permeability is only approximately 1×10^{-6} cm/sec. When saturated, the permeability of the GCL used at the Landfill is less than 5×10^{-9}. The GCL approved for the Landfill is therefore less permeable than the prescriptive liner, provided that the bentonite is well hydrated when it is installed. While the GCL is thinner than a compacted soil liner at this level of permeability, the alternative liner design ensures that the performance standards are met. In addition to its low permeability, the GCL has many advantages over the composite liner. The GCL is rolled out like carpet and is quick and easy to install. It is cost effective, particularly in areas where clay is not available. Because bentonite swells readily when hydrated, it can repair itself if rips or holes occur. It is also more resistant to cracking than compacted clay. The GCL is thin, yet strong. It allows the Landfill to maximize its capacity while continuing to protect ground water, but can also absorb a large amount of stress without losing structural integrity.

The Salt River Pima-Maricopa Indian Community submitted site-specific demonstration to the US EPA Solid Waste Program, showing that its alternative liner design proposal meets the environmental performance criteria set forth in 40 CFR part 258. 40. EPA staff reviewed the Community's site-specific demonstration to determine if the proposed alternative design meets the environmental performance requirements and does not allow for degredation of the groundwater. EPA's review determined that concentration values for parameters listed in Table 1 of 40 CFR 258.40(a)(1) will not be exceeded in the uppermost aquifer.

EPA's review also determined that groundwater models used in the evaluation were appropriate and appropriately used and that results of the computer modelling presented in the evaluation likely provide a reasonable worst case estimate of the concentration of chemicals in the groundwater.

EPA approves use of the GCL at the Landfill. Based on the information submitted by the Community and as discussed above, EPA determined that the alternative liner meets or exceeds the performance standards set forth in § 258.40(a)(1), (c), and (d).

2. Alternative Daily Cover Material (40 CFR 258.21)

The federal revised criteria requires that MSWLF units must use six inches of earthen material to cover disposed solid waste each day. Section 258.21(b) provides flexibility by allowing use of alternative materials and an alternative thickness if control of disease carrying insects and animals, fires, odours, blowing litter, and scavenging is provided without presenting a threat to human health and the environment.

On June 2, 1997, the Community submitted an application to the EPA requesting approval to use any alternative daily cover material that Arizona has approved for that state. These materials consist of tarps, foams, chipped green waste, drinking water treatment residues, and chipped tires. The Community subsequently restricted their current application to the use of tarps as an alternative daily cover material.

The federal revised criteria does not specifically include a procedure for EPA's tentative determination. However, EPA relied on the requirements set forth in § 258.21 as a guideline for analyzing the Community's application. The Community proposes to use the Tarpomatic tarping operation, consisting of a polypropylene tarp rolled over the landfill material at the end of each business day and retrieved at the beginning of the next business day. The Tarpomatic is a polypropylene tarp that is automatically deployed and retrieved by machine. It is fast, easy, and eliminates direct employee contact with waste. Field tests and industry usage show that tarps meet the requirements of § 258.21. In addition, use of the tarping system rather than earthen material extends the life of the landfill, reduces labor in covering the waste, and saves landfill space. However, tarps cannot be used during wind storms as the winds will pick up the tarp and the landfill will not remain covered.

EPA approves use of a tarp at the Landfill. Based on the information submitted by the Community and as discussed above, the proposed alternative daily cover meets or exceeds the performance standards set forth in § 258.21(b).

Authority: This notice is issued under the authority of sections 2002, 4004, 4005, and 4010 of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912, 6944, 6945, and 6949a. The Regional Administrator is making this decision in accordance with EPA Delegations Manual No. 8–47 (October 8, 1993).

EPA approves the applications by the Salt River Pima-Maricopa Indian Community to use an alternative liner system design and an alternative daily cover material for the Salt River Municipal Solid Waste Landfill.

Dated: November 20, 1998.

Felicia Marcus,

Regional Administrator, Region 9.

[FR Doc. 98–32579 Filed 12–10–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–844; FRL 6043–3]

Notice of Filing of Pesticide Petitions

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 the docket control number PF–844, must be received on or before January 11, 1999.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Daniel Kenny	Rm. 227, CM #2, 703–305–7546; e-mail: kenny.daniel@epamail.epa.gov.	1921 Jefferson Davis Hwy., Arlington, VA
Cynthia Giles-Parker	Rm. 247, CM #2, 703–305–7740; e-mail: giles-parker.cynthia@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: 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 Comestic 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.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number PF–844 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number PF–844 and appropriate petition number. Electronic comments on notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: November 25, 1998.

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 with minor, non-substantive editorial changes. 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.

1. Industry Task Force II

PP 4E3060

EPA has received a pesticide petition (PP) 4E3060 from Industry Task Force II, on 2,4-D Research Data, McKenna & Cuneo, 1900 K St., NW., Washington, DC 20006–1108, proposing pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by extending for 3 years, until December 31, 2001, the existing time-limited tolerance for residues of 2,4-dichlorophenoxyacetic acid (2,4-D) in or on the raw agricultural commodity soybeans at 0.02 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant and animal metabolism*. The nature of the residue in plants is adequately understood. Acceptable wheat, lemon, and potato metabolism studies have been submitted. The nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies submitted.

2. *Analytical method*. The residue field tests on soybeans used as gas chromatography (GC) method with electron capture detection (ECD), ENCAS Method ENC–2/93. This GC/ECD method is adequate for determining residues in or on soybeans with a limit of quantitation (LOQ) of 0.01 ppm.

3. *Magnitude of residues*. In 27 tests on soybeans conducted in Arkansas, Illinois, Louisiana, Missouri, and Tennessee, residues of 2,4-D were non-detectable (< 0.01 ppm) in/on all samples of forage and seeds from soybeans treated with a preplant application of 2,4-D (acid, ester, or amine) at 0.5, 1.25, and 2.75 lb active ingredient per acre at lx, 2.5x, and 5.5x rates. Residues of 2,4-D were also non-detectable (< 0.01 ppm) in/on 21 of 27 hay samples from the same tests. Hay samples with detectable residues of 0.01–0.04 ppm only came from 2.5x and 5.5x applications of the 2,4-D 2-ethylhexyl ester (2-EHE). Since the label restriction against feeding/grazing, soybean forage and hay is not proposed for deletion at this time, no tolerances are necessary for these feed items. Since data from the 5.5x application demonstrate that 2,4-D residues on soybean seeds are non-detectable or (<0.05 ppm), a soybean processing study is not required. Based on the residue data for seeds from soybeans, a tolerance of 0.02 ppm in or on the raw agricultural commodity soybeans is more appropriate than the current time-limited tolerance of 0.1 ppm.

B. Toxicological Profile

1. *Acute toxicity*. The oral LD_{50} of 2,4-D acid is 699 milligram/kilogram (mg/kg) in the rat. The dermal LD_{50} in the rabbit is > 2,000 mg/kg. The acute inhalation LC_{50} in the rat is > 1.8 mg/liter. A primary eye irritation study in the rabbit showed severe irritation. A dermal irritation study in the rabbit showed moderate irritation. A dermal sensitization study in the guinea pig showed no skin sensitization. An acute neurotoxicity study in the rat produced a no observed adverse effect (NOAEL) of 227 mg/kg for systemic toxicity and a neurobehavioral NOAEL of 67 mg/kg with a lowest observed effect level (LOEL) of 227 mg/kg.

2. *Genotoxicity*. Mutagenicity studies including gene mutation, chromosomal aberrations, and direct DNA damage tests were negative for mutagenic effects.

3. *Reproductive and developmental toxicity*. A 2-generation reproduction study was conducted in rats with NOAELs for parental and developmental toxicity of 5 mg/kg/day. The LOELs for this study are established at 20 mg/kg/day based on reductions in body weight gain in F_0 and F_{2b} pups, and reduction in pup weight at birth and during lactation. A teratology study in rabbits given gavage doses at 0, 10, 30, and 90 mg/kg on days 6 through 18 of gestation was negative for developmental toxicity at all doses tested. A teratology study in rats given gavage doses at 0, 8, 25, and 75 mg/kg on days 6 through 15 of gestation was negative for developmental toxicity at all doses tested. A NOAEL for fetotoxicity was established at 25 mg/kg/day based on delayed ossification at the 75 mg/kg dose level. The effects on pups occurred in the presence of parental toxicity.

4. *Subchronic toxicity*. A subchronic dietary study was conducted with mice fed diets containing 0, 1, 15, 100, and 300 mg/kg/day with a NOAEL of 15 mg/kg/day. The LOEL was established at 100 mg/kg/day based on decreased glucose and thyroxine levels, increases in absolute and relative kidney weights, and histopathological lesions in the liver and kidneys. A 90–day dietary study in rats fed diets containing 0, 1, 15, 100, or 300 mg/kg/day resulted in a NOAEL of 15 mg/kg/day and an LOEL of 100 mg/kg/day. The LOEL was based on decreases in body weight and food consumption, alteration in clinical pathology, changes in organ weights, and histopathological lesions in the kidney, liver, and adrenal glands of both sexes of rats. A 90–day feeding study was conducted in dogs fed diets containing 0, 0.3, 1, 3, and 10 mg/kg/day with a NOAEL of 1 mg/kg/day. The LOEL was established at 3 mg/kg/day based on histopathological changes in the kidneys of male dogs.

5. *Chronic toxicity*. A 1–year dietary study was conducted in the dog using doses of 0, 1, 5, and 7.5 mg/kg/day. The NOAEL was 1 mg/kg/day and the LOEL was 5 mg/kg/day based on clinical chemistry changes and histopathological lesions in the liver and kidney. A 2–year feeding/carcinogenicity study was conducted in mice fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg/kg/day. The systemic LOEL was established at 15 mg/kg/day based on increased kidney and adrenal weights and homogeneity of renal tubular epithelium due to cytoplasmic vacuoles. No carcinogenic effects were observed under the conditions of the study at any dosage level tested. A second 2–year oncogenicity study was conducted in mice fed diets containing 0, 5, 62.5, and 125 mg/kg/day (males) and 0, 5, 150, and 300 mg/kg/day (females). No treatment-related oncogenicity was observed. A 2–year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg/ kg/day. Although there appeared to be a slight treatment-related incidence of benign brain tumors (astrocytomas) in male rats fed diets containing 45 mg/kg/day, two different statistical evaluations found no strong statistical evidence of carcinogenicity in male rats. There were no carcinogenic effects observed in female rats. A second 2–year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 5, 75, and 150 mg/kg/day. The NOAEL was 5 mg/kg/day and the LOEL was 75 mg/kg/day based on decreased body weight, body weight gain and food consumption; clinical chemistry changes; organ weight changes and histopathological lesions. No treatment-related carcinogenic effects or increased incidences of astrocytomas were observed.

6. *Animal metabolism*. The metabolism of phenyl ring labeled ^{14}C-2,4-D was studied in the rat following a single intravenous or oral dose of approximately 1 mg/kg/day. At 48 hours after treatment, recovery of radioactivity in urine was in excess of 98%. Parent 2,4-D was the major metabolite (72.9% to 90.5%) found in the urine.

7. *Metabolite toxicology*. Because 2,4-D is rapidly excreted without significant metabolism, the toxicology data on the parent compound adequately represents metabolite toxicology.

8. *Endocrine disruption*. Although tests explicitly designed to evaluate the potential endocrine effects of 2,4-D have not been conducted, a large and diverse battery of toxicology studies is available including acute, subchronic, chronic, reproductive and developmental toxicity tests. The results of these studies do not provide a pattern of effects suggestive of endocrine modulated toxicity.

C. Aggregate Exposure

1. *Dietary exposure*. Residues are below the limit of quantification (LOQ = 0.01 ppm) in soybeans. Tolerances have been established (40 CFR 180.142) for residues of 2,4-D as the acid or various of its salts and esters, in or on a variety of raw agricultural commodities. In addition, there are also tolerances for 2,4-D for meat, milk, and eggs.

2. *Drinking water*. 2,4-D is soluble in water. The average field half-life is 10 days. The chemical is potentially mobile, but rapid degradation in soil and removal by plant uptake minimizes leaching. A maximum contaminant level (MCL) of 0.07 mg/liter has been established. In addition, the following Health Advisories have been established: for a 10–kg child, a range of 1 mg/liter from 1–day exposure to 0.1 mg/liter for longer-term exposure up to 7 years; for a 70 kg adult, a range of 0.4 mg/liter for longer-term exposure to 0.07 mg/liter for lifetime exposure.

3. *Non-dietary exposure*. 2,4-D is currently registered for use on the following residential non-food sites: ornamental turf, lawns, and grasses, golf course turf, recreational areas, and several other indoor and outdoor uses. 2,4-D is a commonly-used pesticide in non-agricultural settings. No data exist upon which to base calculation of non-dietary exposure of 2,4-D for purposes of inclusion in an aggregate risk assessment. However, there are several characteristics of 2,4-D which suggest the chemical presents a low risk from non-dietary, non-occupational exposure, particularly the chemical's high acute toxicity NOAEL, the short half life in soil, low dermal penetration, and high acute dietary MOE. Further, EPA has concluded that for the purposes of short- and intermediate-term risk, the inhalation route was of no health concern.

D. Cumulative Effects

There are no available data to determine whether 2,4-D has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 2,4-D does not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination

1. *U.S. population*. For chronic dietary exposure, EPA has established the RfD for 2,4-D at 0.01 mg/kg/day. This RfD is based on a 1–year oral toxicity study in dogs with a NOAEL of 1 mg/kg/day and an uncertainty factor of 100. In the most recent final rule establishing tolerances for 2,4-D (time-limited tolerance in wild rice associated with EPA's granting of an emergency exemption under section 18 of the FIFRA (62 FR 46900; September 5, 1997), EPA calculated aggregate risks for the existing uses of 2,4-D at that time (including soybeans and all other existing uses). Since those uses have not changed in the interim, it is appropriate to utilize the same calculations to

support removal of the expiration date for tolerances in or on soybeans. Using anticipated residue contributions for existing uses and the high-end residue value of 57.1 mg/liter in drinking water, the aggregate exposure to 2,4-D from food and water utilizes 47% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

For acute dietary exposure, the NOAEL of 67 mg/kg/day from the rat acute neurotoxicity study should be used for risk assessment. As neurotoxicity is the effect of concern, the acute dietary risk assessment should evaluate acute dietary risk to all population subgroups. Again, relying upon the EPA calculations underlying the most recent final rule establishing tolerances for 2,4-D cited above, which included soybeans and all other existing uses, EPA calculated acute aggregate risk taking into account MOEs from food and MOEs from water. For the U.S. population, the MOE for food is 223, the MOE for water is 42,000, and together the aggregate MOE is 222. This figure does not exceed EPA's level of concern for acute dietary exposure.

Regarding dietary cancer risk assessment, EPA's Cancer Peer Review Committee has classified 2,4-D as a Group D chemical ''not classifiable as to human carcinogenicity'' on the basis that, ''the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect.''

2. *Infants and children*. The database on 2,4-D relative to pre-and post-natal toxicity is complete with respect to current data requirements. Since the developmental NOAELs for rats and rabbits are 25-fold greater and 90-fold greater, respectively, than the RfD NOAEL of 1 mg/kg/day in the 1–year oral toxicity study in dogs, an additional uncertainty factor to protect infants and children is not warranted.

Using conservative EPA calculations underlying the most recent final rule establishing tolerances for 2,4-D cited above, which included soybeans and all other existing uses, aggregate acute MOEs for exposure to 2,4-D from food and water are 111 for infants less than 1 year old, 147 for children 1–6 years old, and 556 for females 13 and older.

Also using these same conservative assumptions to estimate chronic risk to aggregate chronic exposure to 2,4-D from food and water, 87% of the RfD is utilized for nursing infants, 115% for non-nursing infants, 114% for children 1–6 years old, and 100% for children 7–12 years old.

Further refinement using additional anticipated residue values in crops and percent crop-treated information, and well water monitoring data would result in lower chronic dietary (food) and chronic dietary (water) exposure estimates, thus reducing the aggregate risk estimate.

F. International Tolerances

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for use of 2,4-D on soybeans. FAO review in September 1998 has preliminarily proposed an MRL of 0.01 mg/kg for soybeans. (Dan Kenny)

2. Zeneca Ag Products

PP 8F4995

EPA has received a pesticide petition (PP 8F4995) 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, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing permanent tolerances for residues of azoxystrobin (methyl (*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on the raw agricultural commodities bananas at 2.0 parts per million (ppm), canola at 1.0 ppm, potatoes at 0.03 ppm, stone fruit at 1.5 ppm, and wheat aspirated grain fractions at 15.0 ppm. 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 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 three diverse crops, 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 residue (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 Section of the EPA concluded that the method(s) are adequate for enforcement. Analytical methods are also available for analyzing meat, milk, poultry and eggs which also underwent successful independent laboratory validations.

3. *Magnitude of residues*. Six banana trials were carried out in Central America (Mexico - 2, Guatemala - 2, and Costa Rica - 2) during 1998 in typical commercial banana growing areas in each designated country. Maximum residues of 1.15 ppm in whole bananas resulted from post-harvest treatments. Residue trials on canola were conducted in Canada and the United States in 1996 and 1997 in 12 locations. Maximum residues of 0.8 ppm in canola resulted from multiple foliar applications. No concentration of residues was observed in processing the canola to oil. Sixteen potato trials were carried out in the United States in 1997. Maximum resides of 0.03 ppm in potatoes resulted from multiple foliar applications. No concentration of residues was observed on processing of the potatoes. Over 27 trials were carried out on stone fruits (cherries, peaches and plums) in 1997. Maximum residues of 1.5 ppm on peaches resulted from multiple foliar applications. No concentration of residues were observed in processing of plums to prunes.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral toxicity study in rats of technical azoxystrobin resulted in an LD_{50} 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_{50} of >2,000 mg/kg (limit dose). The acute inhalation study of technical azoxystrobin in rats resulted in an LC_{50} of 0.962 milligrams/liter in males and 0.698 milligrams/liter 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 NOAEL 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 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 7–16 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 8–20 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_{1a} 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 211.0 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 therefore ''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 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. *Endocrine disruption*. EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect.'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry, and research scientists, to develop a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3–years from the passage of the Food Quality Protection Act (FQPA) (until August 3, 1999) to implement this program. When this program is implemented, EPA may require further testing of azoxystrobin and end-use product formulations for endocrine disrupter effects. There are currently no data or information suggesting azoxystrobin has any endocrine effects.

C. Aggregate Exposure

1. *Food*. 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 raw agricultural commodities at levels ranging from 0.01 ppm on pecans to 1.0 ppm on grapes. In addition, time-limited tolerances have been established (40 CFR 180.507(b)) at levels ranging from 0.006 ppm in milk to 20 ppm in rice hulls. The following risk assessments have been conducted to assess dietary exposure and risks from azoxystrobin as follows:

i. *Acute exposure and risk*. The Agency has concluded that there is no toxicological end-point of concern from the review of available data for this scenario. Therefore an acute dietary risk assessment is not necessary.

ii. *Chronic exposure and risk*. In conducting this chronic dietary risk assessment Zeneca has made the a conservative assumption that 100% of all commodities having azoxystrobin tolerances or proposed tolerances will contain azoxystrobin residues at the level of the tolerance. This assumption is termed the Theoretical Maximum Residue Concentration (TMRC). Zeneca's chronic dietary exposure analysis was performed (for combined

years 1989 – 1992 of the U. S. Department of Agriculture's Nationwide Food Consumption Survey) using the Novigen DEEM89N Software.

Population Sub-Group	TMRC (mg/kg/day)	% RfD
U.S. population (48 States)	0.0027	1.8
All infants (<1 year)	0.0087	5.8
Nursing infants (<1 year old)	0.0025	1.7
Non-nursing infants (<1 year old)	0.0113	7.6
Children (1–6 years old)	0.0065	4.3
Children (7–12 years old)	0.0036	2.4
Hispanics	0.0036	2.4
Non-Hispanics Others	0.0047	3.1
U.S. Population (summer season)	0.0032	2.1
Northeast region	0.0031	2.0
Western	0.0030	2.0
Pacific	0.0033	2.2
Females (13–19, non-pregnant or nursing)	0.0020	1.3
Females (13+/nursing)	0.0031	2.0

The subgroups listed above are those for infants and children, females 13–19 not pregnant or nursing and other subgroups for which the percentage of the Reference Dose (RfD) occupied is greater than that occupied by the U.S. population (48 States).

2. *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.

i. *Acute exposure and risk*. An assessment is not appropriate since no toxicological end-point of concern was identified by the Agency for this scenario during review of the available data.

ii. *Chronic exposure and risk*. Based on the chronic dietary (food) exposure estimated, chronic drinking water levels of concern (DWLOC) for azoxystrobin were calculated and summarized in the following table. EPA has estimated that the highest estimated environmental concentration (EEC) of azoxystrobin in surface water is from the application of azoxystrobin on grapes (39µg/L) and is substantially lower than the DWLOC's calculated.

Sub-group	RfD (mg/kg/day)	TMRC (Food) (mg/kg/day)	Max Water Exposure (mg/kg/day)	DWLOC (µg/L)
U.S. Population	0.18	0.0027	0.177	6195
Females (13+ not pregnant or nursing)	0.18	0.0020	0.178	5300
Non-nursing infants (<1 year old)	0.18	0.0113	0.169	1690

iii. *Non-dietary exposure*. The Agency evaluated the existing toxicological database for azoxystrobin and assessed appropriate toxicological end-points 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 end-points 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. Azoxystrobin is currently registered for use on residential non-food sites, only on turf.

D. Cumulative Effects

Azoxystrobin is related to the naturally occurring strobilurins. One other strobilurin-type pesticide has recently been registered with the EPA. Zeneca has 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. *Acute risk*. This safety determination is not applicable since no toxicological end-point of concern was identified for this scenario during Agency review of the available data.

2. *Chronic risk*. The RfD for azoxystrobin is 0.18 mg/kg/day, based on the NOAEL of 18.2 mg/kg/day from the rat chronic toxicity/carcinogenicity feeding study in which 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.

The chronic dietary exposure analysis showed that exposure from the proposed new tolerances in or on bananas, canola, potatoes, stone fruit, and wheat aspirated grain fractions for non-nursing infants (the subgroup with the highest exposure) would be 7.6% of the RfD. The exposure for the general U.S. population would be 1.8% of the RfD.

3. *Short- and intermediate-term risk*. This risk assessment has not previously been performed since no dermal or systemic effects were seen in the repeated dose dermal study at the limit dose. Also, the only indoor or outdoor residential exposure use currently registered for azoxystrobin is residential turf.

F. Additional Safety Factor for Infants and Children

Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the

completeness of the database 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 (MOE) 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/MOE is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor but 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 ad hoc FQPA Safety Factor Committee removed the additional 10x safety factor to account for sensitivity of infants and children.

Zeneca has considered the potential aggregate exposure from food, water and non-occupational exposure routes and concludes 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 the aggregate exposure to azoxystrobin residues.

G. International Tolerances

There are no Codex Maximum Residue Levels established for azoxystrobin. (Cynthia Giles-Parker)

[FR Doc. 98–32884 Filed 12–11–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6200–2]

Proposed CERCLA Administrative Cost Recovery Partial Settlement, Leavenworth Auto Parts Site, Leavenworth, Kansas

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement with the following parties, and request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation and Liability Act (''CERCLA''), notice is hereby given of a proposed Superfund administrative cost recovery settlement between EPA and Jack and Bess Sokolov and Leavenworth Auto Parts and Supply Co., Inc. The proposed settlement, pursuant to CERCLA section 122(h), would recover a portion of the federal government's past response costs at the Leavenworth Auto Parts Site, 777 Cherokee St., Leavenworth, Kansas. Mr. and Mrs. Sokolov would pay to the Hazardous Substance Superfund $100,000 plus 65% of gross revenues from any sale or rental of the property. Leavenworth Auto Parts and Supply Co., Inc. would pay $5,000. The settlement provides a covenant not to sue to the settling parties.

The Agency will receive written comments relating to the settlement until January 11, 1999. The agency will consider all comments received during this period, and may modify or withdraw its consent to the settlement if comments disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the U.S. EPA Region VII office at 726 Minnesota Avenue, Kansas City, Kansas 66101. A copy of the proposed settlement may be obtained from Venessa Cobbs, Regional Hearing Clerk, EPA Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone number (913) 551–7630. Comments should reference the ''Leavenworth Auto Parts Site Ability-to-Pay Settlement'' and EPA Docket No. VII–95–F–0029 and should be addressed to Ms. Cobbs at the above address.

FOR FURTHER INFORMATION CONTACT: Jonathan Kahn, Assistant Regional Counsel, EPA Region VII, Office of Regional Counsel, 726 Minnesota Avenue, Kansas City, Kansas 66101, telephone number (913) 551–7252.

Dated: December 2, 1998.

William Rice,

Acting Regional Administrator, Region VII.

[FR Doc. 98–32893 Filed 12–10–98; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency has submitted the following proposed information collection to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

Title: Emergency Management Institute Resident Course Evaluation Form.

Type of Information Collection: Extension of a currently approved collection.

OMB Number: 3067–0237.

Abstract: Students attending the Emergency Management Institute residential program courses at FEMA's National Emergency Training Center will be asked to complete a course evaluation form. EMI staff will use the information and management to identify problems with course materials, evaluate the quality of the course delivery, facilities, and instructors. The data received will enable them to recommend changes in course materials, student selection criteria, training experience and classroom environment.

Affected Public: State, Local or Tribal Government, Individuals or Households, and Federal Government.

Number of Respondents: 4,000.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 667.

Frequency of Response: The form is completed at the end of each course.

COMMENTS: Interested persons are invited to submit written comments on the proposed information collection to Victoria Wassmer, Desk Officer for the Federal Emergency Management Agency, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 on or before January 11, 1999.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Muriel B. Anderson, FEMA Information Collections Officer, Federal Emergency Management Agency, 500 C Street, SW, Room 316, Washington, DC 20472. Telephone number (202) 646–2625. FAX number (202) 646–3524 or email muriel.anderson@fema.gov.

Dated: December 8, 1998.

Reginald Trujillo,

Director, Program Services Division, Operations Support Directorate.

[FR Doc. 98–32971 Filed 12–10–98; 8:45 am]

BILLING CODE 6718–01–P