please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

EPA is making available the preliminary comparative ecological assessment for nine rodenticides, which included those addressed in the Reregistration Eligibility Decisions (REDs) for the the rodenticide cluster (brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone,) and zinc phosphide, as well as three other rodenticides, warfarin, difethialone, and cholecalciferol. This notice starts a 60–day public comment period for the preliminary comparative ecological assessment. The Agency's preliminary assessment titled: ''Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach,'' is available in the docket.

As additional comments, reviews, and risk assessment modifications become available, these will also be docketed for the nine rodenticides listed in this notice. The Agency cautions that these assessments are preliminary assessments only and that further refinements will be appropriate for some, if not all, of these nine rodenticides. This document reflects only the work and analysis conducted as of the time it was produced and it is appropriate that, as new information becomes available and/or additional analyses are performed, the conclusions contained, therein, may change.

The Agency is providing an opportunity, through this notice, for interested parties to provide written comments and input to the Agency on the preliminary ecological assessment for the chemicals specified in this notice. Such comments and input could address, for example, the availability of additional data to further refine the assessment or address the Agency's risk assessment methodologies and assumptions as applied to these specific chemicals. Comments should be limited to issues raised within the preliminary assessment. Failure to comment on any such issues as part of this opportunity will in no way prejudice or limit a commenter's opportunity to participate fully in later notice and comment processes. All comments should be submitted by February 28, 2003 using the methods in Unit I. Comments will become part of the Agency record for each rodenticide to which it pertains.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: January 18, 2003.

Lois A. Rossi,

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

[FR Doc. 03–2021 Filed 1–28–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0318; FRL–7281–3]

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–2002–0318, must be received on or before February 28, 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: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305–6224; e-mail address: *miller.joanne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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:

- (NAICS 111), e.g., Crop Production
- (NAICS 112), e.g., Animal Production
- (NAICS 311), e.g., Food Manufacturing
- (NAICS 32532), e.g., Pesticide Manufacturing
- (NAICS 32561),e.g., Antimicrobial Pesticide

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 NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in this Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food regarding the applicability of this action to a particular entity , consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0138. 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 in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

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

C. How and To Whom Do I Submit Comments?

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

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any 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–2002–0318. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2002–0318. 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–2002–0318.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2002–0318. 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: January 16, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summaries of the petitions was prepared by the petitioners and represent the views of the petitioners. 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.

6E4638, 8E5011, 6F6751, and 7F4897

EPA has received pesticide petitions (PP 6E4638, 8E5011, 6F6751, and 7F4897) from the Interregional Research Project No. 4 (IR-4), and Syngenta Crop Protection, New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903 and 410 Swing Road, Greensboro, NC 27419, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for residues of S-metolachlor on grasses grown for seed (6E4638), spinach (8E5011), sugar beets and sunflowers (7F4897), and tomato (6F6751). Grasses grown for seed and tomato petitions have been the subject of previous **Federal Register** notices on March 4, 1998, and April 14, 1997, these petitions have been amended to request the establishment of tolerances for S-metolachlor, by establishing a tolerance for residues of S-metolachlor [acetamide, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)-, (S)] (CAS Number 873921–9) 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-morpholinone, each expressed as the parent compound in or on the raw agricultural commodity (RAC) grass forage, grass hay, spinach, sugar beet, sugar beet dried pulp, sugar beet molasses, sugar beet tops, sunflower, sunflower meal, and tomato at 12, 0.2, 0.5, 0.5, 1.0, 3.0, 15.0, 0.5, 1.0, and 0.1 (respectively) 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of 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 (§ 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 detector (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–Grasses grown for seed*. This petition is supported by six field residue tests conducted on grasses grown for seed. Quantitative measurements of the metolachlor hydrolysates, CGA–37913 and CGA–49751, were made for all samples and reported as parent equivalents. In all residue tests, the active ingredient (a.i.) was applied post-emergence at a maximum of 2.0 lbs. a.i./acre at the early regrowth stage prior to weed emergence. The maximum residue in forage was 27 ppm (60–day PHI). Residues in forage declined with increasing PHI. Maximum residues in straw, screenings, and seed were 0.11 ppm, 0.04 ppm, and < 0.08 ppm, respectively.

i. *Spinach*. Magnitude of residue data on the spinach were collected from 12 field trials. In 1994, four field trials were conducted to collect magnitude of residue data in or on spinach. The treated plots each received one post-seeding, pre-emergence, broadcast

application of a.i., targeting a rate of 1.0 lb a.i./acre. The spinach was harvested 45 to 56 days after the application. No residues of CGA–49751 were detected above the LOQ, 0.05 ppm, in spinach samples from two of the three remaining sites. CGA–49751 was detected at 0.1 ppm in one treated sample from Arkansas. Residues of CGA–37913 were detected above the LOQ in samples from all three field sites. The CGA–37913 residues ranged from < 0.10 ppm to 0.33 ppm. The resulting maximum total combined residues of CGA–49751 + CGA–37913 in samples treated at the 1.0 lb a.i./acre rate is < 0.38 ppm.

In 1995, eight field trials were conducted in Maryland, Michigan, New Jersey, Texas, and California. Each of the eight trials consisted of at least an untreated control and one treated plot, where the treated plot received one post-seeding, pre-emergence, broadcast application of a.i., targeting a rate of 1.0 lb a.i./acre. The California and Texas trials also included a second treated plot, which received post-seeding, pre-emergence, broadcast application of a.i., targeting a rate of 2.0 lbs a.i./acre. The spinach was harvested 34 to 69 days after the application. The residues found in 1995 spinach samples, treated targeting the 1.0 lb a.i./acre rate, ranged from less than the LOQ, 0.05 ppm, to 0.85 ppm of CGA–49751, and ranged from less than the LOQ, 0.03 ppm, to 0.107 ppm for CGA–37913 for a maximum combined residue of 0.174 ppm. In the spinach samples treated targeting the 2.0 lbs a.i./acre rate, CGA–49751 residues ranged from < 0.05 ppm to 0.188 ppm and CGA–37913 residues ranged from 0.032 ppm to 0.075 ppm. The maximum combined residues for a.i. at the 2.0 lbs a.i./acre application rate is 0.263. The maximum residues found in or on spinach treated with the proposed labeled rate of 1.0 lbs a.i./acre, was < 0.38 ppm for the combined residues of CGA–37913 and CGA–49741. Residues in spinach treated at the 2.0 lbs a.i./acre application rate did not exceed this combined residues, with a maximum combined residue of 0.263 ppm. IR–4 is conducting additional research to support the 2.0 lbs a.i./acre application rate.

ii. *Sugarbeets*. Eleven sugar beet trials were conducted using six different treatment scenarios. The maximum 1X use rate was 4.0 lbs. a.i./acre applied preplant surface or preplant incorporated (1.33 lbs. a.i./acre) plus a post foliar spray (2.66 lbs. a.i./acre). 3X and 5X treatments were also conducted. Maximum residues at the 1X rate were 14 ppm in sugar beet tops and 0.32 ppm in sugar beet roots. In the processing study, it was determined that tolerances would be required in dried pulp and molasses, but not in refined sugar.

iii. *Sunflower*. A total of 15 residue trials were conducted in major sunflower growing areas of the United States. Applications were made at 1X and 2X the maximum labeled rate of 3.0 lbs. a.i./acre. Processing was also conducted with seeds processed into meal, hulls, crude oil, refined oil and soapstock. Based on these studies, tolerances are proposed in sunflower seed at 0.5 ppm and in sunflower meal at 1.0 ppm.

iv. *Tomato*. Thirteen field trials were conducted in major tomato production areas across the United States. Both tomato and its processed fractions were analyzed for residues of parent, measured as CGA–37913 and CGA–49751. One application at 3.0 lbs. a.i./acre (1X) was made post-foliar to tomato transplants. Exaggerated rate applications (2X, 3X and 5X) were also made. Two of the 13 trials were used for processing into tomato commodity products. No residues LOQ of 0.08 ppm) were found at the 1X rate in the RAC tomatoes. In processed commodities at the 1X rate of 3.0 lbs a.i./acre, residues of parent were found below the method LOQ in tomato puree (0.4 ppm) and above the method LOQ in dry pomace and tomato paste (0.16 and 0.13 ppm, respectively). Because residues in tomato puree and paste (commodities listed in Table 1 of OPPTS 860.1000 as processed commodities of tomatoes) are less than 2X the LOQ of 0.08 ppm, tolerances are not required according to OPPTS 860.1520 (f)(3).

B. Toxicological Profile

1. *Acute toxicity*. The database 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 a.i. was found to be positive in a dermal sensitization test but this effect is mitigated in end-use product formulations.

2. *Genotoxicty*. The database 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 database 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 does tested (HDT). In a 2–generation reproduction study, there was no evidence of parental or reproductive toxicity at the HDT (80 millograms/kilogram/day (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 no observe adversed effect level (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 HDT.

5. *Chronic toxicity*. The database that supports S-metolachlor is considered adequate by EPA. 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 HDT. 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*. The database for S-metolachlor is considered to be complete. 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. The metabolites found are considered to be toxicologically similar to parent. 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, as EPA has agreed, it is not appropriate to include S-metolachlor with the group of

chloroacetanilides that readily undergo dealkylation, producing a common toxic metabolite (quinone imine).

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 (MB) residues. Field trial residues were adjusted for PCT whereas MB residues were not, since this information is inherent in the data. The PCT was assumed to be 100% for all commodities for which no PCT information was available. The chronic assessment was conducted for S-metolachlor using the Dietary Exposure Evaluation Model (DEEM™), version 7.76) by exponent and food consumption information from Department of Agriculture (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 SMBS 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.

The chronic reference dose (RfD) for S-metolachlor is 0.10 mg/kg body weight/day and is based on a 1–year dog study with a NOAEL 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. S-metolachlor is not considered acutely toxic and therefore, acute dietary exposure was not determined. For the purpose of aggregate assessment, the exposure values were expressed in terms of margin of exposure (MOE) which was calculated by dividing the NOAEL by the exposure for each population subgroup. The benchmark MOE for this assessment is 100.

i. *Food.* The risk from chronic dietary exposure to S-metolachlor is considered to be very low. Based on worst-case assumptions, the chronic exposure assessment did not result in any MOE less than 55,428 for even the most impacted population subgroup (children 1-6 years). Syngenta believes that the MOE for chronic exposure would be well above 100 for any population group. A MOE of 100 or more is considered satisfactory. The percent of the chronic RfD ranged from 0.05% for seniors to 0.2% for children 1–6 and Non-nursing infants, theoretically the most exposure population subgroups.

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 a.i./hectare (ha) post-emergence (1.50 kg a.i./ha). The mean annual average EEC was 11.77 part per billion (ppb). It should be noted that extensive monitoring data suggests that this estimated environmental concentration (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 chronic reference dose (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 4,621. 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 or lawn care operators 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 NOAEL 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).

3. *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 MOE_T of 4,630 for the most sensitive subpopulation, non-nursing infants. For this particular subpopulation, there are no non-dietary exposure contributions to the MOE_T 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% of the cRfD for the U.S. population. EPA generally has no concern for exposures below

100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. 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 prenatal and postnatal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to prenatal and postnatal 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 0.2% for non-nursing infants and children 1 to 6 years old, and 0.1% for children 7 to 12 years old. 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-occuptional 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 maximum residue levels (MRL's) established for residues of S-metolachlor in or on raw agricultural commodities.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0001; FRL–7287–6]

Lactofen; Notice of Filing Pesticide Petitions to Establish Tolerances for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP–2003–0001, must be received on or before February 28, 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: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epamail.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 categories and 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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0001. 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 EPA's 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