

the proposed uses of acetamiprid will utilize at most 3.9% of the acute RfD for the U.S. population, and is likely to be much less, as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure to acetamiprid.

2. *Infants and children.* In multi-generation reproduction and teratology studies, NOAEL on reproduction were observed in either rats or rabbits. In the long-term, feeding studies in rats and mice there was no evidence of carcinogenicity. Acetamiprid was not mutagenic under the conditions of testing. Using the conservative exposure assumptions described in the exposure section above, the percent of the RfD that will be used for short-term aggregate exposure to residues of acetamiprid will be 6% for children 1–6 (the most highly exposed sub-group). This value is based on dietary exposure alone as only children over 7 are expected to have residential post-application exposure for the proposed acetamiprid uses. The aggregate exposure for children 7–12 (based on dietary and residential exposure) results in a value of 4.0% of the RfD being used. As in the adult situation, drinking water levels of comparison are much higher than the worst case drinking water estimated concentrations. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of acetamiprid.

#### F. International Tolerances

Acetamiprid is registered for use in Chile, Brazil, Mexico and Japan for use on certain food crops for domestic consumption only. Imported commodities containing residues of acetamiprid should not be encountered in the United States at this time.

[FR Doc. 01–13420 Filed 5–29–01 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

[PF–1022; FRL–6782–2]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket control number PF–1022 must be received on or before June 29, 2001.

**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–1022 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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”, “Regulation and Proposed Rules”, 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–1022. 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–1022 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, 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, 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-1022. 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 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: May 16, 2001.

**James Jones,**

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

### **Summary of Petitions**

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

#### **Interregional Research Project # 4 (IR-4)**

*PP 0E6211, 1E6238, and 1E6264*

EPA has received pesticide petitions (0E6211, 1E6238, and 1E6264) from the Interregional Research Project Number 4 (IR-4), [681 US Highway #1 South, North Brunswick, NJ 08902-3390] 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 180.507 by establishing tolerances for residues of azoxystrobin, (methyl (E)-2-2-6-(2-cyanophenoxy)pyrimidin-4-ylloxy]phenyl-3-methoxyacrylate) and the Z isomer of azoxystrobin, (methyl (Z)-2-2-6-(2-cyanophenoxy)pyrimidin-4-ylloxy]phenyl-3-methoxyacrylate) in or on the following raw agricultural commodities (RACs):

PP# 0E6211 proposes to establish tolerances for strawberry at 10 parts per million (ppm), mint at 30 ppm, grass forage (from grass grown for seed) at 15 ppm, grass (from grass grown for seed) hay at 20 ppm, and 3.0 ppm for watercress, tropical fruits, persimmon, paw paw, tamarind, jackfruit, and loquat.

PP# 1E6238 proposes to establish tolerances for bushberry subgroup, lingonberries, juneberries, and salal at 3.0 ppm.

PP# 1E6264 proposes to establish tolerances for the leafy brassica greens subgroup and turnip greens at 25 ppm, and 2.0 ppm for pepper, eggplant, and okra.

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 support granting of the petitions. Additional data may be needed before EPA rules on these petitions.

#### *A. Residue Chemistry*

1. *Plant metabolism.* The metabolism of azoxystrobin as well as the nature of the residues is adequately understood for purposes of the tolerances.

2. *Analytical method.* Gas chromatography with nitrogen-phosphorus detection (GC-NPD) or in mobile phase by high performance liquid chromatography with ultra-violet detection (HPLC-UV), is available. The method(s) are adequate for enforcement purposes. Analytical methods are also available for analyzing meat, milk, poultry and eggs which underwent successful independent laboratory validations.

3. *Magnitude of residues.* Complete residue data for azoxystrobin (on legume vegetable group, hops, bushberries, lingonberries, salal, juneberries, forage grass, forage hay, jackfruit, loquat, mint, fresh, paw paw, peppermint, persimmon, spearmint, strawberry, tamarind, tropical fruit, watercress, eggplant, leafy brassica subgroup, okra, peppers, and turnip greens) have been submitted. The

requested tolerances are adequately supported.

### B. Toxicological Profile

1. *Acute toxicity.* The acute oral toxicity study in rats of technical azoxystrobin resulted in a lethal dose (LD)<sub>50</sub> of 5,000 milligrams/kilogram (mg/kg) for both males and females. The acute dermal toxicity study in rats of technical azoxystrobin resulted in a (LD)<sub>50</sub> of 2,000 mg/kg. The acute inhalation study of technical azoxystrobin in rats resulted in a lethal concentration LC<sub>50</sub> of 0.962 mg/liter (L) in males and 0.698 m/L in females. In an acute oral neurotoxicity study in rats dosed once by gavage with 0, 200, 600, or 2,000 mg/kg azoxystrobin, the systemic toxicity no observed adverse effect level (NOAEL) was <200 mg/kg and the systemic toxicity lowest observed adverse effect level (LOAEL) was 200 mg/kg, based on the occurrence of transient diarrhea in both sexes. There was no indication of neurotoxicity at the doses tested.

2. *Genotoxicity.* Azoxystrobin was negative for mutagenicity in the salmonella/mammalian activation gene mutation assay, mouse micronucleus test, and unscheduled deoxyribonucleic acid (DNA) synthesis in rat hepatocytes/mammalian cells *in vivo/in vitro* procedure study. In the forward mutation study using L5178 mouse lymphoma cells in culture, azoxystrobin tested positive for forward gene mutation at the TK locus. In the *in vitro* human lymphocytes cytogenetics assay of azoxystrobin, there was evidence of a concentration related induction of chromosomal aberrations over background in the presence of moderate to severe cytotoxicity.

3. *Reproductive and developmental toxicity.* In a prenatal development study in rats gavaged with azoxystrobin at dose levels of 0, 25, 100, or 300 mg/kg/day during days 7 through 16 of gestation, lethality at the highest dose caused the discontinuation of dosing at that level. The developmental NOAEL was greater than or equal to 100 mg/kg/day and the developmental LOAEL was >100 mg/kg/day because no significant adverse developmental effects were observed. In this same study, the maternal NOAEL was not established; the maternal LOAEL was 25 mg/kg/day, based on increased salivation.

In a prenatal developmental study in rabbits gavaged with 0, 50, 150, or 500 mg/kg/day during days 8 through 20 of gestation, the developmental NOAEL was 500 mg/kg/day and the developmental LOAEL was > 500 mg/kg/day because no treatment-related adverse effects on development were

seen. The maternal NOAEL was 150 mg/kg/day and the maternal LOAEL was 500 mg/kg/day, based on decreased body weight gain.

In a 2-generation reproduction study, rats were fed 0, 60, 300, or 1,500 ppm of azoxystrobin. The reproductive NOAEL was 32.2 mg/kg/day. The reproductive LOAEL was 165.4 mg/kg/day; reproductive toxicity was demonstrated as treatment-related reductions in adjusted pup body weights as observed in the F<18 and F<2 pups dosed at 1,500 ppm (165.4 mg/kg/day).

4. *Subchronic toxicity.* In a 90-day rat feeding study the NOAEL was 20.4 mg/kg/day for males and females. The LOAEL was 211 mg/kg/day based on decreased weight gain in both sexes, clinical observations of distended abdomens and reduced body size, and clinical pathology findings attributable to reduced nutritional status.

In a subchronic toxicity study in which azoxystrobin was administered to dogs by capsule for 92 or 93 days, the NOAEL for both males and females was 50 mg/kg/day. The LOAEL was 250 mg/kg/day, based on treatment-related clinical observations and clinical chemistry alterations at this dose.

In a 21-day repeated-dose dermal rat study using azoxystrobin, the NOAEL for both males and females was greater than or equal to 1,000 mg/kg/day (the highest dosing regimen); a LOAEL was therefore not determined.

5. *Chronic toxicity.* In a 2-year feeding study in rat fed diets containing 0, 60, 300, and 750/1,500 ppm (males/females), the systemic toxicity NOAEL was 18.2 mg/kg/day for males and 22.3 mg/kg/day for females. The systemic toxicity LOAEL for males was 34 mg/kg/day, based on reduced body weights, food consumption and efficiency, and bile duct lesions. The systemic toxicity LOAEL for females was 117.1 mg/kg/day, based on reduced body weights. There was no evidence of carcinogenic activity in this study.

In a 1-year feeding study in dogs to which azoxystrobin was fed by capsule at doses of 0, 3, 25, or 200 mg/kg/day, the NOAEL for both males and females was 25 mg/kg/day and the LOAEL was 200 mg/kg/day for both sexes, based on clinical observations, clinical chemistry changes, and liver weight increases that were observed in both sexes.

In a 2-year carcinogenicity feeding study in mice using dosing concentrations of 0, 50, 300, or 2,000 ppm, the systemic toxicity NOAEL was 37.5 mg/kg/day for both males and females. The systemic toxicity LOAEL was 272.4 mg/kg/day for both sexes, based on reduced body weights in both

at this dose. There was no evidence of carcinogenicity at the dose levels tested.

According to the new proposed guidelines for Carcinogen Risk Assessment, the appropriate descriptor for human carcinogenic potential of azoxystrobin is "Not Likely." The appropriate subdescriptor is "has been evaluated in at least two well conducted studies in two appropriate species without demonstrating carcinogenic effects."

6. *Animal metabolism.* In this study, azoxystrobin unlabeled or with a pyrimidinyl, phenylacrylate, or cyanophenyl label was administered to rats by gavage as a single or 14-day repeated doses. Less than 0.5% of the administered dose was detected in the tissues and carcass up to 7 days post-dosing-most of it was in excretion-related organs. There was no evidence of potential for bioaccumulation. The primary route of excretion was via the feces, though 9 to 18% was detected in the urine of the various dose groups. Absorbed azoxystrobin appeared to be extensively metabolized. A metabolic pathway was proposed showing hydrolysis and subsequent glucuronide conjugation as the major biotransformation process.

7. *Metabolite toxicology.* There are no metabolites of concern based on the differential metabolism between plants and animals.

8. *Endocrine disruption.* There is no evidence that azoxystrobin is an endocrine disrupter.

### C. Aggregate Exposure

1. *Dietary exposure.* Permanent tolerances have been established (40 CFR 180.507(a)) for the combined residues of azoxystrobin and its Z isomer, in or on a variety of RACs at levels ranging from 0.02 ppm on tree nuts to 50.0 ppm on leaves of root and tuber vegetables. Included in these tolerances are animal commodities which were established in conjunction with tolerances for animal feed.

i. *Food.* For the purposes of assessing the potential acute and chronic dietary exposure, Syngenta has estimated acute and chronic exposure for all registered crops, (EPA) pending uses, and newly proposed uses. Novigen Sciences', Inc. Dietary Exposure Evaluation Model (DEEM), which is licensed to Syngenta, was used to estimate the chronic and acute dietary exposure.

a. *Acute.* The DEEM model was used for analysis of individual food consumption as reported by the USDA using the Tier I analysis. The Tier I analysis used tolerance values as anticipated residues. Syngenta's acute dietary exposure assessment estimated

percent of the acute population adjusted dose (aPAD) and corresponding margins of exposure (MOE) for the overall U.S. population, infants/children, and females 13+ as presented in Table 1.

TABLE 1.—ACUTE DIETARY RISK ASSESSMENT FOR AZOXYSTROBIN

Population Subgroup	Exposure (mg/kg/day)	Percent aPAD
U.S. population (total)	0.094350	14.0%
Infants/children	0.151589	22.6%
Females 13+	0.088553	13.2%

b. *Chronic.* In conducting this chronic dietary risk assessment Syngenta has made very conservative assumptions—100% of all commodities having azoxystrobin tolerances or proposed tolerances will contain azoxystrobin residues at the level of the tolerance. Default concentration factors have been removed where data show no

concentration of residues (grape juice, grapes, raisins; tomatoes juice, tomatoes, puree; and white/dry potatoes). The chronic reference dose (RfD) = 0.18 mg/kg/day.

The existing azoxystrobin tolerances published and pending result in a theoretical maximum residue contribution (TMRC) that is equivalent

to the following percentage of the Chronic RfD. As the 10X safety factor was removed by EPA, the chronic RfD is equal to the PAD (population-adjusted dose). As a result, the exposure given as a percentage of the total allowable is reported as %PAD. These results are presented in Table 2.

TABLE 2.—CHRONIC DIETARY RISK ASSESSMENT FOR AZOXYSTROBIN

Population Subgroup	Exposure (mg/kg/day)	Percent Reference Dose <sup>1</sup> (%Chronic PAD/RfD)
U.S. population (total)	0.028977	16.1%
All infants <1 year	0.026769	14.9%
Nursing infants <1 year	0.008527	4.7%
Non-nursing infants <1 year	0.032107	17.8%
Children (1–6 years old)	0.047504	26.4%
Children (7–12 years old)	0.031544	17.5%
Western region	0.031923	17.7%
Non-hispanic/non-white/non-black	0.044724	24.8%
Females 13+ (nursing)	0.031485	17.5%

<sup>1</sup> Percentage reference dose (%Chronic PAD)= Exposure x 100% (as RfD=PAD in this case) Chronic PAD

ii. *Drinking water.* There is no established Maximum Concentration Level for residues of azoxystrobin in drinking water. No health advisory levels for azoxystrobin in drinking water have been established. The concentration of azoxystrobin in surface water based on GENEEC (Generic Estimated Environmental Concentration) modeling and in ground water based

on Screening Concentration in Ground Water (SCI-GROW) modeling.

Based on the chronic dietary (food) exposure estimated, chronic drinking water levels of concern (DWLOC) for azoxystrobin were calculated and summarized in the table below. EPA has estimated the highest EEC of azoxystrobin in surface water is from the application of azoxystrobin on grapes (39 µg/L). The estimated environmental concentration (EEC) for

ground water is 0.064 µg/L resulting from use on turf. For purposes of risk assessment, the maximum EEC for azoxystrobin in drinking water (39 µg/L) should be used for comparison to the back-calculated human health drinking water levels of comparison (DWLOC) for the chronic (non-cancer) endpoint. These DWLOCs for various populations categories are summarized in Tables 3 and 4.

TABLE 3.—DRINKING WATER LEVELS OF COMPARISON FOR ACUTE EXPOSURE TO AZOXYSTROBIN

Subgroup <sup>1</sup>	aPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Maximum Water Exposure (mg/kg/day)	DWLOC (µg/L)
U.S. population	0.67	0.094350	0.57565	20147.7 5
Females 13+ (nursing)	0.67	0.088553	0.581447	17443.41

TABLE 3.—DRINKING WATER LEVELS OF COMPARISON FOR ACUTE EXPOSURE TO AZOXYSTROBIN—Continued

Subgroup <sup>1</sup>	aPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Maximum Water Exposure (mg/kg/day)	DWLOC (µg/L)
Children (1-6 years old)	0.67	0.151589	0.518411	5184.11

<sup>1</sup> Within each of these categories, the subgroup with the highest food exposure was selected.

TABLE 4.—DRINKING WATER LEVEL OF COMPARISON FOR CHRONIC EXPOSURE TO AZOXYSTROBIN

Subgroup <sup>1</sup>	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max Water Exposure <sup>2</sup> (mg/kg/day)	DWLOC <sup>3,4,5</sup> (µg/L)
U.S. population	0.18	0.028977	0.151023	5285.805
Females 13+ (nursing)	0.18	0.031485	0.148515	4455.45
Children (1–6 years old)	0.18	0.047504	0.132496	1324.96

<sup>1</sup> Within each of these categories, the subgroup with the highest food exposure was selected.

<sup>2</sup> Maximum Water Exposure (Chronic) (mg/kg/day) = Chronic RfD(mg/kg/day)–Food Exposure (mg/kg/day).

<sup>3</sup> DWLOC (µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ (10–3 µg/µg) \* water consumed daily (L/day).

<sup>4</sup> HED default body weights are: General U.S. population, 70 kg; Females 13+ years old 60 kg; infants and children 10 kg.

<sup>5</sup> HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.

## 2. Non-dietary exposure.

Azoxystrobin is registered for residential use on ornamentals and turf. The Agency evaluated the existing toxicological data base for azoxystrobin and assessed appropriate toxicological endpoints and dose levels of concern that should be assessed for risk assessment purposes. Dermal absorption data indicate that absorption is less than or equal to 4%. Azoxystrobin is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that is appropriate to aggregate chronic food and water and intermediate-term exposures for azoxystrobin. EPA has concluded that food and residential exposures aggregated result in MOEs of 520 (aggregate short-term), and 420 (aggregate intermediate term) for the subgroup children 1–6 years old.

### D. Cumulative Effects

Azoxystrobin is related to the naturally occurring strobilurins. Syngenta concluded that further consideration of a common mechanism of toxicity is not appropriate at this time since there are no data to establish whether a common mechanism exists with any other substance.

### E. Safety Determination

1. *U.S. population.* Based on the exposure assessments described and completeness and reliability of the toxicity data, it can be concluded that there is reasonable certainty that no harm will result from aggregate exposure to azoxystrobin. Total aggregate exposures for all label uses will utilize less than 16.1% of the cPAD for the chronic dietary exposures.

2. *Infants and children.* FFDC 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOAEL in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor. The Agency's Food Quality Protection Act (FQPA) Safety Factor Committee removed the additional 10X safety factor to account for sensitivity of infants and children.

### F. International Tolerances

There are no Codex Maximum Residue Level's established for azoxystrobin.

[FR Doc. 01–13515 Filed 5–29–01; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP–50886; FRL–6781–3]

### Issuance of an Experimental Use Permit

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

**ACTION:** Notice.

**SUMMARY:** EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Office location, telephone number, and e-mail address: 1921 Jefferson Davis Hwy., Rm. 249, Crystal Mall #2, Arlington, VA; (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons