ADDRESSES: The meeting will be held at Doubletree Hotel, 300 Army Navy Drive, Arlington, VA

FOR FURTHER INFORMATION CONTACT: Georgia McDuffie, Field and External Affairs Division (7506c), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0195; fax number: (703) 308–1850; e-mail address: mcduffie.georgia@epa.gov. or Philip H. Gray, SFIREG Executive Secretary, P.O. Box 1249, Hardwick, VT 05843–1249; telephone number: (802) 472–6956; fax (802) 472–6957; e-mail address: aapco@plainfield.bypass.com.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to ''those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug and Cosmetic Act (FFDCA), or the FIFRA''. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2002–0306. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register document electronically through the EPA Internet under the ''Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA dockets. You may use EPA dockets at http://www.epa.gov/edocket/ to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Tentative Agenda:

1. Committee Business Issues.
2. Regional Reports & Introduction of Issue Papers/Action Items.
3. Comments to the Committee/Open Discussion with EPA Senior Managers (To be determined).
4. Worker Protection Standard (WPS) Program Element Review Update.
5. Non-English/Multiple Language Labels.
6. Tribal Pesticide Program Council (TPPC)/Section 18s & other Tribal Issues.
7. Update on Current OPP & OECA Activities.
8. SFIREG Issue Paper Status Report.
9. Closed Session.
10. Pesticide Regulatory Education Program (PREP) Briefing/Issues.
11. Soybean Rust Pest/Section 18s Requests.
12. Status (SLA) Label Improvement Project Proposals i.e. Mosquito Products/West Nile virus Issues
13. States Label Issue Tracking System (SLITS) Update
14. Certification Training Assessment Group (CTAG) Update & Discussion
15. Issue Papers/Past & Present

List of Subjects

Environmental protection, Pesticide and pests.

Dated: November 6, 2002.

Jay Ellenberger,

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

[FR Doc. 02–29171 Filed 11–19–02; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0126; FRL–7184–7]

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 ID number OPP–2002–0126, must be received on or before December 20, 2002.

ADDRESSESS: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0126 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division, Office of Pesticide Programs, (7505C) Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6224; e-mail address: miller.joanne@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 productionmption 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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should examine the applicability provisions in OPP–2002–0126. 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0126. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasable, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any indentifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment,

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2002–0126. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2002–0126. In contrast to EPA's electronic public docket, EPA's email system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that

you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number Opp–2002–0126.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2002–0126. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM ckearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID 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, Pesticides and pests.

Dated: October 27, 2002.

Debra Edwards,

Acting 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 Nichino America Incorporated, and represents the view of Nichino America Incorporated. 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.

Nichino America Incorporated

PP 1F6428

EPA has received a pesticide petition (1F6428) from Nichino America Incorporated, 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing a tolerances for combined residues of pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) and its acid metabolite, E–1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid) expressed as the ester equivalent in or on the raw agricultural commodities (RACs) derived from cotton; undelinted seed at 0.05 parts per million (ppm); and gin byproducts at 1.5 ppm; in or on the RAC potato at 0.02 ppm; in or on the RACs corn grain, corn stover, corn forage, soybean seed, soybean forage, and soybean hay at 0.01 ppm; wheat forage, wheat hay, wheat straw, and wheat grain at 0.01 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residues of pyraflufen-ethyl (ET–751) in cotton, potatoes, corn, soybeans, and wheat is adequately understood. The metabolism of pyraflufen-ethyl has been studied in cotton, wheat, and potato. Metabolism in the plant involves ester hydrolysis, de-methylation on the pyrazole ring and further degradation of the phenoyxyacetate moiety to bound polar metabolites. The nature of the residue is adequately understood and the residues of concern are the parent, pyraflufen-ethyl, and the acid metabolite, E–1, only.

2. *Analytical method*. The enforcement analytical method utilizes gas chromatography/mass spectrophotometry with selected ion monitoring for detecting and measuring levels of pyraflufen-ethyl and the acid metabolite with a general limit of quantification (LOQ) of 0.02 ppm (combined E–1 and parent). This method allows detection of residues at or above the proposed tolerances. The method has undergone independent laboratory validation as required by PR Notices 88–5 and 96–1.

