II. Tentative Agenda

This unit provides tentative agenda topics for the 2–day meeting.

1. FIFRA sections 18 and 24(c)/tribal authority under FIFRA.
2. Basic elements of tribal pesticide.
3. Native American Graves Protection and Repatriation Act issues and updates.
4. Integrated Pest Management (IPM)/ focus on schools and structural.
5. Federal inspector credentials.
6. Worker protection presentation.
7. Presentation by Gila River Indian Community Pesticide Program Reports from TPPC Working Groups.
8. Office of Pesticide Program up-date on funding awards for special projects and water quality.
9. Office of Enforcement and Compliance Assurance up-date on funding, data collections issues, and training.

List of Subjects

Environmental protection, Pesticides.

Dated: August 14, 2001.

Jay Ellenberger,

Acting Division Director, Field and External Affairs Division, Office of Pesticide Programs.

[FR Doc. 01–21446 Filed 8–23–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1038; FRL–6796–7]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1038, must be received on or before September 24, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1038 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: jamerson.hoyt@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'' ''Regulation 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/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1038. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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 Highway, 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1038 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1038. Electronic comments

may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:August 9, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

EPA has received pesticide petitions [0E6202 and 1E6249] from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the herbicide chemical 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-ethylthio-propyl) cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, all expressed as clethodim] in or on the raw agricultural commodities: (1) pesticide petition (1E6249) proposes tolerances for green onions and leaf lettuce at 2.0 ppm, and head and stem Brassica (Crop subgroup 5A) at 3.0 parts per million (ppm), (2) pesticide petition (0E6202) proposes tolerances for flax seed at 0.50 ppm, flax meal at 1.0 ppm, and mustard seed at 0.50 ppm.

EPA has determined that the petition contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

Interregional Research Project Number 4 (IR-4)

PP 0E6202 and 1E6249

A. Background Information and Use Profile

Clethodim is the active ingredient in SELECT 2 EC Herbicide (EPA Reg. No. 59639–3), SELECT Herbicide (also known as PRISM Herbicide, EPA Reg. No. 59639–78), and SELECT SUPER Herbicide (EPA Reg. No. 59639-102) post-emergence herbicides effective against a wide range of annual and perennial grasses. Clethodim Technical is registered by the EPA (EPA Reg. No. 59639–2) as a technical grade active ingredient for manufacturing use. SELECT 2 EC Herbicide is registered for use on alfalfa; cotton; dry beans; peanuts; onions, garlic, and shallots (all dry bulb); soybeans; sugar beets; tomatoes; and is an emulsifiable concentrate containing 2 pounds per gallon (26.4%) of active ingredient. SELECT Herbicide is registered for the same uses and is an emulsifiable concentrate containing 0.94 pounds per gallon (12.6%) of active ingredient. PRISM Herbicide is an alternate brand name for SELECT Herbicide. For optimum grass weed control, both SELECT 2EC and SELECT Herbicides require that adjuvant or crop oil concentrate be added to the spray solution. SELECT SUPER Herbicide is also an emulsifiable concentrate that includes the required adjuvant. SELECT SUPER Herbicide contains 1.0 pound per gallon (13.2%) of active ingredient and is registered on cotton, soybeans and sugar beets only. These products are applied to registered crops via broadcast foliar applications at rates up to 0.25 lb. Active ingredient/Acre (ai/A). For more difficult to control grass weeds, a second application within about 14 days is allowed. The maximum seasonal use rate is 0.5 lb. ai/A.

B. Residue Chemistry

1. *Plant and animal metabolism*. The metabolism of ^{14}C-clethodim labeled in the ring structure and in the side chain has been studied in carrots, soybeans, and cotton as well as in lactating goats and laying hens. The major metabolic pathway in plants is initial sulfoxidation, forming clethodim sulfoxide, followed by further oxidation to form clethodim sulfone. These reactions are apparently followed by elimination of the chloroallyloxy side

chain to give the imine sulfoxide and sulfone, with further hydroxylation to form the 5-OH sulfoxide and 5-OH sulfone. Clethodim sulfoxide and clethodim sulfone conjugates were also detected as major or minor metabolites, depending on plant species and subfractions. Once the side chain is cleaved from clethodim, the chloroallyloxy moiety undergoes extensive metabolism to eliminate chlorine and incorporate three-carbon moieties into natural plant components.

Ruminant and poultry metabolism studies demonstrated that transfer of administered ^{14}C-clethodim residues to tissues was low. Total ^{14}C-residues in goat milk, muscle and tissues accounted for less than 0.5% of the administered dose (24 ppm in diet for 3 days), and were less than 0.4 ppm in all cases. In poultry treated at 2.2 milligram/kilogram/day (mg/kg/day) for 5 days, total ^{14}C residues in eggs, muscle and most tissues were less than 0.3 ppm, although higher in liver, kidney and the gastrointestinal tract (GI tract). Residues in eggs were less than 0.2 ppm.

Comparing metabolites detected and quantified from plant and animal metabolism studies shows that there are no significant aglycones in plants which are not also present in the excreta or tissues of animals. Based on these metabolism studies, the residues of concern in crops and animal products are clethodim and its metabolites containing the cyclohexene moiety, and their sulfoxides and sulfones.

2. *Analytical method*. Practical analytical methods for detecting and measuring levels of clethodim and its metabolites have been developed and validated in/on all appropriate agricultural commodities, respective processing fractions, milk, animal tissues, and environmental samples. The extraction methodology has been validated using aged radio chemical residue samples from ^{14}C-metabolism studies. The methods have been validated at independent laboratories, and EPA has successfully performed an analytical method trial. For most commodities, the primary enforcement method is EPA-RM-26D-3, an high performance liquid chromotography (HPLC) method capable of distinguishing clethodim from the structurally related herbicide sethoxydim. However, for milk, natural interferences prevent adequate quantitation of clethodim moieties and the common-moiety method (RM-26B-2) is the primary enforcement method with EPA-RM-26D-3 as the secondary method if needed to differentiate clethodim from sethoxydim.

3. *Magnitude of residues*. A summary of field residue data supporting the proposed tolerances on green onion, leaf lettuce, head and stem brassica vegetables, flax and mustard seed is presented below.

(a) Green Onion: In three (3) field trials, onions (green) were treated with two post-emergent applications of 0.24 to 0.34 lb. a.i./A and harvested 13 to 15 days after the application. The trials were performed in EPA regions 3, 6, and 10. Residues in onions (green) ranged from <0.20 ppm to 0.87 ppm total clethodim. These residue data support a tolerance for green onion of 2.0 ppm.

(b) Leaf Lettuce: In six (6) field trials conducted in EPA regions 2, 3, and 10, leaf lettuce was treated with two post-emergent applications of 0.23 to 0.32 lb. a.i./A each. Lettuce was harvested 13–16 days after the last application. Clethodim residues ranged from <0.25 to <1.10 ppm total clethodim. These residue data support a tolerance for leaf lettuce of 2.0 ppm.

(c) Head and Stem Brassica: Proposed tolerances for Crop Subgroup 4B are supported by field residue studies in broccoli and cabbage. In six (6) field trials, broccoli was treated with two post-emergent applications of 0.24 to 0.34 lb. a.i./A each, 13–14 days apart, and harvested 29–31 days after the last application. Residues in broccoli ranged from <0.1 ppm to 1.20 ppm total clethodim. In seven (7) field trials, cabbage was treated with two post-emergent applications of 0.25 to 0.37 lb. a.i./A each, 14 days apart, and harvested 28–31 days after the last application. Residues in cabbage ranged from <0.24 ppm to 1.17 ppm total clethodim. These data support a tolerance of 3.0 ppm in head and stem brassica.

(d) Flax: In two (2) field trials, flax was treated with one post-emergent application of 0.09 lb. a.i./A and harvested approximately 84 to 108 days after the last application. These residue trials were performed in Canada in growing regions adjacent to the U.S. areas where flax is grown. These data were used to support a maximum residue level in Canada and are being cited in order to harmonize maximum residue levels between the U.S. and Canada and to remove the existing trade barrier. Clethodim residues ranged from <0.05 to 0.06 ppm total clethodim and support a tolerance for flax seed at 0.50 ppm.

(e) Mustard Seed: Tolerances for mustard seed are supported by residue field trials on flax, summarized above, and a similar oilseed crop, canola. In 18 field trials, canola or rape was treated with one post-emergent application of 0.11 to 0.32 lb. a.i./A and harvested approximately 70 to 98 days after the application. Most of these trials were performed in Canada in growing regions adjacent to the U.S. areas where canola is grown. These data were used to support a maximum residue level in Canada and were cited in a previous petition (7F4873) to harmonize maximum residue levels for canola between the U.S. and Canada and to remove the existing trade barrier. Residues in canola seed samples ranged from < 0.05 ppm to 0.54 ppm. The highest average field trial (HAFT) residue was 0.505 ppm. The averageresidue value for all trials, including samples less than the limit of detection at one-half the limit, was 0.16 ppm (number of samples = 31, standard deviation, n-1 degrees of freedom = 0.14 ppm). Since the highest residues were the result of application rates (0.19 lb. a.i./A) higher than those proposed for the U.S. (0.08 lb. a.i./A), these data support tolerances of 0.50 ppm in mustard seed.

Secondary Residues: The single feed item associated with these uses, flax meal, has potential anticipated clethodim residues well below other feed items with existing tolerances. Thus, clethodim residues in/on this proposed feed item does not effect the theoretical maximum dietary burden for the various livestock diets, and thus does not effect the magnitude of secondary residue tolerances. Therefore, no changes in existing secondary residue tolerances is being proposed.

Rotational Crops: The results of a confined rotational crops accumulation study indicate that no rotational crop tolerances are required.

C. Toxicological Profile

A full battery of toxicology testing including studies of acute, sub-acute, and chronic toxicity; carcinogenicity; developmental and reproductive toxicity; mutagenicity; and rat metabolism is available for clethodim. The acute toxicity of clethodim is low by all routes. Clethodim is not a developmental or reproductive toxicant, and is not mutagenic or carcinogenic. EPA has established a reference dose (RfD) for clethodim of 0.01 mg/kg bwt/day, based on alterations in hematology and increased absolute and relative liver weights at 75 mg/kg/day observed in a chronic toxicity study in dogs with a no observed adverse effect level (NOAEL) of 1 mg/kg/day. An uncertainty factor of 100 is used in calculating the reference dose RfD to account for both inter- and intra-species variations. EPA has (not) identified toxicity endpoints of concern for acute exposures.

1. *Acute toxicity*. Clethodim technical is slightly toxic to animals following acute oral (Toxicity Category III), dermal (Toxicity Category IV), or inhalation exposure (Toxicity Category IV). Clethodim is a moderate eye irritant (Category III), a skin irritant (Category II), and does not cause skin sensitization in the modified Buehler test in guinea pigs. In addition, an acute oral no-observed effect level (NOAEL) has been determined in rats to be 300 mg/kg.

2. *Genotoxicity*. Clethodim does not present a genetic hazard. Clethodim technical did not induce gene mutation in microbial *in vitro* assays. A weak response in an *in vitro* assay for chromosome aberrations was not confirmed when clethodim was tested in an *in vivo* cytogenetics assay up to the maximally tolerated dose level, nor was the response observed *in vitro* using technical material of a higher purity. No evidence of unscheduled DNA synthesis was seen following *in vitro*exposure up to a dose level near the LD_{50} (1.5 g/kg). This evidence indicates that clethodim does not present a genetic hazard to intact animal systems.

3. *Reproductive and developmental toxicity*. No reproductive toxicity was observed with clethodim technical at feeding levels up to 2,500 ppm. Developmental toxicity was observed in 2 rodent species, but only at maternally toxic dose levels. Clethodim is therefore not considered a reproductive or developmental hazard. These studies indicate no unique toxicity to the developing fetus or young, growing animals.

The developmental toxicity study conducted with clethodim technical in the rat resulted in a developmental and maternal NOAEL and lowest observed adverse effect level (LOAEL) of 100 and 350 mg/kg/day, respectively. The NOAEL and LOAEL for developmental toxicity were based on reductions in fetal body weight and increases in skeletal abnormalies.

The developmental toxicity study conducted with clethodim technical in the rabbit resulted in a maternal toxicity NOAEL and LOAEL of 25 and 100 mg/kg/day, respectively. Maternal toxicity was manifested as clinical signs of toxicity and reduced weight gain and food consumption duringtreatment. Developmental toxicity was not observed, and therefore the developmental toxicity NOAEL was 300 mg/kg/day, highest dose tested (HDT).

The 2–generation reproduction study conducted with clethodim technical in the rat resulted in parental toxicity NOAEL and LOAEL of 500 and 2,500 ppm, respectively, based on reductions in body weight in males, and decreased food consumption in both generations. The NOAEL for reproductive toxicity was 2,500 ppm, HDT.

4. *Subchronic toxicity*. Subchronic oral toxicity studies conducted with clethodim technical in the rat and dog indicate a low level of toxicity. Effects observed at high dose levels consisted primarily of decreased body weights, increased liver size (increased weight and cell hypertrophy), and anemia (decreased erythrocyte counts, hemoglobin, or hematocrit) in rats and dogs. The NOAELs from these studies were 500 ppm (ca. 25 mg/kg bw/day) in rats and 25 mg/kg bwt/day in dogs.

A 21–day dermal toxicity study in rats with clethodim technical showed a LOAEL at 100 mg/kg bwt/day and a NOAEL at 1,000 mg/kg bwt/day, the highest dose tested.

5. *Chronic toxicity*. Clethodim technical has been tested in chronic studies with dogs, rats and mice. In chronic studies compound-related effects noted at high doses included decreased body weight, increased liver size (liver weight and hypertrophy), and anemia (decreased hemoglobin, hematocrit, and erythrocyte count). Bone marrow hyperplasia was observed in dogs at the highest dose tested. No treatment-related increases in incidence of neoplasms were observed in any study. Chronic NOAELs were 200 ppm for an 18–month feeding study in mice and 500 ppm for a 24–month study in rats. EPA has established a reference dose (RfD) for clethodim of 0.01 mg/kg bwt/day, based on the NOAEL in the 1–year oral dog study and an uncertainty factor of 100. Effects cited by EPA include, alterations in hematology and increased absolute and relative liver weights at 75 mg/kg/day.

Clethodim technical is not a carcinogen. Studies with clethodim have shown that repeated high dose exposures produced signs of toxicity, but did not produce cancer in test animals. No oncogenic response was observed in a rat 2–year chronic feeding/carcinogenicity study or in a 18–month study on mice. The carcinogenicity classification of clethodim is ''E'' no evidence of carcinogenicity for humans.

A 1–year feeding study with clethodim technical in the dog resulted in a systemic NOAEL of 1 mg/kg/day in both sexes and an LOAEL of 75 mg/kg/day based on increased absolute and relative liver weights, and alteration and clinical chemistry.

An 18–month mouse carcinogenicity feeding study showed clethodim technical to be non-carcinogenic to mice under the conditions of the study. The systemic NOAEL was 200 ppm (8 mg/kg bwt/day), and the systemic LOAEL was 1,000 ppm (50 mg/kg bwt/day) based on treatment-related effects on survival, red cell mass, absolute and relative liver weights, and microscopic findings in liver and lung.

A 2–year chronic toxicity/carcinogenicity feeding study performed in the rat found clethodim technical to be noncarcinogenic to rats under the conditions of the study. The systemic NOAEL was 500 ppm (approximately 19 mg/kg bwt/day), and the systemic LOAEL was 2,500 ppm (approximately 100 mg/kg bwt/day) based on the observed body weight gain, the increases in liver weights, and the presence of centrilobular hepatic hypertrophy.

6. *Animal metabolism*. The absorption, tissue distribution, metabolism and excretion of ring- and side chain-labeled ^{14}C- clethodim were studied in rats after single oral doses of 468 or 4.4 mg/kg/ bwt, and after a single oral dose of 4.8 mg/kg bwt $_{14}C$-clethodim following 14 daily oral doses at 4.5 mg/kg bwt of unlabelled material. For all dose groups, most $_{14}C$-clethodim (88–96%) of the administered radiolabel was excreted in the urine and feces within 2 days after radiolabeled test material dosing, and 92–98% of the administered dose was excreted within seven days. The low dose groups eliminated clethodim slightly faster than the high dose group, and repeated exposure to clethodim prior to radiolabel dosing did not affect the rate of elimination or distribution of recovered radiolabel. There were no apparent sex differences with respect to elimination or distribution of metabolites. Seven days after dosing, tissue residues were generally low, accounting for no more than 0.3% of the dosed ^{14}C. Radiocarbon concentrations in fat were the higher than in other tissues analyzed. Recovery in tissues over time indicates that the potential for bioaccumulation is minimal. The primary excretory metabolites were identified as clethodim sulfoxide (48–63%), clethodim S-methyl sulfoxide (6–12%), clethodim imine sulfoxide (7–10%), and clethodim 5-hydroxy sulfoxide (3–5%). Minor metabolites included clethodim oxazole sulfoxide (2–3%), clethodim trione sulfoxide (1%), clethodim (1%), clethodim 5-hydroxy sulfone (0.3–1%), clethodim sulfone (0.1–1%), aromatic sulfone (0.2–0.7%), and S-methyl sulfone (0–0.4%).

7. *Metabolite toxicology*. Metabolism studies of clethodim in rats, crop plants, goats and hens demonstrate that the parent is very rapidly metabolized and, in animals, eliminated. Because parent and metabolites are not retained in the

body, the potential for acute toxicity from *in situ* formed metabolites is low. The potential for chronic toxicity is adequately tested by chronic exposure to the parent at the MTD and consequent chronic exposure to the internally formed metabolites. Two metabolites of clethodim, clethodim imine sulfone and clethodim 5-hydroxy sulfone, have been tested in toxicity screening studies to evaluate the potential impact of these metabolites on the toxicity of clethodim. In general, these metabolites were found to be less toxic than Clethodim Technical for acute and oral toxicity studies; reproduction and teratology screening studies; and several mutagenicity studies.

8. *Dermal Penetration*. The dermal penetration of SELECT 2 EC Herbicide, the end-use product, was tested on unabraded, shaved skin of rats. Single doses of approximately 0.05, 0.5, and 5.0 mg of radiolabeled ^{14}C-clethodim) SELECT 2 EC Herbicide, were applied topically to 10 cm2 sites on the dorsal trunk. Clethodim was found to be slowly absorbed through the skin in a time-dependent manner. The percent of dose absorbed increased with length of exposure and decreased with increasing dose. Ten-hour absorption rates ranged from 7.5% to 30.0%. Most of the absorbed material was found in the urine and carcass, and most of the unabsorbed material was found in the skin scrubbings indicating that material was still on the skin surface.

9. *Endocrine disruption*. No special studies to investigate the potential for estrogenic or other endocrine effects of clethodim have been performed. However, as summarized above, a large and detailed toxicology data base exists for the compound including studies acceptable to the Agency in all required categories. These studies include acute, sub-chronic, chronic, developmental, and reproductive toxicology studies including detailed histology and histopathology of numerous tissues, including endocrine organs, following repeated or long term exposure. These studies are considered capable of revealing endocrine effects, and the results of all of these studies show no evidence of any endocrine-mediated effects and no pathology of the endocrine organs. Consequently, it is concluded that clethodim does not possess estrogenic or endocrine disrupting properties.

C. Aggregate Exposure

1. *Dietary exposure*. EPA has established a RfD for clethodim of 0.01 mg/kg bwt/day, based on the NOAEL in the 1–year oral dog study and an uncertainty factor of 100. Effects cited by EPA include, alterations in hematology and increased absolute and relative liver weights at 75 mg/kg/day. Toxic endpoints of concern have not been identified for acute or short-term exposures by any route, or chronic endpoints of concern by any route other than oral. Therefore, only aggregate chronic dietary risk analyses are required.

i. *Food*. Chronic dietary exposure to clethodim residues was calculated for established and pending uses of clethodim for the U.S. population and 26 population subgroups using anticipated residues (average residues from field residue studies) and accounting for the percent of the crop treated.

ii. *Drinking water*. Since clethodim is applied outdoors postemergence to growing agricultural crops, the potential exists for clethodim and/or its metabolites to reach ground or surface water that may be used for drinking water. To model very conservative estimates of the potential concentrations of clethodim and its sulfoxide metabolite in drinking water, the Agency used screening concentration in ground water (SCI-GROW), and generic expected environmental concentration (GENEEC) for surface water. The sum of the parent and metabolite estimated concentrations in surface water greatly exceeded those in groundwater. Dividing the GENEEC derived 56–day average concentration by three gives 10 micrograms per liter (ppb) as the Agency's worse case estimate for drinking water contamination [Federal Register 63(67): 1701–8 (April 8, 1998). Using standard assumptions about body weight and water consumption, the chronic exposure from this drinking water would be 0.00029 and 0.001 mg/kg bwt/day for adults and children, respectively; 10% of the RfD for children. Based on this worse case analysis, the contribution of water to the chronic dietary risk exceeds food, but is still acceptable.

2. *Non-dietary exposure*. Clethodim is currently registered for use as a broadcast application on winter dormant perennial turf to control annual grasses. It is conceivable that this outdoor uses could result in acute or short- and/or intermediate- term residential exposure. Under current EPA criteria, the registered and proposed uses of clethodim would not constitute a chronic residential exposure scenario. Because toxic endpoints of concern have not been identified for short- or intermediate-term exposure, these risk analyses are not necessary.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that the Agency must consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Available information in this context 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.

There are other pesticidal compounds that are structurally related to clethodim including sethoxydim, cycloxydim, and tralkoxydim. Analytical methods convert some of these herbicides and their metabolites to common moieties. Plant and animal metabolism data demonstrates that no common metabolites are formed. In consideration of potential cumulative effects of clethodim and other substances that may have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by clethodim would be cumulative with those of other chemical compounds. Thus, only the potential risks of clethodim have been considered in this assessment of aggregate exposure and effects.

Valent will submit information for EPA to consider concerning potential cumulative effects of clethodim consistent with the schedule established by EPA at 62 Federal Register 42020 (August 4, 1997) and other subsequent EPA publications pursuant to the Food Quality Protection Act (FQPA).

E. Safety Determination

An acute dietary endpoint was not identified. Thus, the risk from acute aggregate dietary exposure to clethodim is considered to be negligible. Aggregate chronic dietary exposure to various sub-populations of children and adults demonstrate acceptable risk. Aggregate chronic exposures to clethodim for all population subgroups occupy considerably less than 100% of the RfD. It should be noted that the bulk of the calculated aggregate chronic exposures consist of very conservatively estimated

concentrations of clethodim and its sulfoxide metabolite in drinking water. Because there are no identified short- or intermediate-term dermal toxic endpoints of concern, these risk analyses are not necessary.

It can be concluded that there is a reasonable certainty that no harm will result to individuals in the U.S. population or in any sub-group of the U.S. population, including infants and children, from aggregate chronic exposures to clethodim residues resulting from approved and pending uses.

1. *U.S. population*. Using the dietary exposure assessment procedures described above for clethodim, calculated chronic dietary exposure — taking into account percent of crop treated and using anticipated residues — from existing and proposed uses of clethodim is minimal. The estimated chronic dietary exposure from food for the overall U.S. population and many non-child/infant subgroups is 0.000174 to 0.000204 mg/kg bwt/day, 1.7 to 2.0% of the RfD. Addition of the small but worse case potential chronic exposure from drinking water (calculated above) increases exposure by 0.0003 mg/kg bwt/day and the maximum occupancy of the RfD from 2.0 per cent to 5.0%. Generally, the Agency has no cause for concern if total residue contribution is less than 100% of the RfD. It can be concluded that there is a reasonable certainty that no harm will result to the overall U.S. Population and many non-child/infant subgroups from aggregate, chronic exposure to clethodim residues.

2. *Infants and children*. Safety Factor for Infants and Children: In assessing the potential for additional sensitivity of infants and children to residues of clethodim, FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to ten-fold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children.

The toxicological data base for evaluating pre- and post-natal toxicity for clethodim is complete with respect to current data requirements. There are no special pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 3–generation reproductive toxicity study in rats. Reliable data support use of the standard 100-fold uncertainty factor and an additional uncertainty factor is not needed for clethodim to be further protective of infants and children.

Chronic Exposure and Risk — Infant and child sub-populations: Using the conservative exposure assumptions described above (anticipated residues and percent of crop treated), the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of clethodim ranges from 0.7% for nursing infants (<1 year old), up to 4.8 % for children (1–6 years). Adding the worse case potential incremental exposure to infants and children from clethodim in drinking water (0.001 mg/kg bwt/day) greatly increases the aggregate, chronic dietary exposure and the occupancy of the RfD by 10.0 % to 14.8 % for Children (1–6 years). 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. It can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate, chronic exposure to clethodim residues.

F. International Tolerances

Although some have been proposed, there are no Canadian, Mexican, or Codex tolerances or maximum residue limits established for clethodim. There are no conflicts between this proposed action and international residue limits.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–1039; FRL–6796–2]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1039, must be received on or before September 24, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1039 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph M. Tavano, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6411; e-mail address: tavano.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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