aerosol sprays, emulsifiable concentrates, and impregnated materials (pet collars). With the exception of the pet collar uses, consumer use of pyriproxyfen typically results in acute and short-term intermittent exposures.

D. Cumulative Effects

There are no other pesticidal compounds that are structurally related to pyriproxyfen and have similar effects on animals. In consideration of potential cumulative effects of pyriproxyfen and other substances that may have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by pyriproxyfen would be cumulative with those of other chemical compounds. Thus, only the potential risks of pyriproxyfen have been considered in this assessment of aggregate exposure and effects. Valent will submit information for EPA to consider concerning potential cumulative effects of pyriproxyfen consistent with the schedule established by EPA at (62 FR 42020 August 4, 1997) and other subsequent EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population*. Chronic exposure to the overall U.S. population is estimated to be 0.002984 mg/kg/bwt day, representing 0.9% of the Reference Dose (RfD). The results of the chronic dietary exposure assessment demonstrate that estimates of chronic dietary exposure for all existing, pending and proposed uses of pyriproxyfen are well below the chronic RfD of 0.35 mg/kg/bwt day. The estimated chronic dietary exposure from food for the overall U.S. population and many non-child/infant subgroups is from 0.002123 to 0.003884 mg/kg/bwt day, 0.607 to 1.100% of the RfD. Generally, the Agency has no cause for concern if total residue contribution is less than 100% of the RfD. Valent concludes that there is a reasonable certainty that no harm will result to the overall U.S. population or any non-child/infant subgroups from aggregate, chronic dietary exposure to pyriproxyfen residues.

2. *Infants and children—i.* Safety factor for infants and children. In assessing the potential for additional sensitivity of infants and children to residues of pyriproxyfen, FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to 10-fold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children.

The toxicological data base for evaluating prenatal and postnatal toxicity for pyriproxyfen is complete with respect to current data requirements. There are no special prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 2-generation reproductive toxicity study in rats. Valent concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed for pyriproxyfen to be further protective of infants and children.

ii. *Chronic dietary exposure and risk infants and children.* For the most highly exposed sub-population, children 1 to 6 years of age, exposure is calculated to be 0.007438 mg/kg/bwt day, or 2.1% of the RfD. Using the conservative exposure assumptions, the percentage of the RfD that will be utilized by chronic dietary (food only) exposure to residues of pyriproxyfen ranges from 0.002601 mg/kg/bwt day for nursing infants, up to 0.007438 mg/kg/bwt day for children (1 to 6 years of age), 0.743 to 2.125% of the RfD, respectively. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Valent concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate, chronic dietary exposure to pyriproxyfen residues.

iii. *Drinking water*. The average 56–day concentration predicted in the simulated pond water was 0.16 parts per billion (ppb). Using standard assumptions about body weight and water consumption, the chronic exposure to pyriproxyfen from this drinking water would be 4.57×10^{-6} and 1.6×10^{-5} mg/kg/bwt day for adults and children, respectively; 0.0046% of the RfD 0.35 mg/kg/day for children. Based on this worse case analysis, the contribution of water to the dietary risk is negligible.

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

F. International Tolerances

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

[FR Doc. 03–5315 Filed 3–6–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0011; FRL–7290–1]

Sulfentrazone; Notice of Filing Pesticide Petitions to Establish Tolerances 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–2003–0011, must be received on or before April 7, 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: brothers.shaja@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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in insert appropriate cite to either another unit in the preamble or a section in a rule. 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 identification (ID) number OPP–2003–0011. 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–2003–0011 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–2003–0011. 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–2003–0011.

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–2003–0011. 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 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 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:January 30, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner's summaries of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summaries of the petitions was prepared by FMC Corporation and represents the view of FMC Corporation. The petitions summaries announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 and FMC Corporation

PP (0E6149, 1E6311, 2E6405, 2E6498, 2E6500, 0F6116, and 2F6391

EPA has received pesticide petitions (0E6149, 1E6311, 2E6405, 2E6498, and 2E6500) from Interregional Research Project Number (IR–4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902. EPA has also received pesticide petitions (0F6116 and 2F6391) from FMC Corporation, Agricultural Products Group, 1735 Market Street, Philadelphia, PA 19103 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.498 by establishing tolerances for residues of sulfentrazone (*N*-2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl-methanesulfonamide) and its metabolites 3-hydroxymethyl-sulfentrazone (*N*-2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and 3-desmethyl sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) in or on the following raw agricultural commodities:

1. PP 0E6149 proposes the establishment of a tolerance for sunflower, seed at 0.2 parts per million (ppm).

2. PP 1E6311 proposes the establishment of tolerances for horseradish, roots at 0.2 ppm, cabbage at 0.2 ppm, peppermint, tops at 0.3 ppm, and spearmint, tops at 0.3 ppm.

3. PP 2E6405 proposes the establishment of a tolerance for potato at 0.1 ppm.

4. PP 2E6498 proposes the establishment of a tolerance for bean, lima, succulent at 0.15 ppm.

5. PP 2E6500 proposes the establishment of a tolerance for asparagus at 0.15 ppm.

6. PP 0F6116 proposes the establishment of tolerances for peanut nutmeat and its processed parts at 0.2 ppm, and sugarcane and its processed parts at 0.1 ppm.

7. PP 2F6391 proposes the establishment of tolerances for corn, field, forage at 0.25 ppm, corn, field,

stover at 0.35 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes summaries of the petitions prepared by FMC Corporation, Philadelphia, PA 19103.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of sulfentrazone in plants is adequately understood for the existing and proposed tolerances.

2. *Analytical method*. The proposed analytical method for determining residues of sulfentrazone is hydrolysis followed by gas chromatographic separation.

3. *Magnitude of residues*. The magnitude of residues is adequately understood for the proposed commodities.

B. Toxicological Profile

1. *Acute toxicity*. A battery of acute toxicity studies placed technical sulfentrazone in toxicity categories III and IV. No evidence of sensitization was observed following dermal application in guinea pigs. In an acute neurotoxicity study in rats at gavage doses of 0, 750, or 2,000 milligrams/kilogram (mg/kg), the no observable adverse effect level (NOAEL) of 250 mg/kg and the lowest observable adverse effect level (LOAEL) of 750 mg/kg were based upon increased incidences of clinical signs, Functional Observation Battery (FOB) findings, and decreased motor activity which were reversed by day 14 post-dose. There was no evidence of neuropathology.

2. *Genotoxicity*. A reverse gene mutation assay (*salmonella typhimurium*) yielded negative results, both with and without metabolic activation. A mouse lymphoma forward gene mutation assay yielded negative results with equivocal results without activation. A mouse micronucleus assay test was negative following intraperitoneal injection of 340 mg/kg.

3. *Reproductive and developmental toxicity*. In a dermal developmental study in the rat at doses of 0, 5, 25, 50, 100, and 250 mg/kg/day, a maternal (systemic) NOAEL was established at 250 mg/kg/day. Significant treatment-related increases in the fetal and litter incidences of incompletely ossified lumbar vertebral arches, hypoplastic or wavy ribs, and incompletely ossified or nonossified ischia or pubes occurred at the high-dose (250 mg/kg/day). An additional significant increase in the high-dose fetal incidence of variations in the sternebrae (incompletely ossified or unossified) was not judged to be treatment-related. At 250 mg/kg/day, the mean numbers of thoracic vertebral and rib ossification sites were significantly decreased, a high-dose effect of treatment with sulfentrazone consistent with the significant treatment-related hypoplasia observed in the skeletal evaluation of the ribs. Therefore, the developmental (fetal) LOAEL is 250 mg/kg/day based on decreased fetal body weight; increased incidences of fetal variations: Hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubes; and reduced number of thoracic vertebral and rib ossification sites. The developmental (fetal) NOAEL is 100 mg/kg/day.

A developmental toxicity study in rabbits was conducted at gavage dose levels of 0, 100, 250, or 375 mg/kg/day. Treatment-related incidences of decreased feces and hematuria were noted at 250 mg/kg/day or greater. In addition, at the 375 mg/kg/day dose level, 5 rabbits aborted. Significant reductions in mean body weight change were observed for the dosing period (GD 7–19) and for the study duration (GD 0–29, both before and after adjustment for gravid uterine weight) at the 250 and 375 mg/kg/day dose levels. Therefore, the maternal (systemic) LOAEL is 250 mg/kg/day, based upon increased abortions, clinical signs (hematuria and decreased feces), and reduced body weight gain. The maternal (systemic) NOAEL is 100 mg/kg/day. Skeletal evaluation in fetuses revealed dose-related and treatment-related findings at the 375 mg/kg/day dose level. These included significant increases in both the fetal and litter incidences of fused caudal vertebrae (a malformation) and of partially fused nasal bones (a variation). In addition, at 375 mg/kg/day, significant treatment-related reductions in ossification site averages were observed for metacarpals and both forepaw and hindpaw phalanges. Therefore, the developmental (fetal) LOAEL is 250 mg/kg/day, based upon increased resorptions, decreased live fetuses per litter, and decreased fetal weight. The developmental (fetal) NOAEL is 100 mg/kg/day.

A 2–generation reproduction study in the rat at dietary levels of 14, 33, or 46 mg/kg/day in males and 16, 40, or 56 mg/kg/day in females established a NOAEL for systemic and reproductive/developmental parameters of 14 mg/kg/day for males and 16 mg/kg/day for females. The LOAEL for systemic and reproductive/development parameters was 33 mg/kg/day for males and 40 mg/kg/day for females. Systemic effects were comprised of decreased body weight gains, while reproductive/developmental effect at the LOAEL included degeneration and/or atrophy in the testes, with epididymal sperm deficits, in the second (F1) generation males. Male fertility in the F1 generation was reduced at higher doses; litter size, pup survival, and pup body weight for both generations were also effected at higher doses.

4. *Subchronic toxicity.* A 90–day subchronic toxicity study was conducted in rats, with dietary intake levels of 0, 3.3, 6.7, 19.9, 65.8, 199.3, or 534.9 mg/kg/day for males and 0, 4, 7.7, 23.1, 78.1, 230.5, or 404.3 mg/kg/day for females respectively. NOAELs of 19.9 mg/kg/day in males and 23.1 mg/kg/day in females were based on clinical anemia.

A 90–day subchronic feeding study was conducted in mice by dietary admix at doses of 0, 10.3, 17.8, 60.0, 108.4, or 194.4 mg/kg/day for males and 0, 13.9, 29.0, 79.8, 143.6, or 257.0 mg/kg/day for females, respectively. NOAELs of 60 mg/kg/day (males) and 79.8 mg/kg/day (females) were based on decreases in body weights and/or gains; decreased erythrocytes, hemoglobin (Hgb) and hematocrit (HCT) values; and splenic microscopic pathology.

In a 90–day subchronic feeding study in dogs administered by dietary admix at doses of 0, 10, 28, or 57 mg/kg/day for males and 0, 10, 28, or 73 mg/kg/day for females, a NOAEL of 28 mg/kg/day was determined for both males and females based on decreases in Hgb and HCT, elevated alkaline phosphatase levels, increased liver weights and microscopic liver as well as splenic changes.

A 90–day subchronic neurotoxicity study in the rat was conducted at dietary levels of 30, 150, or 265 mg/kg/day in males, and 37, 180, or 292 mg/kg/day in females, with a NOAEL of 30 mg/kg/day in males and 37 mg/kg/day in females. The LOAEL was 150 mg/kg/day for males and 180 mg/kg/day for females based on increased incidences of clinical signs, decreased body weights, body weight gains, and food consumption in females and increased motor activity in females at week 13. There were no neurohistopathological effects on the peripheral or central nervous system.

5. *Chronic toxicity*. A 12–month feeding study in dogs was dosed at levels of 0.0, 24.9, or 61.2 mg/kg/day for male dogs and 0.0, 10.4, 29.6, or 61.9

mg/kg/day for female dogs in the control through high-dose groups, respectively, with a NOAEL of 24.9 mg/kg/day for males and 29.6 mg/kg/day for females based on hematology effects and microscopic liver changes.

An 18–month feeding/carcinogenicity study in mice was conducted with dietary intake of 0, 46.6, 93.9, 160.5, or 337.6 mg/kg/day for males and 0, 58.0, 116.9, 198.0, or 407.1 mg/kg/day for females. A NOAEL of 93.9 mg/kg/day in males and 116.9 mg/kg/day in females was based on decreases in Hgb and HCT. There were no treatment-related increases in tumors of any kind observed at any dose level.

In a 24–month chronic feeding/carcinogenicity study in rats at dietary doses of 0, 24.3, 40.0, 82.8, or 123.5 mg/kg/day for males and 20.0, 36.4, 67.0, or 124.7 mg/kg/day for females, an overall NOAEL of 40.0 mg/kg/day in males and 36.4 mg/kg/day in females was based on hematology effects and reduced body weights. There was no evidence of a carcinogenic response.

6. *Animal metabolism*. A metabolism study in rats indicated that approximately 84 to 104% of the orally administered dose of sulfentrazone was excreted in the urine, and that the pooled urinary radioactivity consisted almost entirely of 3-hydroxymethyl sulfentrazone. Pooled fecal radioactivity showed that the major metabolite consisted of 3-hydroxymethyl-sulfentrazone (1.26 to 2.55% of the administered dose). The proposed metabolic pathway appeared to be conversion of the parent compound mainly to 3-hydroxymethyl-sulfentrazone (excreted in urine and feces).

7. *Endocrine disruption*. An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however, no evidence of such effects were reported in the chronic or reproductive toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that sulfentrazone causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. A Tier 3 short-term exposure analysis has been performed to estimate the exposure for all adults, adult females, and toddlers (3 to 4 years of age) in the U.S. population for these raw commodities and processed commodities. This analysis utilized Novigen's (Novigen Sciences, Inc.) Dietary Exposure Evaluation Model (DEEM) software; field trial data for registered and pending crop uses; percent crop treated information; and consumption data from the United States Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals (CSFIIs), conducted from 1994–1996.

ii. *Drinking water*. A Tier 1 short-term drinking water exposure assessment was conducted to determine exposure risk of sulfentrazone residues from consumption of water. This analysis was performed utilizing EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure Risk Assessments (DUS EPA, 1997b), the absorbed (systemic) aggregate exposure estimates, and water data from FMC Corporation ground water study conducted in North Carolina.

2. *Non-dietary exposure*. The primary source for human non-dietary exposure to sulfentrazone will be from post-application exposure to treated residential turf grass. The routes of sulfentrazone exposure were dermal post-application exposure for adults and toddlers, and post-application incidental ingestion of sulfentrazone due to the hand-to-mouth behavior of toddlers. A worst case short-term non-dietary exposure analysis was conducted using algorithms and default factors published in EPA's SOPs for Residential Exposure Assessments.

D. Cumulative Effects

Cumulative exposure to substances with common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers ''available information'' concerning the cumulative effects of a particular pesticide residue and ''other substances that have a common mechanism of toxicity.''

In the case of sulfentrazone, EPA has determined that it does not have the capability to apply the information in its files to a resolution of common mechanism issues in a manner that would be useful in a risk assessment. This tolerance determination therefore does not take into account common mechanism issues. The Agency will reexamine the tolerances for sulfentrazone, if reexamination is appropriate, after the Agency has determined how to apply common mechanism issues to its pesticide risk assessments.

E. Safety Determination

1. *U.S. population*. The absorbed (systemic) aggregate exposure estimates for all adults, and adult females were found to be 0.0015 mg/kg/day and 0.0017 mg/kg/day, respectively. The acute dietary (99.9%), non-dietary, and aggregate margin of exposure (MOE) for all adults were found to be 12,353, 7,571, and 6,726 respectively. The acute dietary (99.9%), non-dietary and aggregate MOE for adult females were 22,857, 6,327, and 5,717 respectively. The MOE from the limited potential for short-term exposure from residential uses was >1,000. Based on these assessments, it can be concluded that there is reasonable certainty of no harm to the U.S. population from exposure to sulfentrazone.

2. *Infants and children*. The absorbed (systemic) aggregate exposure estimates for toddlers were found to be 0.0054 mg/kg/day. The acute dietary (99.9%), non-dietary, and aggregate MOE for toddlers were found to be 6,721, 2,048, and 1,869 respectively. The MOE from the limited potential for short-term exposure from residential uses was >1,000. Based on these assessments, it can be concluded that there is reasonable certainty of no harm to infants and children from exposure to sulfentrazone.

The calculated drinking water levels of concern for all adults, and adult females were estimated to be 298 parts per billion (ppb), 250 ppb, respectively. These values exceed the maximum water-monitoring residue of 42 ppb (from the North Carolina study). Therefore, the data indicate a low risk potential due to the aggregate (food, water and residential) exposures to sulfentrazone residues.

F. International Tolerances

There are no Codex Alimentarius Commission (Codex) maximum residue levels for sulfentrazone.

[FR Doc. 03–5319 Filed 3–6–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0350; FRL–7285–8]

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–2002–0350, must be received on or before April 7, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or