

Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective April 24, 2000 without further notice unless the Agency receives adverse comments by March 24, 2000.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on April 24, 2000 and no further action will be taken on the proposed rule.

#### IV. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). For the same reason, this rule also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the

Clean Air Act. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 24, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the

purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Methane, Municipal solid waste landfills, Nonmethane organic compounds, Reporting and recordkeeping requirements.

Dated: February 3, 2000.

**A. Stanley Meiburg,**

*Acting Regional Administrator, Region 4.*

Part 62 of chapter I, title 40, Code of Federal Regulations, is amended as follows:

#### PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

**Authority:** 42 U.S.C. 7401-7642.

#### Subpart RR—Tennessee

2. Section 62.10626, is amended by adding paragraph (b)(5) to read as follows:

#### § 62.10626 Identification of plan.

\* \* \* \* \*

(b) \* \* \*

(5) Chattanooga-Hamilton County Air Pollution Control Bureau Clean Air Act Section 111(d) Plan for Municipal Solid Waste Landfills, submitted on April 26, 1999, by the State of Tennessee Department of Environment and Conservation.

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-300968; FRL-6490-3]

#### RIN 2070-AB78

#### Furilazole; Time-Limited Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited 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, (grain, forage, and stover), at 0.01 ppm. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and be revoked on February 25, 2002.

**DATES:** This regulation is effective February 23, 2000. Objections and requests for hearings, identified by docket control number OPP-300968, must be received by EPA on or before April 24, 2000.

**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-300968 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-6379; and e-mail address: gairola.indira@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does This Action Apply to Me?*

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

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

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

regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300968. 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 (furilazole) in or on corn commodities, (grain, fodder, and forage), at 0.01 ppm were previously established as requested by Monsanto Company under the Federal Food, Drug, and Cosmetic Act in a pesticide tolerance rule dated May 10, 1994 (59 FR 24059) (FRL-4777-2). These tolerances expired on June 30, 1996.

In the **Federal Register** of October 20, 1999, (64 FR 56502-56505) (FRL-6386-9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (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 Company, 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), which is also known as furilazole in or on the following corn commodities: (fodder, forage and grain) at 0.01 parts per million (ppm). The tolerances will expire on February 25, 2002.

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. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings. 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 (grain, forage, and stover) at 0.01 ppm. EPA's assessment of the dietary 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 furilazole are discussed in this unit.

1. *Acute toxicity.* Six acute toxicity studies were conducted and the results are summarized as follows:

i. *Oral.* In the acute oral toxicity study for rats, the LD<sub>50</sub> was equal to 521 mg/kg in males and was classified as Toxicity Category III.

ii. *Dermal.* In the acute dermal toxicity study for rats, the LD<sub>50</sub> was equal to >5,000 mg/kg and was classified as Toxicity Category IV.

iii. *Inhalation.* In the acute inhalation, toxicity study for rats, the LC<sub>50</sub> was equal to >2.3 mg/L and was classified as Toxicity Category IV.

iv. *Primary eye irritation.* In a primary eye irritation study in rabbits, furilazole was found to be a mild irritant and is classified as Toxicity Category III.

v. *Primary skin irritation.* In a primary skin irritation study in rabbits, furilazole was found to be a negligible irritant and is classified as Toxicity Category IV.

vi. *Dermal sensitization.* In a dermal sensitization study furilazole was not a sensitizer.

2. *Subchronic and chronic toxicity.* This section summarizes the results of subchronic, and chronic toxicity studies in animals.

i. *Subchronic toxicity.* In a 3-month rat feeding study, the no observed adverse effect level (NOAEL) is 100 ppm (7 mg/kg/day for males and females) and the lowest observed adverse effect level (LOAEL) is 500 ppm (34 mg/kg/day for males and 38 mg/kg/day for females) based on the increased absolute liver

weight in males, increased liver-to-body weight ratio in males and females, and increased levels of gamma glutamyltransferase in females.

In a 90-day dog study, the NOAEL is 5 mg/kg/day. The LOAEL for this study is 15 mg/kg/day based on bile duct inflammation in one female and decreased body weight gain in females.

In a 21-day dermal toxicity study, the NOAEL for systemic effects in both sexes is  $\geq 1,000$  mg/kg, the limit dose. A LOAEL was not established.

ii. *Chronic toxicity.* In a 2-year rat feeding chronic toxicity/carcinogenicity study, the NOAEL for chronic toxicity is 5 ppm (0.26 mg/kg/day) for males and 100 ppm (6.03 mg/kg/day) for females. The LOAEL is 100 ppm (5.05 mg/kg/day) for males based on significantly increased absolute and/or relative liver and kidney weights. The LOAEL is 1,000 ppm (61 mg/kg/day) for females based on significantly increased absolute and/or relative liver and kidney weight, kidney nephropathy, increased GGT, decreased body weight gain, and a moderate increase in non-neoplastic liver lesions (eosinophilic focus, cystic degeneration, and telangiectasis). Under the conditions of this study, furilazole appeared to be carcinogenic in both sexes.

In an 18-month mouse dietary carcinogenicity study, the NOAEL for systemic toxicity is 40 ppm (5.9 mg/kg/day) for males and 400 ppm (92.0 mg/kg/day) for females. The systemic toxicity LOAEL in males is 400 ppm (60.2 mg/kg/day) based on increased incidence of mortality and elevated alanine aminotransferase. The systemic toxicity LOAEL in females was 1,250 ppm (289.5 mg/kg/day), based on increased liver weight, increased incidence of hepatocellular hypertrophy of the panlobular area, and chronic inflammation of the lungs. At the doses tested, there was a treatment-related increase in tumor incidence.

3. *Developmental toxicity.* In a developmental toxicity study in rats, the maternal toxicity NOAEL is 10 mg/kg/day and the maternal toxicity LOAEL is 75 mg/kg/day based on increased liver weight. The developmental toxicity NOAEL is 10 mg/kg/day and the developmental LOAEL is 75 mg/kg/day based on increased number of resorptions.

4. *Reproductive toxicity.* In a two-generation reproduction study in rats, the NOAEL for systemic toxicity is 150 ppm (8.97 mg/kg/day in males and 10.67 mg/kg/day in females). The LOAEL for systemic toxicity is 1,500 ppm (92.39 mg/kg/day in males and 106.42 mg/kg/day in females) based on decreased body weight gains in the

adults and offspring of both generations and microscopic lesions of the liver in F<sub>0</sub> and F<sub>1</sub> males and females and kidneys of F<sub>0</sub> females and F<sub>1</sub> males and females. The NOAEL for reproductive toxicity is  $\geq 1,500$  ppm ( $\geq 92.39$  mg/kg/day in males and  $\geq 106.42$  mg/kg/day, in females), the highest dose tested. The reproductive toxicity LOAEL was not determined.

5. *Mutagenicity.* Furilazole induced a weak positive response for inducing reverse gene mutations at high precipitating doses in *Salmonella typhimurium* but was negative in cultured mammalian cells. Furilazole was also negative for the induction of micronuclei in the bone marrow cells of mice and negative for the induction of unscheduled DNA synthesis (UDS) in rat primary hepatocytes.

#### B. Toxicological Endpoints

1. *Acute dietary toxicity.* For an acute dietary risk assessment, for females ages 13–50 years, the Agency selected a developmental toxicity NOAEL of 10 mg/kg/day from a developmental toxicity study in rats. The developmental toxicity LOAEL of 75 mg/kg/day for this developmental study was based on increased resorptions.

For an acute dietary risk assessment for the general population including infants and children, the Agency selected a maternal toxicity NOAEL of 75 mg/kg/day from a developmental toxicity study in the rat. The maternal toxicity LOAEL of 175 mg/kg/day for this study was based on decreased maternal body weight.

2. *Dermal toxicity.* For a short-term dermal risk assessment, the Agency selected a NOAEL of 10 mg/kg/day from a developmental toxicity study in rats. The LOAEL of 75 mg/kg/day for this study was based on increased resorptions. Since an oral NOAEL was selected for dermal risk assessment a dermal absorption factor (30%) was used.

For an intermediate-term dermal risk assessment the Agency selected a NOAEL of 7 mg/kg/day from a 90-day feeding study in rats. The LOAEL of 34 mg/kg/day for males and 38 mg/kg/day for females for this study was based on increased absolute liver weights in males, increased liver-to-body weight ratio in males and females, and increased gamma glutamyltransferase in females. Since an oral NOAEL was selected for dermal risk assessment a dermal absorption factor (30%) was used.

A long-term dermal exposure scenario is not required for this use since furilazole is applied once per year.

3. *Chronic dietary toxicity.* For a chronic dietary risk assessment, the Agency selected a NOAEL of 0.26 mg/kg/day from the chronic toxicity/carcinogenicity study in rats. The LOAEL of 5.05 mg/kg/day was based on significantly increased absolute and/or relative liver and kidney weights in males.

4. *Carcinogenicity.* EPA has classified furilazole as "likely to be carcinogenic to humans" by the oral route in accordance with the EPA Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996), based on multiple tumors seen at multiple sites in two species including both benign and malignant liver tumors in male and female rat and mice, rare tumors such as stomach and testicular tumors in male rats, and lung tumors in both sexes of mice. A  $Q_1^*$  was calculated to be  $8.22 \times 10^{-2}$  (mg/kg/day)<sup>-1</sup> based on male mouse bronchiolar-alveolar adenoma and/or carcinoma combined tumor rates.

5. *Inhalation toxicity.* For a short-term inhalation risk assessment the Agency selected an oral NOAEL of 10 mg/kg/day from the developmental toxicity study in rats. The LOAEL of 75 mg/kg/day was based on increased resorptions.

For the intermediate-term risk assessment, the Agency selected a NOAEL of 7 mg/kg/day from a 90 day feeding study in rats as the endpoint. The LOAEL of 34 mg/kg/day for males and 38 mg/kg/day for females for this study was based on increased absolute liver weights in males, increased liver-to-body weight ratio in males and females, and increased gamma glutamyltransferase in females.

A long-term inhalation exposure scenario is not required for this use, since furilazole is applied once per year.

6. *Dermal penetration.* A dermal absorption factor of 30% was extrapolated by the Agency from a developmental toxicity study and a 21-day dermal toxicity study both in the rat, where effects on liver weights were seen by both routes of exposure. In the developmental toxicity study in the rat, increased liver weight was seen at the maternal toxicity LOAEL of 75 mg/kg/day. In the 21-day dermal toxicity study in the rat, adaptive effects on liver weights were seen at 250 mg/kg/day and are indicative of absorption. The Agency determined a dermal absorption ratio of 75/250 or 30%.

7. *Safety (uncertainty) factors, including FQPA safety factor.* The Agency will use the above NOAELs and LOAELs to assess the risks of using furilazole to the general population and certain subgroups of the general population. However, the Agency first

modifies these values numerically, downward, by dividing the NOAEL by two or more safety factors. The standard safety (uncertainty) factors used are: a tenfold factor to account for intraspecies variability (the differences in how the test animals reacted to the test substance), and a tenfold factor to account for interspecies variation (the use of animal studies to predict human risk).

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 post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. As noted, the Agency has used an additional 10-fold safety factor for the acute dietary assessment for females 13–50 only.

The basis for this conclusion is that in the rat development toxicity study, although the NOAELs and LOAELs for maternal and developmental toxicity were the same, there does appear to be an increased severity of developmental effects in comparison to maternal effects. Increased resorptions (or death of fetuses) seen at the LOAEL is a more severe effect than increased maternal liver weight seen at the same level. Additionally, the database is incomplete since there is a data gap for a developmental toxicity study in rabbits.

i. *Acute dietary toxicity (females 13–50).* For an acute dietary risk assessment for females ages 13–50 years old the Agency divided the NOAEL of 10 mg/kg/day from a developmental toxicity study in the rat by an uncertainty factor of 1,000 (10x for interspecies difference, 10x for intraspecies variations, and 10x safety factor to address additional susceptibility in fetus and data gaps). The acute Population Adjusted Dose (aPAD) is 0.010 mg/kg/day.

ii. *Acute dietary toxicity (general population and infants and children).* For an acute dietary risk assessment (general population and infants and children) the Agency divided the NOAEL of 75 mg/kg/day from the developmental rat study by an uncertainty factor of 100 (10x for interspecies difference, 10x for intraspecies variations and 1x for FQPA safety factor). The aPAD is 0.75 mg/kg/day.

iii. *Chronic toxicity.* For a chronic dietary risk assessment the Agency divided the NOAEL of 0.26 mg/kg/day from a 2-year combined chronic toxicity/carcinogenicity study in the rat by an uncertainty factor of 300 (10x for interspecies differences, 10x for intraspecies variations and 3x for lack of

chronic toxicity study in the dog and 1x for FQPA safety factor). The chronic Population Adjusted Dose (cPAD) is 0.0009 mg/kg/day.

### C. Exposures and Risks

1. *From food and feed uses.* Time-limited tolerances were previously established (40 CFR 180.471) for the residues of furilazole, in or on corn commodities (grain, forage, and fodder) at 0.01 ppm. Risk assessments were conducted by EPA to assess dietary exposures from furilazole as follows:

i. *Acute exposure and risk.* 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 1-day or single exposure. An acute dietary risk assessment was performed for furilazole. The acute dietary analysis for furilazole is a conservative estimate of dietary exposure from food, or Tier 1 assessment, with the use of tolerance level residues for all corn commodities at 0.01 ppm, and 100 percent crop treated (PCT) information. The Agency's level of concern is for acute dietary exposures greater than 100% aPAD. The acute dietary exposure analysis was performed for the U.S. population and 26 subgroups. Acute estimates of the per capita dietary exposures from food at the 95<sup>th</sup> percentile for the U.S. population and all subgroups are <1% aPAD which is less than the Agency's level of concern.

ii. *Chronic exposure and risk.* A chronic dietary risk assessment was performed for furilazole. The chronic dietary analysis for furilazole is a refined estimate, or Tier 3 assessment, with the use of anticipated residues (ARs) (calculated from field trial data using half the level of quantitation) for all commodities and PCT information. EPA's level of concern is for chronic dietary exposures greater than 100% cPAD. For the U.S. population and all subgroups, including infants and children, <1% of the cPAD is occupied by dietary (food) exposure. The results of this analysis indicate that the estimated chronic dietary risk associated with the use of furilazole on corn is below EPA's level of concern.

iii. *Carcinogenic exposure and risk.* A cancer dietary risk assessment was performed. ARs and PCT were used to calculate the upper bound lifetime risk for dietary exposure to furilazole. EPA generally considers  $1 \times 10^{-6}$  as negligible risk (i.e., less than 1 in 1 million) for cancer. The results of this analysis indicate that the cancer dietary risk of  $7.2 \times 10^{-8}$  associated with the use of furilazole on corn is below the Agency's level of concern.

iv. *Use of anticipated residues and percent crop treated information.* Section 408(b)(2)(E) 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. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: For the acute dietary risk assessment, the Agency assumed 100% crop treated i.e., that the entire crop was treated. For chronic (non-cancer and cancer) dietary analyses it was assumed that 25% of the corn was treated.

For assessing chronic dietary risk, the Agency believes that the three conditions listed above have been met. With respect to Condition 1, it was assumed that 25% of the corn was treated. The petitioner supplied the percent crop treated data to the Agency. The information was based on the amount of acetochlor since furilazole is used as a safener with acetochlor to treat corn. The Agency reviewed the estimate and found it to be reasonable. The Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. As to

Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which furilazole may be applied in a particular area.

## 2. *From drinking water—*

### i. *Chemical specific information.*

Based on laboratory data, furilazole and its principal degradates show low to moderate persistence and high mobility. Furilazole is stable against simple hydrolysis. Photolysis and soil metabolism are its main routes of transformation. "Half-lives" for parent in the laboratory vary from 8 days to 95 days. Furilazole is likely to be highly mobile. Bioconcentration is not expected. Major degradates identified included N (dichloroacetyl) glycine, furilazole oxazolidine acid, and furilazole oxamic acid. These degradates could be produced in soil and natural waters.

ii. *Ground water.* The Agency used its SCI-GROW (Screening Concentration in Ground Water) screening model and environmental fate data to determine the estimated environmental concentrations (EECs) of furilazole in ground water. SCI-GROW is an empirical model based upon actual ground water monitoring data collected for the registration of a number of pesticides that serve as benchmarks for the model. The current version of SCI-GROW appears to provide realistic estimates of pesticide concentrations in shallow, highly vulnerable ground water sites (i.e., sites with sandy soils and depth to ground water of 10 to 20 feet). The SCI-GROW ground water screening concentration is 0.019 ppb.

iii. *Surface water.* The Agency used its PRZM (Pesticide Root Zone Model)/EXAMS (Exposure Analysis Modeling System) screening model and environmental fate data to determine the EECs of furilazole in surface water. PRZM/EXAMS simulates a 1 hectare by 2 meter deep edge-of-the-field farm pond which receives pesticide runoff

from a treated 10 hectare field. PRZM/EXAMS can overestimate true pesticide concentrations in drinking water. It has certain limitations and is not the ideal tool for use in drinking water risk assessments. However, it can be used in screening calculations and does provide an upper bound on the concentration of pesticide that can be found in drinking water.

Using the PRZM/EXAMS model and available environmental fate data, EPA calculated the following Tier 2 EECs for furilazole:

Acute (Peak) EEC: 1.007 ppb  
Mean (chronic) EEC: 0.214 ppb

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses. Different populations will have different DWLOCs. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential dietary exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water.

It is current Agency policy that the following subpopulations be addressed when calculating drinking water levels of comparison U.S. population (48 States), any other adult populations whose %PAD is greater than that of the U.S. population, and the Female and Infant/Children subgroups (1 each) with the highest food exposure. The subgroups which are listed below are those which fall into these categories.

iv. *Acute exposure and risk.* Based on the acute dietary exposure estimates from food, acute drinking water levels of comparison for furilazole were calculated to be 26,250 ppb for the U.S. population, 26,250 ppb for Non-Hispanic Blacks, 7,500 ppb for non-nursing infants (<1 year), and 300 ppb for Females (13–19 yrs/np/nn).

v. *Chronic (non-cancer) exposure and risk.* Based on the chronic dietary exposure estimates from food, chronic drinking water levels of comparison for furilazole were calculated, and are summarized below:

U.S. population (48 States): 31 ppb  
Females 13–50 years: 27 ppb  
Children (non nursing infants): 9 ppb

vi. *Carcinogenic exposure and risk.* Based on the carcinogenic dietary

exposure estimates from food, a carcinogenic drinking water level of comparison for furilazole in water was calculated to be 0.36 ppb for the U.S. Population (48 States).

vii. *Drinking water risks.* The modeled groundwater and surface water concentrations are less than the DWLOCs for furilazole in drinking water for acute, chronic (non-cancer) and cancer aggregate exposures. Thus, the Agency is able to screen out furilazole drinking water risks.

3. *From non-dietary exposure.* There are no currently registered residential uses for furilazole. Therefore a non-dietary assessment was not performed.

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." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues

can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether furilazole (3-dichloroacetyl-5-(2-furanyl)-2,2-dimethylloxazolidine) has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Furilazole is structurally related to chloroacetanilides such as alachlor and acetochlor. However at this time the Agency has not yet made a final decision concerning a possible common mechanism of toxicity for the chloroacetanilides. For the purposes of this tolerance action, therefore, EPA has not assumed that furilazole has a common mechanism of toxicity with other substances.

#### *D. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute risk.* For the U.S. population and all subgroups, including infants and children, < 1% of the aPAD is occupied by exposure through food, which is below EPA's level of concern of 100%. The estimated acute concentrations of furilazole in surface and ground water are less than EPA's levels of comparison for furilazole in drinking water. Therefore, EPA does not expect the aggregate risk to exceed 100% of the aPAD.

2. *Chronic (non-cancer) risk.* Since there are no residential uses for furilazole, the chronic (non-cancer) aggregate exposure includes only food and water. For the U.S. population and all subgroups, including infants and children, < 1% of the cPAD is occupied by exposure through food which is below EPA's level of concern of 100%. The estimated average concentrations of furilazole in surface and ground water are less than EPA's levels of comparison for furilazole in drinking water. Therefore, EPA does not expect the aggregate risk to exceed 100% of the cPAD.

3. *Short-and intermediate-term risk.* Short-and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Since there are no residential uses or exposure scenarios, short,

intermediate, and long-term aggregate risk assessments were not conducted.

4. *Aggregate cancer risk for U.S. population.* For the U.S. population, the cancer dietary risk from food of  $7.2 \times 10^{-8}$  from food exposure is below the Agency's level of concern for excess lifetime cancer risk. The estimated average concentrations of furilazole in surface and ground water are less than EPA's drinking water level of comparison for furilazole in drinking water. Therefore, EPA does not expect aggregate risk to exceed  $1 \times 10^{-6}$  as negligible risk (i.e., less than 1 in 1 million).

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to furilazole residues.

#### *E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of furilazole, EPA considered data from a developmental toxicity study in the rat and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. The Agency is requiring a developmental toxicity study in the rabbit.

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 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. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and the additional 3-fold uncertainty factor, as described above, when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a

compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Conclusion.* There is not a complete toxicity data base for furilazole. EPA concluded that the 10x safety factor should be retained and is applicable to females 13–15 years only. This decision was based on the following: (a) There is a data gap for a developmental toxicity study in rabbits; and (b) There is evidence of qualitative increased susceptibility in the developmental toxicity study in rats. Increased resorptions (or death of fetuses) seen at the LOAEL is a more severe effect than increased maternal liver weight seen at the same level.

2. *Acute risk.* For infants and children, < 1% of the aPAD is occupied by dietary exposure through food which is below EPA's level of concern of 100%. The estimated acute concentrations of furilazole in surface and ground water are less than EPA's levels of comparison for furilazole in drinking water. Therefore, EPA does not expect the aggregate risk to exceed 100% of the aPAD.

3. *Chronic (non-cancer) risk.* Using the exposure assumptions previously described, EPA has concluded that aggregate exposure to furilazole from food will utilize less than 1 percent of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The estimated average concentrations of furilazole in surface and ground water are less than EPA's levels of comparison for furilazole in drinking water. Therefore, EPA does not expect the aggregate risk to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk.* Since there are no residential uses or exposure scenarios, short, intermediate, and long-term aggregate risk assessments were not conducted.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to furilazole residues.

#### IV. Other Considerations

##### A. Endocrine Disruptor Effects

FQPA requires EPA to develop a screening program to determine whether certain substances (including all pesticides and inert or inactive 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. As the Agency proceeds with implementation of this program, further testing of products containing furilazole (3-dichloroacetyl-5-(2-furanyl)-2,2-dimethylloxazolidine) for endocrine effects may be required.

