C. Aggregate Exposure

1. *Dietary exposure*. A dietary assessment was conducted to evaluate the potential risk due to chronic dietary exposure of the U.S. population and all sub-populations to residues of fenpropimorph. Fenpropimorph is not registered in the United States so no tolerances have previously been established.

This dietary analysis was conducted to evaluate the proposed import tolerance for banana pulp at 0.3 ppm. The dietary assessment was conducted using tolerance level residues, default processing factors, and 100% crop treated factors. These assumptions are conservative because it assumes all bananas imported into the United States will be at tolerance level and 100% of all the import bananas will have been treated with fenpropimorph. Inadvertent residues in animal commodities (i.e., meat, meat byproducts, milk, eggs) were not considered because imported bananas will not be used as an animal feed commodity.

i. *Food*. Acute dietary exposure assessment for fenpropimorph. BASF believes there is no concern regarding acute dietary risk since the available toxicity data do not indicate any evidence of significant toxicity from a 1 day or single, event exposure by the oral route.

ii. *Chronic dietary exposure assessment*.Achronic assessment was conducted for all subpopulations. The chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with Food Commodity Intake Database (DEEM-FCID). The chronic population adjusted dose (cPAD) used for all subpopulations was 0.003 mg/kg bwt/day. Using the exposure assumptions discussed above, fenpropimorph chronic dietary exposure from food is less than 19% cPAD for all subpopulations. The most highly exposed subpopulation was children 1-2 years old and utilized 18.4 % of the cPAD. The results of the chronic dietary assessment are presented in Table 1.

TABLE 1.— SUMMARY OF CHRONIC DIETARY EXPOSURE ASSESSMENT CONSIDERING CROPS WITH ESTABLISHED AND PROPOSED TOLERANCES FOR FENPROPIMORPH.

Population Subgroups	Exposure Estimate (mg/kg bw/day)	%cPAD
U.S. population	0.0001140	3.8

TABLE 1.— SUMMARY OF CHRONIC DIETARY EXPOSURE ASSESSMENT CONSIDERING CROPS WITH ESTABLISHED AND PROPOSED TOLERANCES FOR FENPROPIMORPH.—Continued

Population Subgroups	Exposure Estimate (mg/kg bw/day)	%cPAD
All Infants	0.0004320	14.4
Children (1-2 years)	0.0005520	18.4
Children (3-5 years)	0.0002880	9.6
Children (6-12 years)	0.0001200	4.0
Females (13-19 years)	0.0000720	2.4
Youth (13-19 years)	0.0000480	1.6

Results of the chronic dietary exposure analysis demonstrate a reasonable certainty that no harm to the general U.S. population or any subpopulation would results from importing bananas treated with fenpropimorph.

iii. *Drinking water*. Fenpropimorph is not registered for use within the United States and therefore exposure through drinking water will not occur.

An aggregate exposure assessment for fenpropimorph is not needed because the only exposure to fenpropimorph will occur from the dietary food route. Fenpropimorph is not registered within the United States for any uses. The dietary assessment conducted above demonstrates that there are no safety concerns for any subpopulation, and that the results clearly meet the FQPA standard of reasonable certainty of no harm.

2. *Non-dietary exposure*. Fenpropimorph is not registered for use within the United States. Thus, residential exposure is not possible.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Results for toxicity studies indicate that toxic effects produced by fenpropimorph would not be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population*. Based on this risk assessment, BASF concludes that there is a reasonable certainty that no harm will result to the general population from the aggregate exposure to fenpropimorph residues.

2. *Infants and children*. Based on this risk assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants or children from the aggregate exposure to fenpropimorph.

F. International Tolerances

A maximum residue level has not been established under Codex Alimentarius Commission for fenpropimorph in bananas.

[FR Doc. 05–12079 Filed 6–21–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0032; FRL–7718–7]

Propazine; 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–2005–0032, must be received on or before July 22, 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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 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–2005–0032. 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–2005–0032. 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–2005–0032. 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–2005–0032.

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–2005–0032. 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: June 3, 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 Griffin Corporation, 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.

Griffin Corporation

PP 7F4837

EPA has received a pesticide petition (PP 7F4837) from Griffin Corporation, P.O. Box 1847, Valdosta, GA 31603–1847 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 a tolerance for residues of propazine 2-chloro-4,6-bis(isopropyamine)-s-triazine and its 2 chloro metabolites, 2-amino-4-chloro, 6-isopropylamino-s-triazine (G–30033) and 2,4-diamino-6-chloro-striazine (G-28273) in or on the raw agricultural commodity sorghum, stover, forage, and grain at 0.25 parts per million (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.* In sorghum, metabolism occurs by the three following reactions: N-dealkylation of the side-chains, hydrolytic dehalogenation or nucleophilic displacement of the 2-chloro group with glutathione (GSH). The dehalogenation and formation of GSH conjugates are the two predominant pathways and only small amounts of the chloro residues were found in forage and stover. No chloro residues were detected in sorghum grain in two propazine metabolism studies that were conducted. Griffin believes the metabolism is well characterized in plants and animals and the pathways of metabolism are very similar to those defined for other triazines. The metabolism profile supports the use of an analytical enforcement method that accounts for parent propazine and its two chloro metabolites, 2-amino-chloro-6-isopropyl-amino-s-triazine (G–30033) and 2-chloro-4,6-di-amino-s-triazine (G–28273) in the raw agricultural commodity (RAC's) of grain sorghum and further supports the current tolerance of 0.25 ppm to include the two chloro metabolites.

2. *Analytical method.* A practical analytical method has been submitted, as a part of the sorghum residue study. The method involves extraction, evaporation solid phase clean-up

column and quantitation by high performance liquid chromotography (HPLC) equipped with a ultraviolet ray (UV) detector. One aliquot is used for assaying for propazine and G–30033 and another aliquot is used for quantitating G–27283. The limit of quanitation (LOQ) for propazine and each of its chloro metabolites in each raw agricultural commodities (RAC) and each chloro residue is 0.05 ppm.

3. *Magnitude of residues.* A total of 13 sorghum field residue trails were conducted in the major sorghum growing areas of the United States. No quantifiable residues of parent or the two chloro metabolites were detected in the RAC's of the 13 field residue studies when treated at the 1x rate. Only four samples for sorghum forage contained residues of G–28273 which were quantifiable and residues ranged from 0.05 ppm to 0.087 ppm. The treatment rate for these studies exceeded the maximum proposed use rate and the extrapolated range of residues for the four samples was 0.024 to 0.069 ppm.

The RAC's of sorghum are only used as feed for cattle and poultry. Only the grain is fed to chickens and there were no chloro residues present in grain; therefore, no chloro residues would be expected in eggs and poultry products. The level of chloro residues in forage and fodder are sufficiently low in the metabolism and residue studies to demonstrate that any potential transfer of propazine and its chloro metabolites to milk and meat is not expected. For rotational crops, no chloro residues were present in root and grain crops when planted more than 129 days after treatment. Chloro residues were present in leafy vegetables grown in soils with pH values above 7 and under inclimate growing conditions. One field sample of wheat forage contained low levels of parent propazine but this sample was taken at an interval shorter than will be proposed on the label for plant back and, in addition, the pH of the soil was above 7.

An amendment of the current tolerance of 0.25 ppm to include parent propazine and its two chloro metabolites, G–30033 and G–28273, is proposed for each of the RAC's of grain sorghum. The metabolism and field residue results show that chloro residues of propazine should not exceed 0.25 ppm in any of the RAC's. Potential transfer of propazine and its two chloro metabolites to milk and meat is not expected. Therefore, tolerances in milk, meat, poultry and eggs are not required. The data show that root and grain crops can be rotated with sorghum treated with propazine, but leafy vegetable crops should not be rotated with sorghum in soils with pH values above 7.

B. Toxicological Profile

1. *Acute toxicity.* A complete battery of acute toxicity studies for propazine technical was completed. The acute oral toxicity study resulted in a LD_{50} of greater than 5,050 milligram kilogram (mg/kg) for both sexes. The acute dermal toxicity in rabbits resulted in an LD_{50} in either sex of greater than 5,050 mg/kg. The acute inhalation study in rats resulted in an LC_{50} of greater than 1.22 mg/l. Propazine was non-irritating to the skin of rabbits in the primary dermal irritation study. In the primary eye irritation study in rabbits, no irritation was noted. The dermal sensitization study in guinea pigs indicated that propazine is not a sensitizer. Based on these results, propazine technical is placed in toxicity Category III.

2. *Genotoxicity* Propazine was positive without activation and weakly positive with activation in an *in vitro* Chinese hamster cell point mutation assay. It did not affect DNA repair in rat hepatocytes. In *in vivo* assays, propazine was negative for both production anomalies in Chinese hamster somatic cell nuclei in interphase and induction structural damage (chromosome aberrations) in mouse spermatogonial cells.

3. *Reproductive and developmental toxicity.* The potential maternal and developmental toxicity of propazine were evaluated in rabbits. Propazine technical was suspended in corn oil and administered orally by gavage to three groups of 20 artificially inseminated New Zealand White rabbits as a single daily dose from gestation days 6–18. In the range-finding study, rabbits were dosed at levels of 0, 10, 50, 100, 200, and 400 milligram kilogram/day (mg/kg/day). Maternal toxicity was exhibited by decreased defecation, body weight losses and decreased food consumption during the treatment period at 50, 100, 200 and 400 mg/kg/day. Abortions also occurred at levels of 200 and 400 mg/kg/day. Dose levels of 0, 2, 10, and 50 mg/kg/day were selected based on the results of this study. In the definitive study, no test article related deaths occurred at any dose level tested. The only clinical sign observed was decreased defecation in the 50 mg/kg/day group. Inhibition of body weight gain occurred during the first 6 days of dosing and inhibition of food consumption occurred throughout the treatment period in the 50 mg/kg/day group. No other treatment related findings were noted in the dams at any dose level. Intrauterine parameters were unaffected by treatment. There were no treatment related effects on fetal malformations or developmental variations.

The data from the developmental toxicity studies on propazine show no evidence of a potential for developmental effects (malformations or variations) at doses that are not maternally toxic. The no observed adverse effect level (NOAEL) for maternal toxicity in rabbits was 10 mg/kg/day and the NOAEL for developmental toxicity was 50 mg/kg/day.

4. *Subchronic toxicity.* No test article related deaths occurred at any dose level. Very minimal dermal irritation was noted in the 100 and 1,000 mg/kg/day females. Body weight gain was slightly inhibited in the high dose group during weeks 0–1 (both sexes) and 2–3 (males only). There were no treatment related effects on the clinical observations, food consumption, hematology and serum chemistry parameters or organ weights were observed at any dose level. Macroscopic and microscopic examinations revealed no treatment related lesions at any dose level. Based on the 21 day dermal study in rats, the NOAEL for systemic toxicity was 100 mg/kg/day due to reduced body weight gain at 1,000 mg/kg/day.

5. *Chronic toxicity.* Griffin conclude that the body weight gain and survival data clearly indicate that the high dietary concentration of 1,000 ppm (68 mg/kg/day) for female rats exceeded the maximum tolerance dose (MTD), and therefore, the high dose female group should be excluded from any risk assessment or weight-of-evidence arguments concerning this study. Additionally, the incidence of mammary gland tumors in all doses in this study were within the range of current laboratory historical control incidences and those reported by the breeder, Charles River. No adverse treatment related effects were observed at levels below the MTD (100 ppm or lower for females).

6. *Animal metabolism.* The absorption, distribution, excretion, and metabolism of propazine (ring-UL-14C propazine) was investigated in Sprague-Dawley CD rats. One group of rats was administered a single oral dose at 1.0 mg/kg (low dose), one group was administered a single oral dose at 100 mg/kg (high dose), and a third group was administered fourteen consecutive oral daily doses of non-radioactive propazine at 1.0 mg/kg, followed by a single oral dose of 14C-propazine at 1.0 mg/kg (consecutive dose group). A fourth group of animals (3 rats/sex) was administered a single oral dose of the vehicle only (corn oil), and served as

controls. Since propazine is not soluble in water, it was not possible to include an intravenous dose group. Excretion patterns were very similar in all dose groups. Nearly all of the radioactivity administered was recovered in the excreta within 24 to 48 hours after dosing. The majority of the administered radioactivity was excreted in the urine (66.2–70.5%), and this finding shows that the majority of the administered dose was bioavailable and rapidly absorbed from the gastrointestinal tract. High performance liquid chromotography (HPLC) analysis of the urine indicated a similar profile among all dose groups and both sexes. The excretion of radioactivity in the feces was significantly lower than in the urine (range: 19.9–28.6%) in all dose groups and both sexes. Analysis of this radioactivity demonstrated a relatively consistent pattern among the various dose groups with females containing a quantitatively higher level of the parent compound. The recovery of expired radioactivity was shown in a pilot study to be negligible (< 0.1%), indicating little or no 14CO2 production during the metabolism of propazine.

Seven days post-treatment all animals were sacrificed and the total radioactive residue was quantified in bone, brain, fat (visceral), gastrointestinal tract (including contents), heart, kidney, liver, lung, muscle (thigh), ovary, plasma, red blood cells (RBC), skin, spleen, testis, thyroid, uterus, and residual carcass. Highest concentrations were found in the RBCs of all dose groups (0.472–0.577 ppm parent equivalents at 1.0 mg/kg and 44.649–55.287 ppm at 100 mg/kg). Residue concentration in the remaining tissues ranged from 0.007 to 0.468 ppm at the low and consecutive dose groups, and from 0.859 to 13.246 ppm at the high dose. Mean body burdens for the low, high, and consecutive dose groups accounted for 10.3, 5.9 and 7.1% of the dose, respectively. Material balances were quantitative and accounted for 102.5, 101.1 and 96.3% of the dose, respectively. Metabolite characterization of excreta indicated a biotransformation pathway consistent with historical metabolism of alkylated s-triazines. Confirmed metabolite identification showed that propazine was metabolized via Ndealkylation mechanisms and excreted in urine primarily as the G–27283 metabolite (approximately 27% of the total dose). Unmetabolized parent propazine was the predominant identified compound in the feces (13.8% in the high dose male group). The fact that a greater percentage of administered 14C-propazine was found in the feces of the high dose group probably indicated some degree of saturation of the absorption mechanism. Propazine technical is not metabolized to breakdown products which accumulate in sufficient quantities that can be reasonably expected to present any chronic dietary risk.

7. *Metabolite toxicology.* The hydroxy metabolite of atrazine, an analog of propazine has been shown not to exhibit carcinogenic effects.

8. *Endocrine disruption.* There is no evidence that propazine has endocrinemodulation characteristics as demonstrated by the lack of endocrine effects in developmental, subchronic and chronic studies.

C. Aggregate Exposure

1. *Dietary exposure—i. Food.* A dietary risk exposure study dietary risk evaluation system (DRES) for Griffin for the purpose of estimating dietary exposure to propazine residues. Grain sorghum is the only proposed food or food use of propazine. Therefore, there exists no potential for human consumption of crops treated with propazine. Sorghum (grain, forage and stover) is, however, fed to livestock. Grain is the only sorghum commodity fed to poultry. There are no chloro residues, the residues of toxicological concern, in the grain. In turn, there is no potential for poultry to be exposed to propazine or related residues. Beef and dairy cattle are fed all sorghum commodities: grain, forage, stover, and aspirated grain fractions. Therefore, in evaluating potential human dietary exposure to propazine, the potential exposure via secondary residues in meat and milk must be considered. The total chloro residues for a goat dosed at 9.9 ppm in a metabolism study were low. Specifically, the highest total residue while the lowest residue of < 0.002 ppm was observed in kidney.

