TABLE 2— AMENDED THIRAM PRODUCTS

EPA Company No.	Company Name and Address
45728	Taminco, Inc. 1950 Lake Park Drive Smyrna, GA 30080

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the April 27, 2005 **Federal Register** notice announcing the Agency's receipt of the request for voluntary amendment to terminate uses of thiram.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested amendment to terminate uses of thiram registrations identified in Table 1 of Unit II. Accordingly, the Agency orders that the thiram product registrations identified in Table 1 are hereby amended to terminate the affected uses. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the Provisions for Disposition of Existing Stocks set forth below in Unit VI. will be considered a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the Administrator may approve such a request.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The cancellation order issued in this Notice includes the following existing stocks provisions.

Persons other than the registrant may continue to sell and/or use existing stocks of amended products until such stocks are exhausted, provided that such use is consistent with the terms of the previously approved labeling on, or that accompanied, the amended product. This order specifically prohibits any use of existing stocks that is not consistent with such previously approved labeling.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: August 18, 2005.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 05–17126 Filed 8–30–05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0195; FRL–7730–4]

Ethalfluralin; 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 identification (ID) number OPP–2005–0195, must be received on or before September 30, 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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address:*jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you 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–2005–0195. 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, 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. 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–2005–0195. 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–2005–0195. 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–2005–0195.

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–2005–0195. 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 19, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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

Interregional Research Project Number 4 (IR-4)

PP 1E6326, PP 2E6360 and PP 2E6466

EPA has received pesticide petitions 1E6326, 2E6360 and from the Interregional Research Project Number 4 (IR-4), P.O. Box 231, Rutgers University, New Brunswick, NJ 08903 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing tolerances for residues of ethalfluralin in or on the raw agricultural commodities rapeseed, canola, crambe, and mustard seed at 0.05 parts per million (ppm), potato at 0.05 ppm, and dill, at 0.05 ppm. IR-4 submitted the petitions on behalf of the registrant, Dow AgroSciences LLC, who prepared this notice of filing. 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 petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* Nature of residue studies with 14C-ethalfluralin have demonstrated very low terminal residues and that ethalfluralin per se is the residue of concern in plants grown in soil treated with this compound and that there are no significant metabolic products. These studies indicate that it is appropriate to base a tolerance on residues of the parent compound, ethalfluralin.

2. *Analytical method*—i. *Rapeseed.* A residue method has been developed and validated at a limit of quantitation (LOQ) of 0.02 µg/g for the determination of ethalfluralin in rapeseed seed which utilizes capillary gas chromatography with mass selective detection (GC/MSD). Validation data were generated using this method during the analysis of the canola seed field samples from the magnitude of residue studies.

ii. *Potato.* The residue method used for determination of ethalfluralin in potato was based upon Analytical Method No. AM-AA-CA-R025-AB-755, ''Determination of Ethalfluralin in Agricultural Crops and Soil; Determination of Ethalfluralin in Potato and Potato Processed Products.'' Analysis was by gas chromatography using an electron capture detector. The analytical method was determined to have an LOQ of 0.05 ppm and a limit of detection (LOD) of 0.016 ppm.

iii. *Canola.* A residue method has been developed and validated at an LOQ of 0.02 µg/g for the determination of ethalfluralin in canola seed which utilizes capillary gas chromatography with mass selective detection (GC/MSD). Validation data were generated using this method during the analysis of the canola seed field samples from the magnitude of residue studies.

iv. *Safflower.* Adequate residue analytical methods are available for purposes of registration based upon the analytical method for sunflower. A GC method, Method I, with electron capture detection is listed in the Pesticide Analytical Manual (PAM, Vol. II, Section 180.416) for tolerance enforcement. Method I is applicable for analysis of ethalfluralin residues in or on sunflower seed. The LOD is 0.01 ppm.

v. *Dill.* Dill was analyzed by the method ''Determination of Ethalfluralin in Agricultural Crops and Soil, '' Residue Method Number AM-AA-CA-R025-AB-755, Lilly Research Laboratories, Greenfield, IN (currently Dow AgroSciences). The LOQ was 0.050 ppm by a gas chromatograph with a Ni63 electron capture detector(ECD). Method validation was performed both prior to and concurrently with sample analysis.

3. *Magnitude of residues*—i. *Canola.* In the magnitude of residue field studies, herbicides containing the active ingredient ethalfluralin N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl) benzenamine were applied in 1996 at eight sites as a preplant incorporated application. Sonalan* 10G herbicide was applied directly to the soil surface and Sonalan* HFP herbicide was diluted in water and applied in a spray volume of 16–23 gallon/Acre (gal/A). The applications were made to field plots of canola at the rate of 1.25 lb active ingredient/Acre (a.i./A) at all sites except GA and WA, and at the rate of 0.75 lb a.i./A (GA and WA). Three to five days after application, a second incorporation was done and canola seeds were planted. Samples of canola seeds were collected at normal harvest, 87–216 days after the last application. Residues in canola seed collected at normal harvest were non-detectable based on a method lower limit of detection of 0.004 ppm.

ii. *Potato.* In the magnitude of residue field studies, ethalfluralin N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl) benzenamine was applied as a preemergence broadcast treatment at a nominal rate of 1.0 lb a.i./acre and was incorporated into the soil

with the use of sprinkler irrigation or a drag harrow. Samples of marketable potatoes were collected at normal harvest, 65–143 days after treatment application. No residues of ethalfluralin above the limit of detection were observed in the potato raw agricultural commodity (RAC) or processed fractions (chips, flakes, and wet peel).

iii. *Safflower.* The magnitude of residue data from sunflower are surrogate data for safflower. The registered uses of ethalfluralin on sunflowers along with the established tolerances on these commodities are supported by acceptable field residue data from trials reflecting the maximum registered use patterns. In all cases, the residues were <0.01 ppm. The reregistration requirements for processing studies were fulfilled. Adequate processing studies have been conducted on sunflower seed. Field residue data resulting from up to 5X label rates showed non-detectable (<0.01 ppm) residues of ethalfluralin in sunflower seed.

iv. *Dill.* In the magnitude of residue field studies, herbicides containing the active ingredient ethalfluralin N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl) benzenamine were applied in 1997 at three sites. Ethalfluralin formulated as Curbit EC was applied directly to the soil surface, diluted in water and applied in a spray volume of 36 gal/A. The applications were made to field plots of canola at the rate of 1.5 lb a.i./A and incorporated by sprinkler irrigation. Samples of dill were collected at normal harvest, 91–100 days after the last application. Residues in fresh and dried dill collected at normal harvest were non-detectable based on a method lower limit of detection of 0.05 ppm.

B. Toxicological Profile

1. *Acute toxicity.* Ethalfluralin is of relatively low toxicity. The rat oral lethal dose, LD_{50} is >10,000 mg/kg. The acute dermal LD_{50} in rabbits is >2,000 milligram/kilogram (mg/kg) and the acute rat inhalation lethal concentration LC_{50} is >0.94 mg/liter (L) air. Ethalfluralin produced slight eye irritation and slight dermal irritation in rabbits. A guinea pig dermal sensitization study conducted by the modified Buehler method found no sensitization, whereas a study conducted by the Magnusson and Kligman maximization method showed a positive sensitization reaction. The signal word for the technical grade active ingredient is ''Caution.''

2. *Genotoxicty.* Ethalfluralin was weakly mutagenic in activated strains TA1535 and TA100 of *salmonella typhimurium*, but not in strains TA1537, TA1538, and TA98 in an Ames assay. In a modified Ames assay with *salmonella typhimurium* and *e- coli*, ethalfluralin was weakly mutagenic in strains TA1535 and TA100, with and without activation, and in strain TA98 without activation, at the highest dose. No mutagenicity was found in the mouse lymphoma assay for forward mutation. Ethalfluralin did not induce unscheduled DNA synthesis in rat hepatocytes. In Chinese hamster ovary cells, ethalfluralin was negative without S9 activation, but it was clastogenic with activation.

