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). In addition, 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

Since this extension of an existing time-limited tolerance does 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

IV. 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 rule in the **Federal Register**. This 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: March 23, 1998.

James Jones,

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. 346a and 371.

§ 180.448 [Amended]

2. In § 180.448, by amending paragraph (b) by changing the date ''10/1/98'' to read ''10/1/99'' wherever it appears.

[FR Doc. 98–8794 Filed 4–7–98 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300642; FRL–5784–9]

RIN 2070–AB78

Clethodim; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, all expressed as clethodim in or on alfalfa, forage; alfalfa, hay; dry beans; peanuts; peanut, hay; peanut, meal; tomatoes; tomato, puree; tomato, paste. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170). The tolerances will expire on April 30, 2001.

DATES: This regulation is effective April 8, 1998. Objections and requests for hearings must be received byEPA on or before June 8, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300620], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300620], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300620]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-305-6224, e-mail: joanne.miller@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 1997 (62 FR 6530–6534) (FRL–5586–3), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by Valent U.S.A. Corporation, 1333 N. California Blvd., Walnut Creek, CA 94596. This notice included a summary of the petition prepared by Valent, the registrant. There were no comments

received in response to the notice of filing.

The petition requested that 40 CFR 180.458 be amended by establishing time-limited tolerances for combined residues of the herbicide clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, all expressed as clethodim, in or on alfalfa, forage at 6 part per million (ppm); alfalfa, hay at 10 ppm; dry beans at 2 ppm; peanuts at 3 ppm; peanut, hay at 3 ppm; peanut, meal at 5 ppm; tomatoes at 1 ppm; tomato, puree at 2 ppm; and tomato, paste at 3 ppm. This tolerance will expire on April 30, 2001.

I. Risk Assessment and Statutory Findings

New 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. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months

to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup was not regionally based.

II. 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 clethodim and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, all expressed as clethodim on alfalfa, forage at 6 ppm; alfalfa, hay at 10 ppm; dry beans at 2 ppm; peanuts at 3 ppm; peanut, hay at 3 ppm; peanut, meal at 5 ppm; tomatoes at 1 ppm; tomato, puree at 2 ppm; and tomato, paste at 3 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by clethodim are discussed below.

1. Several acute toxicology studies places the technical-grade herbicide in Toxicity Category II.

2. A 2-year rat chronic toxicity/carcinogenicity study found the compound to be noncarcinogenic to rats under the conditions of the study. The systemic no-observed-effect level (NOEL) was 500 ppm (approximately 19 milligram/kilograms/day (mg/kg/day)), and the systemic lowest-observed-effect-level (LOEL) was 2,500 ppm (approximately 100 mg/kg/day) based on the observed body weight gain, the increases in liver weights, and the presence of centrilobular hepatic hypertrophy.

3. An 18-month mouse carcinogenicity study which showed the compound to be noncarcinogenic to mice under the conditions of the study. The systemic NOEL was 200 ppm (8 mg/kg/day), and the systemic LOEL was 1,000 ppm (50 mg/kg/day) based on treatment-related effects on survival, red cell mass, absolute and relative liver weights, and microscopic findings in liver and lung.

4. A 1-year feeding study in dogs with a systemic NOEL of 1 mg/kg/day in both sexes and an LOEL of 75 mg/kg/day based on increased absolute and relative liver weights, and alteration and clinical chemistry.

5. A developmental toxicity study in rats with a developmental and maternal NOEL and LOEL of 100 and 350 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity were based on reductions in fetal body weight and increases in skeletal anomalies.

6. A developmental toxicity study in rabbits with a maternal toxicity NOEL and LOEL of 25 and 100 mg/kg/day, respectively. Maternal toxicity was manifested as clinical signs of toxicity and reduced weight gain and food consumption during treatment. Developmental toxicity was not observed, and therefore the developmental toxicity NOEL was 300 mg/kg/day, highest dose tested (HDT).

7. A two-generation reproduction study in the rat with parental toxicity NOEL and LOEL of 500 and 2,500 ppm (51 and 263 mg/kg/day), respectively, based on reductions in body weight in males, and decreased food consumption in both generations. The NOEL for reproductive toxicity was 2,500 ppm (263 mg/kg/day, HDT).

8. A mutagenicity test with *Salmonella* Ames assay showed nonmutagenicity in three strains. Clethodim imine sulfone was negative for reverse gene mutation in *Salmonella* and *E. Coli* exposed up to 10,000 ug/plate with or without activation. Clethodim was negative for chromosomal damage in bone marrow cells of rats treated orally up to toxic dose (1,500 mg/kg).

B. Toxicological Endpoints

1. *Acute toxicity*. There were no effects observed in oral developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, a dose and an endpoint were not selected.

2. *Short - and intermediate - term toxicity*— i. *Dermal absorption*. In a dermal penetration study, groups of 12 male Sprague-Dawley rats received a single dermal application of [^{14}C]-clethodim in deionized water at 0.05, 0.5, or 5 mg/rat onto an area of 10 cm^2. Dermal absorption was assessed in 4 rats/dose/time period after 2, 10 and 24 hours post-treatment. A dermal absorption factor of 30% was selected for risk assessment based on the results observed at 10 hours in rats administered the 0.05 mg/rat dose.

ii. *Short-term toxicity* . A dermal equivalent dose was calculated as 350 mg/kg/day. This dermal equivalent dose was estimated by applying the 30% dermal absorption (DA) rate to the oral NOEL of 100 mg/kg/day in a rat developmental toxicity study (oral NOEL 100 / 30% DA x 100 = 333 mg/kg/day, dermal equivalent dose). Similarly, when the 30% DA is applied to the oral LOEL of 350 mg/kg/day in that study, the resulting dermal equivalent dose of 1167 mg/kg/day (oral LOEL 350 / 30% DA x 100) approximates the LOEL of 1,000 mg/kg/day established in the 21-day dermal study.

In a 21-day dermal toxicity study with technical clethodim, there was a wide range between the mid (100 mg/kg/day) and the high (1,000 mg/kg/day) doses. This broad range obscured the detection of a true NOEL which could have been anywhere in between these doses which were the study NOEL (100 mg/kg/day) and the LOEL (1,000 mg/kg/day). The Office of Pesticide's Health Effects Division's Hazard Identification Review Committee (HAZID Committee) also noted the 10-fold difference between the LOELs established with the Technical (1,000 mg/kg/day) and Formulated (100 mg/kg/day) products in the 21-day dermal toxicity studies. Therefore, based on these factors, the HAZID Committee calculated a dermal equivalent dose for short-term occupational and residential risk assessments.

iii. *Intermediate-term toxicity.* A dermal equivalent dose was calculated as 75 mg/kg/day. This dermal equivalent dose was estimated by applying the 30% dermal absorption (DA) rate to the oral NOEL of 25 mg/kg/day in the dog oral toxicity study (oral NOEL/30% DA x 100 = 75 mg/kg/day, dermal equivalent dose).

This dose (25 mg/kg/day) is supported by the NOEL of 30 mg/kg/day established in the 90-day oral feeding study in rats. In that study, the LOEL of 134 mg/kg/day was based on increased absolute and relative liver weights as well as increases in centrilobular hypertrophy. Liver was shown to be the target organ for clethodim-induced toxicity at comparable doses in two species, dogs and rats.

Since an oral dose was identified, a dermal absorption (DA) rate of 30% should be used for risk assessments. Application of the 30% DA is applied to the oral NOEL in the dog (25 mg/kg/day) and rat (30 mg/kg/day), and yields dermal equivalent doses of 75 and 100 mg/kg/day (25/30 mg/kg/day / 30% x 100 = 75/100 mg/kg/day), which approximates the NOEL of 100 mg/kg/day established in the 21-day dermal toxicity study with the technical product.

3. *Chronic toxicity.* EPA has established the RfD for clethodim at 0.01 mg/kg/day. This RfD is based on alterations in hematology, a clinical chemistry parameter and increased absolute and relative liver weights at 75 mg/kg/day observed in a chronic toxicity study in dogs with a NOEL of 1 mg/kg/day. An uncertainty factor of 100 was used in calculating the RfD to account for both inter- and intra-species variations.

4. *Carcinogenicity.* The Office of Pesticide Programs' Health Effects Division's Carcinogenicity Peer Review Committee (CPRC) has classified clethodim in Group E carcinogen (no evidence of carcinogenicity) under the Agency's ''Guidelines for Carcinogen Risk Assessment,'' published in the **Federal Register** of September 24, 1986 (51 FR 33992). In its evaluation, CPRC gave consideration to the weight change in the 2-year feeding study in rats and the 18 month feeding study in mice.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.458) for the combined residues of clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, all expressed as clethodim, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from clethodim as follows:

i. *Acute exposure and risk.* 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. No acute dietary endpoint was determined for clethodim, so an acute risk assessment was not required.

ii. *Chronic exposure and risk.* The chronic dietary exposure analysis from food sources was conducted using the reference dose (RfD) of 0.01 mg/kg/day and an uncertainty factor (UF) of 100 applicable to all population subgroups. In conducting this chronic dietary (food) risk assessment, residues were used for alfalfa, dry beans, peanuts and tomatoes, and all other commodities with published or pending, permanent or time-limited clethodim tolerances. Residues were used at tolerance levels for some of these crops and at anticipated residue levels for others. Thus, this risk assessment should be viewed as partially refined. Further refinement using additional anticipated residue levels and percent crop-treated information would result in a lower estimate of chronic dietary exposure.

The estimated exposure levels for existing and proposed clethodim uses vary between 0.001034 and 0.008411 mg/kg/day for the population subgroups (the U.S. population (48 states)), those for infants and children, females (13 to 19 years old, not pregnant and not nursing), and the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states); and occupied between 10% and 84% of the RfD.

When EPA establishes, modifies, or leaves in effect a tolerance, section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided five years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than five years from the date of issuance of this tolerance.

2. *From drinking water.* Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic drinking water levels of concern (DWLOC) for drinking water were calcualted. To calculate the DWLOC, the chronic dietary food exposure (from the DRES analysis) was subtracted from the RfD.

For chronic exposure, based on an adult body weight of 70 kg and 2L consumption of water per day, the level of concern from chronic exposure estimates for the U.S. population is 212 ppb and 1031 ppb for females 13 years and older, not pregnant or nursing. For infants and children (10 kg and 1L water/day) our level of concern for drinking water is 16 ppb. Agency estimates for contamination of drinking water from the registered uses of clethodim is 10 ppb. This level is lower than the chronic DWLOCs for the U.S. population (212 ppb) and females 13 years and older, not pregnant or nursing (1,031 ppb), and infants and children (16 ppb). Therefore, EPA concludes with reasonable certainty that the chronic exposure to clethodim in surface water is less than our level of concern.

3. *From non-dietary exposure.* Clethodim is currently registered for use on the following residential non-food sites: ornamental plants, wooden containers for growing plants, along driveways, patios, golf course turf, walkways, trails, and paths. There are no indoor uses registered for clethodim. It is conceivable that these outdoor uses could result in residential exposure. However, under current EPA criteria, the registered and proposed uses of clethodim would not constitute a chronic residential exposure scenario. Clethodim does not control broadleaf weeds and therefore is registered for use on edges and walkways, thus greatly reducing the risk of residential exposure.

The short- and intermediate aggregate MOEs for residential applicators using a low pressure handwand ranged from 7,300 to 1,600. The post-application aggregate short- and intermediate-term MOEs for the U.S. population ranged from 520 to 110. The post-application aggregate short- and intermediate-term MOEs for infants/children range from 540 to 115. Short- and intermediate-term aggregate exposure takes into account chronic dietary exposure plus indoor and outdoor residential exposures. These exposure assessments assumed the maximum application rate for turf and garden uses and two hours as the duration of exposure, and a 20% dislodgeable foliar residue. These assumptions are considered conservative and protective.

4. *Cumulative exposure to substances with 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* There were no effects observed in oral developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, a dose and an endpoint were not selected, and EPA concludes that there is a reasonable certainty that no harm will result from aggregate acute exposure to clethodim residues.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to clethodim from food will utilize 39% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children one to six years of age and is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to clethodim in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate chronic exposure to clethodim residues.

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

Clethodim is registered for uses that could result in short- and intermediate-term exposures. The short- and intermediate aggregate margins of exposure (MOEs) for residential applicators using a low pressure handwand ranged from 7,300 to 1,600. The postapplication aggregate short- and intermediate-term MOEs for the U.S. population ranged from 520 to 110. The postapplication aggregate short- and intermediate-term MOEs for infants/children range from 540 to 115. Short- and intermediate-term aggregate exposure takes into account chronic dietary exposure plus indoor and outdoor residential exposures. These exposure assessments assumed the maximum application rate for turf and garden uses and two hours as the duration of exposure, and a 20% dislodgeable foliar residue. These assumptions are considered conservative and protective. Short- and intermediate term MOEs for occupational workers ranged from 620 for aerial mixer/loaders to 60,000 for ground applicators. These estimates do not exceed EPA's level of concern. EPA concludes that there is a reasonable certainty that no harm will result from aggregate short- and intermediate-term exposure to clethodim residues.

E. Aggregate Cancer Risk for U.S. Population

Clethodim has been classified as a Group E chemical (no evidence of carcinogenicity), and EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to clethodim residues.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the

potential for additional sensitivity of infants and children to residues of clethodim, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 pre-and post-natal toxicity and the completeness of the database 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a prenatal developmental toxicity study in Sprague-Dawley rats, clethodim (82.6%) was administered at doses of 0, 10, 100, 350, or 700 mg/kg/day by gavage in 10 mg/kg of 0.7% carboxy methylcellulose and Tween 80 on gestation days 6-15. For maternal toxicity, the NOEL was 100 mg/kg/day and the LOEL was 350 mg/kg/day based upon decreased body weight gain and clinical signs of toxicity (salivation). The developmental NOEL was 100 mg/kg/day and the developmental LOEL was 350 mg/kg/day, based upon reductions in fetal body weight and an increase in the incidence of skeletal anomalies.

A prenatal developmental toxicity study was conducted in pregnant New Zealand white rabbits in which clethodim (82.6%) was administered by gavage in 5 ml/kg at doses of 0, 25, 100, or 300 mg/kg/day in 0.7% carboxy methylcellulose and Tween 80 on gestation days 7-19. For maternal toxicity, the NOEL was 25 mg/kg/day and the LOEL was 100 mg/kg/day, based on clinical signs of toxicity (dried feces and blood in the cage pan) and reduced body weight and food consumption during treatment. There was no developmental toxicity noted. For developmental toxicity, the NOEL was ≥ 300; a LOEL was not established.

iii. *Reproductive toxicity study.* In a two-generation reproductive study, Sprague-Dawley rats received clethodim (83.2%) in the diet at 0, 5, 20, 500, or 2,500 ppm. The parental systemic NOEL was 500 ppm (51 mg/kg/day) and the parental systemic LOEL was 2,500 ppm (263 mg/kg/day), based on decreased body weights (particularly in males) and food consumption for both generations. There were no effects on reproduction, nor was there evidence of toxicity to the offspring (offspring NOEL ≥ 2,500 ppm).

iv. *Pre- and post-natal sensitivity.* The data base is complete. The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to in utero exposure to clethodim. Therefore, EPA concludes that reliable data show that the standard uncertainty factor of 100 will be safe for infants and children.

2. *Acute risk.* There were no effects observed in oral developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, a dose and an endpoint were not selected, and EPA concludes that there is a reasonable certainty that no harm will result from aggregate acute exposure to clethodim residues.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to clethodim from food will utilize 45% of the RfD for non-nursing infants less than one year old, and 84% for children ages one through six years of age. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to clethodim in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to clethodim residues.

4. *Short- or intermediate-term risk.* The postapplication aggregate short- and intermediate-term MOEs for infants/children range from 540 to 115. Short- and intermediate-term aggregate exposure takes into account chronic dietary exposure plus indoor and outdoor residential exposures. These exposure assessments assumed the maximum application rate for turf and garden uses and two hours as the duration of exposure, and a 20% dislodgeable foliar residue. These assumptions are considered conservative and protective. These estimates do not exceed EPA's level of concern. EPA concludes that there is a reasonable certainty that no harm will result from aggregate short- and intermediate-term exposure to clethodim residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of clethodim residues in plants, ruminants, and poultry is adequately understood for the purposes of these subject petitions. The residues of concern are as defined in 40 CFR 180.485(b).

B. Analytical Enforcement Methodology

Analytical methods are available for enforcement. Method EPA-RM-26D-2 [HPLC-UV], ''Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissues, and Mail and Eggs,'' which distinguishes clethodim residues from residues of the structurally similar herbicide sethoxydim, and Method RM-26B-2 [GLC-FPD-S], ''Analytical Method for the Determination of Clethodim Residues,'' the common moiety method, have undergone successful EPA Method Validation. Revisions to EPA-RM-26D-2 are requested prior to establishment of permanent tolerances on these subject crops. The method may be obtained from: Calvin Furlow, PRRIB, IRSD, (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 119FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5229).

C. Magnitude of Residues

The crop field trial data are adequate for the purposes of these time-limited tolerances. To support future permanent tolerances, Valent U.S.A. Corp. must submit three additional dry bean field trials from Region 5, four additional peanut field trials from Region 2, and four additional tomato field trials from California, each conducted at the maximum use rates and proposed pre-harvest intervals. Field trial regions are defined in EPA OPPTS Guideline 860.1500.

D. International Residue Limits

There are no Codex, Canadian or Mexican tolerances or maximum residue limits established for clethodim

on tomatoes, alfalfa, peanuts, or dry beans. There are no conflicts between this proposed action and international residue limits.

E. Rotational Crop Restrictions

A confined rotational crop study of [ring-4,6-^{14}C]-clethodim with carrots, lettuce, and wheat was reported. Results indicate there is no need for field rotational crop trials.

IV. Conclusion

Therefore, the time-limited tolerances are is established for combined residues of clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, all expressed as clethodim in alfalfa, forage at 6 ppm; alfalfa, hay at 10 ppm; dry beans at 2 ppm; peanuts at 3 ppm; peanut, hay at 3 ppm; peanut, meal at 5 ppm; tomatoes at 1 ppm; tomato, puree at 2 ppm; and tomato, paste at 3 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 8, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300620] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the time-limited tolerances 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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 the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: April 3, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

Authority: 21 U.S.C. 346a and 371.

b. Section 180.458 is amended as follows:

i. By adding a heading to paragraph (a) and designating the text as paragraph (a)(1).

ii. By adding paragraph (a)(2).

iii. By redesignating paragraph (b) as paragraph (a)(3).

iv. By adding with headings and reserving paragraphs (b), (c), and (d).

The added text reads as follows:

§ 180.458 Clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one); tolerances for residues.

(a) *General.* * * *

(2) Time-limited tolerances are established for the combined residues of 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)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Alfalfa, forage	6	4/30/01
Alfalfa, hay	10	4/30/01
Dry beans	2	4/30/01
Peanut, hay	3	4/30/01
Peanut, meal	5	4/30/01
Peanuts	3	4/30/01
Tomatoes	1	4/30/01
Tomato, paste ...	3	4/30/01
Tomato, puree ...	2	4/30/01

* * * * *

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

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

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

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.1075 [Removed]

b. In § 185.1075:

i. By transferring the text and table to § 180.458 and redesignating as paragraph (a)(4).

ii. The remainder of § 185.1075 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.1075 [Removed]

b. In § 186.1075:

i. Paragraphs (a) and (b) are transferred to § 180.458 and redesignated as paragraphs (a)(5) and (a)(6) respectively.

ii. The remainder of § 186.1075 is removed.

[FR Doc. 98–9392 Filed 4–7––98; 8:45 am]

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 206

RIN 3067–AC67

Disaster Assistance; Public Assistance Program Appeals; Hazard Mitigation Grant Program Appeals

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This final rule changes the procedure for the review and disposition of appeals related to Public Assistance grants or related to the Hazard Mitigation Grant Program (HMGP). The rule reduces from three to two the number of appeals allowed and thus will allow faster final determination of decisions on appeal.

EFFECTIVE DATE: This rule is effective May 8, 1998.

FOR FURTHER INFORMATION CONTACT: Robert F. Shea, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3619, (facsimile) (202) 646–3104, about HMGP appeals; or Melissa M. Howard, Response and Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3053, facsimile (202) 646–3304, about Public Assistance appeals.

SUPPLEMENTARY INFORMATION:

Background

Under § 423 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5189a, any decision regarding eligibility or amount of assistance may be appealed. Current FEMA regulations at 44 CFR 202.206 and 206.440 provide for a three-stage appellate process, with appeals directed to the Regional Director, the Associate Director, and to the Director.

Proposed Rule

On November 24, 1997 FEMA published a proposed rule, 62 FR 62540—62542, to reduce from three to one the number of appeals allowed. As proposed, the authority for appeal decisions would have rested solely with the Regional Director, who would have had to consult with FEMA Headquarters on all potential appeal denials when the amount in question was $1,000,000 or more in Federal funds.

Public Comments

FEMA received 29 responses to the proposed rule. The most cited argument against placing the final agency decision