system. Pyraclostrobin also acts curatively to prevent the increase and spread of fungal infections by inhibiting mycelial growth and sporulation on the leaf surface. BAS 500F inhibits spore germination, germ tube growth and penetration into the host tissues.

The EPA is currently developing methodology to perform cumulative risk assessments. At this time, there is no available data to determine whether BAS 500F has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyraclostrobin does not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination.

U.S. population. Adding the proposed uses to those crops already on the pyraclostrobin label, aggregate exposure to adults in the U.S. population utilized at most 67% of the aPAD and 40% of the cPAD. Therefore, no harm to the overall U.S. population would result from the use of pyraclostrobin on the proposed and existing label crops.

Infants and children. All subpopulations based on age were considered. The highest potential exposure was predicted for children age 1-6. Using the FQPA safety factor of 3X when appropriate, the addition of the proposed crops to those on the label would use less than 1% of the aPAD and use 89% of the cPAD for children age 1–6. BASF concludes that there is reasonable certainty that no harm will result to infants or children from aggregate exposure to pyraclostrobin residues on the proposed and existing label crops.

F. International Tolerances.

Maximum Residue Levels (MRLs) have been established for pyraclostrobin in Canada. No MRLs have been established by the Codex Alimentarius Commission.

[FR Doc. 03–20641 Filed 8–12–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0260]; FRL–7320–9]

S-Metolachlor; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0260, must be received on or before September 12, 2003.

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: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9368]; e-mail address: *jamerson.hoyt@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–2003–0260. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. 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–2003–0260. 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–2003–0260. Incontrast 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–2003–0260.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0260. 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 pesticide petitions 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 these petitions contain 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 these petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: August 4, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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 Syngenta Crop Protection, 410 Swing Road, Greeensboro, NC 276419, and represents the view of the Syngenta Crop Protection. 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.

Syngenta Crop Protection

PP 7E4916, 8E5029, 8E5030, 9E6055, and 2E6374

EPA has received pesticide petitions (7E4916, 8E5029, 8E5030, 9E6055, and 2E6374) from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902 proposing 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 combined residues of s-metolachlor and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholine, each expressed as the parent compound s-metolachlor in or on the following raw agricultural commodities:

1. PP 4E4420 proposes the establishment of tolerances for pepper, bell and pepper, nonbell at 0.50 part per million (ppm).

2. PP 7E4916 proposes the establishment of a tolerance for carrot, root and horseradish at 0.1 ppm.

3. PP 8E5029 proposes the establishment of a tolerance for rhubarb at 0.1 ppm.

4. PP 8E5030 proposes the establishment of a tolerance for swiss chard at 0.1 ppm.

5. PP 9E6055 proposes the establishment of a tolerance for asparagus at 0.1 ppm.

6. PP 2E6374 proposes the establishment of a tolerance for onion, green at 0.2 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 supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism*. [The qualitative nature of S-metolachlor residues in plants is adequately understood based upon available EPA approved corn, potato, and soybean metabolism studies. The metabolism of S-metolachlor involves conjugation with glutathione, breakage of this bond to form the mercaptan, conjugation of the mercaptan with glucuronic acid, hydrolysis of the methyl ether, and conjugation of the resultant alcohol with a neutral sugar. EPA has determined that residues of concern in plants include parent and metabolites, determined as the derivatives CGA-37913 and CGA-49751.

2. *Analytical method*. The Pesticide Analytical Manual (PAM) Vol. II, Pesticide Regulation Section 180.368 lists a gas chromatography/nitrogen phosphorous detector (GC/NPD) method (Method 1) for determining residues in or on plants and a gas chromatography/mass spectrometry methos (GC/MSD) method for determining residues in livestock commodities. These methods determine residues of S-metolachlor and its metabolites as either CGA-37913 or CGA-49751 following acid hydrolysis. The limit of quantitation (LOQ) for the method is 0.03 ppm for CGA-37913 and 0.05 ppm for CGA-49751.

3. *Magnitude of residues.*—i. *Asparagus.* Magnitude of residue trials were conducted under the direction of IR-4 in EPA regions 2, 5, and 11 in New Jersey, Michigan, and Washington. Applications were made pre-emergence to dormant asparagus in the spring and samples were collected for analysis 16 days after application. There were no detectable residues found in asparagus at harvest.

ii. *Carrot.* Field trials were conducted in Florida, Michigan, and New York to support the proposed tolerance for S-metolachlor in or on carrots grow on high organic matter (muck) soils.

iii. *Green onion.* Magnitude of residue trials were completed by IR-4 in New York, California, and Michigan (EPA region 1, 10, and 5, respectively). One post-emergence broadcast application was made when the onions had 2 true leaves. Marketable green onion plants were collected 43 to 45 days following the application. Maximum residues found were 0.168 ppm.

iv. *Rhubarb and Swiss chard.* As the EPA review announced in the October 2002 TRED has confirmed that a 0.1 ppm tolerance is appropriate for S-metolachlor in celery and as celery is the representative crop for the Leafy Petiole Subgroup, IR-4 has proposed tolerances be established for rhubarb and Swiss chard.

B. Toxicological Profile

1. *Acute toxicity*. [The data base for acute toxicity for S-metolachlor is complete. S-metolachlor is moderately acutely toxic (Toxicity Category III) by the oral and dermal route and relatively non-toxic (Toxicity category IV) by the inhalation route. It causes slight eye irritation (Toxicity Category III) and is non-irritating dermally (Toxicity Category IV); the active ingredient was found to be positive in a dermal sensitization test but this effect is mitigated in end-use product formulations.]

2. *Genotoxicty*. The data base for S-metolachlor has been deemed to be adequate by EPA. Gene mutation studies (Guideline 870.5100), micronucleus (Guideline 870.5395), and unscheduled DNA synthesis (Guideline 870.5550) studies have recently been reviewed and approved by EPA. There is no evidence of a mutagenic or cytogentic effect *in vivo* or *in vitro* with S-metolachlor.

3. *Reproductive and developmental toxicity*. The data base for developmental and reproductive toxicity for S-metolachlor are considered complete according to EPA reviews. The prenatal developmental studies in the rat and rabbit with S-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. No significant developmental toxicity was observed in most studies even at the highest doses tested. In a two-generation reproduction study, there was no evidence of parental or reproductive toxicity at the highest dose tested (80 mg/kg/day). The results indicate that S-metolachlor is not

embryotoxic or teratogenic in either species at maternally toxic doses.

4. *Subchronic toxicity*. In a 90–day dietary study in rats with S-metolachlor, no effects were observed in male or females at 208 and 236 mg/kg/day, respectively. In another 90–day dietary study in rats, decreased body weight, reduced food consumption and food efficiency in both sexes and increased kidney weight in males at 150 mg/kg/day; the NOAEL was 15 mg/kg/day. A 90–day dog study with S-metolachlor in dogs has been accepted by EPA; no effects were observed in males and females at 62 mg/kg/day and 74 mg/kg/day, respectively, the highest doses tested.

5. *Chronic toxicity*. A combined chronic toxicity/carcinogenic study in the rat satisfies the requirements for both the chronic toxicity and carcinogenicity studies. No significant chronic toxicity was found in either rats or dogs. In the rat, a decrease in body weight was observed at the highest dose tested. In the chronic dog study that supports S-metolachlor, the only adverse effect was decreased body weight gain in females at 33 mg/kg/day; the NOAEL was 10 mg/kg/day.

6. *Animal metabolism*. In animals, S-metolachlor is extensively absorbed, rapidly metabolized and almost totally eliminated in the excreta of rats, goats, and poultry. Metabolism in animals proceeds through common Phase 1 intermediates and glutathione conjugation.

7. *Metabolite toxicology*. The metabolism of S-metolachlor has been well characterized in standard FIFRA metabolism studies. S-metolachlor does not readily undergo dealkylation to form an aniline or quinone imine as has been reported for other members of the chloroacetanilide class of chemicals. Therefore, it is not appropriate to include S-metolachlor with the group of chloroacetanilides that readily undergo dealkylation, producing a common toxic metabolite (quinone imine). New toxicology data submitted by Syngenta demonstrate that the S-metolachlor metabolites ethane sulfonic acid (CGA 354743) and oxanilic acid (CGA 51202) are not absorbed by mammalian systems and / or have a significantly lower level of mammalian toxicity when compared to parent.

8. *Endocrine disruption*. S-Metolachlor does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. There is no evidence that S-metolachlor has any effect on endocrine function in developmental or reproduction studies. Furthermore, histological investigation of endocrine organs in the chronic dog, rat and mouse studies did not indicate that the endocrine system is targeted by S-metolachlor, even at maximally tolerated doses administered for a lifetime. There is no evidence that S-metolachlor bioaccumulates in the environment.

C. Aggregate Exposure

1. *Dietary exposure*. A Tier III/IV chronic dietary exposure analysis was conducted on S-metolachlor using field trial and market basket survey residues. Field trial residues were adjusted for percent of crop treated whereas market basket residues were not, since this information is inherent in the data. The percent of crop treated was assumed to be 100% for all commodities for which no percent of crop treated information was available. The chronic assessment was conducted for S-metolachlor using the Dietary Exposure Evaluation Model ($DEEM_{TM}$, version 7.76) by Exponent and food consumption information from USDA's 1994-96 Continuing Survey of Food Intake by Individuals (CSFII) and the Supplemental CSFII children's survey (1998). For this chronic assessment, the field trial values were averaged and entered into the DEEM™ software.

Syngenta Market Basket Survey (SMBS) S-metolachlor data were available for the following commodities: milk, potatoes and tomatoes. The Syngenta market basket survey was conducted from September 1999 through September 2000. Following the Agency tier ranking system, these chronic dietary assessments are considered as Tier III (utilizing field trial data) and Tier IV (utilizing SMBS and PDP data) assessments.

S-metolachlor is not considered acutely toxic and therefore acute dietary exposure was not determined; however, in the October 2002 TRED EPA conducted an acute assessment of the majority of the crops included in this petition and determined acute risks to be <1% of the aPAD in the most exposed population subgroup.

The chronic RfD for S-metolachlor is 0.10 mg/kg body weight/day and is based on a one-year dog study with a NOEL of 9.7 mg/kg body weight/day and a safety factor of 100X. No additional FQPA safety factor is required; nor was applied in this assessment.

i. *Food*. The risk from chronic dietary exposure to S-metolachlor is considered to be very low. The percentages of the chronic RfD ranged from 0.17% for Seniors to 0.64% for Children 1–2 years old, theoretically the most exposure population subgroup.

ii. *Drinking water*. Other potential sources of exposure of the general population to residues of S-metolachlor are residues in drinking water and exposure from non-occupational sources. The degradation of S-metolachlor is microbially mediated with an aerobic soil metabolism primary half-life of less than 30 days and subsequently soil binding predominates. S-metolachlor Koc's vary from 110- 369. S-metolachlor is stable to hydrolysis and while aqueous and soil photolysis occur, they are not expected to be prominent pathways in the environment.

The predominant crop for S-metolachlor is corn and accordingly an Index Reservoir PRZM/EXAMS was run using EPA's standard corn scenario. The model simulated two applications to the same plot: pre-emergence (2.67 kg ai/ha) and post-emergence (1.50 kg a.i./ha). The mean annual average estimated environmental concentrations (EEC) was 11.77 ppb. It should be noted that extensive monitoring data suggests that this EEC is a conservative estimate. For the vast majority of locations sampled, the peak measured concentration does not approach 12 ppb, and the annual average would be expected to be much lower.

The Chronic drinking water levels of concern (DWLOC) was calculated based on a cRfD of 0.097 mg/kg/day. Non-nursing infants are the most sensitive subpopulation and their DWLOC is estimated to be 544 ppb which corresponds to a %cRfD value of 2.2% with an MOE value of 4621. Thus, the DWLOC is considerably higher than the EEC of 11.77 ppb and the MOE is well above the benchmark value of 100.

2. *Non-dietary exposure*. S-metolachlor is labeled for use on warm-season turf and landscape ornamentals. Although, it is primarily used on sod farms and commercial landscape ornamentals, it can be used by licensed pest control operators (PCO) or lawn care operators (LCO) on residential turf. Since S-metolachlor can only be applied to warm-season turf varieties (bermudagrass, Zoysiagrass, St. Augustinegrass, and Centipedegrass), its use on turf is limited to the southern states.

Non-dietary residential exposure may occur to homeowners or children as a result of exposure during re-entry activities. Using surrogate dislodgeable foliar residue data, and conservative standard EPA exposure scenarios, exposure through the dermal route was calculated. Based on the use pattern, which restricts to number of application to one per year, only short-term risks need to be considered. The relevant

toxicological endpoint for short-term dermal risks is the NOEL of 100 mg/kg/day from a 21–day dermal toxicity study in rabbits. No acute oral hazard has been identified following an acute exposure to S-metolachlor and, therefore, no nondietary assessment is needed.

The short-term dermal post-application risks for adults and children are acceptable, ranging from 520 to 870. These risk estimates exceed the EPA's level of concern for S-metolachlor (all MOEs are greater than 100).

Aggregate exposure. (Drinking Water and Dietary Exposure). Using the total MOE equation for the determination of aggregate chronic exposure (food and drinking water only) resulted in an aggregate MOET of >4,000 for the most sensitive subpopulation, non-nursing infants. For this particular subpopulation, there are no non-dietary exposure contributions to the MOET aggregate value.

D. Cumulative Effects

EPA has examined the common mechanism potential for S-metolachlor and has concluded that S-metolachlor should not be included with some pesticides that comprise the class of chloroacetanilides included in a ''Common Mechanism Group.'' Therefore, a cumulative assessment is not necessary for S-metolachlor.

E. Safety Determination

1. *U.S. population*. Based on the aggregate assessment described above and the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to S-metolachlor (including the proposed uses) in food will utilize less than 0.1 percent of the cRfD for the U.S. population. EPA generally has no concern for exposures below 100 percent 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. Despite the potential for exposure to S-metolachlor in drinking water and from non-dietary, non-occupational exposures, the assessment presented above demonstrates that the high levels of safety exist for current and proposed uses of S-metolachlor; it is not expected that aggregate exposure from all sources will exceed 100% of the RfD. Therefore, one can conclude there is a reasonable certainty that no harm will result from aggregate exposure to S-metolachlor.

2. *Infants and children*. [FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete. A full consideration of the available reproductive toxicity data supporting S-metolachlor demonstrates no increased sensitivity to infants and children. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that the cRfD at 0.1 mg/kg/day is appropriate for assessing aggregate risk to infants and children from use of S-metolachlor.

Based on the aggregate assessment described above, the percent of the cRfD that will be utilized by aggregate exposure to residues of S-metolachlor is less than 0.7 percent for all children subpopulations. 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. Despite the potential for exposure to S-metolachlor in drinking water and from non-dietary, non-occupational exposure, the assessment described above demonstrates that it is not expected that aggregate exposure from all sources provides for a large margin of safety and will exceed 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the exposure assessment, it is concluded there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to S-metolachlor residues.

F. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRL's) established for residues of S-metolachlor in or on raw agricultural commodities.

[FR Doc. 03–20643 Filed 8–12–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0271; FRL–7322–6]

Etoxazole; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0271, must be received on or before September 12, 2003.

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: Daniel Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7546; e-mail address: *kenny.dan@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–2003–0271. 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