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: August 30, 2001.

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. 321(q), 346(a) and 371.

2. Section 180.535 is amended by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *		
Grass, forage	120	6/30/03
Grass hay	160	6/30/03
Kidney, cattle	1.5	6/30/03
Kidney, goat	1.5	6/30/03
Kidney, hog	1.5	6/30/03
Kidney, horse	1.5	6/30/03
Kidney, sheep	1.5	6/30/03
Milk	0.30	6/30/03

* * * * *

[FR Doc. 01–23092 Filed 9–14–01; 8:45am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301168; FRL–6800–9]

RIN 2070–AB78

Clethodim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of clethodim in or on green onion, leaf lettuce, Brassica, head and stem, subgroup, flax seed, flax meal, mustard seed, canola seed, and canola meal. The Interregional Research Project Number-4 (IR-4) and Valent U.S.A. Corporation requested these tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This final rule establishes permanent tolerances for clethodim and as part of that process the Agency has reassessed existing tolerances. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. All permanent tolerances for clethodim that existed on August 2, 1996 were previously reassessed in the **Federal Register** of April 8, 1998 (63 FR 17101) (FRL–5784–9). Consequently, regarding the actions in this final rule, no tolerance reassessments are counted toward the August 2002 review deadline of FFDCA section 408(q).

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301168, must be received by EPA on or before November 16, 2001.

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 control number OPP–301168 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; and 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_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301168. 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 December 3, 1997 (62 FR 63942) (FRL–5756–1) EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a as amended by FQPA (Public Law 104–170) announcing the filing of pesticide petitions (PP 0E6202 and 1E6249) for tolerances by IR-4, 681 U.S. Highway #1 South, North New Brunswick, NJ 08902 and PP 7F4873 by Valent U.S.A. Corporation, 1333 N. California Blvd., Walnut Creek, California 94596. These notices included summaries 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 combined residues of the herbicide clethodim, [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one) moieties and their sulphoxides and sulphones, all expressed as clethodim, on various commodities as follows:

(1). *PP 1E6249*. IR-4 proposed tolerances for green onion and leaf lettuce at 2.0 parts per million (ppm), and Brassica head and stem subgroup at 3.0 ppm.

(2). *PP 0E6202*. IR-4 proposed tolerance for flax seed and mustard seed at 0.5 ppm and flax meal at 1.0 ppm.

(3). *PP 7F4873*. Valent U.S.A. Corporation proposed tolerances for canola seed at 0.5 ppm and canola meal at 1.5 ppm. The petition was subsequently amended to propose tolerances for canola seed at 0.5 ppm and canola meal at 1.0 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 these actions. 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 combined residues of clethodim on green onion at 2.0 ppm, leaf lettuce at 2.0 ppm, Brassica head and stem subgroup at 3.0 ppm, flax seed at 0.50 ppm, flax meal at 1.0 ppm, mustard seed at 0.50 ppm, canola seed at 0.50 ppm, and canola meal at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances 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 in Unit III.A. of the **Federal Register** of March 14, 2001 (66 FR 14829) (FRL–6770–8).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer}= point of departure/exposures) is calculated. A summary of the toxicological endpoints for clethodim used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLETHODIM FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary All populations	Not applicable	Not applicable	None Selected There were no effects observed in oral toxicity studies including developmental toxicity studies in rats and rabbits that could be attributable to a single dose (exposure). Therefore, a dose and endpoint were not selected for this risk assessment.
Chronic dietary All populations	NOAEL = 1.0 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD÷FQPA SF = 0.01 mg/kg/day	Chronic toxicity-Dog (1 year). Alterations in hematology and clinical chemistry parameters and increased absolute and relative liver weights observed at the LOAEL of 75 mg/kg/day.
Short-term dermal (1 to 7 days) (Residential)	Oral study maternal NOAEL = 100 mg/kg/day (Dermal absorption rate = 30%)	LOC for MOE = 100 (Residential)	Developmental toxicity-Rat. LOAEL = 350 mg/kg/day based on decreased body weight gain and clinical signs of toxicity (salivation).
Intermediate-term dermal (1 week to several months) (Residential)	Oral study NOAEL = 25 mg/kg/day (Dermal absorption rate = 30%)	LOC for MOE = 100 (Residential)	Subchronic toxicity-Dog (90 days). LOAEL = 75 mg/kg/day based on increased absolute and relative liver weights.
Long-term dermal (several months to lifetime) (Residential)	Oral study NOAEL = 1.0 mg/kg/day (Dermal absorption rate = 30%)	LOC for MOE =100 (Residential)	Chronic toxicity-Dog (1 year). LOAEL = 75 mg/kg/day based on alterations in hematology and clinical chemistry parameters as well as increases in absolute and relative liver weights.
Short-term inhalation (1 to 7 days) (Residential)	Oral study Maternal NOAEL= 100 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE =100 (Residential)	Developmental-Rat LOAEL = 350 mg/kg/day based on decreased body weight gain and clinical signs of toxicity (salivation).
Intermediate-term inhalation (1 week to several months) (Residential)	Oral study NOAEL = 25 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Subchronic toxicity-Dog (90 days). LOAEL = 75 mg/kg/day based on increased absolute and relative liver weights.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLETHODIM FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Long-term inhalation (several months to lifetime) (Residential)	Oral study NOAEL = 1.0 mg/kg/day (Dermal absorption rate = 30%)	LOC for MOE =100 (Residential)	Chronic toxicity-Dog (1 year). LOAEL = 75 mg/kg/day based on alterations in hematology and clinical chemistry parameters as well as increases in absolute and relative liver weights.
Cancer (oral, dermal, inhalation)	N/A	N/A	Clethodim is classified as a ''Not Likely'' carcinogen

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

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 food commodities. Recent tolerances established for the 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 include tuberous and corm vegetables crop subgroup 1c, fruiting vegetables crop group, root vegetables (except sugar beets) crop subgroup 1b, leaves of root and tuber vegetables (excluding sugar beets, crop group 2), sugar beet, tops and sugar beet, molasses at 1.0 ppm, leaf petioles crop subgroup 4b at 0.6 ppm, melon crop subgroup 9a at 2.0 ppm, squash/cucumber crop subgroup 9b and cranberry at 0.5 ppm, sugar beets, roots at 0.20 ppm, sunflower seed at 5.0 ppm, strawberry at 3.0 ppm, sunflower, meal and clover, forage at 10.0 ppm, and clover, hay at 20.0 ppm. 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: The 3–day average of consumption for each sub-population is combined with residues to determine average exposure as mg/kg/day. The chronic analysis was performed using tolerance level residues for all crops and livestock commodities. Projected percent crop treated (PCT) data were used for lettuce, broccoli, cauliflower, cabbage, onions, and Brussels sprouts. Weighted average percent of crop treated data were used for certain existing registrations (cotton, onions, peanuts, soybeans, sugar beets, and tomatoes) and 100% crop treated data were used for the remaining new uses and existing uses.

iii. *Cancer.* Clethodim has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. 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 subpopulation 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 PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information for certain registered uses as follows:

- 3% for cotton;
- 8% for onions;
- 3% for peanuts;
- 4% for soybeans;
- 15% for sugar beets, and
- 1% for tomatoes.

The Agency used PCT information for the new uses as follows:

- 2% for lettuce, broccoli and cauliflower;
- 15% for cabbage;
- 25% for onion, and
- 1% for brussels sprouts.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates were derived for the registered uses (cotton, onions, peanuts, soybeans, sugar beets and tomatoes) 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. With respect to the new uses (lettuce, broccoli, cabbage, and onion) the registrant estimated PCT based on percent market share information. The registrant based their projected clethodim PCT for these new uses based on the share of each crop that is treated with registered herbicides that control the same pests. They then projected what part of the market they could capture from those products. The Agency used a similar process for projecting percent of crop treated for Brussels sprouts and cauliflower. The Agency considers the clethodim percent of crop treated projections to be reasonable and conservative.

As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which clethodim may be applied in a particular area.

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

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 Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. 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 percent referenced dose or percent population adjusted dose. 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 below. Tier 1 surface water concentrations for parent clethodim and total toxic residues (parent + sulfoxide + sulfone) were estimated using the GENEEC model. Based on the GENEEC model, the peak EECs of clethodim for surface water were estimated to be 24.2 parts per billion (ppb), and 18.3 ppb for chronic exposure. The agency allows for a 3–fold reduction of GENEEC 56–day estimates, which result in a chronic value of 6.1 ppb for surface water. Based on the SCI-GROW model, the EECs of clethodim for ground water were estimated to be 0.49 ppb for acute exposure and 0.08 ppb for chronic exposure.

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 not registered for use on any sites that would result in residential exposure. Based on recently revised clethodim labels, there are no use sites through which homeowners or the public are likely to become exposed to clethodim residues, either directly through application or indirectly by contact with residues on treated surfaces. Therefore, non-occupation 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 is complete or is estimated based on data that reasonably account for potential exposures. Based on the above, EPA determined that the 10X safety factor to protect infants and children should be removed.

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, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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 for acute dietary exposure was not identified since no effects were observed in oral toxicity studies that could be attributable to a single dose.

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 30% of the cPAD for the U.S. population, 23% of the cPAD for females (13–50 years old) and 61% of the cPAD for children 1–6 years old. There are no residential uses for clethodim that result in chronic residential exposure to clethodim. 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 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO CLETHODIM

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population (total)	0.01	30%	6.1	0.08	250
Children (1–6 years)	0.01	61%	6.1	0.08	40
Females (13–50 years)	0.01	23%	6.1	0.08	230

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

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

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

5. *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

Method RM-26A-1, a gas-liquid chromatographic (GLC) procedure, was validated for the analyses of residues of clethodim sulfoxide and its metabolite (5-OH clethodim sulfone) in/on flax at fortification levels of 0.05 ppm and 0.5 ppm, and on canola at a fortification level of 0.2 ppm. Method RM-26A-1 can determine all clethodim metabolites retaining the cyclohex-1-one moiety (DME and DME-OH). The Method RM-26A-1 for the determination of clethodim and its metabolites in mustard, seed and flax is acceptable for data collection.

Method RM-26B-2 was validated for the analyses of residues of clethodim sulfoxide and its metabolite (5-OH clethodim sulfone) in/on broccoli. The fortification levels for clethodim sulfoxide and 5-OH-clethodim sulfone were each 0.05 ppm, 1.0 ppm and 2.0 ppm. Recoveries of residues of clethodim sulfoxide in broccoli were within the acceptable range at the fortification level of 0.05 ppm. Recoveries of residues of 5-OH-clethodim sulfone in broccoli were within the acceptable range at fortification levels of 0.05, 1.0 and 2.0 ppm. Recoveries of residues of clethodim sulfoxide in broccoli were low at the fortification levels of 1.0 and 2.0 ppm. The Method RM-26B-2 for the determination of clethodim and its metabolites in broccoli is acceptable for data collection and enforcement purposes.

Method RM-26B-3 (a modification of RM-26B-2) was validated for the analyses of residues of clethodim sulfoxide and its metabolite (5-OH clethodim sulfone) in/on green onions, leaf lettuce, and cabbage. The fortification levels for clethodim sulfoxide and 5-OH clethodim sulfone were 0.11 ppm - 2.0 ppm for green onions, 0.11 ppm - 0.91 ppm for leaf lettuce, 0.11 ppm - 1.1 ppm for cabbage. Recoveries of residues of clethodim sulfoxide in green onions, leaf lettuce, and cabbage were within the acceptable range at all fortification levels tested. Recoveries of residues of 5-OH-clethodim sulfone were within the acceptable range except for low recoveries in green onions fortified at 2.0 ppm and cabbage fortified at 0.77 and 0.98 ppm. The Method RM-26B-3 for the determination of clethodim and its metabolites in green onions, leaf lettuce, and cabbage is acceptable for data collection.

The common moiety Method RM-26B-3 for the determination of clethodim and its metabolites is similar to the common moiety Method RM-26B-2. The Method RM-26B-2 has previously undergone a successful Petition Method Validation by the Agency. Method RM-26B-2 as an enforcement method and Method RM-26B-3 as a letter method have been forwarded to FDA for inclusion in PAM II.

Livestock feed items are associated with canola and flax seed uses. The Agency has previously concluded that adequate analytical methodology is available to enforce tolerances for residues of clethodim in livestock commodities. The compound specific method, EPA-RM-26D-2, is suitable for enforcement of tolerances for total clethodim residues in crops and livestock tissues, and it has been forwarded to FDA for publication in the Pesticide Analytical Manual, Volume II (PAM II). The common moiety method, RM-26B-2, serves as the enforcement method for milk as RM-26D-2 and is not quantitative for residues in milk.

The Methods may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort George G. Mead, Maryland, 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no established Codex maximum residue limits (MRLs) 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. Codex MRLs are currently established on various crop and livestock commodities in terms of the sum of clethodim and its metabolites containing 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim. There are established Canadian residue limits for clethodim residues and its metabolites containing the 2-cyclohex-1-enone moiety on mustard, seed at 0.4 ppm, on flax at 0.3 ppm and on canola at 0.5 ppm. However, based on the submitted residue data, HED can not harmonize the tolerances of flax and mustard, seed with Canadian residue limits.

C. Conditions

The registration for the use of clethodim on leaf lettuce will be made conditional based upon the need for additional crop field trial data for clethodim on leaf lettuce. The registration for use of clethodim on canola and flax will be made conditional based upon the requirement for a canola processing study.

V. Conclusion

Therefore, tolerances are established for 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], in or on green onion at 2.0 ppm, leaf lettuce at 2.0 ppm, brassica head and stem subgroup at 3.0 ppm, flax seed at 0.50 ppm, flax meal at 1.0 ppm, mustard seed at 0.50 ppm, canola seed at 0.50 ppm, and canola meal at 1.0 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 control number OPP–301168 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 November 16, 2001.

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 e-mail at 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 control number OPP–301168, 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. 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 as required 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: September 6, 2001

Peter Caulkins,

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 371.

2. Section 180.458 is amended by revising the section heading, the introductory text paragraph (a)(3), and alphabetically adding commodities to the table in paragraph (a)(3) to read as follows:

§ 180.458 Clethodim; tolerances for residues.

(a) * * *

(3) Tolerances are established for the combined residues of the herbicide clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones, expressed as clethodim tolerance residues for the following commodities.

Commodity	Parts per million
* * * * *	
Brassica, head and stem, subgroup	3.0
Canola, meal	1.0
Canola, seed	0.50
* * * * *	
Flax, meal	1.0
Flax, seed	0.50
* * * * *	
Lettuce, leaf	2.0
* * * * *	
Mustard, seed	0.50
* * * * *	
Onion, green	2.0
* * * * *	

* * * * *

[FR Doc. 01–23086 Filed 9–14–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301171; FRL–6801–1]

RIN 2070–AB78

Zeta-cypermethrin and its Inactive R-isomers; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zeta-cypermethrin and its inactive R-isomers in or on alfalfa, hay at 15 parts per million (ppm), alfalfa, forage at 5.0 ppm, alfalfa, seed at 0.5 ppm; beets, sugar, roots at 0.05 ppm, beets, sugar, tops at 0.20 ppm; corn, field, grain at 0.05 ppm, corn, pop, grain at 0.05 ppm, corn, field, forage at 0.20 ppm, corn, field, stover at 3.0 ppm, corn, pop, stover at 3.0 ppm, corn, sweet, (K + CWHR) at 0.05 ppm, corn, sweet, forage at 15 ppm, corn, sweet, stover at 15 ppm; onions, green at 3.0 ppm; leafy vegetables except Brassica at 10 ppm, head and stem Brassica at 2.0 ppm, leafy Brassica at 14 ppm; sugarcane at 0.6 ppm; rice, grain at 1.5 ppm, rice, straw at 2.0 ppm, rice, hulls at 6.0 ppm; fat of cattle, goat, horse, sheep, hogs at 1.0 ppm, meat of cattle, goat, horse, sheep, hogs at 0.1 ppm, milk, fat at 2.50 ppm (reflecting 0.10 ppm in whole milk), poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, poultry, meat by-products at 0.05 ppm, and eggs at 0.05 ppm. FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301171, must be received by EPA on or before November 16, 2001.

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 control number OPP–301171 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda A. DeLuise, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460; telephone number: (703) 305–5428; e-mail address: deluise.linda@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: