

program will serve as a "strawman" proposal, which EPA will make available prior to the second meeting. EPA expects the "strawman" proposal and proposals submitted by other groups to be a major subject of comment at the roundtable discussions at both of the subsequent meetings. At the end of each roundtable discussion, comments will also be solicited from other stakeholders attending the meeting as described in Unit IV. of this document.

The tentative dates for the two subsequent meetings are November 30-December 1, 1999 and January 19-20, 2000. These will be the dates unless a **Federal Register** document is published changing the dates or canceling the meetings. The dates will also be confirmed on the website at <http://www.epa.gov/chemrtk/childhlt.htm>. All meetings will be held in the Washington, DC area and will be open to the public. Summaries of the meetings will be placed in the public record, OPPTS-00274.

VI. Public Record

At this time, the public record version of the official record contains the following:

A. United States Environmental Protection Agency (USEPA). "Background Information on the Children's Health Chemical Testing Program." Prepared by Chemical Information and Testing Branch, Chemical Control Division, Office of Pollution Prevention and Toxics (August 19, 1999).

B. Meridian Institute and The Keystone Center. "Preliminary Findings and Recommendations: Voluntary Children's Health Testing Program Stakeholder Involvement Process." Prepared by Tim Mealey and Paul De Morgan for the USEPA and other interested stakeholders (July 30, 1999).

List of Subjects

Environmental protection, Chemicals, Children, Hazardous substances, Health and safety.

Dated: August 20, 1999.

Susan H. Wayland,

Deputy Assistant Administrator for Prevention, Pesticides and Toxics.

[FR Doc. 99-22203 Filed 8-23-99; 4:11 pm]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-880; FRL-6090-1]

Notice of Filing; Pesticide Petition

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 chlorfenapyr in or on various food commodities. **DATES:** Comments, identified by the docket control number PF-880, must be received on or before September 27, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION (CBI)." No confidential business information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Ann Sibold, Insecticide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 212, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6502; e-mail: sibold.ann@epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues

of chlorfenapyr 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-880] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF-880) and appropriate petition number. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: August 19, 1999.

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 views 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.

American Cyanamid

PP 6E4683

EPA has received a pesticide petition (6E4683) from American Cyanamid, P.O. Box 400, Princeton, NJ 08543-0400 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180 by establishing a tolerance for residues of chlorfenapyr [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1-pyrrole-3-carbonitrile] in or on the raw agricultural commodity (RAC) imported citrus at 0.5 ppm. As citrus processed commodities fed to food animals may be transferred to milk and edible tissues, tolerances are also proposed for the following ruminant food items, milk at 0.01 parts per million (ppm); milk fat at 0.15 ppm; meat at 0.01 ppm; and meat byproducts (including fat) at 0.10 ppm. EPA has determined that the petition contains 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 petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residues of chlorfenapyr in plants is adequately understood and the residue of concern in citrus consists of the parent molecule. Expressed on a whole basis, the parent compound accounted for 56-75% of the total radioactive residue (TRR) 98% of which was associated with the external rinse and peel.

2. *Analytical method.* The gas chromatography (GC) analytical method M2284, which is proposed as the enforcement method for the residues of chlorfenapyr in citrus, has a limit of detection (LOD) of 0.01 ppm (0.025 ppm for juice), and a limit of quantitation (LOQ) of 0.05 ppm.

3. *Magnitude of residues.* Extensive citrus field trials have been conducted over multiple growing seasons in all major citrus growing regions of the United States, Argentina, and Brazil. The results of these studies indicate that at application rates of 1.05 lbs active ingredient acre (ai/A), the maximum expected chlorfenapyr residues are 0.4 ppm in oranges, 0.38 ppm in lemons, and 0.27 ppm in grapefruit samples

harvested at a minimum of 7 days following the last application. These field trial data are adequate to support the proposed tolerance of 0.5 ppm in/on citrus. The results of processing studies indicate that chlorfenapyr residues do not concentrate in molasses and juice. The actual concentration factors in dried pulp (2.4x), and citrus oil (70x) are well below the maximum theoretical concentration factors for these commodities. Although citrus oil is not considered to be a ready-to-eat item and is not expected to contribute to the dietary exposure, a tolerance at 35 ppm (0.5 ppm x 70) is proposed for enforcement purposes.

B. Toxicological Profile

1. *Acute toxicity.* Based on EPA's toxicity category criteria, the acute toxicity category for chlorfenapyr technical is Category II or moderately toxic (signal word WARNING), and the acute toxicity category for the 2SC formulation is Category III or slightly toxic (signal word CAUTION). Males appear to be more sensitive to the effects of chlorfenapyr than females. The acute toxicity profile indicates that absorption by the oral route appears to be greater than by the dermal route. The following are the results from the acute toxicity tests conducted on the technical material.

i. *Rat oral LD₅₀* 441/1,152 milligrams/kilograms/body weight (mg/kg/bwt) male/female -- Toxicity Category II.

ii. *Rabbit dermal LD₅₀*: > 2,000 mg/kg/bwt male/female -- Toxicity Category III.

iii. *Acute inhalation.* LC₅₀ 0.83/ > 2.7 milligrams per liter (mg/L) male/female -- Toxicity Category III.

iv. *Eye irritation.* Moderately irritating -- Toxicity Category III.

v. *Dermal irritation.* Non-irritating -- Toxicity Category IV.

vi. *Dermal sensitization.* Non-sensitizer -- Non Sensitizer.

vii. *Acute neurotoxicity.* No observed adverse effect level (NOAEL) 45 mg/kg bwt. Not an acute neurotoxicant.

2. *Genotoxicity.* Chlorfenapyr technical (94.5% a.i.) was examined in a battery of *in vitro*, and *in vivo* tests to assess its genotoxicity and its potential for carcinogenicity. These tests are summarized below.

i. *Microbial/microsome mutagenicity assay.* Non-mutagenic.

ii. *Mammalian Cell Chinese hamster ovary/hypoxanthine guanine phosphoribosyl transferase (CHO/HGPRT) Mutagenicity Assay.* Non-mutagenic.

iii. *In vivo micronucleus assay.* Non-genotoxic.

iv. *In vitro--chromosome aberration assay in CHO.* Non-clastogenic.

v. *In vitro--chromosome aberration assay in CHLC.* Non-clastogenic.

vi. *Unscheduled DNA synthesis (UDS) assay.* Non-genotoxic.

3. *Reproductive and developmental toxicity.* Chlorfenapyr is neither a reproductive or developmental toxicant and is not a teratogenic agent in the Sprague-Dawley rat, or the New Zealand white rabbit. This is demonstrated by the results of the following studies:

i. *Rat oral teratology.* NOAEL for maternal toxicity 25 mg/kg bwt/day, and NOAEL for fetal/development toxicity 225 mg/kg/bwt/day.

ii. *Rabbit oral teratology.* NOAEL for maternal toxicity 5 mg/kg/ bwt/day and NOAEL for fetal/development toxicity 30 mg/kg/bwt/day.

iii. *Rat 2-generation reproduction.* NOAEL for parental toxicity/growth and offspring development 60 ppm (5 mg/kg/bwt/day). NOAEL for reproductive performance 600 ppm (44 mg/kg/bwt/day).

4. *Subchronic toxicity.* The following are the results of the subchronic toxicity tests that have been conducted with chlorfenapyr:

i. *28-Day rabbit dermal.* NOAEL 100 mg/kg/bwt/day.

ii. *28-Day rat feeding.* NOAEL > 600 ppm (< 71.6 mg/kg/bwt/day).

iii. *28-Day mouse feeding.* NOAEL > 160 ppm (< 32 mg/kg/bwt/day).

iv. *13-Week rat dietary.* NOAEL 150 ppm (11.7 mg/kg/bwt/day).

v. *13-Week mouse dietary.* NOAEL 40 ppm (8.2 mg/kg/bwt/day).

vi. *13-Week dog dietary.* NOAEL 120 ppm (4.2 mg/kg/bwt/day).

5. *Chronic toxicity.* Chlorfenapyr is not oncogenic in either Sprague Dawley rats or CD-1 mice and is not likely to be carcinogenic in humans. The following are the results of the chronic toxicity tests that have been conducted with chlorfenapyr:

i. *1-Year neurotoxicity in rats.* NOAEL 60 ppm (2.6/3.4 mg/kg/bwt/day male/female).

ii. *1-Year dog dietary.* NOAEL 120 ppm (4.0/4.5 mg/kg/bwt/day male/female).

iii. *24-Month rat dietary.* NOAEL for chronic effects 60 ppm (2.9/3.6 mg/kg/bwt/day male/female) and NOAEL for oncogenic effects 600 ppm (31/37 mg/kg/bwt/day male/female).

iv. *18-Month mouse dietary.* NOAEL for chronic effects 20 ppm (2.8/3.7 mg/kg/bwt/day male/female) and NOAEL for oncogenic effects 240 ppm (34.5/44.5 mg/kg/bwt/day male/female).

6. *Animal metabolism.* A metabolism study was conducted in Sprague Dawley rats at approximately 20 and 200 mg/kg/bwt using radiolabeled chlorfenapyr. Approximately 65% of the administered

dose was eliminated during the first 24 hours (62% in feces and 3% in urine) and by 48 hours following dosing, approximately 85% of the dose had been excreted (80% in feces and 5% in urine). The absorbed chlorfenapyr-related residues were distributed throughout the body and detected in tissues and organs of all treatment groups. The principal route of elimination was via feces, mainly as unchanged parent plus minor N-dealkylated, debrominated and hydroxylated oxidation products. The metabolic pathway of chlorfenapyr in the laying hen and the lactating goat was also similar to that in laboratory rats.

7. *Metabolite toxicology.* The parent molecule is the only moiety of toxicological significance which needs regulation in plant and animal commodities.

8. *Endocrine disruption.* Collective organ weights and histopathological findings from the 2-generation rat reproduction study, as well as from the subchronic and chronic toxicity studies in two or more animal species, demonstrate no apparent estrogenic effects or effects on the endocrine system. There is no information available which suggests that chlorfenapyr would be associated with endocrine effects.

C. Aggregate Exposure

1. *Food.* For purposes of assessing the potential dietary exposure, a Theoretical Maximum Residue Contribution (TMRC) has been calculated from the tolerance of chlorfenapyr in/on citrus at 0.5 ppm. This exposure assessment is based on very conservative assumptions, namely 100% of all citrus is treated with chlorfenapyr and that the residues of chlorfenapyr in citrus are at the tolerance level. Although there are no other established United States permanent tolerances for chlorfenapyr, a petition for a permanent tolerance at 0.5 ppm in cottonseed is pending at the Agency. Therefore, the dietary exposures to residues of chlorfenapyr in or on food will be limited to residues in cottonseed, citrus and food and feed items derived from them. As dried citrus pulp is a dairy and beef cattle feed item, a cold feeding study with dairy cattle was conducted. Since this study demonstrated that measurable residues of chlorfenapyr may occur in milk, meat, and meat byproducts, appropriate residue tolerances for these items are proposed. The contribution of the citrus tolerances alone to the daily consumption uses only 0.23% of the reference dose (RfD) for the overall U.S. population. The combined contributions

of the citrus and the pending cottonseed tolerances to the daily consumption uses less than 1% (actual 0.85%) of the RfD for the overall U.S. population and less than 3% (actual 2.23%) and less than 1% (actual 0.89%) of the RfD for children aged 1-6 and for non-nursing infants, respectively.

2. *Drinking water.* This proposed tolerance is for imported citrus. Since there are no currently registered uses of chlorfenapyr in the United States, potential exposure from drinking water is not relevant to this petition.

3. *Non-dietary exposure.* This petition is for a tolerance on imported citrus. As there are no registered uses of chlorfenapyr in the United States at present, the potential for non-dietary exposure is not pertinent to this petition.

D. Cumulative Effects

The pyrrole insecticides represent a new class of chemistry with a unique mechanism of action. The parent molecule, AC 303,630 is a pro-insecticide which is converted to the active form, CL 303,268, via rapid metabolism by mixed function oxidases (MFOs). The active form uncouples oxidative phosphorylation in the insect mitochondria by disrupting the proton gradient across the mitochondrial membrane. The production of adenosine triphosphate (ATP) is inhibited resulting in the cessation of all cellular functions. Because of this unique mechanism of action, it is highly unlikely that toxic effects produced by chlorfenapyr would be cumulative with those of any other pesticide chemical.

In mammals, there is a lower titer of MFOs, and chlorfenapyr is metabolized by different pathways (including dehalogenation, oxidation and ring hydroxylation) to other polar metabolites without any significant accumulation of the potent uncoupler, CL 303,268. In the rat, approximately 85% of the administered dose is excreted in the feces within 48 hours, thereby reducing the levels of AC 303,630 and CL 303,268 that are capable of reaching the mitochondria. This differential metabolism of AC 303,630 to CL 303,268 in insects versus to other polar metabolites in mammals is responsible for the selective insect toxicity of the pyrroles.

E. Safety Determination

1. *U.S. population.* The RfD of 0.03 mg/kg/bwt/day for the residues of chlorfenapyr in citrus is calculated by applying a 100-fold safety factor to the overall NOAEL of 3 mg/kg/bwt/day. This NOAEL is based on the results of the chronic feeding studies in the rat

and mouse and the 2-generation reproduction study in the rat. The theoretical maximum residue contribution (TMRC) for the proposed tolerances in citrus alone, (0.0000692 mg/kg/bwt/day), will utilize only 0.23% of the RfD for the general U.S. population and the combined TMRC for the proposed chlorfenapyr tolerances in cottonseed, citrus, milk, and meat (0.0002558 mg/kg/bwt/day) will utilize approximately 0.85% of the RfD for the general U.S. population.

2. *Infants and children.* The TMRC in milk consumed by a non-nursing infant (> 1-year of age) is 0.0002435 mg/kg/bwt/day. The combined tolerances will use less than 1% (actual 0.89%) of the RfD for non-nursing infants. The TMRC in milk consumed by a child (1-6 years of age) is 0.0003886 mg/kg/bwt/day. The combined TMRC for the proposed chlorfenapyr tolerances in cottonseed, citrus meat and milk consumed by a child 1-6 years of age is 0.0006708 mg/kg/bwt/day, which is less than 3% (actual 2.23%) of the RfD. Therefore, the results of the toxicology and metabolism studies support both the safety of chlorfenapyr to humans based on the intended use as an insecticide-miticide on citrus and cottonseed and the granting of the requested tolerances in cottonseed, citrus, milk, milk fat solids, meat, and meat by-products.

Based on the conservative assumptions used in proposing the above tolerances and the absence of other non-dietary routes of exposure to chlorfenapyr, and since the calculated exposures are well below 100% of the reference dose, there is a reasonable certainty that no harm will result from aggregate exposure to residues of chlorfenapyr, including all anticipated dietary exposure and all other non-occupational exposures. The use of a 100-fold safety factor ensures an acceptable margin of safety for both the overall U.S. population as well as infants and children. As the toxicology database (reproduction/developmental and teratology studies) is complete, valid and reliable, no additional safety factor is needed.

The 100-fold margin of safety is adequate to assure a reasonable certainty of no harm to infants and children from the proposed use. As stated earlier, the NOAEL is based on the effects observed in the rat and mouse chronic oncogenicity studies, (reduced bwt gains, increased globulin and cholesterol values and increased liver weights in the rat and reduced bwt gains and vacuolation of white matter of the mouse brain), the 1-year neurotoxicity study in the rat, (reduced bwt gains and vacuolar myelinopathy of

the brain and spinal cord that is completely reversible following termination of treatment and is not associated with any damage to neuronal cell bodies or axons; vacuolation of the white matter is a consequence of edema (water) formation between the myelin layers which result from the unrestricted movement of ions across the cell membranes) and the 2-generation rat reproduction study, (reduced bwt gains for parental animals and reduced pup body weights for the F1 and F2 litters; however no behavioral changes were observed in either F1 or F2 offsprings in the 2-generation reproduction study). Moreover, as the NOAELs for fetal/developmental toxicity are significantly higher than those for maternal toxicity, the results indicate that chlorfenapyr is neither a developmental toxicant nor a teratogenic agent in either the Sprague-Dawley rat or New Zealand White rabbit. Thus, there is no reliable information to indicate that there would be a variability in the sensitivities of infants and children and adults to the effects of exposure to chlorfenapyr.

F. International Tolerances

Section 408(b)(4) of the amended FFDCA requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. There is neither a Codex proposal, nor Canadian, or Mexican tolerances/limits for residues of chlorfenapyr in/on citrus. Therefore, a compatibility issue is not relevant to the proposed tolerance.

[FR Doc. 99-22190 Filed 8-25-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-819A; FRL-6099-8]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the filing of an amended pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF-819A, must be received on or before September 10, 1999.

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" section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-819A in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Fungicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-7740; and e-mail address: giles-parker.cynthia@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	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 in the "FOR FURTHER INFORMATION CONTACT" section.

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" 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-819A. 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-819A 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, 401 M St., SW., 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