ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0339; FRL–7285–1]

Fluroxypyr; 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 fluroxypyr in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0339, must be received on or before February 14, 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 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–2002–0339. 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–2002–0339. 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–2002–0339. 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–2002–0339.

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–2002–0339. 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: December 31, 2002.

Meredith F. Laws,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner 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.

Dow AgroSciences

PP 9F6050

EPA has received a pesticide petition (9F6050) from Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dicloro-6-fluoro-2-pyridinyl)oxy)acetate or fluroxypyr MHE] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid], free and conjugated, all expressed as fluroxypyr, in or on the following raw

agricultural commodities at 0.02 parts per million (ppm) for kernels plus cob with husk removed, and 1.0 ppm for forage. Tolerances for residues of fluroxypyr MHE in or on field corn are being proposed in support of this registration as follows: Grain, 0.02 ppm; forage, 1.0 ppm; and stover, 0.5 ppm. Tolerances for residues of fluroxypyr MHE in or on sorghum as follows: Sorghum grain, 0.02 ppm; sorghum forage, 2.0 ppm; sorghum stover, 4.0 ppm. Tolerances for residues of fluroxypyr MHE in or on grasses as follows: Grass forage, 120 ppm; grass hay, 160 ppm; and grass silage, 100 ppm. Based on the above tolerances and an animal feeding study, increased tolerances are also proposed for fluroxypyr MHE and fluroxypyr, expressed as combined residues of total fluroxypyr, in or on the following animal commodities: Milk of cattle, goats, hogs, horses and sheep, 0.3 ppm; and kidney of cattle, goats, hogs, horses and sheep, 1.5 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*. Fluroxypyr is a systemic herbicide that is readily translocated and rapidly converts to the acid form following absorption. Fluroxypyr moves readily throughout the plant via the phloem (nutrient transporting) system and to a lesser extent through the xylem (water-transporting). Fluroxypyr is distributed throughout the entire plant, including the meristems and other developing plant parts.

2. *Analytical method*. There is a practical method (GC with MS detection) for measuring levels of fluroxypyr MHE in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set for, the proposed tolerances. Fluroxypyr has been tested through the FDAs Multi-residue Methodology, Protocols C, D. and E. The results have been published in the FDA Pesticide Analytical Manual, Volume I.

3. *Magnitude of residues*. The metabolism of fluroxypyr MHE in plants and animals (goats and poultry) is adequately understood for the purposes of these tolerances. Magnitudes of residue studies were conducted for field corn, sweet corn, sorghum and grasses. A process products study was not conducted in field corn since residues of fluroxypyr MHE were not detected in corn grain at 5X the application rate. In addition, processing of sorghum was not conducted since residue data for flour are not required at this time because sorghum flour is used exclusively in the U.S. as a component for drywall, and not as either a human food or a feedstuff. No residues of fluroxypyr are expected in root or leafy vegetable crops grown in rotation to fluroxypyr-treated field corn, sweet corn, sorghum, and grasses, after a 30–day plant-back interval at the maximum allowable label rate of 8 oz active ingredient/Acre. Field corn, sweet corn, sorghum and grasses grown in rotation may contain low levels of fluroxypyr residues; however, the tolerance values proposed for these crops will adequately assure compliance with the labeled use patterns.

B. Toxicological Profile

1. *Acute toxicity*. Fluroxypyr MHE has low acute toxicity. The rat oral LD_{50} is >5,000 milligrams/kilogram (mg/kg), the rabbit dermal LD_{50} is >2,000 mg/kg, and the rat inhalation LC_{50} is >1.0 mg/L (1,000 mg/cubic meter). In addition, fluroxypyr MHE is not a skin sensitizer in guinea pigs, has no dermal irritation in rabbits, and shows mild ocular irritation in rabbits. The end use formulation of fluroxypyr MHE has a similar low acute toxicity profile.

2. *Genotoxicity*. Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* chromosomal aberration assay using rat lymphocytes, and an *in vivo* cytogenetic assay in the mouse bone marrow (micronucleus test) have been conducted with fluroxypyr MHE. These studies show a lack of genotoxicity. In addition, short-term assays for genotoxicity consisting of an Ames metabolic activation test, possible induction of point mutations at the HGPRT-Locus of Chinese hamster ovary cells, *in vivo* and *in vitro* chromosomal aberrations in the Chinese hamster ovary cells, unscheduled DNA synthesis in human embryonic cells, and an assay in mouse lymphoma cells have been conducted with fluroxypyr. These studies also show a lack of genotoxicity.

3. *Reproductive and developmental toxicity*. Developmental studies in rats and rabbits were conducted with both fluroxypyr MHE and fluroxypyr. Studies with fluroxypyr MHE showed maternal and fetal no observed adverse effect levels (NOAELs) of 300 mg/kg/day (rat) and 500 mg/kg/day (rabbit). Studies with fluroxypyr showed NOAELs in the rat of 250 mg/kg/day for maternal effects and 500 mg/kg/day for fetal effects and a NOAEL in the rabbit of 250 mg/kg/day for both maternal and fetal effects. These studies show that fluroxypyr and fluroxypyr MHE are not teratogenic nor will they interfere with *in utero* development. Two multi-generation reproduction studies were conducted with fluroxypyr in rats. The first in Wistar rats showed no effect on fertility or reproductive performance and had a NOAEL of 500 mg/kg/day (highest dose tested). The second study in Sprague-Dawley rats showed a parental NOAEL for systemic effects of 100 mg/kg/day in male rats and 500 mg/kg/day in female rats. The NOAEL for reproductive effects was 750 mg/kg/day for males and 1,000 mg/kg/day for females (highest dose tested). The NOAEL for neonatal effects was 500 mg/kg/day.

4. *Subchronic toxicity*. Fluroxypyr MHE showed a NOAEL of 1,000 mg/kg/day in a 90–day rat dietary study and a 21–day rabbit dermal study. Ninety–day feeding studies with fluroxypyr showed NOAELs of 80 mg/kg/day (Wistar rats), 700 mg/kg/day (Fischer 344 rats), 1,342 mg/kg/day (male mice), and 1,748 mg/kg/day (female mice). In a 4–week dietary, range finding study with fluroxypyr in dogs, the NOAEL found was >50 mg/kg/day.

5. *Chronic toxicity*. Based on chronic testing with fluroxypyr in the mouse, dog, and rat (two studies), a reference dose (RfD) of 0.8 mg/kg/day is proposed for fluroxypyr and fluroxypyr MHE. The RfD has incorporated a 100-fold safety factor to the NOAEL found in the rat chronic test. NOAELs found in the chronic dietary studies are as follows: 150 mg/kg/day (dog), 300 mg/kg/day (mouse), 80 mg/kg/day (Wistar rats), 100 mg/kg/day (male Fischer 344 rats), and 500 mg/kg/day (female Fischer 344 rats).

6. *Animal metabolism*. Both fluroxypyr and fluroxypyr MHE have been evaluated in rat metabolism studies. In summary, these studies show that fluroxypyr MHE is rapidly hydrolyzed and the fate of the hydrolysis products, fluroxypyr and 1-methylheptanol, are independent of whether they were given as the ester or the acid. Fluroxypyr, *per se*, was extensively absorbed and rapidly excreted principally unchanged in the urine; 1-methylheptanol also was rapidly absorbed and rapidly eliminated. Repeated administration of fluroxypyr MHE was not associated with accumulation in tissues. Also, the metabolism and pharmacokinetics of 1-methylheptanol are comparable to that of the methylheptyl portion of fluroxypyr MHE.

7. *Metabolite toxicology*. Administration of fluroxypyr, as the

acid or methylheptyl ester, in a variety of toxicological studies has produced similar effects. The principal response to sufficiently high dosages, whether administered over the short-term or, in some cases, over a lifetime, was nephrosis. Fluroxypyr is an organic acid that is actively excreted into the urine by the kidney. Thus, the target organ and dose response relationship for fluroxypyr toxicity is entirely consistent with the data on the toxicokinetics of fluroxypyr. Metabolism studies have shown that fluroxypyr MHE is rapidly and completely hydrolyzed to fluroxypyr acid and methylheptanol.

8. *Endocrine disruption*. There is no evidence to suggest that fluroxypyr and fluroxypyr MHE have an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure—Acute dietary exposure and risk*. A Tier I acute dietary exposure and risk assessment was conducted. Potential dietary exposure and risk was estimated using DEEM™ software (Dietary Exposure Evaluation Model, Version 7.075, Novigen Sciences, Inc., Washington, DC). A deterministic analysis was conducted by combining the distribution of single-day food consumption events with residues assumed at tolerance levels for each commodity to obtain a distribution of exposure. In this report, acute dietary risk was assessed at the 95th percentile of exposure.

i. *Food*. Very conservative assumptions were made in this dietary risk assessment. The dietary exposure assessment was based on all commodities with tolerances for fluroxypyr established at 40 CFR 180.535 together with proposed tolerances for field corn, sweet corn, grain sorghum, and forage grass and hay, including revised tolerances for milk and meat. It was assumed that fluroxypyr residues were present at tolerance or proposed tolerance levels and that 100% of the crops were treated. The USDA food consumption data from 1989–92 were used by DEEM in estimating acute dietary exposure. Acute dietary risk was assessed using an acute RfD of 1.25 mg/kg/day, based on a maternal NOAEL of 125 mg/kg/day from a rat developmental toxicity study and an uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variation). There was no indication of increased susceptibility in young animals to prenatal or postnatal exposure to fluroxypyr in the toxicology studies. Therefore, an FQPA additional safety factor for infants and children was not included in this assessment. Acute dietary exposure at the 95th percentile for females 13 to 50 years old is estimated at 0.004939 mg/kg/day, which occupies 0.4% of the acute RfD. Pregnant females are estimated to have acute dietary exposure of 0.006582 mg/kg/day at the 95th percentile, which occupies 0.53% of the acute RfD. Adverse effects are not expected for exposures occupying 100% or less of the RfD. Therefore, acute dietary exposure and risk are well within acceptable levels.

A chronic dietary assessment estimated that dietary exposure would occupy only 0.4% of the RfD for the overall U.S. population and 1.3% of the RfD for children 1 to 6 years of age, the population subgroup estimated to be most highly exposed.

ii. *Drinking water—Acute drinking water exposure and risk*. There are no established Maximum Contaminant Levels for residues of fluroxypyr in drinking water and health advisory levels for fluroxypyr in drinking water have not been established.

Potential drinking water concentrations of fluroxypyr were estimated in ground water and surface water using the Screening Concentration in Ground Water (SCI-GROW) and the Generic Expected Environmental Concentration (GENEEC) models, respectively. Both GENEEC and SCI-GROW are Tier I screening level models that use conservative assumptions. SCI-GROW estimates pesticide concentrations in shallow, highly vulnerable ground water. GENEEC simulates a 1 hectare by 2 meters deep edge of the field farm pond that receives pesticide runoff from a treated 10 hectare field. The estimated concentration of fluroxypyr in ground water according to SCI-GROW is 0.16 µg/L. The estimated peak concentration of fluroxypyr in surface water using GENEEC is 20.88 µg/L.

To calculate the Drinking Water Levels of Concern (DWLOC) for acute exposure relative to an acute toxicity endpoint, the acute dietary exposure (from the DEEM analysis) was subtracted from the acute RfD to obtain the acceptable upper limit of fluroxypyr in drinking water for acute exposure. DWLOCs were then calculated using default values for adult female body weight (60 kg) and water consumption (2 L/day).

The upper-bound estimated fluroxypyr concentration in ground water (0.16 µg/L) and surface water (20.88 µg/L) are substantially below the acute DWLOCs of 37,352 µg/L and 37,303 for females 13 to 50 years old and pregnant females, respectively. Aggregated acute fluroxypyr exposure for pregnant females and females 13 to 50 years old resulting from dietary exposure and upper-bound drinking water exposure is well within acceptable limits of exposure and risk.

The chronic DWLOC for both the overall U.S. population and children 1 to 6 years of age was over 3,000-fold greater than residue levels in surface water or ground water estimated by conservative screening-level models. Therefore, chronic exposure and risk is expected to be well within acceptable levels.

2. *Non-dietary exposure*. The proposed use of fluroxypyr on residential turf presents the potential for non-occupational, non-dietary (or residential) exposure. Transferable foliar residue data from a fluroxypyr study on turf was used instead of default residue values.

Post-application dermal exposure for adults and toddlers was estimated for the day of application (day 0) since the exposure potential is greatest at this time. Transferable residue of fluroxypyr from turf was found to range from 0.03 to 0.74% (used as a high end stimate) of the fluroxypyr applied and to dissipate with a half-life ranging from 1.4 to 2.5 days.

Homeowners may be exposed to fluroxypyr during application to turf and also may have dermal exposure due to post-application activity on the treated turf.

Homeowner exposure during the application of fluroxypyr to turf includes both dermal and inhalation exposure. Surrogate dermal and inhalation exposure data from Pesticide Handlers Exposure Database (PHED V1.1) was used in estimating applicator exposure. The PHED surrogate data used to estimate exposure assumes residential applicator attire to include short pants, short-sleeve shirt, and no gloves. The applicator exposure estimate was based on a broadcast application using a garden hose end sprayer. Applicator dermal and inhalation exposure was estimated to be 0.0986 mg/kg/day and 0.00003 mg/kg/day, respectively.

Adult post-application dermal exposure from treated turf on the day of application was estimated to be 0.0172 mg/kg/day. The combined dermal exposure from application along with post-application activity is 0.1158 mg/kg/day (0.0986 mg/kg/day + 0.0172 mg/kg/day). Oral post-application exposure is not expected for adults and was not included in this assessment. The Margin of Exposure (MOE) for dermal exposure is 8,635 and for inhalation exposure 2,666,667. These MOEs are substantially greater than 100, indicating that risk

from these potential exposures is well within an acceptable level.

Consistent with the scenario described above for the general adult population, female adult homeowners may experience exposure to fluroxypyr during application to turf as well as from post-application exposure. Female applicator dermal and inhalation exposure was estimated to be 0.115 mg/kg/day and 0.00004 mg/kg/day, respectively. Additionally, female adults may also experience post-application dermal exposure from treated turf on the day of application. Post-application dermal exposure for females was estimated to be 0.0201 mg/kg/day. Since dermal absorption is assumed to be 100% and since both dermal and inhalation exposure are being evaluated against the same toxicity endpoint, total potential exposure from fluroxypyr use on turf can be estimated by simply adding the dermal and inhalation exposure. The combined exposure is 0.13514 mg/kg/day (0.115 mg/kg/day + 0.00004 mg/kg/day + 0.0201 mg/kg/day). Using a NOAEL of 125 mg/kg/day, the MOE is calculated to be 925 (125 mg/kg/day / 0.13514 mg/kg/day). The MOE for female adults as a result of potential dermal and inhalation exposure from residential use of fluroxypyr on turf is well above 100, indicating that risk is within acceptable levels.

Golfers may have dermal exposure to fluroxypyr due to post-application activity on the treated turf. Dermal exposure for adult golfers was estimated on the day of treatment (day 0) to provide a high-end estimate of exposure. Exposure was estimated based on a transfer coefficient of 500 cm^2/hr ([1]) and an exposure time of 4 hours. Exposure was estimated to be 0.001186 mg/kg/day. A MOE of 843,170 was calculated based on an assumption of 100% dermal absorption and a NOAEL of 1,000 mg/kg/day. Given a MOE of three orders of magnitude greater than 100, risk is well within acceptable levels.

Potential exposure for female golfers was estimated to be 0.001383 mg/kg/day. A MOE of 90,383 was calculated based on an assumption of 100% dermal absorption and a NOAEL of 125 mg/kg/day. The MOE is substantially greater than 100, indicating that risk is well within acceptable levels.

Toddlers may have exposure due to post-application activity on treated turf. When a pesticide in liquid formulation is applied to turfgrass, toddlers may experience post-application exposure through dermal exposure and also through oral exposure due to hand-to-mouth transfer of pesticide residue, ingestion of treated turfgrass and incidental ingestion of soil from treated areas.

Toddler post-application dermal exposure from treated turf on the day of application was estimated to be 0.0288 mg/kg/day. Oral exposure due to hand-to-mouth transfer of residues was estimated to be 0.0011 mg/kg/day. Oral exposure due to ingestion of treated grass was estimated to be 0.0019 mg/kg/day. Combined oral exposure from hand-to-mouth transfer of residues and ingestion of treated grass is 0.0030 mg/kg/day (0.0011 mg/kg/day + 0.0019 mg/kg/day). The MOE for dermal exposure is 34,722 and oral exposure is 26,667, both of them well above 100, indicating that risk is well within acceptable levels.

Use of fluroxypyr on turf results in potential short-term residential exposure for adults and children. Potential short-term dietary and residential exposures were combined into aggregate MOE values. Potential exposure through drinking water was not included in the aggregate MOEs, but was evaluated in aggregate through use of a DWLOC calculated for short-term exposure. The aggregate MOEs for adults and toddlers ranged from 906 to 29,335, but all were well above 100, indicating an adequate margin of safety. Additionally, the short-term DWLOCs for toddlers and adults were over 3,000-fold greater than potential fluroxypyr residues in drinking water predicted by conservative screening level models. Therefore, aggregate short-term exposure and risk for children and adults is expected to be well within acceptable levels.

D. Cumulative Effects

The potential for cumulative effects of fluroxypyr MHE and fluroxypyr and other substances that have a common mechanism of toxicity is also considered. There is no reliable information to indicate that toxic effects produced by fluroxypyr MHE and fluroxypyr would be cumulative with those of any other pesticide chemical. Thus, it is appropriate to consider only the potential risks of fluroxypyr MHE and fluroxypyr in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population.* Acute dietary exposure for pregnant females to residues of fluroxypyr from current and proposed uses was estimated to occupy 0.53% of the acute RfD, indicating very little risk. Additionally, the acute DWLOC was calculated to be over 1,700 fold greater than potential fluroxypyr residue in drinking water predicted by conservative screening level models.

Potential dietary and residential exposures were combined into an aggregate MOE value. Those MOEs range from 906 to 29,335. The aggregate MOEs are well above 100, indicating risk is well within acceptable levels. Additionally, the DWLOCs were over 11,000-fold greater than potential fluroxypyr residue in drinking water. Chronic dietary exposure to residues of fluroxypyr from current and proposed uses was estimated to occupy 0.4% of the RfD. The DWLOC was calculated to be over 11,000 fold greater than potential fluroxypyr residue in drinking water.

It is concluded that there is a reasonable certainty that no harm will result to the general U.S. population, pregnant females or developing young from acute aggregate, short-term or chronic aggregate exposures to fluroxypyr residues from current and proposed uses.

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 data base. Based on the current toxicological data requirements, the data base for fluroxypyr MHE relative to prenatal and postnatal effects for children is complete. There were no indications of neurotoxicity and developmental toxicity was not observed in the absence of maternal toxicity. It is concluded that there is no indication of increased sensitivity of infants and children relative to adults and that an additional FQPA safety factor is not required.

The acute and short-term exposures were assessed for pregnant females to evaluate the risk for developmental toxicity and it was concluded that there was reasonable certainty of no harm from aggregate acute or short-term exposures resulting from current and proposed uses of fluroxypyr.

Toddlers may experience short-term dermal and oral exposure to fluroxypyr as a result of post-application activities on treated residential turf. Additionally, there is the potential for exposure to fluroxypyr through residue in food and drinking water. Tier I assessments were conducted to develop very conservative estimates of potential exposure through residential, dietary and drinking water pathways.

Potential dietary and residential exposures were combined into an aggregate MOE value. The aggregate MOE was 5,120, well above 100, indicating risk is well within acceptable

levels. Additionally, the DWLOC was over 3,000-fold greater than potential fluroxypyr residue in drinking water.

Chronic dietary exposure to residues of fluroxypyr from current and proposed uses was estimated to occupy 1.3% of the RfD for children 1 to 6 years old, the population subgroup predicted to be most highly exposed. Additionally, the DWLOC was calculated to be over 3,000 fold greater than potential fluroxypyr residue in drinking water predicted by conservative screening level models.

Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from acute dietary, short-term and chronic aggregate exposures to fluroxypyr residues from current and proposed uses.

F. International Tolerances

There are no Codex maximum residue levels established for residues of fluroxypyr MHE and fluroxypyr on any food or feed crop.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0356; FRL–7286–4]

Bifenazate; 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 Bifenazate in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0356, must be received on or before February 14, 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 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 identification (ID) number OPP–2002–0356. 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