3. *Magnitude of residues in crops*—i. *Potato.* No apparent residues of pyraflufen-ethyl were observed in potato at or above 0.02 ppm (the LOQ

for the analytical method). The field studies, conducted at 3x the highest intended label use rate, in 16 trials in 11 states, clearly support the proposed tolerances of 0.02 ppm (combined E–1 and parent). No detectable residues of parent or the acid metabolite were observed in any processed potato fraction at 5x the maximum proposed application rate and proposed pre-harvest interval (PHI) in a field study, with the LOQ of 0.02 ppm (combined E–1 and parent). The tolerance that is being proposed for the use of pyraflufen-ethyl plus the acid metabolite on potato is 0.02 ppm.

ii. *Cotton.* Twelve field residue trials were conducted in seven different states. Applications in the trials were 3x the proposed label directions for use and at the proposed PHI of 7 days. Analysis of the treated samples showed that the residues of pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) plus its acid metabolite, E–1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid) expressed as the ester equivalent at the exaggerated rate, were below the proposed tolerance of 0.05 ppm in cotton seed at the proposed labeled PHI in all samples. No residues were seen in the processed fractions of meal, hull, and oil, when one trial was run in a typical cotton growing area. The application rate for this processing study was 15x the maximum proposed application rate and at the proposed PHI. This indicates that there is no concentration of pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) plus its acid metabolite, E–1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid), expressed as the ester equivalent in any of the processed fractions. Low residues seen in the undelinted cottonseed were consistent with the magnitude of residue trials. Combined residues of pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) plus its acid metabolite, E–1 (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid) in cotton gin byproducts from applications at 3x the proposed application rate ranged from 0.125 ppm to 1.314 ppm, and averaged 0.035 ppm from applications made at 1x the proposed application rate. The proposed tolerance of 0.05 ppm for pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-fluorophenoxyacetate) plus its acid metabolite, E–1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid) in cotton seed and 1.5 ppm in cotton gin byproducts are supported by the field residue data.

iii. *Corn.* Three exaggerated rate residue trials were conducted in three different states on different soil types. Applications in the trials were 5x to 10x the proposed label directions for use as a pre-plant burndown herbicide. Analysis of the treated samples showed zero residues of pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) plus its acid metabolite, E–1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid) expressed as the ester equivalent at the exaggerated rate. The LOQ for the parent and the metabolite was 0.005 ppm in each case. Since no residues were observed at exaggerated rates in RACs, no processing studies were conducted.

iv. *Soybean.* Three exaggerated rate residue trials were conducted in three different states on different soil types. Applications in the trials were 5x to 10x the proposed label directions for use as a pre-plant burndown herbicide. Analysis of the treated samples showed zero residues of pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) plus its acid metabolite, E-1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid) expressed as the ester equivalent at the exaggerated rate. The LOQ for the parent and the metabolite was 0.005 ppm in each case. Since no residues were observed at exaggerated rates in RACs, no processing studies were conducted.

v. *Wheat.* Three exaggerated rate residue trials were conducted in three different states on different soil types. Applications in the trials were 5x to 10x the proposed label directions for use as a pre-plant burndown herbicide. Analysis of the treated samples showed zero residues of pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) plus its acid metabolite, E–1, (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid) expressed as the ester equivalent at the exaggerated rate. The LOQ for the parent and the metabolite was 0.005 ppm in each case. Since no residues were observed at exaggerated rates in RACs, no processing studies were conducted.

4. *Magnitude of the residue in animals.*—i. *Ruminants.* The maximum dietary burden in beef and dairy cows results from a diet comprised of undelinted cottonseed, cotton meal, cotton hulls, cotton gin byproducts, potato culls, potato waste, and from grain (seed), forage, hay, stover (fodder), silage, meal, hulls, straw, aspirated grain fractions, and milled byproducts of corn, soybeans, and wheat for a total dietary burden that is significantly lower than levels that would require the proposal of tolerances in ruminants. This conclusion is based on exaggerated rate animal metabolism studies carried out on pyraflufen-ethyl and its significant metabolites. Therefore, an exemption from tolerances in milk, meat, and meat by-products under 40 CFR 180.6(a)(3) and (b) is proposed as it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

ii. *Poultry.* The maximum poultry dietary burden results from a diet comprised of cotton meal, corn grain, corn milled byproducts, soybean seed, soybean meal, soybean hulls, wheat grain, and wheat milled byproducts for a total dietary burden that is significantly lower than the levels that would require the proposal of tolerances in poultry. This conclusion is based on the exaggerated rate metabolism studies carried out on pyraflufen-ethyl and its acid metabolite. Therefore, an exemption from tolerances in poultry meat, meat byproducts, fat, and eggs under 40 CFR 180.6(a)(3) and (b) is proposed as it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

B. Toxicological Profile

1. *Acute toxicity.* Pyraflufen-ethyl technical is considered to be nontoxic (toxicity category IV) to the rat by the oral route of exposure. In an acute oral toxicity study conducted in rats, the oral LD_{50} value for technical pyraflufen-ethyl was determined to be >5,000 milligrams/kilograms body weight (mg/kg bwt). The results from the acute dermal toxicity study in rabbits indicate that pyraflufen-ethyl is slightly toxic (toxicity category III) to rabbits by the dermal route of exposure. The dermal LD_{50} value of technical pyraflufen-ethyl was determined to be >2,000 mg/kg for both male and female rabbits. Pyraflufen-ethyl technical is considered to be nontoxic (toxicity category IV) to the rat by the respiratory route of exposure. Inhalation exposure of rats to pyraflufen-ethyl technical resulted in an

LC_{50} >5.53 milligrams/Liter (mg/L) (analytical) for both males and females. Pyraflufen-ethyl technical was shown to be non-irritating to rabbit skin (toxicity category IV). Pyraflufen-ethyl technical was shown to be slightly irritating to rabbit eyes (toxicity category III). Application of technical material to the rabbit eye resulted in iris and conjunctival irritation from 1 to 24 hours, which was clear by 72 hours. Based on the results of a dermal sensitization study, pyraflufen-ethyl technical is not considered a sensitizer in guinea pigs.

2. *Genotoxicity.* Pyraflufen-ethyl technical was not mutagenic in any of the following genotoxicity studies. Point mutations in bacteria in an Ames study with *Salmonella typhimurium,* and *Escherichia coli;* negative in chromosome aberrations *in vitro* human lymphocytes, and in the mouse micronucleus; negative for DNA repair in *in vitro* and *in vivo* rat liver hepatocyte assays and *Bacillus subtillis.* For mammalian gene mutation, in one *in vitro* mouse lymphoma mutation assay, no evidence of mutagenicity was seen in the absence of metabolic activation. With S9 activation at levels up to 200 ìg/Liter, equivocal results were seen. The study report provided no criteria for positive or negative responses. When this *in vitro* study was repeated, no positive or equivocal results in the presence of activation with S9 at levels of S9 up to 350 ìg/Liter were seen. These levels of activation were greater than those tested in the earlier study and both small and large colonies were counted. The overall weight of evidence indicates that pyraflufen-ethyl is not genotoxic.

3. *Reproductive and developmental toxicity.* The developmental toxicity study in rats conducted with pyraflufen-ethyl technical showed no evidence of teratogenic effects in fetuses and no evidence of developmental toxicity. Thus, pyraflufen-ethyl is neither a developmental toxicant nor a teratogen in the rat. Pyraflufen-ethyl was administered by gavage during gestation and showed no adverse effects on dams or fetuses at dose levels of 0, 100, 300, up to and including a limit dose of 1,000 mg/kg/day. The maternal and developmental toxicity no observe adverse effects (NOAELs) were both >1,000 mg/kg/day. Results from a developmental toxicity study in rabbits conducted with pyrafluflen-ethyl technical also indicated no evidence of teratogenicity or developmental toxicity. Thus, pyraflufen-ethyl technical is neither a developmental toxicant nor a teratogen in the rabbit. Rabbits fed pyraflufen-ethyl at 0, 20, 60, or 150 mg/kg/day, resulted in severe maternal toxicity, including lethality, from gastrointestinal irritation at doses of 60 and 150 mg/kg/day. The maternal NOAEL was 20 mg/kg/day. The NOAEL for the offspring was 60 mg/kg/day, based on increased post-implantation loss observed at 150 mg/kg/day. Neither the rat nor the rabbit developmental study showed evidence of unique fetal susceptibility to pyraflufen-ethyl.

In a multigeneration rat reproduction study conducted at dietary concentrations of 0, 100, 1,000 and 10,000 ppm, pyraflufen-ethyl had no effect on reproductive parameters, including mating indices, fertility index, gestation index, duration of gestation, numbers of implantation sites, numbers and morphology of epididymal sperm, and estrous cycle at any dose level. Reproductive performance was not affected by pyraflufen-ethyl at the highest dose level of 10,000 ppm (male 721 to 844 mg/kg/day and female 813 to 901 mg/kg/day). The pup NOAEL was 1,000 ppm, based on decreased body weight in the F1 and F2 male and female pups on day 17 at the 10,000 ppm dose level. Results from the reproduction study and the developmental toxicity studies conducted with pyraflufen-ethyl technical show no increased sensitivity to developing offspring as compared to parental animals, because the NOAELs for growth and development of offspring were equal to or greater than the NOAELs for parental or maternal toxicity.

4. *Subchronic toxicity.* A short-term (28–day) dermal study in rabbits was conducted with pyraflufen-ethyl technical. Pyraflufen-ethyl was administered dermally to rats for 28 days at dose levels of 0, 300, and 1000 mg/kg day. Slight, transient erythema was observed during week 3 in 3 treated males. This finding was not dose-related, was not considered to be adverse, and the relationship to the test material administration was unclear. The NOAEL was considered to be 1,000 mg/kg/day. A 90–day rat feeding study was conducted at dose levels of 0, 200, 1,000, 5,000, or 15,000 ppm pyraflufen-ethyl. The NOAEL in this study was considered to be 1,000 ppm (85.6 mg/kg/day for males and 95.4 mg/kg/day for females), based on slightly increased phosphorous concentrations in females and hepatocytic hypertrophy in males at 5,000 ppm. In addition, the highest dose of 15,000 ppm resulted in erythocyte toxicity, mitochondrial changes in the hepatocytes and the presence of Kupffer cells. Also, at the high dose level increased kidney weights in males and increased absolute and relative spleen weights in both sexes were observed.

In a 90–day oral toxicity study in dogs, pyraflufen-ethyl was administered via capsule at dose levels of 0, 40, 200, and 1,000 mg/kg/day. No treatment-related findings were observed and the NOAEL was determined to be >1,000 mg/kg/day. At the limit dose, no effects in body weight or organ weights, clinical chemistry, hematology, histopathology, and gross pathology were observed. To determine whether the test material was absorbed or not, plasma was collected 1–hour after administration of pyraflufen-ethyl during week 13. The detection of 2 major degradation products, E–1 and E–9, confirmed the adsorption and gastrointestinal and systemic exposure to pyraflufen-ethyl.

5. *Chronic toxicity.* A 1–year chronic dog study was conducted in Beagle dogs, with pyraflufen-ethyl administered orally by gelatin capsule at doses of 0, 40, 200, and 1,000 mg/kg/day. There were no mortalities and no clinical signs of toxicity. No treatment-related effects were noted on body weights, food consumption, hematology and clinical chemistry parameters, urinalysis, ophthmoscopy, and organ weights. No macrosopic or microscopic lesions were noted. The NOAEL was >1,000 mg/kg/day.

In a 2–year chronic toxicity/oncogenicity study, pyraflufen-ethyl was administered to CD rats at dietary levels of 0, 80, 400, 2,000, or 10,000 ppm (equivalent to 0, 3.4, 17.2, 86.7, and 468.1 mg/kg/day for males and 0, 4.4, 21.8, 111.5, and 578.5 mg/kg/day for females). Mortality was unaffected by treatment. Body weight gain was statistically significantly depressed for those rats fed 10,000 ppm at 1–year compared to the control. Treatment-related histopathology was seen in the kidney, liver, and bile duct at 10, 000 ppm. At 2,000 and 10,000 ppm, vacuoles within the mitochondria of centriacinar and periacinar hepatocytes were seen. Effects on urine volume, urine specific gravity, and kidney weights were seen at 2,000 ppm in males. The NOAEL was 17.2 mg/kg/day for males and 21.8 mg/kg/day for females. No evidence of carcinogenicity was observed.

In a 78–week carcinogenicity study, mice were fed pyraflufen-ethyl in the diet at levels of 0, 200, 1,000, or 5,000 ppm (equivalent to 0, 21, 110, 547 mg/kg/day for males and 0. 20, 98, 524 mg/kg/day for females). An maximum tolerance dose (MTD) was reached at 1,000 ppm, based on increased liver weight and liver histopathological changes (including necrosis) seen at this

feeding level. In the highest dose group, effects of pyraflufen-ethyl on hematological parameters were observed. The incidence of hepatocellular adenoma was increased in animals receiving 5,000 ppm, compared to controls. This benign tumor was likely induced by the adaptive response to the hepatocellular degeneration and not as a result of any genotoxic potential of pyraflufen-ethyl. In addition the response was observed only at a dose level that was in excess of an MTD.

6. *Animal metabolism*. The qualitative nature of the residues of pyraflufen-ethyl and its acid metabolite, E–1, in animals is adequately understood. Pyraflufen-ethyl is rapidly absorbed, metabolized, and excreted to feces and urine, with greater than 90% of the administered dose excreted within 24 hours in rats. Based on metabolism studies with goats, hens, and rats, there is no reasonable expectation that measurable pyraflufen-ethyl-related residues will occur in meat, milk, poultry, or eggs from the proposed use.

7. *Metabolite toxicology*. No toxicologically significant metabolites were detected in plant or animal metabolism studies for cotton or potatoes.

8. *Endocrine disruption*. Chronic, lifespan, and multigenerational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal any endocrine effects for pyraflufen-ethyl. Any endocrine related effects would have been detected in this comprehensive series of required tests. The probability of any such effect due to agricultural uses of pyraflufen-ethyl is negligible.

C. Aggregate Exposure

1. *Dietary exposure*. The potential dietary exposure to pyraflufen-ethyl has been calculated from the proposed tolerances for use on cotton, and potato. While tolerances at the LOQ are proposed for corn, soybean, and wheat, it is concluded that there is no potential for residues in these crops and thus no dietary exposure. These very conservative chronic dietary exposure estimates used the tolerance value for all the raw agricultural commodities. In addition these estimates assume that 100% of the cotton and potato crops contain pyraflufen-ethyl residues.

i. *Food*. The chronic population adjusted dose (cPAD) for the general population, based on residues at the tolerance levels and 100% of potato and cotton crops treated is expected to be approximately 0.000020 mg/kg bwt/day or <0.1% of the reference dose (RFD) (0.172 mg/kg/day). Of the standard subgroups analyzed by the dietary exposure evaluation model (DEEM), the subgroup with the highest exposures are children ages 1 to 6 years, with a cPAD of 0.000041 mg/kg/day or less than 0.1% of the RfD mg/kg/day. With children ages 7 to 12 with exposures of 0.000027 mg/kg/day, the exposure is less than 0.1% of the RfD.

ii. *Drinking water*. As a screening level assessment for aggregate exposure, EPA evaluates drinking water level of comparison (DWLOC), which is the maximum concentration of a chemical in drinking water that would be acceptable in terms of total aggregate exposure to that chemical. Based on the chronic RFD of 0.172 mg/kg/day, based on the NOAEL of 17.2 mg/kg/day observed in the chronic rat feeding study and an uncertainty factor (UF) of 100, and EPA's default factors for body weight and drinking water consumption, the DWLOCs have been calculated to assess the potential dietary exposure from residues of pyraflufen-ethyl and the acid metabolite, E–1, in water. For the adult population, the chronic DWLOC was 35,086 parts per billion (ppb) for the U.S. population, and for children 10,172 ppb.

Chronic drinking water exposure analyses were calculated using EPA screening models, screening concentration in ground water (SCI-GROW) for ground water and generic expected environmental concentration (GENEEC) for surface water). The calculated peak GENEEC value for the acid metabolite, E–1, the major degradation of pyraflufen-ethyl which is formed within an hour of addition to a water solution or to soil, is 0.3321 ppb and the SCI-GROW value is 0.00024 ppb. These values are very conservative estimates compared to the values derived from the parent. Nonetheless, for the U.S. adult population, the estimated exposures of the E–1 acid metabolite in surface water and ground water are approximately 0.00094% and 0.0000007%, respectively, of the DWLOC. For children, the estimated exposures of the acid metabolite in surface water and ground water are approximately 0.0033% and 0.000002%, respectively of the DWLOC. Therefore, the exposures to drinking water from the acid metabolite are negligible. Based on the dietary and drinking water assessments, aggregate exposure to residues of pyraflufen-ethyl and the acid metabolite in food and water can be considered to be negligible.

2. *Non-dietary exposure*. It is being proposed that pyraflufen-ethyl be registered in the following non-food sites: airports, commercial plants, fence lines, farmyards, and farm buildings; storage and lumber yards; barrier strips and firebreaks; equipment areas, nurseries and ornamental plantings; established ornamental turf; railroad, roadside, and utility rights-of-ways; dry ditches and ditch banks; fuel tank farms and pumping stations; other similar non-crop areas. Exposure to pyraflufen-ethyl for the mixer/loader/groundboom/aerial applicator was calculated using the Pesticides Handlers Exposure Database (PHED). These PHED assessments were based on a 70 kg operator treating 80 acres per day using ground boom equipment on both cotton and potato fields; an operator treating 1,200 acres per day using aerial equipment on cotton fields; and an operator treating 350 acres per day using aerial equipment on potato fields (EPA, 1999) at a maximum use rate of 0.009 pounds active ingredient per acre for potato and 0.0045 pounds active ingredient per acre for cotton. All workers were assumed to be wearing long pants and long-sleeved shirts. Mixer-loaders were assumed to be wearing gloves, while aerial and ground applicators and flaggers were not assumed to be wearing gloves. Margins of exposure (MOE) for acute and short-term exposure were calculated utilizing a dermal and inhalation NOAEL of 20 mg/kg/day, based on maternal toxicity seen in the rabbit teratology study at 60 mg/kg/day, and assuming 100% dermal absorption. MOEs for intermediate-term exposure were calculated utilizing a dermal endpoint of 250 mg/kg/day, the systemic NOAEL from the 28–day dermal toxicity study in the rat with the 2.5% EC formulation. This was the highest dose level in the study and no systemic effects were seen at this dose level. For the acute inhalation endpoint we used 86 mg/kg/day, based on a NOAEL of 1,000 ppm or 85.6 mg/kg/day in males in the 90–day oral feeding study in the rat. The combined MOE (inhalation plus dermal) for pyraflufen-ethyl was greater than 4,900 for acute and short-term exposure, while the intermediate-term total MOEs were all greater than 56,000. The results indicate that large margins of safety exist for the proposed uses of pyraflufen-ethyl.

D. Cumulative Effects

Pyraflufen-ethyl belongs to the protox inhibitor class of compounds, and chemically is a 3-phenylpyrazole. The herbicidal activity of protox inhibitors is due to the inhibition of protoporphyrinogen IX oxidase. All relevant toxicological data has been provided to EPA. Chemicals with a similar mode of action, i.e., the protox inhibitors, have different chemical

structures compared to pyraflufen-ethyl. Although other protox inhibitors have a similar herbicidal mode of action, there is no information available to suggest that these compounds exhibit a similar toxicity profile in the mammalian system. We are aware of no information to indicate or suggest that pyraflufen-ethyl has any toxic effects on mammals that would be cumulative with those of any other chemical. Since pyraflufen-ethyl is relatively non-toxic, cumulative effects of residues and other compounds are not anticipated. Therefore, for the purposes of this Food Quality Protection Act (FQPA) document, there should be no consideration of cumulative risk that would require assessment.

E. Safety Determination

1. *U.S. population*. Based on the chronic toxicity data, the RfD for pyraflufen-ethyl is considered to be 0.172 mg/kg/day. This value is based on the NOAEL of 17.2 mg/kg/day observed in the chronic rat feeding study and a safety (uncertainty) factor of 100, the worse case estimate of chronic dietary exposure of pyraflufen-ethyl from cotton, potatoes, corn, or soybean will utilize less than 0.1% of the RfD for the general U.S. population. 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. The complete and reliable toxicity data and the conservative chronic exposure assumptions support the conclusion that there is a reasonable certainty of no harm from dietary (food) exposure to pyraflufen-ethyl and the acid metabolite residues. Moreover, as exposure to residues of pyraflufen-ethyl and the acid metabolite via water is negligible, there is a reasonable certainty of no harm from aggregate exposure to pyraflufen-ethyl and the acid metabolite residues.

2. *Infants and children.* The conservative estimates, as described above, indicate that chronic dietary exposure of pyraflufen-ethyl and the acid metabolite from cotton and potato will utilize less than 0.1% of the RfD for non-nursing infants, less than 0.1% of the RfD for children ages 1 to 6; and less than 0.1% of the RfD for all populations examined. No developmental, reproductive, or fetotoxic effects were noted at the highest doses of pyraflufen-ethyl tested in guideline reproductive or developmental toxicity studies. Based on the current toxicological data requirements, the data base relative to prenatal and postnatal effects for children is complete, valid and reliable. Results from the teratology studies and the 2–generation reproduction study support NOAELs for fetal/developmental effects or reproductive/offspring effects, respectively, equivalent to the highest concentrations tested. As such, there is no increased sensitivity of infants and children to residues of pyraflufen-ethyl. Therefore, an additional safety (uncertainty) factor is not warranted, and the RfD of 0.172 mg/kg/day, which utilizes a 100–fold safety factor, is appropriate to assure a reasonable certainty of no harm to infants and children.

F. International Tolerances

There is no Codex maximum residue level established for residues of pyraflufen-ethyl and the acid metabolite on any crops.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7410–5]

Notice of Availability of Enforcement and Compliance History Online Web Site for 60-Day Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of information availability and request for comments.

SUMMARY: The Office of Compliance (OC), within EPA's Office of Enforcement and Compliance Assurance (OECA), announces the availability of and invites comments on its new Web site, Enforcement and Compliance History Online (ECHO), which contains searchable, facility-level enforcement and compliance information.

DATES: Comments must be submitted no later than January 21, 2003.

ADDRESSES: The Web site is available at *http://www.epa.gov/echo*. Comments may be submitted to *echo@epa.gov* as a Word or WordPerfect file or mailed to Rebecca Kane, Environmental Protection Agency, Office of Enforcement and Compliance Assurance, MC 2222A, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Specific data errors should be submitted using the error correction process on the ECHO site.

FOR FURTHER INFORMATION CONTACT: Rebecca Kane at *kane.rebecca@epa.gov* or (202) 564–5960.

SUPPLEMENTARY INFORMATION:

I. ECHO Background

EPA is committed to public access to environmental information and has worked to develop a format for providing Internet access to facility-level compliance and enforcement information contained in core EPA data systems. Though the data included within ECHO previously were available to the public primarily through Freedom of Information Act requests, the information was not available in a searchable Web format. This new e-government initiative makes it much easier for the public to obtain these data records on the Internet.

EPA has worked with State governments to develop the content of the site and ensure accurate data and has pilot tested Internet access. A Joint EPA-State Enforcement and Compliance Public Access Workgroup developed the template for the type, sources, and amount of data to be included within ECHO. This workgroup, developed in partnership with the Environmental Council of the States (ECOS), made its recommendations in June 2000. EPA has field tested the approach and the data through: the Sector Facility Indexing Project (*http://www.epa.gov/sfipmtn1/*), which shows data for a limited number of industrial sectors, and a four-State pilot in the Pacific Northwest (*http://www.epa.gov/idea/region10*). Public feedback and lessons learned from these projects contributed to the development of the ECHO site.

To prepare for launch of ECHO, EPA and the States conducted a comprehensive data review to ensure high quality information. ECHO also includes on the site an online error reporting process that allows users to alert EPA and the States to possible errors. This notice announces a 60-day comment period, which is being provided to give interested parties, particularly those responsible for facilities included within the database, the opportunity to review ECHO's content, design, and accuracy of data.

II. ECHO Data

ECHO provides integrated compliance and enforcement information for approximately 800,000 regulated facilities nationwide. The site allows users to find facility-level inspection, violation, enforcement action, and penalty information for the past two years. Facilities regulated under the Clean Air Act (CAA) Stationary Source Program, Clean Water Act (CWA) National Pollutant Elimination Discharge System (NPDES), and Resource Conservation and Recovery Act (RCRA) are included. ECHO reports provide a snapshot of a facility's environmental record, showing dates and types of violations, as well as the State or Federal government's response.