G. Mead, MD 20755-5350; telephone number (410) 305-2905; griffith.francis@epa.gov.

##### B. International Residue Limits

There are no established Codex, Canadian, or Mexican maximum residue limits (MRLs) or tolerance for residues of clethodim in/on the commodities discussed in the subject petition; therefore, there are no questions with respect to Codex/U.S. tolerance compatibility.

#### V. Conclusion

Therefore, these tolerances are established for residues of clethodim, (E)-(±)-2-1-(3-chloro-2-propenyl)oxyiminopropyl-5-2-(ethylthio)propyl-3-hydroxy-2-cyclohexene-1-one and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulphones, in or on alfalfa forage at 6.0 ppm, alfalfa hay at 10 ppm, dry bean at 2.5 ppm, Brassica, leafy greens, subgroup at 3.0 ppm, peanut at 3.0 ppm, peanut hay at 3.0 ppm, peanut meal at 5.0 ppm, and turnip greens at 3.0 ppm, peppermint and spearmint tops at 5.0 ppm, and spinach at 2.0 ppm.

#### VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the

FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

##### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0129 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 on or before September 16, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by email at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP-2002-0129, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption.

Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### *B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### **VII. Regulatory Assessment Requirements**

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the

distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: July 2, 2002.  
**Debra Edwards,**  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

**Authority:** 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.458 is amended by removing the entries for "Alfalfa, forage"; "Alfalfa, hay"; "Dry beans"; "Peanuts"; "Peanut, hay"; and "Peanut, meal" from the table in paragraph (a)(2) and 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
Alfalfa, forage .....	6.0
Alfalfa, hay .....	10
Bean, dry .....	2.5
.....*	
Brassica, leafy greens, subgroup .....	3.0
.....*	
Peanut .....	3.0
Peanut, hay .....	3.0
Peanut, meal .....	5.0
Peppermint, tops .....	5.0
.....*	
Spearmint, tops .....	5.0
Spinach .....	2.0
.....*	
Turnip, greens .....	3.0
.....*	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0068; FRL-7177-7]

Benomyl; Tolerance Revocations

**AGENCY:** Environmental Protection Agency (EPA).  
**ACTION:** Final rule.

**SUMMARY:** This document revokes all tolerances for residues of the fungicide benomyl because this pesticide active ingredient is no longer registered for food uses in the United States. The regulatory actions in this document are part of the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q), as amended by the Food Quality

Protection Act (FQPA) of 1996. By law, EPA is required by August 2002 to reassess 66% of the tolerances in existence on August 2, 1996, or about 6,400 tolerances. The regulatory actions in this document pertain to the revocation of 100 tolerances which are counted among tolerance/exemption reassessments made toward the August, 2002 review deadline.

**DATES:** This regulation is effective October 15, 2002; however, certain regulatory actions will not occur until the date specified in the regulatory text. Objections and requests for hearings, identified by docket control number OPP-2002-0068, must be received by EPA on or before September 16, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-2002-0068

in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8037; e-mail address: nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS codes	Examples of Poten-tially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing