

metabolites. The metabolites are then photolyzed and further degraded and finally mineralized to CO<sub>2</sub>. Leaching studies and lysimeter studies indicate that under typical agricultural conditions, neither pyridate nor its metabolites were detected below 30 centimeters. Ground water monitoring studies conducted in Europe have not confirmed any detection of pyridate or metabolites. Therefore, significant movement of pyridate is not likely and is not a considerable factor in assessing human health risk.

3. *Non-dietary exposure.* There are no registered uses for pyridate on residential or recreational turf. Therefore, non-dietary exposure of pyridate is not likely and not a factor in assessing human health risk.

#### D. Cumulative Effects

Pyridate belongs to the pyridazine group of herbicidal compounds and has a unique mode of action in plants. Sandoz does not have data to indicate a common mechanism of toxicity to other compounds in humans. Therefore cumulative effects from common mechanisms of action are unlikely.

#### E. Safety Determination

1. *U.S. population.* The cPAD is calculated to be 0.11 mg/kg bwt/day. The estimates of exposure are based on conservative assumptions that all crops with a tolerance for pyridate are treated and that all residues found are at the maximum or tolerance level. The dietary exposure to the U.S. population for the current uses plus the corn grain, peanut butter, and cabbage uses is estimated at most to be  $6.0 \times 10^{-5}$  mg/kg/bwt/day, which is 0.1% of the cPAD. Therefore, Novartis concludes that there is reasonable certainty of no harm from aggregate exposure of residues of pyridate or its metabolites including all dietary and other non-occupational exposures.

2. *Infants and children.* Pyridate is not a reproductive or developmental toxicant. Therefore no specific effects on infants and children are expected. Based on the weight of evidence of the toxicity studies, an additional safety factor is not warranted.

Using the same assumptions as above, the exposure to infants and children is presented as a percent of cPAD. The dietary exposure for the current uses plus the corn grain, peanut butter, and cabbage uses for non-nursing infants is estimated as  $1.25 \times 10^{-4}$  mg/kg/bwt/day, which is 0.1% of the cPAD. For children age 1–6, the estimated exposure is  $1.43 \times 10^{-4}$  mg/kg/day, 0.1% of the cPAD. Therefore, Sandoz concludes that there is reasonable certainty of no harm from

aggregate exposure of residues of pyridate or its metabolites including all dietary and other non-occupational exposures.

#### F. International Tolerances

No international tolerances have been established for pyridate on peppermint tops and spearmint tops by CODEX Alimentarius Commission.

[FR Doc. 00–1553 Filed 1–21–00; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

[PF–914; FRL–6486–8]

### Notice of Filing Pesticide Petitions 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–914, must be received on or before February 23, 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–914 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Mary Waller, 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) 308–9354; e-mail address: waller.mary@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
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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–914. 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-914 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) 305-5805.

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-914. 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain 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: January 7, 2000.

**James Jones,**

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

### **Summaries of Petitions**

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The

summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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.

#### **AgrEvo USA Company**

*PP 6F4693; 4F4380*

EPA has received pesticide petitions (PP 6F4693, PP 4F4380) from AgrEvo USA Company, 2711 Centerville Road, Wilmington, DE 19808 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 residues of flutolanil in or on the raw agricultural commodities potatoes at 0.20 parts per million (ppm), and potato waste (wet) at 0.40 ppm, rice at 2.0 ppm, rice straw at 12.0 ppm, and in or on the processed food commodities rice hulls at 7.0 ppm and rice bran at 3.0 ppm. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

#### *A. Residue Chemistry*

1. *Plant metabolism.* The metabolism of flutolanil in plants is adequately understood for the purposes of this petition. Plant metabolism studies have been conducted in rice, cucumber, and peanuts. The metabolic profile for flutolanil was similar in all three crops. The major route of degradation was 4'-O-dealkylation to desisopropylflutolanil, followed by conjugation. Other metabolites may occur at very low levels due to hydroxylation and oxidation of the side chain, hydroxylation of the aniline ring, and methylation of the hydroxyl groups. These minor metabolites were also subject to conjugation. The residues of concern are the parent, flutolanil, and desisopropylflutolanil.

2. *Analytical method.* The analytical method designated AU-95R-04 has been independently validated and is adequate for enforcement purposes. A multi-residue method for flutolanil has been previously submitted to the EPA. The method is for use only by

experienced chemists who have demonstrated knowledge of the principles of trace organic analysis and have proven skills and abilities to run a complex residue analytical method, obtaining accurate results at the part per billion level. Users of this method are expected to perform additional method validation prior to using the method for either monitoring or enforcement. The method can detect gross misuse.

3. *Magnitude of residues.* Fourteen residue trials were conducted to determine the residues of flutolanil in potatoes after use as a seed piece protectant. Potato seed pieces were treated with flutolanil, planted, and the harvested potatoes analyzed for residues of flutolanil. In these studies, flutolanil-derived residues ranged from non-detectable (< 0.05 ppm) to 0.11 ppm in potato tubers.

A processing study was also conducted to support the use of flutolanil as a potato seed piece protectant. Concentration of residues was observed into wet peel (1.7x). No concentration was observed in potato granules, chips, or flakes.

#### B. Toxicological Profile

1. *Acute toxicity.* A battery of acute studies was conducted indicating an acute oral lethal dose<sup>50</sup> (LD<sup>50</sup>) of > 10,000 milligrams/kilograms (mg/kg) for rats and mice; an acute rat dermal LD<sup>50</sup> of > 2,000 mg/kg; an acute rat inhalation LC<sup>50</sup> of > 5.98 mg/L; no dermal irritation; slight eye irritation; and no evidence of dermal sensitization.

2. *Genotoxicity.* Flutolanil has been tested in a battery of *in vitro* and *in vivo* assays. No evidence of genotoxicity was noted in gene mutation assays with *Salmonella*, *E. coli* or mouse lymphoma cells; a mouse micronucleus assay, or in an *in vitro* unscheduled DNA synthesis assay. A weakly positive response was noted in an *in vitro* cytogenetics assay in Chinese hamster lung cells but no evidence of clastogenicity was noted in an *in vitro* cytogenetics assay in human lymphocytes. The overall weight of evidence indicates that flutolanil is not genotoxic.

3. *Reproductive and developmental toxicity.* A 3-generation rat reproduction study was conducted at dietary concentrations of 0, 1,000 and 10,000 ppm. The no observed adverse effect level (NOAEL) for this study is considered to be 1,000 ppm (equivalent to 63 mg/kg/day), based on reduced pup weights late in lactation at 10,000 ppm. Because the Agency considered this study supplementary, a 2-generation rat reproduction study was subsequently conducted at dietary concentrations of 200, 2,000 and 20,000 ppm (equivalent

to 1,936 mg/kg/day). The Agency, however, has concluded that the NOAEL of the original study (63 mg/kg/day) should continue to be used for risk assessment.

4. *Subchronic toxicity.* A 90-day rat feeding study was conducted at dose levels of 500, 4,000 and 20,000 ppm. The NOAEL in this study was considered to be 500 ppm (equivalent to 37 mg/kg/day for males and 44 mg/kg/day for females) based on increased liver weights at 4,000 ppm and slightly decreased body weights at 20,000 ppm.

5. *Chronic toxicity.* In a 2-year chronic toxicity/oncogenicity study, flutolanil was administered to rats at dietary levels of 0, 40, 200, 2,000 and 10,000 ppm. The NOAEL was considered to be 2,000 ppm (86.9 mg/kg/day for males and 103.1 mg/kg/day for females) based on reduced body weight gain in males and increased liver weights in females at 10,000 ppm. No evidence of carcinogenicity was observed.

6. *Animal metabolism.* Studies in rats, ruminants and poultry suggest that flutolanil is not well-absorbed following oral administration. Once absorbed, however, it is rapidly metabolized, primarily to desisopropylflutolanil and its conjugates, and rapidly excreted via urine and feces.

7. *Endocrine effects.* No special studies have been conducted to investigate the potential of flutolanil to induce estrogenic or other endocrine effects. However, no evidence of such effects has been observed in the subchronic, chronic or reproductive studies previously discussed. Thus, the potential for flutolanil to cause endocrine effects is considered to be minimal.

8. *Toxicity endpoint selection.* Flutolanil is of low acute toxicity via all routes of administration and did not induce significant maternal or developmental toxicity in either rats or rabbits, even at the limit dose of 1,000 mg/kg/day. Furthermore, no evidence of toxicity was noted following repeated dosing at 1,000 mg/kg/day in a 21-day dermal toxicity study.

Thus, acute dietary, occupational and residential risk assessments are not considered necessary. The Agency has concluded that the chronic Reference Dose (RfD) for flutolanil should be 0.63 mg/kg/day, based on the NOAEL of 63 mg/kg/day from the first rat multigeneration reproduction study and a 100-fold Uncertainty Factor. The Agency has also determined that the carcinogenicity classification for flutolanil should be "Group E—Evidence of Non-Carcinogenicity for Humans."

#### C. Aggregate Exposure

1. *Dietary exposure.* Flutolanil is registered for use on rice, peanuts, and turf and ornamentals. Registration for use on potatoes as a seed piece treatment has been proposed. Potential sources of non-occupational exposure would consist of any potential residues in food and drinking water, and from uses of flutolanil on residential turf or ornamentals. As previously indicated, in the absence of any acute toxicity concerns, only chronic exposures have been evaluated.

i. *Food.* Time-limited tolerances have been previously established for flutolanil in/on rice commodities, and tolerances with no time limitations are established for peanut commodities, meat, milk, and eggs. Tolerances have been proposed for flutolanil on potatoes. Potential dietary exposures to flutolanil from these food commodities were assessed using the Exposure<sup>®</sup> 1 software system (TAS, Inc.) and food consumption data from the 1977–1978 USDA Continuing Surveys of Food Consumption by Individuals (CSFII). For the purposes of this assessment, it was assumed that 100% of all of the above commodities contained residues of flutolanil at the existing or proposed tolerance levels.

ii. *Drinking water.* The potential for flutolanil to leach into ground water has been assessed in two terrestrial field dissipation studies, a long-term terrestrial field dissipation study, and an aquatic field dissipation study. Under field conditions, the half-life of flutolanil varied from 101 to 123 days in the long-term field soil dissipation study, which was consistent with the other field studies, and was approximately 180 days in the aquatic environment. Flutolanil strongly adsorbs to soil following application and did not exhibit mobility under either terrestrial or aquatic conditions. The water solubility of flutolanil is quite low (equivalent to 5.0 ppm). Based on these environmental fate data and the conditions of use, the potential for movement of flutolanil into ground water is very low, and as such the potential contribution of any such residues to the total dietary intake of flutolanil will be negligible. No Maximum Contaminant Level or Health Advisory Level for residues of flutolanil in drinking water has been established.

2. *Non-dietary exposure.* As a professional use turf and ornamental fungicide, flutolanil is used primarily (> 95%) on golf courses for control of brown patch disease (*Rhizoctonia solani*). Very limited use of flutolanil may occur on commercial ornamental

turf by professional lawn care applicators or on sod farms. The product is rarely, if ever, used on homeowner turf due to the fact that the diseases it controls (Brown patch, Fairy ring, and snow molds) occur in high-fertility, high-maintenance turf (e.g., golf courses), not in homeowner lawns. Thus, non-dietary exposure to flutolanil would be minimal. Furthermore, no dermal toxicity endpoints of concern have been identified for flutolanil. Thus, an assessment of non-dietary exposure and risk is not considered to be necessary.

#### D. Cumulative Effects

Flutolanil has demonstrated only minimal toxicity in animal studies. The mechanism of this toxicity is unknown. Furthermore, there are no available data to indicate that flutolanil has a common mechanism of toxicity with other substances. Thus, only the potential risks from flutolanil are being considered in this document.

#### E. Safety Determination

1. *U.S. population.* Based on the existing and proposed tolerances in potatoes, rice, peanuts and, secondary commodities, the Theoretical Maximum Residue Contribution (TMRC) of the current action is estimated to be 0.001353 mg/kg/day for the U.S. population in general. This exposure would utilize less than 1% of the RfD. There is generally no concern for exposures below 100% of the RfD since the RfD represents the exposure level at or below which daily exposure over a lifetime will not pose any appreciable risks to human health. Therefore, there is a reasonable certainty that no harm will result in the U.S. population in general from aggregate exposure to flutolanil.

2. *Infants and children.* Data from reproductive and developmental toxicity studies are generally used to assess the potential for increased sensitivity of infants and children. No evidence of developmental toxicity was noted in rats or rabbits, even at the limit dose of 1,000 mg/kg/day. Reduced pup weights in the absence of parental toxicity were noted at the high-dose level (10,000 ppm) in a 3-generation rat reproduction study. However, no such effects were noted in a subsequent reproduction study, even at a higher dose level (20,000 ppm). Furthermore, the reduced weight gain in the first study began late in the lactation period, at a time when the pups were likely ingesting significant quantities of diet. Feed intake is much higher in young animals than in adults and the apparent increase in sensitivity may simply

reflect the higher test material intake in these pups on a mg/kg basis compared to the adults. Thus, AgrEvo believes that the overall weight of evidence does not indicate any special concern for infants and children, and that no additional safety factor is necessary.

Based on the existing and proposed tolerances in rice, potatoes, peanuts, and secondary commodities, the TMRC from the current petition is estimated to be 0.006498 mg/kg/day for the most highly exposed subpopulation, non-nursing infants (less than 1 year old). This exposure would utilize approximately 1% of the RfD. Therefore, there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to flutolanil.

#### F. International Tolerances

No Codex Alimentarius Commission (CODEX) tolerances have been established for flutolanil.

[FR Doc. 00-1551 Filed 1-21-00; 8:45 am]

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### ENVIRONMENTAL PROTECTION AGENCY

[PF-911; FRL-6485-5]

#### 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-911, must be received on or before February 23, 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-911 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Judy Loranger, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-8056; e-mail address: loranger.judy@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
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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-911. 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