

warrant the preparation of a Federalism Assessment. This rulemaking only removes the definition and term accident in part 659 and replaces it with the definition and phrase "major incident;" therefore a Federal assessment is unnecessary.

#### Other Executive Orders

There are a number of other Executive Orders that can affect rulemakings. These include Executive Orders 13084 (Consultation and Coordination with Indian Tribal Governments), 12988 (Civil Justice Reform), 12875 (Enhancing the Intergovernmental Partnership), 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights), 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations), 13045 (Protection of Children from Environmental Health Risks and Safety Risks), and 12889 (Implementation of North American Free Trade Agreement). We have considered these Executive Orders in the context of this rule, and we believe that the rule does not directly affect the matters covered by the Executive Orders.

#### List of Subjects in 49 CFR Part 659

Railroads.

For the reasons discussed in the preamble, FTA amends 49 CFR Part 659 as follows:

#### PART 659—RAIL FIXED GUIDEWAY SYSTEMS: STATE SAFETY OVERSIGHT

1. The authority citation for Part 659 continues to read as follows:

**Authority:** 49 U.S.C. 5330.

2. Amend § 659.5 by removing the definition for "Accident" and adding in alphabetical order a new definition for "Major Incident" and revising the definition for "Investigation" as follows:

##### § 659.5 Definitions.

*Investigation* means a process to determine the probable cause of a major incident or an unacceptable hazardous condition; it may involve no more than a review and approval of the transit agency's determination of the probable cause of a major incident or unacceptable hazardous condition.

*Major Incident* means any event involving a transit vehicle or occurring on a transit-controlled property, involving one or more of the following:

- (1) A fatality;
- (2) Injuries requiring immediate medical attention away from the scene for two or more persons;

(3) Property damage equal to or exceeding \$25,000;

(4) An evacuation due to life safety reasons;

(5) A collision at a grade crossing;

(6) A main-line derailment;

(7) A collision with person(s) on a right-of-way resulting in injuries that require immediate medical attention away from the scene for one or more persons; and

(8) A collision between a rail transit vehicle and other rail transit vehicle or a transit non-revenue vehicle resulting in injuries that require immediate medical attention away from the scene for one or more persons.

\* \* \* \* \*

##### § 659.39 [Amended]

3. Amend § 659.39 by removing the word "accidents" from the paragraph and section heading and add in its place the words "major incidents."

##### § 659.41 [Amended]

4. Amend § 659.41 by removing the word "accidents" in paragraphs (a) and (b) and add in its place the word "major incidents."

##### § 659.45 [Amended]

5. Amend § 659.45 by removing the word "accidents" in paragraphs (b) and (c) and add in its place the word "major incidents."

Dated: March 28, 2002.

**Jennifer L. Dorn,**  
Administrator, Federal Transit  
Administration.

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#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 180

[OPP-301223; FRL-6828-4]

RIN 2070-AB78

##### Furilazole; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of the inert ingredient (herbicide safener) 3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine, which is also known as furilazole (CAS Reg. No. 121776-33-8)] in or on corn commodities. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective April 3, 2002. Objections and requests for hearings, identified by docket control number OPP-301223, must be received by EPA on or before June 3, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301223 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 305-6304; and e-mail address: boyle.kathryn@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from

the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>. A frequently updated electronic version of 40 CFR part 180 is available at: [http://www.access.gpo.gov/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/cfr/cfrhtml_00/Title_40/40cfr180_00.html), beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301223. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

## II. Background and Statutory Findings

Time-limited tolerances for 3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine, also known as furilazole, in or on corn commodities have been established as requested by Monsanto Company under the Federal Food, Drug, and Cosmetic Act (FFDCA).

In the **Federal Register** of October 20, 1999 (64 FR 56502)(FRL-6386-9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 1E4031) for tolerance by Monsanto, Suite 1100, 700 14<sup>th</sup> Street NW, Washington DC 20005. This notice included a summary of the petition prepared by Monsanto, the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.471 be amended to establish again tolerances for residues of the inert ingredient (herbicide safener) 3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine, in or on corn commodities at 0.01 part per million (ppm). Time-limited tolerances, expiring February 25, 2002, were established in the **Federal Register** of February 23, 2000, (65 FR 8859) (FRL-6490-3). Permanent tolerances were not established due to an incomplete data base. The following data gaps were identified: Animal metabolism studies, radiovalidation and specificity studies for the analytical enforcement method for plants, field trial data, chronic toxicity study in the dog, developmental toxicity study in the rabbit, general metabolism study, and in vitro cytogenetic assay. These data gaps have now been either fulfilled or addressed in another manner, such as a data waiver.

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) 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) 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 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), 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), for a tolerance for residues of furilazole on corn commodities at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing the furilazole tolerances 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 furilazole are discussed in the following Table 1 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 rodents	NOAEL = 7 mg/kg/day LOAEL = 34/38 mg/kg/day (male/female) based on increased absolute liver weight in males, increased liver-to-body weight ratio in males and females, and increased gamma glutamyltransferase in females.
870.3150	90-Day oral toxicity in nonrodents	NOAEL = 5 mg/kg/day LOAEL = 15 mg/kg/day based on decreased body weight gain and bile duct inflammation in one-fourth of females.

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

Guideline No.	Study Type	Results
870.3200	21-Day dermal toxicity	Systemic NOAEL = 25 mg/kg/day Systemic LOAEL = 250 mg/kg/day based on increased liver weights.
870.3700a	Prenatal developmental in rodents	Maternal NOAEL = 10 mg/kg/day LOAEL = 75 mg/kg/day based on increased liver weight. Developmental NOAEL = 10 mg/kg/day LOAEL = 75 mg/kg/day based on increased number of resorptions.
870.3700b	Prenatal developmental in nonrodents	Maternal NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on clinical signs of toxicity and reductions in body weight, body weight changes, and food consumption. Developmental NOAEL = greater than or equal to 50 mg/kg/day LOAEL = is not identified, but would be greater than 50 mg/kg/day
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 8.97/10.67 mg/kg/day male/female LOAEL = 92.39/106.42 mg/kg/day male/female based on lower body weight gains and microscopic lesions of the liver, kidneys (females) . Reproductive NOAEL = equal to or greater than 92.39/106.42 mg/kg/day male/female LOAEL = is not identified, but would be greater than 92.39/106.42 mg/kg/day male/female Offspring NOAEL = 8.97/10.67 mg/kg/day male/female LOAEL = 92.39/106.42 mg/kg/day based on decreased body weight gains in both generations and microscopic lesions of the liver and kidneys of F1 males and females.
870.4200	Combined rats Chronic/Carcinogenicity	Chronic NOAEL = 0.26 mg/kg/day (males) LOAEL = 5.05 mg/kg/day (males) based on increased absolute and relative liver and kidney weights in males and females, and kidney nephropathy, increased gamma glutamyl transferase, decreased body weight gain, and moderate increase in non-neoplastic liver lesions in females. Carcinogenic (hepatocellular carcinoma/adenoma) in both sexes.
870.4300	Carcinogenicity mice	Chronic NOAEL = 5.9 mg/kg/day (males) LOAEL = 60.2 mg/kg/day (males) based on increased incidence of mortality and elevated alanine aminotransferase in males and increased liver weights, increased incidence of panlobular hepatocellular hypertrophy and chronic lung inflammation in females. Carcinogenic (hepatocellular carcinoma/adenoma and bronchio-alveolar carcinoma/adenoma) in both sexes
870.5100 and 5300	Gene Mutation	There was a weak positive response for inducing reverse gene mutations at high precipitating doses in <i>Salmonella typhimurium</i> , but the response was negative in cultured mammalian cells.
870.5375	Cytogenetics	Induced dose-related chromosomal aberrations over background
870.5385	Cytogenetics	Did not induce chromosomal aberration in bone marrow cells
870.5395	Cytogenetics	Did not yield convincing evidence that the compound was clastogenic or aneugenic in this <i>in vivo</i> system; however, the maximum tolerated dose was not achieved.
870.5550	Other Effects	Negative for the induction of unscheduled DNA synthesis in rat primary hepatocytes.
870.7485	Metabolism and pharmacokinetics	The compound undergoes rapid absorption and nearly complete excretion within 48 hours. The total recovery of administered radioactivity was 87.7 - 95.1% for all treatment groups. Primary route of excretion was via the feces which accounted for 58 - 77% of the administered dose; excreting greater than or equal to 94% within 48 hours. Urinary excretion was minor and accounted for 13 - 24% of the administered dose and most of it ( greater than or equal to 84%) was excreted within 24 hours.
870.7600	Dermal penetration	A dermal absorption study is not available. A dermal absorption factor of 30 % was extrapolated from the developmental toxicity study and the 21-day dermal toxicity study, both in the rat.

### 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). 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 intra species differences. An additional uncertainty factor of 3X was used to account for the lack of a chronic dog study.

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 factor 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 Safety Factor.

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  $1 \times 10^{-6}$  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 ( $\text{MOE}_{\text{cancer}} = \text{point of departure/exposures}$ ) is calculated. A summary of the toxicological endpoints for furilazole used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FURILAZOLE 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	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/FQPA SF = 0.1 mg/kg/day	Developmental Toxicity Study in the rat LOAEL = 75 mg/kg/day based on increased number of resorptions.
Chronic Dietary all populations	NOAEL = 0.26 mg/kg/day UF = 300 Chronic RfD = 0.0009 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.0009 mg/kg/day	Combined Chronic/Carcinogenicity Study in the rat LOAEL = 5.05 mg/kg/day based on increased absolute and relative liver and kidney weights in males
Short-Term Incidental Oral (1 to 7 days) (Residential)	oral study NOAEL = 10 mg/kg/day	LOC for MOE = 100 (Residential)	Developmental Toxicity Study in the rat LOAEL = 75 mg/kg/day based on increased liver weights, decreased body weights, body weight gains and food consumption.
Intermediate-Term Incidental Oral (1 week to several months) (Residential)	oral study NOAEL = 7 mg/kg/day	LOC for MOE = 100 (Residential)	90-Day rat LOAEL = 34 mg/kg/day based on increased absolute and relative liver weights and alterations in clinical chemistry parameters.
Short-Term Dermal (1 to 7 days) (Residential)	dermal study NOAEL = 25 mg/kg/day (dermal absorption rate = N/A%)	LOC for MOE = 100 (Residential)	21-Day Dermal in the rat LOAEL = 250 mg/kg/day based on increased liver weights.
Intermediate-Term Dermal (1 week to several months) (Residential)	dermal study NOAEL = 25 mg/kg/day (dermal absorption rate = N/A%)	LOC for MOE = 100 (Residential)	21-Day Dermal in the rat LOAEL = 250 mg/kg/day based on increased liver weights.
Long-Term Dermal (several months to lifetime) (Residential)	oral study NOAEL = 0.26 mg/kg/day (dermal absorption rate = 30 %)	LOC for MOE = 100 (Residential)	Combined Chronic/Carcinogenicity Study in the rat LOAEL = 5.05 mg/kg/day based on increased absolute and relative liver and kidney weights in males
Short-Term Inhalation (1 to 7 days) (Residential)	oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental Toxicity Study in the rat LOAEL = 75 mg/kg/day based on increased liver weights, decreased body weights, body weight gains and food consumption.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Inhalation (1 week to several months) (Residential)	oral study NOAEL = 7 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	90-Day rat LOAEL = 34 mg/kg/day based on increased absolute and relative liver weights and alterations in clinical chemistry parameters.
Long-Term Inhalation (several months to lifetime) (Residential)	oral study NOAEL = 0.26 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Combined Chronic/Carcinogenicity Study in the rat LOAEL = 5.05 mg/kg/day based on increased absolute and relative liver and kidney weights in males
Cancer (oral, dermal, inhalation)	oral study Q1* = 0.0274 (mg/kg/day) <sup>1</sup> (dermal absorption rate = 30 % inhalation absorption rate = 100%)	LOC = the range of 1 x 10 <sup>6</sup>	Classified as likely to be carcinogenic to humans by all routes of exposure based on hepatocellular adenomas and carcinomas in rats and mice, bronchio-alveolar adenomas and carcinomas in female mice, testicular interstitial cell tumors in male rats and stomach tumors in female mice.

\* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Time-limited tolerances (expiring February 25, 2002) have been established (40 CFR 180.471) for the residues of furilazole, in or on corn commodities. Risk assessments were conducted by EPA to assess dietary exposures from furilazole 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. The Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The Agency made the following assumptions for the acute exposure assessment: that 100% of the entire corn crop received an application of furilazole, i.e. 100% crop treated (PCT), and that all corn commodities contained residues of furilazole at the tolerance level.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The same assumptions were made for the

chronic exposure assessments: That 100% of the entire corn crop received an application of furilazole, i.e. 100% crop treated (PCT), and that all corn commodities contained residues of furilazole at the tolerance level.

iii. *Cancer.* In conducting this carcinogenic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The same assumptions were made for the cancer exposure assessments: That 100% of the entire corn crop received an application of furilazole, i.e. 100% crop treated (PCT), and that all corn commodities contained residues of furilazole at the tolerance level.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for furilazole in drinking water. 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 furilazole.

The Agency used the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir for an Ohio corn crop. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum

percent crop coverage within a watershed or drainage basin. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater.

Neither 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever 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 furilazole they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS model the estimated environmental concentrations (EECs) of furilazole for acute exposures are estimated to be 1.2 parts per billion (ppb), for chronic (non-

cancer) exposures are estimated to be 0.8 ppb, and for cancer exposures are estimated to be 0.22 ppb for surface water. Based on the SCI-GROW model the estimated environmental concentrations (EECs) of furilazole for acute, chronic and cancer exposures are estimated to be 0.02 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). Furilazole 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) 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 furilazole 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, furilazole 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 furilazole 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.* 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 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 margin of exposure (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.* No qualitative or quantitative evidence of increased susceptibility in the rat or rabbit fetuses following *in utero* exposure in the developmental toxicity studies nor to the offspring following pre/post natal exposure in the two generation reproduction study.

3. *Conclusion.* With the exception of the chronic dog study, there is a complete toxicity data base for furilazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Taking into account the lack of increased susceptibility and the completeness of the data on toxicity and exposure, EPA determined that the 10X safety factor to protect infants and children should be removed.

#### 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 (EECs). 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: 2L/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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure (at the 95th percentile) from food to furilazole is less than one percent of the aPAD for females 13 to 50 years. In addition, there is potential for acute dietary exposure to furilazole in drinking water. The acute DWLOC is 3000 ppb. Since, the DWLOC is greater than the EEC for surface or ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to furilazole from food will utilize 1.4 % of the cPAD for the U.S. population, and 3.4 % of the cPAD for all infants less than 1 year old. Percent PADs for all other population subgroups are less than 3.4%. 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:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0009	1.4	0.8	0.02	31
All infants (less than 1 year old)	0.0009	3.4	0.8	0.02	8.7
Children 1-6 years old	0.0009	3.3	0.8	0.02	8.7
Children 7-12 years old	0.0009	2.5	0.8	0.02	8.7

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). Furilazole 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). Furilazole 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.* Using the exposure assumptions discussed in this unit for cancer exposure, the cancer dietary exposure from food to furilazole is  $3.5 \times 10^{-7}$ . In addition, there is potential for cancer dietary exposure to furilazole in drinking water. The cancer DWLOC is 1.3 ppb. Since, the DWLOC is greater than the EEC for surface or groundwater, EPA does not expect the aggregate exposure to exceed the range of  $1 \times 10^{-6}$ .

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, and to infants and children from aggregate exposure to furilazole residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromatography using electron capture detection) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

##### B. International Residue Limits

There are no CODEX, Canadian or Mexican limits for residues of furilazole in corn raw agricultural commodities.

#### V. Conclusion

Therefore, tolerances are established for residues of furilazole, 3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine, which is also known as furilazole (CAS Reg. No. 121776-33-8), in or on corn commodities at 0.01 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP-301223 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 June 3, 2002.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260-4865.

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.

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.

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.2. Mail your copies, identified by docket control number OPP-301223, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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. Regulatory Assessment Requirements**

This final rule establishes a tolerance under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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. Submission to Congress and the Comptroller General**

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: March 19, 2002.

**Peter Caulkins,**

*Acting Director, Registration Division, 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 180.471 is amended by revising paragraph (a) to read as follows:

#### **§ 180.471 Furilazole; tolerances for residues.**

(a) *General.* Tolerances are established for residues of furilazole; 3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine (CAS Reg. No. 121776-33-8) when used as an inert ingredient (safener) in pesticide formulations in or on the following raw agricultural commodities when applied at an annual application rate of 0.1 pound of safener per acre:

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain ...	0.01
Corn, field, stover	0.01
Corn, pop, grain ....	0.01
Corn, pop, stover ..	0.01

\* \* \* \* \*

[FR Doc. 02-8060 Filed 4-2-02; 8:45 am]

BILLING CODE 6560-50-S

## **FEDERAL COMMUNICATIONS COMMISSION**

### **47 CFR Part 73**

[DA 02-712, MM Docket No. 01-162, RM-10183]

#### **Digital Television Broadcast Service; Cocoa, FL**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Good Life Broadcasting, Inc., licensee of station WTGL-TV, substitutes DTV channel 53c for DTV channel 51. *See* 66 FR 39726, August 1, 2001. DTV channel 53c can be allotted to Cocoa, Florida, in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates (28-35-12 N. and 81-04-58 W.) with a power of 13.0, HAAT of 514 meters and with a DTV service population of 1876 thousand.

With this action, this proceeding is terminated.

**DATES:** Effective May 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418-1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 01-162, adopted March 25, 2002, and released April 1, 2002. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., CY-B402, Washington, DC 20554, telephone 202-863-2893, facsimile 202-863-2898, or via e-mail [qualexint@aol.com](mailto:qualexint@aol.com).

#### **List of Subjects in 47 CFR Part 73**

Television, Digital television broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

#### **PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334, 336.

#### **§ 73.622 [Amended]**

2. Section 73.622(b), the Table of Digital Television Allotments under Florida, is amended by removing DTV channel 51 and adding DTV channel 53c at Cocoa.

Federal Communications Commission.

**Barbara A. Kreisman,**  
*Chief, Video Division, Media Bureau.*

[FR Doc. 02-7978 Filed 4-2-02; 8:45 am]

BILLING CODE 6712-01-P

## **FEDERAL COMMUNICATIONS COMMISSION**

### **47 CFR Part 73**

[DA 02-620; MM Docket No. 99-244; RM-9678, 9873]

#### **Radio Broadcasting Services; Cumberland, KY and Weber City, Glade Spring, Marion, Richlands and Grundy, VA.**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Holston Valley Broadcasting Corporation, allots Channel 274A at Glade Spring, Virginia, as the community's first local aural transmission service (RM-9873). To accommodate the allotment, we will (1) substitute Channel 263A for Channel 273A at Marion, Virginia, and modify Station WOLD-FM's license accordingly; (2) substitute Channel 249A for Channel 264A at Richlands, Virginia, and modify Station WRIC-FM's license accordingly; and (3) substitute Channel 2654A for Channel 249A at Grundy, Virginia, and modify Station WMJD(FM)'s license accordingly. We also deny the petition for rule making filed by Cumberland City Broadcasting Company requesting the substitution of Channel 274C3 for Channel 274A at Cumberland, the reallocation of Channel 274C3 from Cumberland to Weber City, Virginia, and the modification of Station WSEH(FM)'s license accordingly (RM-9678). *See* 64 FR 37925, July 14, 1999. *See* Supplementary Information, *infra*. **DATES:** Effective May 3, 2002. A window for Channel 274A at Glade Spring, Virginia, will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent order.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Sharon P. McDonald, Mass Media Bureau, (202) 418-2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 99-244, adopted March 6, 2002, and released March 19, 2002. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20054.

Channel 274A can be allotted to Glade Spring in compliance with the Commission's minimum distance separation requirements with a site restriction of 13.3 kilometers (8.3 miles) east at petitioner's requested site. The coordinates for Channel 274A at Glade Spring are 36-45-15 North Latitude and 81-37-56 West Longitude. Additionally, Channel 263A can be substituted at Marion with a site restriction of 2.2 kilometers (1.3 miles) north at