withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

V. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in the **Federal Register** of June 26, 1991 (56 FR 29362) (FRL–3846–4). Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold, or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product. Exception to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in a Special Review action, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: August 3, 2005.

Arnold E. Layne,

Director, Information Technology and Resource Management Division, Office of Pesticide Programs.

[FR Doc. 05–16194 Filed 8–16–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0234; FRL–7732–1]

Pyriproxyfen; 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 pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0234, must be received on or before September 16, 2005.

ADDRESSES: 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**.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS 32532)

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. 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. 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 ID number OPP–2005–0234. 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, 1801 S. Bell St., 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, to 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.

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 feasible, 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 on 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 identifying 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–2005–0234. 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–2005–0234. In contrast to EPA's electronic public docket, EPA's e-mail 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–2005–0234.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0234. 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 clearly 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. 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 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 FFDCA 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 11, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by Interregional Research Project Number 4 (IR-4), and represents the view of the petitioner. The petion summary announces the availabilty 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.

Interregional Research Project

PP 3E6582, PP 3E6596, PP 3E6750, PP 4E6865, PP 4E6866

EPA has received pesticide petitions (PP) 3E6582, 3E6596, 3E6750, 4E6865, and 4E6866 from the Interregional Research Project Number 4 IR-4, Technology Center of New Jersey, Rutgers, the State University of New Jersey, 681 U.S. Highway #1 S., North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy) ethoxy]pyridine, in or on raw agricultural commodities as follows:

1. PP 3E6582 proposes a tolerance for white sapote and Ugli fruit at 0.3 parts per million (ppm).

2. PP 3E6596 proposes a tolerance for legume vegetables, crop subgroups 6a, 6b, and 6c at 0.2 ppm.

3. PP 3E6750 proposes a tolerance for onion, dry bulb at 0.05 ppm.

4. PP 4E6865 proposes a tolerance for strawberry at 0.3 ppm.

5. PP 4E6866 proposes a tolerance for grape at 2.5 ppm and raisin at 4.0 ppm.

EPA has determined that the petitions 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 support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant and animal metabolism.* Metabolism of ^{14}C-pyriproxyfen labeled in the phenoxyphenyl ring and in the pyridyl ring has been studied in cotton, apples, tomatoes, lactating goats, laying hens, and rats. The major metabolic pathways in plants is aryl hydroxylation and cleavage of the ether linkage, followed by further metabolism into more polar products by further oxidation and/or conjugation reactions. However, the bulk of the radiochemical residue on raw agricultural commodities (RAC) samples remained as parent. Comparing metabolites detected and quantified from cotton, apple, tomato, goat, hen, and rat shows that there are no significant aglycones in plants which are not also present in the excreta or tissues of animals. The residue of concern is best defined as the parent, pyriproxyfen.

Ruminant and poultry metabolism studies demonstrated that transfer of administered ^{14}C-residues to tissues was low. Total ^{14}C-residues in goat milk, muscle and tissues accounted for less than 2% of the administered dose, and were less than 1 part per million (ppm) in all cases. In poultry, total ^{14}C-residues in eggs, muscle and tissues accounted for about 2.7% of the administered dose, and were less than 1 ppm in all cases except for gizzard.

2. *Analytical method.* Practical analytical methods for detecting and measuring levels of pyriproxyfen (and relevant metabolites) have been developed and validated in or on all appropriate agricultural commodities, respective processing fractions, milk, animal tissues, and environmental samples. The extraction methodology has been validated using aged radiochemical residue samples from metabolism studies. The methods have been validated in cottonseed, apples, soil, and oranges at independent laboratories. EPA has successfully validated the analytical methods for analysis of cottonseed, pome fruit, nutmeats, almond hulls, and fruiting vegetables. The limit of detection of pyriproxyfen in the methods is 0.01 ppm which will allow monitoring of food with residues at the levels proposed for the tolerances.

3. *Magnitude of residues.* Residue data were generated with pyriproxyfen for tolerance setting and dietary exposure estimates. Adequate residue trials were performed with pyriproxyfen to support the uses described in this notice of filing.

