

water). The calculated peak GENECC value is 0.44 ppb and the SCI-GROW value is 0.055 ppb. For the U.S. adult population, the estimated exposures of imazamox residues in surface water and ground, water are approximately 0.0004% and 0.0005%, respectively, of the DWLOC. For children, the estimated exposures of imazamox residues in surface water and ground water are approximately 0.002% and 0.0002%, respectively of the DWLOC. Therefore, the exposures to drinking water from imazamox use are negligible.

Based on the dietary and drinking water assessments, aggregate exposure to residues of imazamox in food and water can be considered to be negligible.

2. *Non-dietary exposure.* There is no available information quantifying non-dietary exposure to imazamox. However, based on the physical and chemical characteristics of the compound, the proposed use pattern and available information concerning its environmental fate, non-dietary exposure is not expected.

#### D. Cumulative Effects

Imazamox belongs to the imidazolinone class of compounds. The herbicidal activity of the imidazolinones is due to the inhibition of acetohydroxy acid synthase (AHAS), an enzyme only found in plants. AHAS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack AHAS and this biosynthetic pathway. This lack of AHAS contributes to the extremely low toxicity of imazamox in mammals. Although other registered imidazolinones have a similar herbicidal mode of action, there is no information available to suggest that these compounds exhibit a similar toxicity profile in the mammalian system. We are aware of no information to indicate or suggest that imazamox has any toxic effects on mammals that would be cumulative with those of any other chemical. Since imazamox is relatively non-toxic, cumulative effects of residues of imazamox and other compounds are not anticipated. Therefore, for the purposes of this tolerance petition no assumption has been made with regard to cumulative exposure with other compounds having a common mode of herbicidal action.

#### E. Safety Determination

1. *U.S. population.* Based on a RfD of 3.0 mg/kg bwt day determined from a NOAEL of 300 mg/kg bwt day, from the rabbit developmental toxicity study and a safety (uncertainty) factor of 100, the worse case estimate of chronic dietary exposure of imazamox from soybeans,

the other members of the legume vegetable crop grouping (6), canola, wheat and alfalfa will utilize approximately 0.02% of the RfD for the general U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The complete and reliable toxicity data and the conservative chronic exposure assumptions support the conclusion that there is a reasonable certainty of no harm from dietary (food) exposure to imazamox residues. Moreover, as exposure to residues of imazamox via water is negligible, there is a reasonable certainty of no harm from aggregate exposure to imazamox residues.

2. *Infants and children.* The conservative estimates, as described above, indicate that dietary exposure of imazamox from soybeans, the other members of the legume vegetable crop grouping, canola, wheat and alfalfa will utilize: approximately 0.02% of the RfD for non-nursing infants; approximately 0.04% of the RfD for children ages 1 to 6; and approximately 0.03% of the RfD for children ages 7 to 12.

No developmental, reproductive, or fetotoxic effects were noted at the highest doses of imazamox tested in guideline reproductive or developmental toxicity studies. The only maternal effects in the rat and rabbit teratology studies were decreased body weights, body weight gains and/or absolute and relative feed consumption in the higher dose groups of each study.

Based on the current toxicological data requirements, the data base relative to prenatal and postnatal effects for children is complete, valid and reliable. Results from the teratology studies and the two-generation reproduction study support NOAELs for fetal/developmental effects or reproductive/offspring effects, respectively, equivalent to the highest concentrations tested. As such, there is no increased sensitivity of infants and children to residues of imazamox. Therefore, an additional safety (uncertainty) factor is not warranted, and the RfD of 3.0 mg/kg bwt day, which utilizes a 100-fold safety factor, is appropriate to assure a reasonable certainty of no harm to infants and children.

#### F. International Tolerances

There is no Codex Maximum Residue Level Established for Residues of Imazamox on any Crops.

[FR Doc. 00-7739 Filed 3-28-00; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-925; FRL-6496-9]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals 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 control number PF-925, must be received on or before April 28, 2000.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-925 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: James Tompkins, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5697; e-mail address: Tompkins.Jim@epamail.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:

Cat-egories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-925. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

*C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-925 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division

(7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5697.

3. *Electronically.* You may submit your comments electronically by e-mail to: "[opp-docket@epa.gov](mailto:opp-docket@epa.gov)," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-925. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

**List of Subjects**

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

Dated: March 21, 2000.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

**Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. 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 Corporation**

0F6095

EPA has received a pesticide petition (0F6095) from Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120-0013 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 180.527 by establishing a tolerance for residues of flufenacet, N-(4-fluorophenyl)-N-(1-methylethyl)-2-5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl oxyacetamide and metabolites containing the 4-fluoro-N-methylethyl benzenamine moiety in or on the raw agricultural commodities (RAC) wheat grain, wheat forage, wheat hay, wheat bran, wheat germ, wheat straw, seed-grass forage, seed-grass forage from re-growth, seed-grass hay from re-growth, seed-grass straw, sweet corn kernel plus cob with husks removed at 0.5, 9.0, 1.0, 1.0, 0.5, 18.0, 0.1, 0.5, 0.5, 0.05 parts per million (ppm), respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

**A. Residue Chemistry**

1. *Plant metabolism.* The nature of the residue in field corn, sweet corn, wheat, seed-grasses, soybeans, rotational crops, and livestock is adequately understood. The residues of concern for the tolerance expression are flufenacet parent and its metabolites containing the 4-fluoro-N-methylethyl benzenamine moiety. Based on the results of animal metabolism studies it is unlikely that secondary residues would occur in animal commodities from the use of flufenacet on field corn, sweet corn, soybeans, wheat, and seed-grasses.

2. *Analytical method.* An adequate analytical method, gas chromatography/mass spectrometry (GC/MS) with selected ion monitoring, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental

Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703-305-5937).

3. *Magnitude of residues.* Time-limited tolerances exist for the combined residues of flufenacet, N-(4-fluorophenyl)-N-(1-methylethyl)-2-5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl oxyacetamide and metabolites containing the 4-fluoro-N-methylethyl benzenamine moiety in or on field corn grain at 0.05 ppm, field corn forage at 0.4 ppm, field corn stover at 0.4 ppm, soybean seed at 0.1 ppm, alfalfa forage at 0.1 ppm, alfalfa hay at 0.1 ppm, alfalfa seed at 0.1 ppm, clover forage at 0.1 ppm, clover hay at 0.1 ppm, Crop Group 15 (cereal grains) at 0.1 ppm, Crop Group 16 (forage, stover and hay of cereal grains) at 0.1 ppm, and Group 17 (grass forage and grass hay) at 0.1 ppm.

**B. Toxicological Profile**

1. *Acute toxicity*—i. Technical grade flufenacet has a low to moderate order of toxicity in rats by the oral route of exposure. The acute oral LD<sub>50</sub> was 1,617 milligrams/kilograms (mg/kg) for males and 589 mg/kg for females.

ii. A dermal toxicity study on technical grade flufenacet revealed low acute toxicity to rats. The dermal LD<sub>50</sub> for both sexes was > 2,000 mg/kg, the highest dose tested (HDT).

iii. An acute inhalation study on technical grade flufenacet showed low toxicity in rats with a 4-hour liquid aerosol LC<sub>50</sub> for males and females of > 3,740 mg/m<sup>3</sup> air, the highest concentration tested.

iv. An eye irritation study on technical grade flufenacet in rabbits showed minimal irritation to the conjunctiva completely reversible within 7 days.

v. A dermal irritation study on technical grade flufenacet in rabbits did not produced any irritation.

vi. Skin sensitization studies on technical grade flufenacet in guinea pigs have produced equivocal results. A skin sensitization potential was exhibited under the conditions of a maximization test, whereby, there was no skin sensitization potential when tested by the Buehler topical closed patch technique.

2. *Genotoxicity.* Flufenacet was negative for mutagenic/genotoxic effects in a Gene mutation/*in vitro* assay in bacteria, a Gene mutation/*in vitro* assay in Chinese hamster (CH) lung fibroblasts cells, a Cytogenetics/*in vitro* assay in CH ovary cells, a Cytogenetics/*in vivo* mouse micronucleus assay, and an *in vitro* unscheduled DNA synthesis assay in primary rat hepatocytes.

3. *Reproductive and developmental toxicity*—i. A 2-generation rat reproduction study with a parental systemic no observed adverse effect level (NOAEL) of 20 ppm (1.4 mg/kg/day in males and 1.5 mg/kg/day in females) and a reproductive NOAEL of 20 ppm (1.3 mg/kg/day) and a parental systemic lowest observed adverse effect level (LOAEL) of 100 ppm (7.4 mg/kg/day in males and 8.2 mg/kg/day in females), based on increased liver weight in F<sub>1</sub> females and hepatocytomegaly in F<sub>1</sub> males, and a reproductive LOAEL of 100 ppm (6.9 mg/kg/day) based on increased pup death in early lactation (including cannibalism) for F<sub>1</sub> litters and the same effects in both F<sub>1</sub> and F<sub>2</sub> pups at the high dose level of 500 ppm (37.2 mg/kg/day in males and 41.5 mg/kg/day in females), respectively.

ii. A rat developmental study with a maternal NOAEL of 25 mg/kg/day and with a maternal LOAEL of 125 mg/kg/day based on decreased body weight gain initially and a developmental NOAEL of 25 mg/kg/day and a developmental LOAEL of 125 mg/kg/day based on decreased fetal body weight, delayed development mainly delays in ossification in the skull, vertebrae, sternbrae, and appendages, and an increase in the incidence of extra ribs.

iii. A rabbit developmental study with a maternal NOAEL of 5 mg/kg/day and a maternal LOAEL of 25 mg/kg/day based on histopathological finds in the liver and a developmental NOAEL of 25 mg/kg/day and a developmental LOAEL of 125 mg/kg/day based on increased skeletal variations.

4. *Subchronic toxicity*—i. A 84-day rat feeding study with a NOAEL less than 100 ppm (6.0 mg/kg/day) for males and a NOAEL of 100 ppm (7.2 mg/kg/day) for females and with a LOAEL of 100 ppm (6.8 mg/kg/day) for males based on suppression of thyroxine (T<sub>4</sub>) level, and a LOAEL of 400 ppm (28.8 mg/kg/day) for females based on hematology, and clinical chemistry findings.

ii. A 13-week mouse feeding study with a NOAEL of 100 ppm (18.2 mg/kg/day for males and 24.5 mg/kg/day for females), and a LOAEL of 400 ppm (64.2 mg/kg/day for males and 91.3 mg/kg/day for females) based on histopathology of the liver, spleen and thyroid.

iii. A 13-week dog dietary study with a NOAEL of 50 ppm (1.70 mg/kg/day for males and 1.67 mg/kg/day for females), and a LOAEL of 200 ppm (6.90 mg/kg/day for males and 7.20 mg/kg/day for females), based on evidence that the bio-transformation capacity of the liver has

been exceeded (as indicated by increase in LDH, liver weight, ALK and hepatomegaly), globulin and spleen pigment in females, decreased T4 and ALT values in both sexes, decreased albumin in males, and decreased serum glucose in females.

iv. A 21-day rabbit dermal study with the dermal irritation NOAEL of 1,000 mg/kg/day for males and females, and a systemic NOAEL of 20 mg/kg/day for males and 150 mg/kg/day for females, and a systemic LOAEL of 150 mg/kg/day for males and 1,000 mg/kg/day for females based on clinical chemistry data (decreased T4 and FT4 levels in both sexes) and centrilobular hepatocytomegaly in females.

5. *Chronic toxicity*—i. A 1-year dog chronic feeding study with a NOAEL was 40 ppm (1.29 mg/kg/day in males and 1.14 mg/kg/day in females), and a LOAEL of 800 ppm (27.75 mg/kg/day in males and 26.82 mg/kg/day in females) based on increased alkaline phosphatase, kidney, and liver weight in both sexes, increased cholesterol in males, decreased T2, T4 and ALT values in both sexes, and increased incidences of microscopic lesions in the brain, eye, kidney, spinal cord, sciatic nerve, and liver.

ii. A rat chronic feeding/carcinogenicity study with a NOAEL less than 25 ppm (1.2 mg/kg/day in males and 1.5 mg/kg/day in females), and a LOAEL of 25 ppm (1.2 mg/kg/day in males and 1.5 mg/kg/day in females) based on methemoglobinemia, and multi-organ effects in blood, kidney, spleen, heart, and uterus. Under experimental conditions the treatment did not alter the spontaneous tumor profile.

iii. In a mouse carcinogenicity study the NOAEL was less than 50 ppm (7.4 mg/kg/day) for males and the NOAEL was 50 ppm (9.4 mg/kg/day) for females. The LOAEL was 50 ppm (7.4 mg/kg/day) for males and the LOAEL was 200 ppm (38.4 mg/kg/day) for females based on cataract incidence and severity. There was no evidence of carcinogenicity for flufenacet in this study.

6. *Animal metabolism*. A rat metabolism study showed that radio-labeled flufenacet was rapidly absorbed and metabolized by both sexes. Urine was the major route of excretion at all dose levels and smaller amounts were excreted via the feces.

7. *Metabolite toxicology*. A 55-day dog study with subcutaneous administration of thiadone flufenacet metabolite supports the hypothesis that limitations in glutathione interdependent pathways and antioxidant stress result in metabolic

lesions in the brain and heart following flufenacet exposure.

8. *Endocrine disruption*. EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effect. The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects. Based on the toxicological findings for flufenacet relating to endocrine disruption effects, flufenacet should be considered as a candidate for evaluation as an endocrine disrupter when the criteria are established.

9. *Other studies*—i. An acute rat neurotoxicity study with a NOAEL less than 75 mg/kg/day and a LOAEL of 75 mg/kg/day based on decreased motor activity in males.

ii. A rat subchronic neurotoxicity study with a NOAEL of 120 ppm (7.3 mg/kg/day in males and 8.4 mg/kg/day in females), and a LOAEL of 600 ppm (38.1 mg/kg/day in males and 42.6 mg/kg/day in females) based on microscopic lesions in the cerebellum/medulla and spinal cords.

#### C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. In evaluating food exposures, varying consumption patterns of major identifiable subgroups of consumers, including infants and children is taken into account. A refined dietary risk assessment was performed and adjustments were made to account for market share and processing factors. The residues in the diet (food only) are calculated to be 0.000078 mg/kg bwt day or 1.9% of the RfD for the general U.S. population and 0.000174 mg/kg bwt day or 4.4% of the RfD for non-nursing infants (> 1-year)

ii. *Drinking water*. Residues of flufenacet in drinking water may comprise up to 0.0039 mg/kg bwt day (0.0040-0.000078 mg/kg bwt day) for the U.S. population and 0.0038 mg/kg bwt

day (0.00400-0.000174 mg/kg bwt day) for children 1–6 years old.

The drinking water levels of concern (DWLOCs) for chronic exposure to flufenacet in drinking water calculated for the U.S. population was 136 parts per billion (ppb) assuming that an adult weighs 70 kg and consumes a maximum of 2 liters of water per day. For children (1–6 years old), the DWLOC was 37.7 ppb assuming that a child weighs 10 kg and consumes a maximum of 1 liter of water per day.

The drinking water estimated concentration (DWECs) for ground water (parent flufenacet and degradate thiadone) calculated from the monitoring data is 0.03 ppb for chronic concentrations which does not exceed DWLOC of 37.7 ppb for children (1–6 years old). The DWEC for surface water based on the computer models PRZM 2.3 and EXAMS 2.97.5 was calculated to be 14.2 ppb for chronic concentration (parent flufenacet and degradate thiadone) which does not exceed the DWLOC of 37.7 ppb for children (1–6 years old).

2. *Non-dietary exposure*. There are no non-food uses of flufenacet currently registered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

#### D. Cumulative Effects

Flufenacet is structurally a thiadiazole. EPA is not aware of any other pesticides with this structure. For flufenacet, EPA has not yet conducted a detailed review of common mechanisms to determine whether it is appropriate, or how to include this chemical in a cumulative risk assessment. After EPA develops a methodology to address common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine these tolerance decisions. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, flufenacet does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance actions, therefore, EPA has not assumed that flufenacet has a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population*. As presented previously, the exposure of the U.S. general population to flufenacet is low, and the risks, based on comparisons to the RfD, are minimal. The margins of safety from the use of flufenacet are within EPA's acceptable limits. Bayer

Corporation concludes that there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposure to flufenacet residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of flufenacet, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Although there is no indication of increased sensitivity to young rats or rabbits following prenatal and/or postnatal exposure to flufenacet in the standard developmental and reproductive toxicity studies, an additional developmental neurotoxicity study, which is not normally required, is needed to access the susceptibility of the offspring in function/neurological development. Therefore, EPA has required that a developmental neurotoxicity study be conducted with flufenacet and a threefold safety factor for children and infants will be used in the aggregate dietary acute and chronic risk assessment. Although there is no indication of additional sensitivity to young rats or rabbits following prenatal and/or postnatal exposure to flufenacet in the developmental and reproductive toxicity studies; the Agency concluded that the FQPA safety factor should not be removed but instead reduced because: (i) There was no assessment of susceptibility of the offspring in functional/neurological developmental and reproductive studies; (ii) there is evidence of neurotoxicity in mice, rats, and dogs; (iii) there is concern for thyroid hormone disruption.

*F. International Tolerances*

Maximum residue levels are established or proposed for countries of the European Communities in the following commodities: cereals at 0.5 ppm, corn at 0.5 ppm, potato at 0.1 ppm, sunflower at 0.05 ppm, soybean at

0.05 ppm, animal meat at 0.05 ppm, animal edible offal's at 0.05 ppm, animal fat at 0.05 ppm, milk at 0.01 ppm, and eggs at 0.05 ppm.

[FR Doc. 00-7742 Filed 3-28-00; 8:45 am]

BILLING CODE 6560-50-F

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-924; FRL-6495-5]

**Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket control number PF-924, must be received on or before April 28, 2000.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-924 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Shaja R. Brothers, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 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:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
	32532	Pesticide manufac-turing

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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-924. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing