F. International Tolerances

There are no CODEX maximum residue limits established for formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl) in or on crops or commodities at this time.

[FR Doc. 03–26667 Filed 10–21–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0257; FRL–7322–5]

Mesosulfuron-methyl; 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–2003–0257, must be received on or before November 21, 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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–2003–0257. 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–2003–0257. 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–2003–0257. 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–2003–0257.

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–2003–0257. 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: October 9, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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

Bayer CropScience

PP 1F6298

EPA has received a pesticide petition (1F6298) from Bayer CropScience, 2

T.W. Alexander Drive, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of methyl 2-[[[[(4,6-dimethoxy-2-pyrimidinyl) amino]carbonyl]amino-]sulfonyl]-4-[[(methylsulfonyl) amino]methyl]benzoate, CAS No. 208465–21–8 (Mesosulfuron-methyl, Company Code AE F130060) in or on the raw agricultural commodities wheat grain at 0.03, wheat forage at 0.60, wheat straw at 0.30, wheat hay at 0.06, wheat germ at 0.10, aspirated grain fractions at 0.25, and milled byproducts at 0.03 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of mesosulfuron-methyl in wheat has been investigated and is understood. Identification of the extractable residues in grain was not possible due to the extremely low residue levels. In mature straw, three metabolites were identified at very low levels in addition to the parent AE F130060. Demethylation of one methoxy group on the pyrimidyl ring led to methyl 2-[3-(4-hydroxy-6-methoxy-pyrimidin-2-yl)ureidosulfonyl]-4-methanesulfonamidomethylbenzoate. Cleavage of the sulfonylurea bridge formed the interim phenyl metabolite, methyl-4-methanesulfonamidomethyl-2-sulfamoyl-benzoate, which further cyclised to 6-methanesulfonamidomethyl-1,2-benzisothiazol-3(2H)-one 1,1-dioxide. The same metabolites were also detected in green plants (forage stage) as the main components; however, the parent substance contributed to a higher proportion to the total radioactive residue. All metabolites detected in plants were also found in animal metabolism studies.

2. *Analytical method*. Based on the results of the metabolism studies, the analytical target selected was the parent compound mesosulfuron-methyl (AE F130060). Extractable residues of AE F130060 are extracted from the crop matrix by blending with a solution of acetonitrile, water and triethylamine. After filtration, the extract is partitioned with hexane, then concentrated to a reduced volume. The resulting solution is diluted with 0.01M formic acid, and partitioned with ethyl acetate. An aliquot of ethyl acetate is evaporated to dryness and reconstituted in acetonitrile/water. This acetonitrile/water extract is analyzed by HPLC-MS/MS for AE F130060. For some forage samples, an additional solid phase extraction clean up was required to suppress matrix enhancement effects.

3. *Magnitude of residues*. The metabolism studies with 14C-labelled mesosulfuron-methyl in wheat demonstrated that in general, low residues were detected in the plant samples. These results have been confirmed in a total of 24 North American residue field trials using a water dispersible granule (WG) formulation containing 75% weight/weight (w/w) mesosulfuron-methyl. The preparation was applied in a single application, at a rate of 25 g a.i./ha. Pre-harvest intervals were between 4 and 68 days, 21 and 96 days, 50 and 91 or 50 and 134 days respectively for forage, hay, straw and grain. Residues in forage and straw ranged from below the limit of quantitation (LOQ), (0.05 milligrams/kilogram (mg/kg)) to 0.55 mg/kg and 0.25 mg/kg respectively. No residues above the LOQ of 0.05 mg/kg were observed in hay. Residues in grain ranged from below the LOQ (0.01 mg/kg) to 0.026 mg/kg. Tolerances for mesosulfuron-methyl are proposed at 0.6 mg/kg, 0.06 mg/kg, 0.3 mg/kg and 0.03 mg/kg respectively, for wheat forage, hay, straw and grain. In a wheat processing study, residues of mesosulfuron-methyl in the grain reached 0.011 mg/kg following treatment of the wheat at 75 g a.i./ha. This exaggerated rate is approximately 5 times the maximum proposed label rate. In the processed fractions, residues of mesosulfuron-methyl were 0.014 mg/kg, 0.045 mg/kg and 0.014 mg/kg respectively in shorts, wheat germ and bran. No mesosulfuron-methyl residues above the LOQ (0.01 mg/kg) were observed in flour or middlings. Concentration factors of 1.3, 4.2 and 1.3, respectively were estimated for shorts, wheat germ and bran. Therefore, tolerances are proposed at 0.1 mg/kg for wheat germ and 0.03 mg/kg for milled by-products (shorts, middlings and bran). No tolerance is proposed for flour since there was no evidence of concentration. Therefore, the tolerance for wheat grain will cover flour. In the same study, samples of aspirated grain dust were collected and found to contain residues of 0.23 mg/kg. Accordingly, a tolerance of 0.25 mg/kg is proposed for aspirated grain fractions. Although, wheat grain is fed to poultry, and cattle may be grazed on forage or fed grain, hay or straw, tolerances in meat, milk or eggs are not necessary because dietary burden calculations have demonstrated that quantifiable residues of mesosulfuron-methyl will not occur in animal tissues.

B. Toxicological Profile

1. *Acute toxicity*. Mesosulfuron-methyl has very low acute toxicity to mammals by all tested routes of exposure. Both the oral and dermal LD_{50}'s in the rat are greater than 5,000 milligrams/kilogram body weight (mg/kg bwt). The acute inhalation LC_{50} (4–hour) is greater than 1.33 milligrams per liter (mg/L) air, the maximum attainable concentration. Mesosulfuron-methyl was not irritating to rabbit skin and only slightly irritating to the eye. Mesosulfuron-methyl did not induce delayed contact hypersensitivity (skin sensitization) in the maximization test. Based on these results, mesosulfuron-methyl is expected to be in EPA Category III or IV for all routes of acute exposure.

2. *Genotoxicty*. Testing for possible genotoxic properties of mesosulfuron-methyl *in vivo* and *in vitro* gave consistently negative results. The *in vitro* test battery included investigations for gene mutation in bacteria and mammalian cells, examination of chromosomal aberrations in Chinese hamster cells and testing for unscheduled DNA-synthesis (UDS) in primary rat hepatocytes. The *in vivo* mouse micronucleus assay was also conducted. As all five tests were negative and no evidence for carcinogenicity was seen in life-time experiments in two species, results indicate that mesosulfuron-methyl does not possess significant genotoxic activity.

3. *Reproductive and developmental toxicity*. A two-generation reproduction study in rats was conducted with dietary dose levels of 0, 160, 1,600 and 16,000 ppm of technical mesosulfuron-methyl. There were no treatment-related adverse effects of the test material in any groups up to and including 16,000 ppm in the P and F1 generation male or female rats. This included mortality, clinical observations, general behavior, body weights, body weight gain, feed consumption, estrus cycle, sperm production, fertility, parturition, lactation, organ weights or microscopic findings. Therefore, the no observed adverse effect level (NOAEL) for the F0 and F1 parental animals for toxicity and reproductive effects is 16,000 ppm. The NOAEL for toxicity, growth and development of the F1a, F1b, F2a, and F2b offspring is 16,000 ppm, equivalent

to a mean daily test substance intake of at least 1,175 and 1,388 mg/kg bwt for males and females, respectively.

A rat developmental toxicity (teratogenicity) study was conducted with dose levels of 0, 100, 315 and 1,000 mg mesosulfuron-methyl/kg bwt. Treatment did not cause lethality or effects on body weight. There were no clinical signs of toxicity. Pregnancy indices were unaffected. No treatment-related effects were observed in fetuses upon external, internal or skeletal evaluation. Therefore, the no observed effect level (NOEL) for both maternal and embryo-fetal toxicity was the limit dose of 1,000 mg/kg. Mesosulfuron-methyl was not teratogenic in rats.

The rabbit developmental toxicity (teratogenicity) study was conducted with dose levels of 0, 100, 315 and 1,000 mg mesosulfuron-methyl/kg body weight/day. No treatment-related deaths or clinical signs were seen. There were no effects on body weight development. No treatment-related effects were observed in fetuses upon external, internal or skeletal examination. Therefore, the NOAEL for maternal and developmental toxicity was the limit dose of 1,000 mg/kg. Mesosulfuron-methyl was not teratogenic in the rabbit. In reproductive and developmental toxicity studies, mesosulfuron-methyl gave no evidence of reproductive, embryo-fetal or neonatal toxicity. Therefore, the potential for reproductive toxicity-related to mesosulfuron-methyl is low.

4. *Subchronic toxicity.* In a 90–day rat feeding study, groups of 10 male and 10 female Wistar rats were fed diets containing either 0, 240, 1,200, 6,000 or 12,000 ppm of mesosulfuron-methyl. The administration of mesosulfuron-methyl up to the limit dose of 12,000 ppm was well tolerated. There were no mortalities and no adverse clinical findings. Body weight gains and feed consumption were comparable in all groups. There were no adverse behavioral, neurological or ophthalmoscopic findings. There were no effects on organ weights or histopathology. The NOAEL for this study was considered to be 12,000 ppm, corresponding to a daily substance intake of 907.5 mg/kg bwt in males and 976.5 mg/kg in females.

In a 90–day feeding study in mice, mesosulfuron-methyl was administered at dietary concentrations of 0, 140, 1,000, and 7,000 ppm. Leukocyte counts were slightly lower in males at 1,000 and 7,000 ppm. However, since there were no corresponding histopathology findings, in particular no compensatory effect in the bone marrow and no adverse clinical effects associated with this finding, the NOAEL was 7,000 ppm mesosulfuron-methyl, equivalent to daily intakes of 1,238 mg/kg bwt/day in males and 1,603 mg/kg bwt/day in females.

Groups of 4 male and 4 female beagle dogs were administered mesosulfuron-methyl at dietary concentrations of 0, 2,000, 10,000, and 20,000 mg/kg/ bwt/day for 13 consecutive weeks. Mesosulfuron-methyl at concentrations of up to 20,000 ppm did not affect the general health status, behavior, body weight development or food consumption in dogs. No adverse effects were seen in hematology or biochemistry at any dose. There were no treatment-related changes in organ weights or histopathology. The NOAEL was 20,000 ppm (equating to 648 mg/kg bwt/day for males and 734 mg/kg bwt/day for females).

5. *Chronic toxicity.* A 1–year study was conducted in beagle dogs at doses of 1, 400, 4,000 and 16,000 ppm in the diet. There were no treatment-related effects noted other than non-specific signs of stomach irritation in some high dose dogs. The NOAEL was considered to be 16,000 ppm, equivalent to 574 mg/kg of body weight per day.

The oncogenic potential of mesosulfuron-methyl was examined in bioassays with rats and mice over dietary exposure periods of 24 months and 18 months, respectively.

Dietary administration of technical mesosulfuron-methyl to groups of 80 male and 80 female Wistar rats at concentrations of 0, 160, 1,600 or 16,000, ppm (corresponding to a daily substance intake of up to 865 mg/kg bwt for males and 1,056 mg/kg bwt for females) did not cause clinical symptoms or changes in hematology or biochemistry. All neoplastic and non-neoplastic lesions noted in the study were considered to be incidental findings commonly noted in rats of this strain and age and not related to treatment. The NOAEL for the daily administration of technical mesosulfuron-methyl for 12 or 24 months to male and female Wistar rats is 16,000 ppm.

Groups of 60 male and 60 female CD-1 mice were given dietary concentrations of 0, 80, 800, or 8,000 ppm technical mesosulfuron-methyl for up to 78 weeks. Mesosulfuron-methyl was not tumorigenic and did not cause non-neoplastic lesions. Leukocyte counts were increased in males and females at 8,000 ppm and in males at 800 ppm. However, as there were no indications for any adverse clinical or morphological effects related to the increased leukocyte values (and decreased values were seen in the 90–day study), 800 ppm is considered to be the NOAEL in the 18-month study. The NOAEL is based on lower body weight gains in females at the high dose level. This is equivalent to a mean achieved intake of 103 and 130 mg test substance/kg bwt/day in males and females, respectively.

Mesosulfuron-methyl is expected to be classified as ''Not Likely'' to be a carcinogen based on the lack of carcinogenic findings in rats and mice.

6. *Animal metabolism.* Following a single oral administration of either 10 or 1,000 mg/kg mesosulfuron-methyl to rats, 95.1% of the dose was found in the excreta 24 hours post-dosing. Fecal excretion was predominant, while only 12.8% and 1.3% of the low and high dose, respectively, were found in the urine. The predominant excretion product was unchanged mesosulfuron-methyl (>68%). The main metabolic pathway was cleavage of the sulfonylurea-bridge leading to the pyrimidine moiety (2-amino-4,6-dihydroxypyrimidine) and the resulting phenyl moiety which further cyclised to 6-methanesulfonamidomethyl-1,2-benzisothiazol-3(2H)-one 1,1-dioxide. Minor metabolic reactions observed were O-demethylation of the intact molecule at the pyrimidine moiety, cleavage of the sulfonylurea-bridge to form 4-hydroxy-6-methoxypyrimidin-2-yl-urea, and additional O-demethylation to 4,6-dihydroxypyrimidin-2-yl-urea. In addition, cleavage of the methanesulfonamidomethyl side chain leading to the free amine with further transformation to the alcohol (2-[3-(4,6-dimethoxypyrimidin-2-yl)ureidosulfonyl]-4-methanesulfonamidomethyl-benzoic acid) was also seen. An additional minor metabolite was a benzoic acid metabolite, formed by hydrolysis of the methyl ester of the parent.

Metabolism studies on mesosulfuron-methyl in ruminants and poultry were performed with application of dose levels which were equivalent to 20 ppm and 10 ppm, respectively. The results showed that mesosulfuron-methyl is predominantly excreted with little systemic distribution and limited metabolism. Residue levels in milk, meat and eggs were extremely low and the elimination from tissues was rapid. No tolerances have been proposed for animal tissues. The metabolic pathway in ruminants and poultry was similar to that in rats.

7. *Endocrine disruption.* No special studies investigating potential estrogenic or endocrine effects of mesosulfuron-methyl have been conducted. However, the standard battery of required studies has been

completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects and no such effects were noted in any of the studies with mesosulfuron-methyl.

C. Aggregate Exposure

1. *Dietary exposure*. Mesosulfuron-methyl is proposed for use as an herbicide on cereals. No non-agricultural uses are anticipated. The potential sources of exposure would consist of any potential residues in food and drinking water.

i. *Food*. Chronic dietary analysis was conducted to estimate exposure to potential mesosulfuron-methyl residues in/on wheat. A Tier I analysis was conducted using the DEEM™ software and the 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) food consumption data. It was assumed that residues were at tolerance levels of 0.03 ppm in grain and that 100% of crop was treated. Additionally, based on the results from appropriate studies, it was assumed that there was no concentration into processed commodities and that contributions from residues in meat, milk or eggs are not required. A chronic RfD of 1 mg/kg/day is derived from the 18–month mouse NOAEL of 103 mg/kg bwt/day, applying an uncertainty factor of 100 to account for intra-species variation and inter-species extrapolation. Using these input parameters, chronic exposure estimates for the U.S. population and all 25 population subgroups utilized less than 0.01% of the chronic reference dose. The most highly exposed population subgroup was non-nursing infants (<0.01% cRfD). These values are highly conservative, having been based on worst case assumptions of tolerance level residues and 100% of the crop treated.

ii. *Drinking water*. EPA's standard operating procedure (SOP) for drinking water exposure and risk assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct a screening level drinking water assessment. These tools include water models such as Screening Concentration in Groundwater (SCI-GROW), Generic Expected Environmental Concentration (GENEEC), EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZMS/EXAMS), the Food Quality Act (FQPA) Index Reservoir Screening Tool, and monitoring data. If monitoring data are not available, then models are used to predict potential residues in surface water and ground water and the highest value is assumed to be the potential drinking water residue. In the case of mesosulfuron-methyl, monitoring data do not exist; therefore, a Tier 1 model calculation was conducted to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for chronic exposures for adults is 35,000 ppb (35 ppm). The chronic DWLOC for children/toddlers is 15,000 ppb (15 ppm). The worst case chronic drinking water estimated concentration (DWEC) is 0.105 ppb based on the FQPA Index Reservoir Screening Tool simulation of runoff into surface water in a standard EPA exposure assessment scenario. The calculated DWLOCs for chronic exposures for all adults and children, therefore, greatly exceed the DWECs from the models.

2. *Non-dietary exposure*. Exposure to mesosulfuron-methyl for the mixer/loader/ground boom/aerial applicator was calculated using the Pesticide Handlers Exposure Database (PHED). It was assumed that the product would be applied to a maximum of 32 hectares per day (80 A/day) by ground boom applicator and 140 hectares per day (350 A/day) by aerial applicator at a maximum use rate of 15 grams active ingredient/hectares (a.i./ha.) Normal work attire consisting of long-sleeved shirt, long pants, and protective gloves was assumed in the PHED assessment. Margin of exposures (MOEs) for a 70 kg operator were calculated utilizing the NOAEL of 648 mg/kg body weight/day from the 90–day dog dietary study, which is adjusted for a 15% dermal absorption as revealed in an *in vivo* dermal absorption study, and 100% inhalation absorption to obtain the absorbed dermal and inhalation dose, respectively. The combined MOE (inhalation plus dermal) for mesosulfuron-methyl was 3,240,000 for a ground operator undertaking mixing, loading and spraying. For aerial application where the mixer/loader was assumed to be a different operator from the pilot, combined MOEs were 926,000 for the mixer/loader and 12,000,000 for the pilot. The results indicate that large margins of safety exist for the proposed use of mesosulfuron-methyl.

D. Cumulative Effects

There is no available data at this time to determine whether mesosulfuron-methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Therefore, a cumulative assessment was not done for this chemical.

E. Safety Determination

1. *U.S. population*. Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure, in this case food only, to the proposed uses of mesosulfuron-methyl will utilize <0.01% of the reference dose for the U.S. population. The actual exposure is likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. Drinking water levels of comparison based on the dietary exposure are much greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to mesosulfuron-methyl.

2. *Infants and children*. No evidence of increased sensitivity to fetuses was noted in developmental toxicity studies in rats or rabbits. There has been no indication of reproductive effects or indication of increased sensitivity to the offspring in the 2-generation rat reproduction study. No additional safety factor to protect infants and children is necessary as there is no evidence of increased sensitivity in infants and children.

Using the conservative assumptions described in the exposure section above, the percent of the reference dose that will be used for exposure to residues of mesosulfuron-methyl in food for non-nursing infants (the most highly exposed sub group) is <0.01%. The children (1–6) exposure uses are also <0.01% of the reference dose. As in the adult situation, drinking water levels of comparison are much higher than the worst case drinking water estimated concentrations and are expected to use well below 100% of the reference dose, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of mesosulfuron-methyl.

F. International Tolerances

There are no Codex Alimentarius Commission maximum residue levels established for residues of mesosulfuron-methyl.

[FR Doc. 03–26670 Filed 10–21–03; 8:45 am]

BILLING CODE 6560–50–S