B. Toxicological Profile

An assessment of toxic effects caused by pyriproxyfen is discussed in Unit III.A. and Unit III.B. of the **Federal Register** of April 4, 2001, (66 FR 17883) (FRL–6772–4).

1. *Animal metabolism.* The absorption, tissue distribution, metabolism and excretion of ^{14}C-labeled pyriproxyfen were studied in rats after single oral doses of 2 or 1,000 milligrams/kilograms body weight (mg/kg bwt) (phenoxyphenyl and pyridyl label), and after a single oral dose of 2 mg/kg bwt, phenoxyphenyl label only, following 14 daily oral doses at 2 mg/kg bwt of unlabeled material. For all dose groups, most (–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 7 days. 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 higher than in other tissues analyzed. Recovery in tissues over time indicates that the potential for bioaccumulation is minimal. There were no significant sex or dose-related differences in excretion or metabolism.

2. *Metabolite toxicology.* Metabolism studies of pyriproxyfen in rats, goats and hens, as well as the fish bioaccumulation study demonstrate that the parent is very rapidly metabolized and eliminated. In the rat, most (88–96%) of the administered radiolabel was excreted in the urine and feces within 2 days of dosing, and 92–98% of the administered dose was excreted within 7 days. Tissue residues were low 7 days after dosing, accounting for no more than 0.3% of the dosed ^{14}C. 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 maximum tolerated dose (MTD) and consequent chronic exposure to the internally formed metabolites.

Seven metabolites of pyriproxyfen, 4'-OH-pyriproxyfen, 5'-OH-pyriproxyfen, desphenyl-pyriproxyfen, POPA, PYPAC, 2-OH-pyridine and 2,5-diOH-pyridine, have been tested for mutagenicity, via Ames Assay, and acute oral toxicity to mice. All seven metabolites were tested in the Ames assay with and without S9 at doses up to 5,000 micro-grams per plate or up to the growth inhibitory dose. The metabolites did not induce any significant increases in revertible colonies in any of the test strains. Positive control chemicals showed marked increases in reverting colonies. The acute toxicity to mice of 4'-OH-pyriproxyfen, 5'-OH-pyriproxyfen, desphenyl-pyriproxyfen, POPA, and PYPAC did not appear to markedly differ from pyriproxyfen, with all metabolites having acute oral lethal dose (LD_{50}) values greater than 2,000 mg/kg bwt. The two pyridines, 2-OH-pyridine and 2,5-diOH-pyridine, gave acute oral LD_{50} values of 124 (male) and 166 (female) mg/kg bwt, and 1,105 (male) and 1,000 (female) mg/kg bwt, respectively.

3. *Endocrine disruption*. Pyriproxyfen is specifically designed to be an insect growth regulator and is known to produce juvenoid effects on arthropod development. However, this mechanism-of-action in target insects and some other arthropods has no relevance to any mammalian endocrine system. While specific tests, uniquely designed to evaluate the potential effects of pyriproxyfen on mammalian endocrine systems have not been conducted, the toxicology of pyriproxyfen has been extensively evaluated in acute, sub-chronic, chronic, developmental, and reproductive toxicology studies including detailed histopathology of numerous tissues. The results of these studies show no evidence of any endocrine-mediated effects and no pathology of the endocrine organs. Consequently, it is concluded that pyriproxyfen does not possess estrogenic or endocrine disrupting properties applicable to mammals.

C. Aggregate Exposure

1. *Dietary exposure*. An evaluation of chronic dietary exposure including both food and drinking water has been performed for the U.S. population and various sub-populations including infants and children. No acute dietary endpoint and dose was identified in the toxicology data base for pyriproxyfen; therefore, Valent Corporation concludes that, there is a reasonable certainty of no harm from acute dietary exposure.

i. *Food*. Chronic dietary exposure to pyriproxyfen residues was calculated for the U.S. population and 16 population subgroups assuming tolerance level residues, processing factors from residue studies, and assuming 100% of the crop will be treated with pyriproxyfen. The analyses included residue data for all existing uses, pending uses, and proposed new uses. The results from several representative subgroups are listed below. Chronic dietary exposure to the overall U.S. population is estimated to be 0.0238 mg/kg bwt/day, representing 6.8% of the reference dose (RfD). For the most highly exposed sub-population, infants, <1 years of age, dietary exposure is calculated to be 0.0245 mg/kg bwt/day, or 7.0% of the RfD. Generally speaking, the Agency has no cause for concern if total residue contribution for established and proposed tolerances is less than 100% of the RfD.

ii. *Drinking water*. Since pyriproxyfen is applied outdoors to growing agricultural crops, the potential exists for pyriproxyfen or its metabolites to reach ground water or surface water that may be used for drinking water. Because of the physical properties of pyriproxyfen, it is unlikely that pyriproxyfen or its metabolites can leach to potable ground water. To quantify potential exposure from drinking water, surface water concentrations for pyriproxyfen were estimated using generic expected environmental concentration (GENEEC). The residue levels in drinking water are the peak chronic residue level as estimated by GENEEC. Using standard assumptions about body weight and water consumption, the chronic exposure to pyriproxyfen from this drinking water would be 0.00009 mg/kg bwt/day for adults and ''0'' year infants, and represent 0.025% of the RfD (0.35 mg/kg/day). Based on this worse case analysis, the contribution of water to the dietary risk is negligible.

2. *Non-dietary exposure.* Pyriproxyfen is currently registered for use on residential non-food sites. Pyriproxyfen is the active ingredient in numerous registered products for flea and tick control. Formulations include foggers, aerosol sprays, emulsifiable concentrates, and impregnated materials (pet collars). With the exception of the pet collar uses, consumer use of pyriproxyfen typically results in acute and short-term intermittent exposures. No acute dermal, or inhalation dose or endpoint was identified in the toxicity data for pyriproxyfen. Similarly, doses and endpoints were not identified for short-term and intermediate-term dermal or inhalation exposure to pyriproxyfen. The Agency has concluded that there are reasonable certainties of no harm from acute, short-term, and intermediate-term dermal and inhalation occupational and residential exposures due to the lack of significant toxicological effects observed.

Chronic residential post-application exposure and risk assessments were conducted to estimate the potential risks from pet collar uses. The risk assessment was conducted using the following assumptions: application rate of 0.58 mg active ingredient (a.i.)/day, average body weight for a 1–6 year old child of 10 kg, the a.i. dissipates uniformly through 365 days (the label instructs to change the collar once a year), 1% of the active ingredient is available for dermal and inhalation exposure per day (assumption from Draft EPA Standard Operating Procedures (SOPs) for Residential Exposure Assessments, December 18, 1997). The assessment also, assumes an absorption rate of 100%. This is a conservative assumption since the dermal absorption was estimated to be 10%. The estimated chronic term MOE was 61,000 for children, and 430,000 for adults. The risk estimates indicate that potential risks from pet collar uses do not exceed the Agency's level of concern.

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 no other pesticidal compounds that are structurally related to pyriproxyfen and have similar effects on animals. In consideration of potential

cumulative effects of pyriproxyfen 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 pyriproxyfen would be cumulative with those of other chemical compounds. Thus, only the potential risks of pyriproxyfen have been considered in this assessment of aggregate exposure and effects.

E. Safety Determination

1. *U.S. population*—i. *Chronic dietary exposure and risk to adult sub-populations.* The results of the chronic dietary exposure assessment described above demonstrate that estimates of chronic dietary exposure for all existing, pending and proposed uses of pyriproxyfen are well below the chronic RfD of 0.35 mg/kg/day. The estimated chronic dietary exposure from food for the overall U.S. population and many non-child/infant subgroups is from 0.006 to 0.0245 mg/kg bwt/day, 1.7 to 7.0% of the RfD. Addition of the small but worse case potential chronic exposure from drinking water (calculated above) increases exposure by only 0.00002 mg/kg bwt/day and does not change the maximum occupancy of the RfD significantly. 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 or any non-child/infant subgroups from aggregate, chronic dietary exposure to pyriproxyfen residues.

ii. *Acute dietary exposure and risk to adult sub-populations.* No acute dietary endpoint and dose were identified in the toxicology data base for pyriproxyfen; therefore, it can be concluded that there is a reasonable certainty that no harm will result to the overall U.S. population or any non-child/infant subgroups from aggregate, acute dietary exposure to pyriproxyfen residues.

iii. *Non-dietary exposure and aggregate risk to adult sub-populations.* Acute, short-term, and intermediate-term dermal and inhalation risk assessments for residential exposure are not required due to the lack of significant toxicological effects observed. The results of a chronic residential post-application exposure and risk assessment for pet collar uses demonstrate that potential risks from pet collar uses do not exceed the Agency's level of concern. The estimated chronic term margin of exposure (MOE) for adults was 5,700.

2. *Infants and children*—i. Safety factor for infants and children. In assessing the potential for additional sensitivity of infants and children to residues of pyriproxyfen, FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to 10-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-natal and post-natal toxicity for pyriproxyfen is complete with respect to current data requirements. There are no special prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 2-generation reproductive toxicity study in rats. Valent concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed for pyriproxyfen to be further protective of infants and children.

ii. *Chronic dietary exposure and risk to infants and children.* Using the conservative exposure assumptions described above, the percentage of the RfD that will be utilized by chronic dietary (food only) exposure to residues of pyriproxyfen ranges from 0.013 mg/kg bwt/day children 6–12 years old, up to 0.0245 mg/kg bwt/day for infants (0 years of age), 3.8 and 7.0% of the RfD, respectively. Adding the worse case potential incremental exposure to infants from pyriproxyfen in drinking water (0.9×10^{-4} mg/kg bwt/day) does not materially increase the aggregate, chronic dietary exposure and only increases the occupancy of the RfD by 0.009%. 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. Valent concludes that, there is a reasonable certainty that no harm will result to infants and children from aggregate, chronic dietary exposure to pyriproxyfen residues.

iii. *Acute dietary exposure and risk infants and children.* No acute dietary endpoint and dose were identified in the toxicology data base for pyriproxyfen; therefore, Valent believes that there is a reasonable certainty that no harm will result to infants and children from aggregate, acute dietary exposure to pyriproxyfen residues.

iv. *Non-dietary exposure and aggregate risk infants and children.* Acute, short-term, and intermediate-term dermal and inhalation risk assessments for residential exposure are not required due to the lack of significant toxicological effects observed. The results of a chronic residential post-application exposure and risk assessment for pet collar uses demonstrate that potential risks from pet collar uses do not exceed the Agency's level of concern. The estimated chronic term MOE for children was 1,425.

F. International Tolerances

There are presently no existing Codex maximum residue levels for pyriproxyfen.

FR Doc. 05–16301 Filed 8–16–05; 8:45 a.m.]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OEI–2005–2006; FRL–7951–5]

Office of Environmental Information; Announcement of Comment Period for Environmental Sampling, Analysis and Results Draft Data Standards

AGENCY: Environmental Protection Agency.

ACTION: Notice of Data Availability & Comment Period.

SUMMARY: Notice of availability for public review for a 90 day comment period is hereby given for the Draft Environmental Sampling, Analysis and Results (ESAR) Data Standards.

The Draft Environmental Sampling, Analysis, and Results Data Standards are a collection of 14 standards that are based on the business processes used to collect and analyze environmental data. The collection is comprised of an Overview, four primary standards and nine supporting components. The fourteen ESAR data standards are designed to provide implementation flexibility and improve the exchange of environmental data across the nation. States and U.S. EPA completed a technical review of these data standards in the Spring of 2004. That review lead to the formation of Air, Waste, and Water teams, which reviewed the comments and produced this final collection of draft data standard documents. Reviewers will see that the standards may not use the specific terminology for a given environmental program. In order to make the standards work for the broadest audience, terms were specifically chosen for relevance to the broadest audience. Similarly, the standards do not address all details of each environmental program. These standards, when final, are intended to serve as a foundation for information