These tissues to feed ratios can then be combined with the worst-case diets derived from a sorghum only ration which includes propazine residues at the tolerance level of 0.25 ppm. (It should be noted that this worst-case diet is not a ration that would be fed to cattle). The results of this indicate that even under theoretically worst-case conditions all meat and milk residues are extremely low (all less than 0.01 ppm; the LOQ in plant matrices is 0.05 ppm). In turn, there is no potential for dietary exposure to propazine via secondary residues in meat and milk. Therefore, tolerances for meat and milk are not required for propazine.

ii. *Drinking water.* Griffin conclude that environmental fate and behavior studies, including aerobic soil metabolism, field lysimeter, and long term soil dissipation, indicate little potential for propazine to reach surface or ground water from its proposed use on grain sorghum. Griffin concludes that, there is little potential for dietary exposure to propazine residues in water exists.

2. *Non-dietary exposure.* There are no residential uses for propazine in the United States, therefore, there is no potential for residential exposure.

D. Cumulative Effects

Because of the benefits of propazine, most of the propazine use on sorghum will be substituted for other triazines and since the proposed use rate is lower than the other triazines the cumulative will not increase and could possibly be reduced as a result of registering propazine for use on grain sorghum.

E. Safety Determination

The reference dose (RfD) is based on the rat chronic study. Using the (no adverse effect level (NOAEL) of 5 mg/kg/day in this study and an additional uncertainty factor (UF) of 300 (100 intraspecies and interspecies uncertainty factor plus an additional uncertainty factor of 3X for lack of a chronic study in dogs) an RfD of 0.02 mg/kg/day was established as the chronic dietary endpoint.

1. *U.S. population.* In the DRES analysis referenced above, it was determined that there is no potential exposure to propazine via dietary, water, or nonoccupational routes.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of propazine, the available developmental toxicity study and the potential for endocrine modulation by propazine were considered. The data from the developmental toxicity studies on propazine show no evidence of a potential for developmental effects (malformations or variations) at doses that are not maternally toxic. The developmental NOAELs and lowest observed effect levels (LOAELs) were at higher dose levels (less toxic), indicating no increase in susceptibility of developing organisms. No evidence of endocrine effects were noted in any study. It is therefore concluded that propazine poses no additional risk for infants and children and no additional uncertainty factor is warranted. Federal food, drug and cosmetic act (FFDCA) section 408 provides that an additional safety factor for infants and children may be applied in the case of threshold effects. Since, as discussed in the previous section, the toxicology studies do not indicate that young animals are

any more susceptible than adult animals and the fact that the current RfD calculated from the NOAEL from the rat chronic study already incorporates a 300x uncertainty factor, Griffin believes that an adequate margin of safety is, therefore, provided by the RfD established by EPA. There is no evidence that propazine has endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, subchronic, and chronic studies. There is no potential exposure to propazine via dietary, water, or non-occupational routes based on the proposed use on grain sorghum. No additional uncertainty factor for infants and children is warranted based on the completeness and reliability of the data base, the demonstrated lack of increased risk to developing organisms, and the lack of endocrine-modulating effects.

F. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRLs) established for residues of propazine and its chloro metabolites in or on raw agricultural commodities.

[FR Doc. 05–12015 Filed 6–21–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0140; FRL–7715–6]

Tralkoxydim; 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–2005–0140, must be received on or before July 22, 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address:*Tompkins.Jim@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 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–2005–0140. 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, 1801S. 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 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