

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 contain data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of 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: July 28, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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

PP 3F6542

EPA has received a pesticide petition (3F6542) from Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing a tolerance for residues of 2-(2,2-difluoroethoxy)-6-trifluoromethyl-N-(5,8-dimethoxy [1,2,4]triazolo-1,5c pyrimidin-2-yl) benzenesulfonamide, (penoxsulam, DE-638) in or on the raw agricultural commodity rice raw agricultural commodities (RACS) and rice processed products at 0.01 part per million (ppm) for rice grain, 0.05 ppm for rice straw, 0.01 ppm for rice hull, 0.01 ppm for rice bran, and 0.01 ppm for polished rice. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The nature of residue study in rice, treated with ^{14}C -labeled DE-638 (2-position on the triazolopyrimidine ring or uniformly labeled in the phenyl ring) at 100 grams (g/ha), demonstrated that no significant residues (0.003–0.022 ppm) were found in mature straw and grain. The residues were fractionated by reversed-phase high performance liquid chromatography (HPLC) and consisted of DE-638, 5-OH DE-638 (identified by retention time), and two unidentified peaks. Each component was $<0.01\text{ }\mu\text{g/g}$ (DE-638 equivalents). Based on the plant metabolism studies, the tolerance expression is the parent, penoxsulam.

Metabolism studies in livestock animals with ^{14}C -labeled DE-638 (2-position on the triazolopyrimidine ring or uniformly labeled in the phenyl ring) at a concentration equivalent to about 10 ppm in the diet indicated that approximately 99% of the administered dose was eliminated in the excreta. The low levels of residues (0.002–0.07 ppm) in fat and edible tissues, milk or eggs demonstrate that residues due to DE-

638 would not accumulate in the animals. Additionally, the dose levels in these studies are about 200 to 1,000 times higher than the theoretical maximum exposure in the animal diet of rice commodities treated with DE-638, therefore, livestock feeding studies are not considered necessary.

A bioconcentration study on crayfish was conducted to determine the residues in edible tissues and estimate the bioconcentration factor. Crayfish (*Procambarus clarkii*) were exposed for 14 days to ^{14}C -DE-638 under flow-through conditions at an average exposure concentration of $494\text{ }\mu\text{g/L}$ (C_w), equivalent to approximately 10x the initial estimated environmental concentration (EEC) based on the maximum application rate of 50 grams active ingredient/ha and one hectare rice paddy with 10 centimeters (cm) depth water.

Plateau of residues in crayfish occurred within 5 days following initiation of exposure with residues in edible tissues reaching an average steady-state concentration of $0.009\text{ }\mu\text{g/g}$ (C_r). The bioconcentration factor (C_r/C_w) was estimated to be <0.1 milligram per liter/gram (mg/L/g), indicating that penoxsulam has very low potential to bioconcentrate in edible tissues of crayfish. Based on the very low residues of $<0.01\text{ }\mu\text{g/g}$ (method limit of detection (LOD) is $0.003\text{ }\mu\text{g/g}$) in edible tissues of crayfish exposed to 10x the peak EEC, no tolerance in crayfish is required.

2. *Analytical method.* An analytical method has been developed and validated to determine the residues of penoxsulam in rice grain, straw, and processed products. The method was based on liquid chromatography with positive ion electrospray tandem mass spectrometry molecular size (LC/MS/MS) with LOD of $0.002\text{ }\mu\text{g/g}$ and limit of quantitation (LOQ) of $0.01\text{ }\mu\text{g/g}$. The method has been successfully validated by an independent laboratory.

B. Toxicological Profile

1. *Acute toxicity.* The acute toxicity of penoxsulam is considered low. The acute oral and dermal LD_{50} s were greater than 5,000 milligrams/kilogram (mg/kg), while the acute inhalation LC_{50} was greater than the highest attainable aerosol concentration (3.50 mg/L). Only very slight, transient dermal irritation was seen, and mild eye irritation was noted. Penoxsulam was negative for skin sensitization in a Magnusson and Kligman maximization test involving intradermal injection of penoxsulam with an adjuvant.