

**III. What is the Agency's Authority for Taking this Action?**

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of

receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

**IV. Loss of Active Ingredient**

Unless the request for cancellation is withdrawn, one pesticide active ingredient will no longer appear in any

registered products. Those who are concerned about the potential loss of this active ingredient for pesticidal use are encouraged to work directly with the registrant to explore the possibility of withdrawing their request for cancellation. The active ingredient is listed in the following Table 3, with the EPA company and CAS number.

TABLE 3.—DISAPPEARING ACTIVE INGREDIENT

CAS No.	Chemical Name	EPA Company No.
11084-85-8	Chlorinated trisodium phosphate	000264

**V. Procedures for Withdrawal of Request**

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before January 29, 2001. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

**VI. Provisions for Disposition of Existing Stocks**

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received by the Agency. This policy is in accordance with the Agency's statement of policy as prescribed in **Federal Register** June 26, 1991; (56 FR 29362) (FRL-3846-4). Exception to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such

further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

**List of Subjects**

Environmental protection, Pesticides and pests, Product registrations.

Dated: July 25, 2000.

**Richard D. Schmitt,**

*Associate Director, Information Resources Services Division, Office of Pesticide Programs.*

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**BILLING CODE 6560-50-F**

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-950; FRL-6592-1]

**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-950, must be received on or before September 1, 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-950 in the subject line on the first page of your response.

**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; telephone number: (703) 305-7740; e-mail address: giles-parker.cynthia@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/fedrgrstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-950. 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-950 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](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-950. 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: July 20, 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 petitioner. 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.

**Zeneca Ag Products**

9F6058

EPA has received pesticide petition 9F6058 from Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850-5458 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 a tolerance for residues of azoxystrobin (methyl (E)-2-(2-

(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate)) and its Z isomer methyl (Z-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-(methoxyacrylate)) in or on the raw agricultural commodities (RAC) apples at 1.5 parts per million (ppm); barley, bran at 0.2 ppm; barley, grain at 0.1 ppm; barley, hay at 15 ppm; barley, straw at 4 ppm; beet, sugar, dried pulp at 0.8 ppm; cattle, fat at 0.03 ppm; cattle, meat by-products at 0.07 ppm; citrus, oil at 15 ppm; coriander, leaves at 30 ppm; coriander, seed at 30 ppm; corn, field, forage at 10 ppm; corn, field, grain at 0.05 ppm; corn, field, refined oil at 0.3 ppm; corn, field, stover at 25 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 25 ppm; corn, sweet, kernal plus cob with husks removed at 0.02 ppm; corn, sweet, forage at 10 ppm; corn, sweet, stover at 25 ppm; cotton at 0.01 ppm; cotton, gin by-products at 0.01 ppm; fruit, citrus, group at 3 ppm; fruit, citrus, dried pulp at 7 ppm; goat, fat at 0.03 ppm; goat, meat by-products at 0.07 ppm; horse, fat at 0.03 ppm; horse, meat by-products at 0.07 ppm; peanut at 0.2 ppm; peanut, hay at 15 ppm; peanut, refined oil at 0.6 ppm; sheep, fat at 0.03 ppm; sheep, meat by-products at 0.07 ppm; soybean, seed at 0.5 ppm; soybean, forage at 25 ppm; soybean, hay at 55 ppm; soybean, hulls at 1.25 ppm; soybean, seed at 0.5 ppm; rice, wild at 5 ppm; vegetable, bulb, group at 7.5 ppm; vegetable, leafy, except brassica vegetables, group at 30 ppm; vegetable, leaves of root and tuber, group at 50 ppm; and vegetable, root and tuber, group at 0.5 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDC; 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 metabolism of azoxystrobin as well as the nature of the residues is adequately understood for purposes of the tolerances. Plant metabolism has been evaluated in four diverse crops: cotton, grapes, wheat, and peanuts, which should serve to define the similar metabolism of azoxystrobin in a wide range of crops. Parent azoxystrobin is the major component found in crops. Azoxystrobin does not accumulate in crop seeds or fruits. Metabolism of azoxystrobin in plants is complex with more than 15 metabolites identified. These metabolites are present at low levels, typically much less than

5% of the total recoverable residues (TRR).

2. *Analytical method.* An adequate 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 for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. The analytical chemistry laboratory of the EPA concluded that the method(s) are adequate for enforcement. For azoxystrobin methods are also available for analyzing meat, milk, poultry, and eggs, and also underwent successful independent laboratory validations.

3. *Magnitude of residues.* Eleven onion trials (green and dry bulb) were carried out in the United States of America (U.S.) in 1998. Maximum residues of 6.9 ppm resulted from multiple foliar applications. Twenty-three citrus fruit trials (grapefruit, lemon and orange) were carried out in the U.S. in 1997-1998. Fourteen citrus fruit trials were carried out in South Africa in 1995-1998. Maximum residues of 2.9 ppm resulted from multiple foliar applications. Twenty corn trials were carried out in the U.S. in 1998. Maximum residues of 0.05 ppm in grain, 0.02 ppm in fresh kernels, 10 ppm in forage, and 25 ppm in stover resulted from multiple foliar applications. Twelve residue trials were carried out in the U.S. in 1997. Maximum residues of 0.01 ppm in cottonseed, and 0.01 ppm in cotton gin by-products resulted from in-furrow application. Twenty-four leafy vegetable (excluding brassica) trials were carried out in 1998. Maximum residues of 30 ppm resulted from multiple foliar applications. Twenty trials on the leaves of root and tuber vegetable group were carried out in the U.S. in 1998, resulting in maximum residues of 45 ppm from multiple foliar applications. Twenty root and tuber vegetable trials were carried out in the U.S. in 1998. Maximum residues of 0.46 ppm in root and tuber vegetables resulted from multiple foliar applications. Sixteen potato trials were carried out in the U.S. in 1997, previously submitted under pesticide petition 8F4995. Maximum residues of 0.03 ppm in potatoes resulted from multiple foliar applications. Twelve peanut trials were carried out in the U.S. in 1997. Maximum residues of 0.14 ppm in peanut, nutmeat, and 13.7 ppm in peanut hay resulted from multiple foliar applications. Twenty soybean trials were carried out in the U.S. in 1998. Maximum residues were 0.36 ppm in

soybean, seed, 9.1 ppm in soybean, forage and 54 ppm in soybean, hay. Concentration of residues was observed in barley, bran; citrus, dried pulp; citrus oil; corn, oil; sugarbeet, dried pulp; peanut, oil; and soybean, hulls.

#### B. Toxicological Profile

1. *Acute toxicity.* The acute oral toxicity study in rats of technical azoxystrobin resulted in a lethal dose 50% (LD<sub>50</sub>) of >5,000 milligrams/kilogram (mg/kg) (limit test) for both males and females. The acute dermal toxicity study in rats of technical azoxystrobin resulted in an LD<sub>50</sub> of >2,000 mg/kg (limit dose (LTD)).

The acute inhalation study of technical azoxystrobin in rats resulted in a lethal concentration 50% (LC<sub>50</sub>) of 0.962 milligrams/liter (mg/L) in males and 0.698 mg/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, the mouse micronucleus test, and the unscheduled deoxyribonucleic acid (DNA) synthesis in rat hepatocytes/mammalian cells in an *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 lowest observed adverse effect level (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 F18 and F2 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 211.0 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 rats 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 food 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 (April 1996), 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, either 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 and 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 a differential metabolism between plants and animals.

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

#### C. Aggregate Exposure

The Agency has concluded from review of available data that there is no acute toxicological endpoint of concern from the review of available data. Therefore, an acute risk assessment is not necessary. For azoxystrobin, only a chronic (noncancer) risk assessment is necessary.

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 RAC at levels ranging from 0.01 ppm on tree nuts to 20.0 ppm on rice hulls. Included in these tolerances are the numerous ones for animal commodities which were established in conjunction with

tolerances for rice and wheat commodities. Time-limited tolerances range from 0.1 ppm in soybeans to 100 ppm in fresh parsley.

i. *Food.* In conducting a chronic dietary risk assessment, Zeneca has made the very conservative assumptions that 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 (grapes, juice, grapes, raisins, tomatoes, juice, tomatoes, puree, and potatoes, white (dry)). The chronic RfD of 0.18 mg/kg/day that was used as the endpoint value was derived from the NOAEL of 18.2 mg/kg/day from the rat chronic toxicity/carcinogenicity feeding study. The endpoint effects were decreased body weight and bile duct lesions that were observed in male rats at the LOAEL of 34 mg/kg/day. This NOAEL was divided by an uncertainty factor of 100 to allow for intraspecies and interspecies variability.

The Novigen Dietary Exposure Evaluation Model (DEEM) system was used for this Chronic Dietary Exposure Analysis. The analysis evaluates individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals (CSFII) survey that was conducted from 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure.

The existing azoxystrobin tolerances (both published and pending; section 18 tolerances have been excluded in this analysis because most are included as pending tolerances in this petition), result in a theoretical maximum residue contribution (TMRC) that is equivalent to the following percentages of the chronic reference dose (RfD). Since the 10x safety factor was removed by EPA, the chronic RfD is equal to the chronic population-adjusted dose (cPAD) and the exposure given as a percentage of the total allowable is reported as the percentage of the cPAD. The U.S. population group will have a food exposure that is estimated as 0.023894 mg/kg/day (13.3% of the cPAD), the subgroup all infants (less than 1-year old) will have an estimated exposure of 0.029771 mg/kg/day (16.5% of the cPAD), the subgroup nursing infants (less than 1 year old) will have an estimated exposure of 0.014637 mg/kg/day (8.1% of the cPAD), the subgroup non-nursing infants (less than 1-year old) will have an estimated exposure of

0.036140 mg/kg/day (20.1% of the cPAD), the subgroup children (1–6 years old) will have an estimated exposure of 0.047270 mg/kg/day (26.3% of the cPAD), the subgroup children (7–12 years old) will have an estimated exposure of 0.032101 mg/kg/day (17.8% of the cPAD), the subgroup hispanics will have an estimated exposure of 0.026050 mg/kg/day (14.5% of the cPAD), the subgroup non-hispanic/non-white/non-black will have an estimated exposure of 0.030275 mg/kg/day (16.8% of the cPAD), and the subgroup females (13+ years old, nursing) will have an estimated 0.028866 mg/kg/day (16.0% of the cPAD).

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 is based on Generic Estimated Environmental Concentration (GENEEC) modeling and in ground water is based on Screening Concentration in Ground Water (SCI-GROW) modeling (both models belong to EPA).

Based on the chronic dietary (food) exposure estimates, chronic drinking water levels of concern (DWLOC) for azoxystrobin were calculated and are summarized below. The group and subgroups that were analyzed are the group U.S. population and the two general subgroups females 13–50 and children. Within each of these two general subgroups, the specific subgroup with the highest food exposure was chosen for the analysis. EPA has determined that the highest estimated environmental concentration (EEC) of azoxystrobin in surface water is from the application of azoxystrobin to grapes (39 micrograms per liter ( $\mu\text{g/L}$ )). The EEC for ground water is 0.064  $\mu\text{g/L}$  resulting from use on turf. For purposes of risk assessment, the maximum EEC for azoxystrobin in drinking water (39  $\mu\text{g/L}$ ) should be used for comparison to the back-calculated human health DWLOC for the chronic (non-cancer) endpoint. The maximum (chronic) water exposure (in mg/kg/day) is calculated by starting with the value for the chronic RfD (in mg/kg/day) and subtracting the food exposure (in mg/kg/day). The DWLOC (in micrograms per liter) ( $\mu\text{g/L}$ ) is calculated by multiplying the maximum water exposure (in mg/kg/day) by the body weight (in kilograms), then dividing by  $10^{-3}$  times the water consumed daily (in liters per day). The default body weights used were 70 kilograms (kg) for the group U.S. population, 60 kg for subgroups of females (13+ years old), and 10 kg for

the subgroups of infants and children. The default drinking water rates used were 2 liters per day (L/day) for adults and 1 L/day for children. The scenarios for various groups and subgroups, leading up to the DWLOC for each, are summarized as follows. For the group U.S. population, the RfD is 0.18 mg/kg/day, the theoretical maximum residue contribution (TMRC) food exposure is 0.023894 mg/kg/day, the maximum water exposure is 0.156106 mg/kg/day, and the DWLOC is 5,463.71 g/L. For the subgroup females (13+, nursing), the RfD is 0.18 mg/kg/day, the TMRC food exposure is 0.028866 mg/kg/day, the maximum water exposure is 0.151134 mg/kg/day, and the DWLOC is 4,534.02 g/L. For the subgroup children (1–6 years old), the RfD is 0.18 mg/kg/day, the TMRC food exposure is 0.047270 mg/kg/day, the maximum water exposure is 0.13273 mg/kg/day, and the DWLOC is 1,327.3 g/L.

#### 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%. No appropriate endpoints were identified for acute dietary or short-term, intermediate-term, and chronic-term (noncancer) dermal and inhalation occupational exposure. Therefore, risk assessments are not required for these exposure scenarios.

#### D. *Cumulative Effects*

Azoxystrobin is related to the naturally occurring strobilurins. There are two other members of this class of fungicides registered with EPA. Zeneca 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*

The acute safety analysis was not applicable since no suitable toxicological end-point of concern was identified during Agency review of the available data. The short-term and intermediate-term safety assessment also was not applicable, in this case because no indoor and outdoor residential exposure uses are currently registered for azoxystrobin. Therefore, only a chronic analysis was needed.

The chronic RfD for azoxystrobin is 0.18 milligrams per kilogram per day (mg/kg/day), based on the NOAEL of

18.2 mg/kg/day from the rat chronic toxicity/carcinogenicity feeding study in which endpoint effects of decreased body weight and bile duct lesions were observed in male rats at the LOAEL of 34 mg/kg/day. This NOAEL was divided by an uncertainty factor of 100, to allow for interspecies sensitivity and intraspecies variability.

1. *U.S. population.* The chronic dietary exposure analysis showed that exposure from the proposed new tolerances in or on apples; barley; coriander; corn, field; corn, pop; corn, sweet; cotton; fruit, citrus, group; rice, wild; vegetable, bulb, group; vegetable, leafy, except brassica vegetables, group; vegetable, leaves of root and tuber, group; vegetable, root and tuber, group; and soybeans for the group U.S. population would be 13.3% of the RfD.

2. *Infants and children.* The chronic dietary exposure analysis showed that exposure from the proposed new tolerances in or on apples; barley; coriander; corn, field; corn, pop; corn, sweet; cotton; fruit, citrus, group; rice, wild; vegetable, bulb, group; vegetable, leafy, except brassica vegetables, group; vegetable, leaves of root and tuber, group; vegetable, root and tuber, group; and soybeans for the subgroup children (1–6 years old) (the subgroup with the highest exposure) would be 26.3% of the RfD.

FFDCA section 408 provides that EPA shall apply an additional ten-fold 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 a margin of exposure analysis or else through use of Uncertainty (Safety) Factors in calculation of 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 no observed effect level in the animal study appropriate to the particular risk assessment. This hundred-fold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined interspecies and intraspecies variability. EPA believes that reliable data support using the standard hundred-fold margin/factor without the additional ten-fold FQPA 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 ad hoc FQPA safety factor committee removed the additional 10x FQPA safety factor that would otherwise be used to account for increased sensitivity of infants and children.

Zeneca has considered the potential aggregate exposure from food, water, and non-occupational exposure routes, concluding that aggregate exposure is not expected to exceed 100% of the RfD and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to azoxystrobin residues.

#### F. International Tolerances

There are no Codex maximum residue levels established for azoxystrobin.

[FR Doc. 00-19378 Filed 8-1-00; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6843-9]

### Notice of Proposed Settlement Trans Circuits, Inc. Superfund Site Lake Park, Palm Beach County, Florida

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed settlement.

**SUMMARY:** Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the United States Environmental Protection Agency (EPA) proposes to enter into a "Prospective Purchaser Agreement" (PPA) concerning property located at 210 Newman Way in an industrial park in Lake Park, Palm Beach County, Florida. EPA proposes to enter into the PPA with the National Land Company (NLC).

The PPA obligates NLC to cooperate fully with any response action EPA may take on the Property. The PPA resolves NLC's potential liability for the Existing Contamination at the Site which would otherwise result from becoming the owner of the Site. This protection is contingent upon NLC fulfilling its obligations under the PPA.

EPA will consider public comment on the proposed settlement for thirty (30) days. EPA may withdraw from or modify the proposed settlement should public comments disclose facts or considerations which indicate that the proposed settlement is inappropriate, improper, or inadequate.

Copies of the proposed settlement are available from: Ms. Paula V. Batchelor, Waste Management Division, U.S. EPA, Region 4, Atlanta Federal Center, 61

Forsyth Street, S.W., Atlanta, GA 30303-3104.

Written comments may be submitted to Ms. Batchelor at the address noted above within thirty (30) calendar days of the date this notice is published.

Dated: July 18, 2000.

**James L. Miller,**

*Acting Chief, CERCLA Program Services Branch, Waste Management Division.*

[FR Doc. 00-19538 Filed 8-1-00; 8:45 am]

BILLING CODE 6560-50-P

## FEDERAL COMMUNICATIONS COMMISSION

### Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

July 25, 2000.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

**DATES:** Written comments should be submitted on or before October 2, 2000. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all comments to Les Smith, Federal Communications Commissions, 445 12th Street, S.W., Room 1-A804, Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collections contact Les Smith at (202) 418-0217 or via the Internet at lesmith@fcc.gov.

#### SUPPLEMENTARY INFORMATION:

*OMB Approval No.:* XXXXXX.

*Title:* Notification of Emergency Alert System Status.

*Type of Review:* New Collection.

*Respondents:* Business or other for-profit; and not-for-profit institutions, state, local or tribal government(s).

*Number of Respondents:* 125.

*Estimate Time Per Response:* 30 minutes.

*Frequency of Response:* On Occasion.

*Total Annual Burden:* 62 hrs.

*Needs and Uses:* The Resident Agent of the Agency's Alaska Office is developing a survey to assess whether FM translators located in isolated areas of Alaska are in compliance with the Emergency Alert System (EAS) rules adopted January 1, 1997. These rules state that FM translators not rebroadcasting the entire programming of other local FM broadcast stations must be in compliance by having EAS equipment installed and working properly. In remote areas of Alaska FM translators provide service to their communities by re-broadcasting programming from other local FM broadcast stations, however, in some cases the FM translators do not rebroadcast the entire contents of the program thus they could inadvertently eliminate any EAS warnings. EAS not only provides the President of the United States the capability to provide immediate communications and information to the general public during periods of national emergency, but it also allows the local and/or state officials the ability to warn the public in the remote areas of Alaska about avalanches, wildfires, etc. Due to its size, remoteness, and isolation, it is difficult for the Resident Agent to make on scene inspections to ensure that the FM translators are in compliance. Using the survey the Resident Agent can find out if licensed FM translators are either rebroadcasting local programming in their entirety including EAS warnings or, if not, then the FM translator station has EAS equipment installed and working properly. FM translator stations not in compliance could present a safety of life issue to the listening public.

*OMB Control Number:* 3060-0771.

*Title:* Procedure for Obtaining a Special Temporary Authorization in the Experimental Radio Service—Section 5.56.

*Form No.:* N/A.

*Type of Review:* Extension of currently approved collection.