3. *Reproductive and developmental toxicity.* The maternal no-observed adverse effect level (NOAEL) of ethalfluralin in rats was 50 mg/kg/day. The maternal lowest observed adverse effect level (LOAEL) was 250 mg/kg/day, based on decreased body weight gain and dark urine. In this rat study there was no observable developmental toxicity. The developmental NOAEL in rats was 1,000 mg/kg/day, the highest dose. In rabbits the NOAELs for maternal and developmental toxicity were 75 mg/kg/day. The maternal LOAEL at 150 mg/kg/day was based on abortions and decreased food consumption. These effects as well as decreased weight gain, enlarged liver, and orange urine were found at 300 mg/kg/day. In this study developmental toxicity was observed. The developmental LOAEL in rabbits was 150 mg/kg/day, based on slightly increased resorptions, abnormal cranial development, and increased sternal variants. In a three-generation rat reproduction study, the parental NOAEL was 12.5 mg/kg/day. The parental LOAEL was 37.5 mg/kg/day, based on depressed mean body weight gains in males in all generations. No treatment-related effects were noted on reproductive parameters and the NOAEL was 37.5 mg/kg/day or greater. A 7–month multigeneration bridging study was conducted with doses equivalent to 0, 8, 20, or 61 mg/kg/day in the diet of Fischer 344 rats. The parental NOAEL was 20 mg/kg/day. The parental LOAEL was 61 mg/kg/day based on increased liver weights. No treatment-related effects were noted on reproductive parameters and the reproductive NOAEL was equal to or greater than 61 mg/kg/day.

4. *Subchronic toxicity.* Ethalfluralin was evaluated in five subchronic dietary studies which showed NOAELs of 560 ppm in a 3-month mouse study, 12 mg/kg/day in a 1–year mouse study, 29 mg/kg/day in a 3-month rat study, 3.9 mg/kg/day in male rats and 4.9 mg/kg/day in female rats in a 1–year study, and 27.5 mg/kg/day in a 3–month dog study. A 21–day dermal study in rabbits showed no systemic toxicity, while slight to severe dermal irritation was observed.

5. *Chronic toxicity.* Ethalfluralin was administered to Fisher 344 rats in the diet for 2 years in combined chronic toxicity and carcinogenicity replicate studies. The doses were equivalent to 0, 4.2, 10.7, or 32.3 mg/kg/day. The NOAEL for systemic effects was 32.3 mg/kg/day. Mammary gland fibroadenomas were found in dosed female rats at statistically significant incidences in the mid and high doses. Ethalfluralin was administered to B6C3F1 mice in the diet for 2 years in combined chronic toxicity and carcinogenicity replicate studies. The doses were equivalent to 0, 10.3, 41.9, or 163.3 mg/kg/day. No increased incidence of neoplasms was attributed to the treatment. The NOAEL was 10.3 mg/kg/day. The mid-dose (LOAEL) and high–dose showed focal hepatocellular hyperplasia in both sexes. There were increased relative liver, kidney, and heart weights in females. Some blood changes were found also, including decreased hematocrit, hemoglobin, and erythrocyte count accompanied by increased mean corpuscular hemoglobin concentration in high dose females. Alkaline phosphatase values were increased at the high dose in both sexes. Body weight gain decreased at the high dose.

Beagle dogs were given 0, 4, 20, or 80 mg/kg/day orally, by capsule, for 1 year. The NOAEL was 4 mg/kg/day. The LOAEL was 20 mg/kg/day, based on increased urinary bilirubin, variations in erythrocyte morphology, increased thrombocyte count, and increased erythroid series of the bone marrow. Elevated alkaline phosphatase levels were found at the two higher doses and siderosis of the liver at the high dose.

EPA's Office of Pesticide Program's Carcinogenicity Peer Review Committee concluded that, ethalfluralin should be classified as Group C, a possible human carcinogen, based on increased mammary gland fibroadenomas and adenomas/fibroadenomas combined in female rats. The tumor incidences were statistically significant at both the mid and high dose, and exceeded the upper range of historical controls. Based on a low dose extrapolation, the Q1* of 8.9 x 10^{-2} $(mg/kg/day)^{-1}$ has been calculated.

6. *Animal metabolism.* Fischer 344 rats were treated orally with a single low dose, a single high dose, or repeated low doses of radiolabeled ethalfluralin. Absorption of ethalfluralin was estimated at 79% - 87% of the dose for all dose levels. Ethalfluralin was rapidly

and extensively metabolized, and 95% of the chemical was excreted in urine and feces by 7 days. The major route of elimination for the radiolabel was in the feces, 50.9% - 63.2%, and the levels remaining in the tissues after 72 hours were negligible. The major metabolites in urine and feces were identified.

7. *Metabolite toxicology*. The residue of concern is ethalfluralin per se, as specified in 40 CFR 180.416. Thus, there is no need to address metabolite toxicity.

8. *Endocrine disruption*. There is no evidence to suggest that ethalfluralin has an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an acute effect of concern occurring as a result of a 1–day or single exposure. EPA has previously used a NOAEL of 75 mg/kg/day from a rabbit developmental toxicity study as the toxicity endpoint for assessing acute dietary risk in females 13–50 years of age. An acute reference dose (aRfD) of 0.75 mg/kg/day was calculated, based on a NOAEL of 75 mg/kg/day and an uncertainty factor of 100 (10 for interspecies extrapolation and 10 for intraspecies variation). EPA has previously added a 3X FQPA safety factor, resulting in an acute popution adjusted dose (aPAD) of 0.25 mg/kg/day. Likewise, in this assessment acute dietary risk to females 13–50 years old was based on an aPAD of 0.25 mg/kg/day.

Chronic dietary exposure to ethalfluralin is possible due to the potential presence of ethalfluralin residue in certain foods. Chronic dietary risk was evaluated using a chronic RfD of 0.04 mg/kg/day, which is based on a NOAEL of 4 mg/kg/day from a chronic dog study along with an uncertainty factor of 100. EPA previously concluded that an FQPA Safety Factor of 1X is appropriate for assessing chronic dietary risk.

EPA has concluded, that ethalfluralin should be classified as group C, a possible human carcinogen, based on increased mammary gland fibroadenomas and adenomas/fibroadenomas combined in female rats. Therefore, a cancer risk assessment was included. Based on a low dose extrapolation, the Q1* of 8.9×10^{-2} $(mg/kg/day)^{-1}$ has been calculated and was used in this cancer risk assessment.

i. *Food*. The dietary exposure assessment was based on all commodities with tolerances for ethalfluralin established at 40 CFR 180.416 together with the proposed tolerances of 0.05 ppm for rapeseed, 0.05 ppm for potatoes, and 0.05 ppm for dill, canola and safflower. The Dietary Exposure Evaluation Model (DEEM™), which is produced by Novigen Sciences, Inc. and licensed to Dow AgroSciences, was used to estimate dietary exposure. This software used the food consumption data for the 1989–1991 USDA Continuing Surveys of Food Intake by Individuals (CSFII 1989–1991).

a. *Acute.* An acute dietary risk assessment was conducted with the conservative assumptions of 100% crop treated and tolerance level residues for all crops. These assumptions result in a very conservative estimate of human exposure and risk. Acute dietary risk for females 13+ years old was assessed using an acute population adjusted dose (aPAD) of 0.25 mg/kg/day. Even with conservative assumptions used in this analysis acute dietary exposure was estimated to occupy only 0.05% of the aPAD for females 13+ years old. Adverse effects are not expected for exposures occupying 100% or less of the aPAD. Therefore, acute exposure and risk from food is well within acceptable levels.

b. *Chronic.* Chronic dietary exposure and risk was estimated with the conservative assumptions of 100% crop treated and tolerance level residues for all crops. The estimate of potential chronic exposure and risk is very conservative and estimated risk would be substantially reduced with further refinement to the exposure estimate. Even with the conservative assumptions used in this analysis, chronic exposure is estimated to occupy only 0.2% of the RfD for the general U.S. population. Chronic dietary exposure is estimated to occupy 0.4% of the RfD for non-nursing infants, the population subgroup estimated to have highest potential exposure. Therefore, chronic exposure and risk from food is well within acceptable levels.

c. *Cancer.* Cancer risk was estimated based on percent crop treated and anticipated residues (AR) as provided in EPA's Reregistration Eligibility Decision (RED) for ethalfluralin and EPA's final rule concerning tolerances for residue of ethalfluralin in or on canola seed and safflower seed (67 FR 2333, January 17, 2002). Since ethalfluralin residue in potatoes was below the LOD, a residue of ½ the LOD or 0.008 ppm was assigned to potatoes for use in cancer risk assessment. Additionally, this dietary risk assessment was based on 40% of the U.S. potato crop being treated with ethalfluralin. Based on both registered and proposed product uses, exposure to ethalfluralin from food is estimated to not exceed a lifetime cancer risk of 8.47×10^{-7}. Cancer risks of less than 1×10^{-6} are generally considered to be negligible.

ii. *Drinking water*. There are no established maximum contaminant levels (MCLs) for residues of ethalfluralin in drinking water and health advisory levels (HALs) for ethalfluralin have not been established. EPA has previously used modeling for a screening level assessment of potential ethalfluralin exposure through drinking water. The Agency has used EPA's pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and screening concentration in ground water (SCI-GRO) to provide a screening level assessment for surface water and ground water, respectively. Based on these models EPA has indicated the estimated environmental concentrations (EECs) for acute exposures are 2.3 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.052 ppb for surface water and 0.02 ppb for ground water. Estimated concentrations of a pesticide are compared to a Drinking Water level of Comparison (DWLOC) as a surrogate estimate of exposure and risk. The DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide.

a. *Acute.* As indicated previously, EPA has used surface water and ground water EECs of 2.3 ppb and 0.02 ppb, respectively, for comparison with the DWLOC in an acute assessment. The DWLOC for acute exposure in females 13+ years old was based on an aPAD of 0.25 mg/kg/day and was calculated to be 7,500 ppb. Therefore, the acute DWLOC for ethalfluralin is over 3,000 fold greater than the EEC for surface water or ground water, indicating that potential acute exposure and risk from drinking water is well within acceptable levels.

b. *Chronic.* As indicated previously, EPA has used surface water and ground water EECs of 0.052 ppb and 0.02 ppb, respectively, for comparison with the DWLOC in a chronic assessment. The chronic DWLOC was calculated based on a chronic RfD of 0.04 mg/kg/day and accounted for potential chronic exposure to ethalfluralin through residues in food. The chronic DWLOC for the general U.S. population and non-nursing infants was calculated to be 1,400 ppb and 400 ppb, respectively. Therefore, chronic DWLOCs are substantially greater than estimated residue concentration in surface water or ground water over a chronic exposure period, indicating that chronic exposure

and risk from drinking water are well within acceptable levels.

c. *Cancer.* The DWLOC for the cancer risk assessment was calculated to be 0.12 ppb. Surface water and ground water EECs of 0.052 ppb and 0.02 ppb, respectively, were used for comparison with the DWLOC. The EECs are below the DWLOC, indicating that the cancer risk would generally be considered negligible.

2. *Non-dietary exposure.* Ethalfluralin is not currently registered for use on any residential non-food sites, and thus, it is not expected that non-occupational, non-dietary exposures will occur.

D. Cumulative Effects

EPA at this time has not established methodologies to resolve the complex issues concerning common mechanism of toxicity in a meaningful way. Although, ethalfluralin is a member of the dinitroaniline class of herbicides, there is no information available at this time to determine whether ethalfluralin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Based on the metabolic profile, the registrant concludes that ethalfluralin does not appear to produce a toxic metabolite produced by other substances. Therefore, only aggregate exposure and risk were considered.

E. Safety Determination

1. *U.S. population.* Using conservative exposure assumptions previously described, chronic dietary exposure to residues of ethalfluralin from current and proposed uses was estimated to occupy only 0.2% of the RfD for the general U.S. population. EPA generally has no concern for exposures below 100% of the RfD since the RfD represents the level at or below which daily exposure over a lifetime will not pose appreciable risks to human health. Additionally, the chronic DWLOC was found to be substantially greater than EECs for ethalfluralin in surface water or ground water, indicating risk is well within acceptable levels. Cancer risk resulting from potential exposure to ethalfluralin through food and drinking water was estimated. Cancer risk from potential dietary and drinking water exposure for the general U.S. population was found to be within a range that EPA has generally considered negligible. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that, there is a reasonable certainty that no harm will result to the general U.S. population from aggregate exposure to ethalfluralin residues from current and proposed uses.

2. *Infants and children.* Risk for developmental toxicity from acute exposure to ethalfluralin was evaluated for females 13+ years old. As indicated in the previous discussion, risk from aggregate acute exposure to ethalfluralin through food and drinking water is well within acceptable levels. It can be concluded that there is a reasonable certainty that no harm will result for both females 13+ years old and for the pre-natal development of infants from aggregate acute exposure to ethalfluralin.

Chronic aggregate exposure and risk was evaluated for non-nursing infants, the population subgroup predicted to be most highly exposed. As indicated previously, risk from aggregate chronic exposure through food and drinking water is well within acceptable levels. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it can be concluded with reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to ethalfluralin based on current and proposed uses.

F. International Tolerances

There are no Codex, Canadian or Mexican maximum residue limits established for ethalfluralin.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0235; FRL–7733–1]

Fenarimol; 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 identification (ID) number OPP–2005–0235, must be received on or before September 30, 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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 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–2005–0235. 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