##### B. Metabolism in Plants and Animals

The nature of the residue in corn was found to be understood based on submitted greenhouse and field metabolism studies. It was concluded that there is possible incorporation into natural plant components. The only residue of concern is parent furilazole.

##### C. Analytical Enforcement Methodology

An adequate enforcement method (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, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

##### D. Magnitude of Residues

Field trials on field corn were conducted and the data submitted. The submitted data support the time-limited tolerance level of 0.01 ppm for corn (grain stover, forage).

##### E. International Residue Limits

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

##### F. Rotational Crop Restrictions

EPA has determined that a plantback interval of 30 days for furilazole is supported by the data.

#### V. Conclusion

Therefore, time-limited tolerances are established for residues of the inert ingredient herbicide safener 3-dichloroacetyl-5-(2-furanyl)-2,2-dimethylloxazolidine, which is also known as furilazole in or on corn commodities, (grain, forage, and stover), at 0.01 ppm. The tolerances will expire and be revoked on February 25, 2002. The following residue chemistry data gaps have been identified for furilazole: (1) Animal metabolism studies (OPPTS GLN 860.1300), (2) radiovalidation and specificity studies for the analytical enforcement method for plants, (3) an additional 10 field trials (OPPTS GLN 860.1500). The following toxicology

data gaps have been identified for furilazole (1) Chronic Toxicity (dog) (OPPTS GLN 870.4100), (2) Developmental Toxicity (rabbit) (OPPTS GLN 870.3700), (3) General Metabolism (870.7485) and (4) *in vitro* cytogenetic assay (OPPTS GLN 870.6375). These datagaps must be addressed to establish permanent tolerances. These tolerances are being established on a time-limited basis due to an incomplete database.

#### 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-300968 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 April 24, 2000.

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, Ariel Rios Bldg., 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](mailto: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, Ariel Rios Bldg., 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, Ariel Rios Bldg., 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-300968, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg.,

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](mailto: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 file format 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). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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).

#### **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: February 15, 2000.

**James Jones,**

*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), 346a and 371.

2. Section 180.471 is revised to read as follows:

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

(a) *General.* Tolerances to expire February 25, 2002 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:

Commodity	Parts per million	Revocations/Expiration Date
Corn, field, forage.	0.01	February 25, 2002
Corn, field, grain.	0.01	February 25, 2002
Corn, field, stover.	0.01	February 25, 2002
Corn, pop, grain.	0.01	February 25, 2002
Corn, pop, stover.	0.01	February 25, 2002

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00-4237 Filed 2-22-00; 8:45 am]

**BILLING CODE 6560-50-F**

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[OPP-300970; FRL-6490-7]

**RIN 2070-AB78**

**Acrylic Graft Copolymer, Polyester Block Copolymer and Polyester Random Copolymer; Tolerance Exemption**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the polymers methyl methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer minimum number average molecular weight (in amu) 2,730, also known as acrylic graft copolymer; 12-hydroxystearic acid-polyethylene glycol copolymer minimum number average molecular weight (in amu) 3,690, also known as polyester block copolymer; and polyethylene glycol-polyisobutene anhydride-tall oil fatty acid copolymer also known as polyester random copolymer minimum number average molecular weight (in amu) 2,960, in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, or animals. Uniqema, formerly ICI Surfactants, 3411 Silverside Road, Box 8340 Wilmington, DE 19803, submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting exemptions from the requirement of a tolerance for these copolymers. This regulation eliminates the need to establish a maximum permissible level for residues of these polymers.

**DATES:** This regulation is effective February 23, 2000. Objections and requests for hearings, identified by docket control number OPP-300970, must be received by EPA on or before April 24, 2000.

**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 XI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300970 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (703) 308-6379 and e-mail address: gairola.indira@epa.gov.

**SUPPLEMENTARY INFORMATION:****I. General Information***A. Does This Action Apply to Me?*

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

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

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

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register—Environmental Documents.**" You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300970. 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).