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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0130; FRL–7310–9]

Famoxadone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of famoxadone (3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione) in or on vegetables, fruiting, group 8 (except tomato) at 4.0 parts per million (ppm), tomato at 1.0 ppm; vegetables cucurbit, group 9 at 0.30 ppm; lettuce, head at 10.0 ppm; potato at 0.02 ppm; grape at 2.50 ppm; grape, raisin at 4.0 ppm; fat of cattle, horses, goats, sheep at 0.02 ppm; liver of cattle, horses, goats, sheep at 0.05 ppm; and milk fat (reflecting negligible residues in whole milk) at 0.060 ppm. E.I. Dupont Nemours and Company (Dupont) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). These reflect the first food tolerances for this fungicide in the United States.

DATES: This regulation is effective July 2, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0130, must be received on or before September 2, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Dennis M. McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–6742; e-mail address: *mcneilly.dennis@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0130. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of January 10, 2001 (66 FR 1981) (FRL–6760–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 0F6070) for establishing tolerances for potatoes at 0.05 ppm, curcurbit vegetable crop group (cucumbers, melon, squash) at 0.7 ppm; fruiting vegetable crop group (tomatoes, and peppers) at 1.0 ppm; and head lettuce at 15 ppm by Dupont, P.O. Box 80038, Wilmington, DE 19880–0038. That notice included a summary of the petition prepared by Dupont, the registrant. There were no comments received in response to the notice of filing.

In a second **Federal Register** of August 1, 2001 (66 FR 39762) (FRL–6789–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 7E4847) for establishing a tolerance for grapes at 2.0 parts per million by Dupont, P.O. Box 80038, Wilmington, DE 19880–0038. That notice included a summary of the petition prepared by Dupont, the registrant. The Agency received a written comment from the World Wildlife Fund (WWF) dated August 31, 2001. The Agency's response to this comment can be found at Unit III.B.

The initial petitions requested that 40 CFR 180.587 be amended by establishing tolerances for residues of the fungicide famoxadone (3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione) in or on potatoes at 0.05 ppm; cucurbit vegetable crop group at 0.7 ppm; fruiting vegetable crop group at 1.0 ppm; head lettuce at 15 ppm; grapes at 2.0 ppm; and raisins at 4.0 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will

result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of famoxadone on vegetables, fruiting, group 8 (except tomato) at 4.0 ppm; tomato at 1.0 ppm; vegetables, cucurbit, group 9 at 0.30 ppm; lettuce, head at 10.0 ppm; potato at 0.02 ppm; grape at 2.50 ppm; grape, raisin at 4.0 ppm; fat of cattle, horses, goats, sheep at 0.02 ppm; liver of cattle, horses, goats, sheep at 0.05 ppm and milk, fat (reflecting negligible residues in whole milk) at 0.060 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by famoxadone are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity in rats	NOAEL = Male (M): 3.3 milligrams/kilogram/day (mg/kg/day); Female (F): 4.2 mg/kg/day. LOAEL = M: 13.0 mg/kg/day based on mild hemolytic anemia and decreased glucose. F: 16.6 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency; mild hemolytic anemia and decreased globulin.
870.3100	90-Day oral toxicity in mice	NOAEL = M: 62.4 mg/kg/day; F: 79.7 mg/kg/day. LOAEL = M: 534 mg/kg/day based on mild hemolytic anemia with secondary responses in spleen and mild hepatotoxicity in the liver. F: 757 mg/kg/day based on mild hemolytic anemia with secondary responses in spleen and mild hepatotoxicity in the liver.
870.3150	90-Day oral toxicity in nonrodents (dogs)	NOAEL = M: 1.3 mg/kg/day; F: 1.4 mg/kg/day LOAEL = M: 10.0 mg/kg/day based on lens cataracts in eyes. At 23.8/21.2 mg/kg/day, also myotonic twitches (starting on day 21); decreased body weight, body weight gain, food consumption, and food efficiency; slight anemia and hyperkalemia. F: 1.4 mg/kg/day based on lens cataracts in eyes. At 10.1 mg/kg/day, no additional effects. At 23.3/20.1 mg/kg/day, same effects as for males at 23.8/21.2 mg/kg/day.
870.3200	28-Day dermal toxicity in rats	NOAEL = M: 250 mg/kg/day; F: 1,000 mg/kg/day LOAEL = M: 500 mg/kg/day based on increased alkaline phosphatase, alanine aminotransferase and sorbitol dehydrogenase; and mild hepatotoxicity in the liver. F: none (>1,000 mg/kg/day). No dermal irritation in M or F.
870.3700	Prenatal developmental in rats	Maternal NOAEL = 250 mg/kg/day LOAEL = 500 mg/kg/day based on transient decreased body weight gain and food consumption. Developmental NOAEL = 1,000 mg/kg/day LOAEL = none (>1,000 mg/kg/day
870.3700	Prenatal developmental in nonrodents (rabbits)	Maternal NOAEL = 350 mg/kg/day LOAEL = 1,000 mg/kg/day based on abortions; decreased body weight, body weight gain, and food consumption; and abnormal stools. Developmental NOAEL = 350 mg/kg/day LOAEL = 1,000 mg/kg/day based on abortions and equivocal increases in postimplantation loss and mean resorptions per dose.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rats)	Parental/Systemic NOAEL = M/F: 11.3/14.2 mg/kg/day LOAEL = M/F: 44.7/53.3 mg/kg/day based on decreased body weight, body weight gain, and food consumption; and hepatotoxicity in the liver. Reproductive NOAEL = M/F: 44.7/53.3 mg/kg/day LOAEL = M/F: none (>44.7/53.3 mg/kg/day Offspring NOAEL = M/F: 11.3/14.2 mg/kg/day LOAEL = M/F: 44.7/53.3 mg/kg/day based on decreased body weights for F_1 and F_2 pups throughout lactation.
870.4100	Chronic toxicity in dogs	NOAEL = M: 1.2 mg/kg/day. F: 1.2 mg/kg/day. LOAEL = M: 8.8 mg/kg/day based on lens cataracts in eyes. F: 9.3 mg/kg/day based on lens cataracts in eyes. No other adverse effects were observed in M or F.
870.4100	Chronic toxicity in Cynomolgus monkeys	NOAEL = M: 100 mg/kg/day. F: 100 mg/kg/day. LOAEL = M: 1,000 mg/kg/day based on mild hemolytic anemia with secondary responses in spleen, liver and kidney; and sinus dilatation in spleen. F: 1,000 mg/kg/day based on mild hemolytic anemia with secondary responses in spleen, liver and kidney; and sinus dilatation in spleen.No evidence of lens cataracts in eyes of M or F.
870.4200	Carcino-genicity in mice	NOAEL = M: 96 mg/kg/day. F: 130 mg/kg/day. LOAEL = M: 274 mg/kg/day based on slight hepatotoxicity in the liver; no anemia. F: 392 mg/kg/day based on amyloidosis and slight hepatotoxicity in the liver; no anemia. No evidence of carcinogenicity in M or F.
870.4300	Combined chronic toxicity/carcinogenicity in rats	NOAEL = M: 8.4 mg/kg/day. F: 2.2 mg/kg/day LOAEL = M: 16.8 mg/kg/day based on slight hemolytic anemia with compensatory erythropoiesis and secondary responses in spleen and bone marrow; and mild hepatotoxicity in the liver. F: 10.7 mg/kg/day based on decreased body weight gain and slight hemolytic anemia. At 23.0 mg/kg/day, also secondary responses to anemia in spleen, bone marrow and/or liver; and mild hepatotoxicity in the liver. No evidence of carcinogenicity M or F.
870.5100	Reverse gene mutation	Negative without and with S-9 activation up to limit dose of 5,000 μgram(g)/plate.
870.5300	Forward gene mutation (*In Vitro Mammalian Cell Gene Mutation Test*)	Negative without and with S-9 activation up to the limit of solubility (in DMSO) of 30 μg/mL.
870.5300	Forward gene mutation (CHO/HGPRT locus)	Negative without and with S-9 activation up to cytotoxic concentrations (≥ 200 μg/mL without S-9 and ≥ 150 μg/mL with S-9).
870.5375	Chromosome aberration (human lymphocytes)	Positive (weak clastogenic effect) without S-9 activation. Statistically significant increases in percentage of aberrant cells at several dose levels ranging from 5–15 μg/mL. Cytotoxicity was observed at 10–18 μg/mL. Negative with S-9 activation.
870.5375	Chromosome aberration (human lymphocytes)	Positive (weak clastogenic effect) without S-9 activation. Statistically significant increases in percentage of aberrant cells at several dose levels ranging from 15–30 μg/mL. Cytotoxicity was observed at 20–30 μg/mL. Negative with S-9 activation.
870.5395	Micronucleus assay (mouse bone marrow)	Negative at single-oral doses of up to limit dose of 5,000 mg/kg.
870.5550	Unscheduled DNA synthesis (rat hepatocytes)	Positive response (increased net nuclear grain counts) observed at several treatment levels ranging from 0.05–10 μg/mL. Cytotoxicity was observed at 10 μg/mL.
870.5550	Unscheduled DNA synthesis (rat hepatocytes)	Negative at treatment levels up to 10 μg/mL. Cytotoxicity was observed at 10 μg/mL.
870.5550	Unscheduled DNA synthesis (prim. rat hepatocytes)	Negative at treatment levels up to 5.0 μg/mL. Cytotoxicity was observed at 2.5 and 5.0 μg/mL.
870.5550	Unscheduled DNA synthesis (hepatocytes derived from male rats given Famoxadone)	Negative at single-oral doses of up to 2,000 mg/kg. No marked increases in net nuclear grain counts or percentage of cells in repair in hepatocyte cultures.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.6200	Acute neurotoxicity screening battery (rats)	NOAEL = M: 1,000 mg/kg F: 2,000 mg/kg. LOAEL = M: 2,000 mg/kg based on decreased body weight gain and food consumption (on days 1–2); and palpebral (eyelid) closure (on day 1 only). F: none (>2,000 mg/kg).
870.6200	Subchronic neurotoxicity screening battery (rats)	NOAEL = M: 11.7 mg/kg/day F: 14.4 mg/kg/day. LOAEL = M: 47 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency. F:59 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency. No evidence of neurotoxicity in M or F.
870.7800	Immunotoxicity study, rats (28-days)	NOAEL = M: 14 mg/kg/day. F: 16 mg/kg/day. LOAEL = M: 55 mg/kg/day based on decreased body weight, body weight gain, food consumption, and food efficiency; and increased spleen weights (probably due to increased pigment in spleen). F: 57 mg/kg/day based on decreased body weight, body weight gain, food consumption, and food efficiency; and increased spleen weights (probably due to increased pigment in spleen). No evidence of immunotoxicity in M or F.
870.7800	Immunotoxicity study,mice (28-days)	NOAEL = M: 1186 mg/kg/day. F: 417 mg/kg/day. LOAEL = M: none (>1,186 mg/kg/day). F: 1,664 mg/kg/day based on increased spleen weights (probably due to increased pigment in spleen). No evidence of immunotoxicity in M or F.
870.7485	Metabolism and pharmacokinetics, rats	Only about 40% of the administered dose was absorbed. Most of the administered dose (87–6%) was eliminated in the feces within 24 hours; very little (3–12%) was eliminated in the urine. Unchanged parent (51–84% of administered dose) and 2 hydroxylated metabolites (IN-KZ534 and IN-KZ007) were the major components recovered in the feces. No significant qualitative or quantitative differences were observed for sex, dose level, or repeated dosing.
870.7485	Metabolism and pharmacokinetics, dogs (males only)	Absorption was limited. Most of the administered dose (62%) was eliminated in the feces within 24 hours; very little (about 8%)was eliminated in the urine. Initially, unchanged parent (94–97% of radioactivity in feces) was recovered in the feces, but later (>24 hrs) unchanged parent (12–35% of radioactivity in feces), IN-KZ007 (21–3% of radioactivity in feces) and IN-ML815 (4–9% of radioactivity in feces) were recovered. Even later (>48 hrs), trace amounts of the hydroxylated metabolites IN-KZ532 and IN-KZ534 were also identified in the feces.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for famoxadone used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FAMOXADONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	Not applicable	Not applicable	No appropriate endpoint attributable to a single-oral dose was identified in the available toxicology studies on famoxadone.
Acute Dietary (General population including infants and children)	Not applicable	Not applicable	No appropriate endpoint attributable to a single-oral dose was identified in the available toxicology studies on famoxadone.
Chronic Dietary (All populations)	LOAEL= 1.4 mg/kg/day UF = 1,000[a] Chronic RfD = 0.0014 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF Chronic PAD = 0.0014 mg/kg/day	13-Week feeding study in dogs.[b] LOAEL = 1.4 mg/kg/day based on microscopic lens lesions (cataracts) in eyes of female dogs.
Cancer (Oral, dermal, and inhalation)	Not applicable	Not applicable	Classification: Not Likely to be carcinogenic to humans.

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

[a] The UF of 1,000 includes the conventional 100 and an additional 10 for the use of the LOAEL and dose from a subchronic (13-week) study for chronic risk assessment.

[b] Regarding the chronic RfD for famoxadone, a 1-year chronic feeding study in dogs is available, but was determined to not be an appropriate study for use in chronic risk assessment at this time. Although the testing laboratory reported a NOAEL of 1.2 mg/kg/day for treatment-related lens lesions (cataracts) in the eyes of the male and female dogs, a subsequent evaluation by a consulting pathologist of the microscopic sections of the eyes from all dogs in this study strongly suggested that a serious fixation artifact affected all the eye sections such that only prominent cataracts were detectable and as a consequence, a NOAEL could not be reliably determined with any degree of confidence. Considering this second evaluation, the Agency concluded that this fixation artifact may have had a profound effect on the interpretation of the histopathological findings in the eyes of all dogs in this study. In view of the considerable uncertainty relating to the microscopic findings in the eyes of all dogs in this study and the resulting uncertainty with regard to determining a NOAEL for eye effects, the Agency decided to not use the results from this 1-year study for the purpose of determining a chronic RfD for famoxadone at this time. Based on a consideration of findings in the eyes of dogs in both the 13-week and 1-year feeding studies, it was determined that the lowest dose at which evidence of cataracts was actually observed was in the female dogs in the 13-week study at the lowest dose tested of 1.4 mg/kg/day (the LOAEL). This 13-week study, rather than the 1-year study, was selected to be the most appropriate study for chronic risk assessment at this time. Since a LOAEL, rather than a NOAEL, and a subchronic study, rather than a chronic study, were used to determine the chronic RfD, an additional 10x UF was added to the conventional UF of 100x. The chronic RfD (LOAEL of 1.4 mg/kg/day/UF of 1,000) for famoxadone was determined to be 0.0014 mg/kg/day.

The comment received from WWF concerned a toxicity issue in particular: The potential for famoxadone to be an endocrine disruptor. WWF quoted the notice of filing which was written by Dupont. ''Chronic, lifespan and multigenerational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal endocrine effects. Any endocrine related effects would have to have been detected in this definitive array of required tests. The probability of any such effects due to agricultural uses of famoxadone is negligible.'' WWF stated that pursuant to FQPA, the Agency is establishing a new endocrine disruptor screening and testing program because existing toxicology protocols are not adequate to detect endocrine disruption. Therefore, Dupont's evaluation of the endocrine disruptor potential is incomplete and consequently misleading. WWF also urges the Agency to consider not only evidence of increasedsusceptibility, but also the significance of endocrine disruptor data gaps when determining the FQPA SF for famoxadone.

In response to the WWF the Agency notes that FQPA requires EPA to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect... EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority-setting scheme. In the available toxicity studies on famoxadone, no evidence of endocrine-related effects was observed. However, famoxadone may be subjected to further screening and/or testing to better characterize potential effects related to endocrine disruption when additional appropriate screening and/or testing protocols have been developed by the Agency's Endocrine Disruptor and Testing Advisory Committee (EDSTAC).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances are being established for (40 CFR 180.587) for the residues of famoxadone, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from famoxadone in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No toxicological endpoint attributable to a single-oral dose was identified in the available toxicology studies on famoxadone that would be applicable to females (13–50 years) or to the general population (including infants and children). Therefore, famoxadone is not expected to pose an acute dietary risk.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998–nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Anticipated residues based upon average field trial values and assumptions that 100% of each crop is treated with famoxadone.

iii. *Cancer.* The Agency has classified famoxadone as not likely to be

carcinogenic to humans. As such, famoxadone is not expected to pose a cancer dietary risk.

iv. *Anticipated residue and percent crop treated (PCT) information.*

Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. No PCT information was used in the risk assessment. The Agency used 100% which would over estimate exposure.

2. *Dietary exposure from drinking water.*

The Agency lacks monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for famoxadone in drinking water because this is a new chemical. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of famoxadone.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The FIRST model is a subset or meta-model of the PRZM/EXAMS model that uses specific high-end runoff scenario for pesticides. FIRST incorporates an index reservoir environment and a percent crop area (PCA), while PRZM/EXAMS incorporate an index reservoir environment, PCA, all available information on the pesticide's fate and use pattern, and site-specific cropping information.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to famoxadone they are further discussed in the aggregate risk sections in Unit E.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of famoxadone for chronic exposures are estimated to be 0.47 parts per billion (ppb) for surface water and 0.23 ppb for ground water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Famoxadone is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether famoxadone 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, famoxadone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that famoxadone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA 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 on toxicity and exposure 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* The Agency concluded that there is not a concern for pre- and/or postnatal toxicity resulting from exposure to famoxadone.

No quantitative or qualitative evidence of increased susceptibility, as compared to adults, of rat or rabbit fetuses to *in utero* exposure to famoxadone was observed in the developmental toxicity studies. No quantitative or qualitative evidence of increased susceptibility, as compared to adults, of rat fetuses or neonates was observed in the 2-generation reproduction study.

In the rat developmental toxicity study, the NOAEL for maternal toxicity was 250 mg/kg/day and the LOAEL was 500 mg/kg/day, based on transient decreases in body weight gain and food consumption. At 1,000 mg/kg/day, no additional treatment-related effects were observed in the dams. No developmental toxicity was observed in the rat study. The NOAEL for developmental toxicity was 1,000 mg/kg/day, the highest dose tested.

In the rabbit developmental toxicity study, the maternal and developmental NOAELs and LOAELs were the same. The NOAEL for maternal toxicity and developmental toxicity was 350 mg/kg/day. The LOAEL for maternal toxicity was 1,000 mg/kg/day, based on abortions in 4 out of 17 does; markedly decreased body weight, reduced body weight gain and reduced food consumption in the same 4 does, and increased number of does with abnormal or little or no stools. The LOAEL for developmental toxicity was 1,000 mg/kg/day; based on abortions in 4 out of 17 does; and equivocal increases in percent post implantation loss and mean number of resorptions

per doe. In the rabbit study, maternal toxicity (does) and developmental toxicity (fetuses) are considered to be equally sensitive to the test material. Therefore, based on the results in these two developmental toxicity studies in rats and rabbits, no increased susceptibility of the fetuses (as compared to adults) was demonstrated for famoxadone.

In the 2-generation reproduction study in rats, the NOAEL for parental toxicity was 200 ppm (equal to 11.3/14.2 mg/kg/day, M/F) and the LOAEL was 800 ppm (44.7/53.3 mg/kg/day, M/F), based on decreased body weight, body weight gain, and food consumption; and heptotoxicity in the liver. Also, at 800 ppm, adaptive hepatocellular responses indicating enzyme induction were observed. No reproductive toxicity was observed in this study. The NOAEL for reproductive toxicity was 800 ppm (44.7/53.3 mg/kg/day, M/F), the highest dose tested. In this same study, the NOAEL for offspring toxicity was 200 ppm (equal to 11.3/14.2 mg/kg/day, M/F) and the LOAEL was 800 ppm (44.7/53.3 mg/kg/day, based on decreased body weights for F_1 and F_2 pups throughout their respective lactation periods.

3. *Neurotoxicity*. The Agency concluded that there is not a concern for developmental neurotoxicity resulting from exposure to famoxadone and that a developmental neurotoxicity study is not required.

Although clinical signs of neurotoxicity were observed in dogs in the 13-week study at the highest dose tested (>20 mg/kg/day), this effect was not observed at lower doses of about 10 mg/kg/day in the same 13-week study or in a subsequently performed 1-year feeding study in dogs. Also, toxicologically significant signs of neurotoxicity were not observed in any of the other studies on famoxadone in any species (including rats, mice, or monkeys) at any time. In addition, pre- and postnatal studies in rats and rabbits demonstrated no increased susceptibility of fetuses or neonates to famoxadone as compared to adults. Toxicologically significant neurotoxic effects would not be expected to occur in an additional study in rats. The clinical signs of neurotoxicity (muscle twitches) observed only in dogs, only in males, and only at the highest dose tested, would not be anticipated to occur in a developmental neurotoxicity study in rats.

4. *Conclusion*. The Agency concluded that the toxicology database was complete for FQPA purposes and that there are no residential uncertainties for pre-/postnatal toxicity. Based on the hazard data, the Agency recommended the special FQPA SF be reduced to 1x. The famoxadone risk assessment team evaluated the quality of the exposure data; and, based on these data, recommended that the special FQPA SF be reduced to 1x. The recommendation is based on the following:

i. There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study.

ii. The chronic dietary food exposure assessment utilizes average field trial residue data and for all proposed uses, 100% crop treated is assumed. The chronic assessment is somewhat refined and based on reliable data derived from studies designed to produce worst-case residues and unlikely to underestimate exposure.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No appropriate endpoint attributable to a single-oral dose was identified in the available toxicology studies on famoxadone. Therefore, no acute risk from famoxadone is not expected.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to famoxadone from food will utilize 36% of the cPAD for the U.S. population, 76% of the cPAD for Children ages 1–2 and 68% of the cPAD for Children ages 3–5. Children ages 1–2 are expected to be the most highly exposed subpopulation to famoxadone. There are no residential uses for famoxadone. In addition, there is potential for chronic dietary exposure to famoxadone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER)EXPOSURE TO FAMOXADONE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0014	36%	0.47	0.23	31

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER)EXPOSURE TO FAMOXADONE—Continued

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children 1–2 years old	0.0014	76%	0.47	0.23	3.4
Children 3–5 years old	0.0014	68%	0.47	0.23	4.5

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background-exposure level). Famoxadone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background-exposure level). Famoxadone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Famoxadone is classified as ''not likely to be carcinogenic to humans.'' As such, no cancer risk is expected.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, including infants and children, from aggregate exposure to famoxadone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Famoxadone was screened through multi-residue methods listed in the Pesticide Analytical Manual Volume I (PAM Vol. I), Third Edition (January 1994), using Protocols C to E. Protocols A and B were not used because famoxadone does not have an n-methyl carbamate structure (Protocol A), nor is it an acid or phenol (Protocol B). Protocol C showed good analytical response using the electron-capture detector (ECD) and nitrogen-phosphorus detector (NPD). Good recoveries were obtained for the analysis of wine, grapes, and tomatoes (92–138%) using Protocol D. Food commodities can be analyzed for famoxadone residues using the appropriate extraction method with the mixed ether elution system, resulting in recovery values of 92 to 108%.

The multi-residue methods testing appears to be scientifically acceptable and has been sent to the FDA for further evaluation. Preliminary analysis suggests that Protocol D may be appropriate for analysis of famoxadone in plant matrices and has the potential to be the primary enforcement method.

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No CODEX maximum residue limits currently exist for famoxadone: Maximum Residue Levels (MRLs) have been established for potatoes in the Netherlands at 0.02 ppm and for grapes in Germany at 2.0 ppm.

V. Conclusion

Therefore, tolerances are established for residues of famoxadone (3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione) in or on vegetables, fruiting, group 8 (except tomato) at 4.0 ppm; tomato at 1 ppm; vegetables cucurbit, group 9 at 0.30 ppm; lettuce, head at 10.0 ppm; potato at 0.02 ppm grape at 2.50 ppm (import only); raisin at 4.0 ppm (import only); fat of cattle, horses, goats, sheep at 0.02 ppm; liver of cattle, horses, goats, sheep at 0.05 ppm; and milk, fat (reflecting negligible residues in whole milk) at 0.060 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0130 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 2, 2003.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information 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.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The

telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0130, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 20, 2003.

Jim Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.587 is added to read as follows:

§ 180.587 Famoxadone.

(a) *General.* Tolerances are established for residues of the fungicide famoxadone (3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione) in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, liver	0.05
Goat, fat	0.02
Goat, liver	0.05
Grape[1]	2.50
Grape, raisin[1]	4.0
Horse, fat	0.02
Horse, liver	0.05
Lettuce, head	10.0
Milk, fat (reflecting negligible residues in whole milk)	0.06
Potato	0.02
Sheep, fat	0.02
Sheep, liver	0.05
Tomato	1.0
Vegetable, cucurbits, group 9	0.30
Vegetable, fruiting, group 8 except tomato	4.0

[1] There are no U.S. registrations as of May 15, 2003.

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertant residues. [Reserved]

[FR Doc. 03–16736 Filed 7–1–03; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0 and 54

[CC Docket No. 02–6; FCC 03–101]

Schools and Libraries Universal Service Support Mechanism

AGENCY: Federal Communications Commission.

ACTION: Final rule, correction.

SUMMARY: This document corrects an error in the **DATES** section and the **SUPPLEMENTARY INFORMATION** portion of a **Federal Register** document regarding the Commission taking major steps to simplify and streamline the operation of our universal service mechanism for schools and libraries, while improving our oversight over the support mechanism. In addition, the Commission adopts a number of rules to streamline program operation, and promote the Commission's goal of reducing the likelihood of fraud, waste, and abuse. The summary was published in the **Federal Register** on June 20, 2003.

DATES: Effective July 2, 2003.

FOR FURTHER INFORMATION CONTACT: Jonathan Secrest and Katherine Tofigh, Attorneys, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418–7400.

SUPPLEMENTARY INFORMATION: This summary contains a correction to the dates section and the **SUPPLEMENTARY INFORMATION** portion of a **Federal Register** summary, 68 FR 36931 (June 20, 2003). The full text of the Commission's Second Report and Order in CC Docket No. 02–6, FCC 03–101 released on April 30, 2003 is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 Twelfth Street, SW., Washington, DC, 20554.

In rule FR Doc. 03–14928 published June 20, 2003 (68 FR 36931) make the following corrections.

1. On page 36931, in the third column, in the **DATES** section, remove ''§ 54.515(b)'' and add ''§ 54.514(b)'' in its place.

2. On page 36941, in the third column, in paragraph 89, seventh line, remove ''§ 54.515(b)'' and add ''§ 54.514(b)'' in its place.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–16533 Filed 7–1–03; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 541

[Docket No. NHTSA–03–14450]

RIN 2127–AI99

Federal Motor Vehicle Theft Prevention Standard; Final Listing of Model Year 2004 High-Theft Vehicle Lines

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This final rule announces NHTSA's determination for model year (MY) 2004 high-theft vehicle lines that are subject to the parts-marking requirements of the Federal motor vehicle theft prevention standard, and high-theft MY 2004 lines that are exempted from the parts-marking requirements because the vehicles are equipped with antitheft devices determined to meet certain statutory criteria pursuant to the statute relating to motor vehicle theft prevention.

EFFECTIVE DATE: The amendment made by this final rule is effective July 2, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Rosalind Proctor, Consumer Standards Division, Office of Planning and Consumer Standards, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. Ms. Proctor's telephone number is (202) 366–0846. Her fax number is (202) 493–2290.

SUPPLEMENTARY INFORMATION: The Anti Car Theft Act of 1992, Pub. L. 102–519, amended the law relating to the parts-marking of major component parts on designated high-theft vehicle lines and