

supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

#### IV. 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 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**. This 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: January 28, 1999.

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. 346a and 371.

#### § 180.482 [Amended]

2. In § 180.482, by amending the table in paragraph (b) by changing the date "2/28/99" to read "8/31/00".

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 180 and 186

[OPP-300781; FRL-6055-6]

RIN 2070-AB78

#### 3,7-Dichloro-8-quinoline carboxylic acid; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of 3,7-dichloro-8-quinoline carboxylic acid in or on wheat forage, grain, straw, milled fractions, and aspirated grain fractions; sorghum grain, grain forage, and grain fodder (stover); fat of cattle, goats, hogs, horses, poultry and sheep; and meat byproducts of cattle, goats, hogs, horses, and sheep. This action is in connection with crisis exemptions declared under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on wheat and sorghum. This regulation establishes a maximum permissible level for residues of 3,7-dichloro-8-quinoline carboxylic acid in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on May 30, 2000.

**DATES:** This regulation is effective February 10, 1999. Objections and requests for hearings must be received by EPA on or before April 12, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP-300781], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300781], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2,

1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300781]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9364, e-mail: pemberton.libby@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing tolerances for residues of the herbicide 3,7-dichloro-8-quinoline carboxylic acid in or on wheat forage at 5 ppm, grain at 4 ppm, straw at 1 ppm, milled fractions at 40 ppm, aspirated grain fractions at 800 ppm; sorghum, grain at 4 ppm, grain forage at 5 ppm, grain fodder (stover) at 1 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.6 ppm; fat of poultry at 0.2 ppm; and meat byproducts of cattle, goats, hogs, horses, and sheep at 1.5 part per million (ppm). These tolerances will expire and are revoked on May 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

#### I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things,

FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL-5572-9).

New 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. . . ."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

## II. Emergency Exemption for 3,7-Dichloro-8-Quinoline Carboxylic Acid on Wheat and Sorghum and FFDCA Tolerances

On May 28, 1998, the North Dakota Department of Agriculture availed itself of the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of 3,7-dichloro-8-quinoline carboxylic acid on wheat for control of volunteer flax. Hail and unusually highwinds struck last fall in the affected area which caused the seeds of flax plants to fall onto the ground before they were harvested. After germination in the spring, the subsequent crop of wheat was found to be severely infested. No other options for control of flax in wheat are available. On June 22, 1998, the Nebraska Department of Agriculture availed itself of the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of 3,7-dichloro-8-quinoline carboxylic acid on sorghum for the control of annual weeds. Extreme heavy rains prevented many producers from cultivating their crops, which resulted in a greater-than-normal weed cover.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of 3,7-dichloro-8-quinoline carboxylic acid in or on wheat forage, grain, straw, milled fractions, and aspirated grain fractions; sorghum grain, grain forage, and grain fodder (stover); fat of cattle, goats, hogs, horses, poultry and sheep; and meat byproducts of cattle, goats, hogs, horses, and sheep. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on May 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on wheat forage, grain, straw, milled fractions, and aspirated grain fractions; sorghum grain, grain forage, and grain fodder (stover); fat of cattle, goats, hogs, horses, poultry and sheep; and meat byproducts of cattle, goats, hogs, horses, and sheep after that

date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether 3,7-dichloro-8-quinoline carboxylic acid meets EPA's registration requirements for use on wheat and sorghum or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of 3,7-dichloro-8-quinoline carboxylic acid by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than North Dakota and Nebraska to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for 3,7-dichloro-8-quinoline carboxylic acid, contact the Agency's Registration Division at the address provided under the ADDRESSES section.

## III. Aggregate Risk Assessment and Determination of Safety

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).

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 3,7-dichloro-8-quinoline carboxylic acid (quinclorac) and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of 3,7-dichloro-8-quinoline carboxylic acid on wheat forage at 5 ppm, grain at 4 ppm, straw at 1 ppm, milled fractions at 40 ppm, aspirated grain fractions at 800 ppm; sorghum, grain at 4 ppm, grain forage at 5 ppm, grain fodder (stover) at 1 ppm; fat of cattle, goats, hogs, horses, and sheep at

0.6 ppm; fat of poultry at 0.2 ppm ; and meat byproducts of cattle, goats, hogs, horses, and sheep at 1.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the 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 3,7-dichloro-8-quinoline carboxylic acid are discussed in this unit.

#### B. Toxicological Endpoint

1. *Acute toxicity.* For acute dietary risk assessment, EPA used the no observed adverse effect level (NOAEL) of 200 milligrams/kilograms/day (mg/kg/day), based on increased incidence of fetal resorptions, decrease in the number of live fetuses, and reduced fetal body weight at the lowest observed effect level (LOEL) of 600 mg/kg/day, from the developmental toxicity study in rabbits and an uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variability). This risk assessment will evaluate acute dietary risk for females 13+ years, the population subgroup of concern, but not to the general population (including infants and children). For the general population, no appropriate endpoint attributable to a single exposure was identified from the oral toxicity studies, including the rat and rabbit developmental toxicity studies.

2. *Short- and intermediate-term toxicity.* EPA did not select either a dose or endpoint for short- and intermediate term dermal exposure since no dermal or systemic toxicity was observed in a dermal toxicity study in New Zealand White rabbits after 21 repeated dermal applications of quinclorac at 0, 10, 200, or 1,000 mg/kg/day, 6 hours/day, 7 days/week. The dose of 1,000 mg/kg/day is the limit dose. Therefore, EPA did not conduct a risk assessment for short- and intermediate-term exposure.

3. *Chronic toxicity.* EPA has established the RfD for 3,7-dichloro-8-quinoline carboxylic acid at 0.4 mg/kg/day. This RfD is based on a carcinogenicity study in mice with a NOAEL of 37.5 mg/kg/day and an uncertainty factor of 100 based on decreased body weights in male and female mice at the LOEL of 150 mg/kg/day.

4. *Carcinogenicity.* After considering an equivocal increase of acinar cell adenomas of the pancreas in male Wistar rats, 3,7-Dichloro-8-quinoline carboxylic acid has been classified as "Group D -- not classifiable as to human carcinogenicity."

#### C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.463) for the residues of 3,7-dichloro-8-quinoline carboxylic acid in or on rice grain (5 ppm); rice straw (12 ppm); fat and meat of cattle, goats, hogs, horses, poultry, and sheep (0.05 ppm); meat-byproducts (mbyp) of cattle, goats, hogs, and horses (0.05 ppm); mbyp of poultry and sheep (0.1 ppm); eggs (0.05 ppm); and, milk (0.05 ppm). Risk assessments were conducted by EPA to assess dietary exposures and risks from 3,7-dichloro-8-quinoline carboxylic acid 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. The acute dietary (food only) risk assessment was conducted via Dietary Exposure Evaluation Model (DEEM), using the theoretical maximum residue contribution (TMRC), which assumes tolerance level residues and 100% crop-treated. Using the formula, % Acute RfD Occupied = (High-End Exposure + Acute RfD) x 100%, the high-end (99.9 percentile) exposure estimate of 0.256735 mg/kg/day for females 13+/nursing, (the subpopulation in the females 13+ years of age subgroup with the highest exposure), occupies 13% of the acute RfD. This result should be viewed as a very conservative risk estimate; refinement using anticipated residue values and percent crop-treated data would result in a lower estimate of acute dietary exposure.

ii. *Chronic exposure and risk.* The chronic analysis for 3,7-dichloro-8-quinoline carboxylic acid is a conservative estimate of dietary exposure with all residues at proposed or published tolerance levels, and 100% of the commodities assumed to be treated. A risk assessment for chronic dietary exposure from food and feed uses was made for all subpopulations. The percent of the RfD occupied ranged from 2% for nursing infants to 34% for children 1-6 years old.

2. *From drinking water.* Quinclorac is rather persistent in soils and prone to leach into groundwater. There is no entry for quinclorac in EPA's Pesticides in Ground Water Database. No established Maximum Contaminant

Level or health advisory levels have been established for residues of quinclorac in drinking water.

i. *Acute exposure and risk.* For purposes of acute risk assessment, the maximum estimated environmental concentration (EEC) for 3,7-dichloro-8-quinoline carboxylic acid in drinking water (26.8 ppb in surface water, GENECC peak value) was used for comparison to the back-calculated human health Drinking Water Level of Comparison (DWLOC) for acute dietary exposure (52,000 µg/L for the only population of concern, females (13+ years/nursing)). The estimated peak concentration in surface water (26.8 µg/L) is significantly less than EPA's level of concern for 3,7-dichloro-8-quinoline carboxylic acid in drinking water as a contribution to acute aggregate exposure.

ii. *Chronic exposure and risk.* For purposes of chronic risk assessment, the maximum EEC for 3,7-dichloro-8-quinoline carboxylic acid in drinking water (25.4 ppb in surface water, rather than 13.8 in ground water, GENECC average 56-day concentration) was used for comparison to the back-calculated human health DWLOCs for chronic dietary exposure (12,000 µg/L for U.S. population; 2,700 µg/L for infants/children). The estimated average concentration in surface water (25.4 µg/L) is significantly less than EPA's level of concern for 3,7-dichloro-8-quinoline carboxylic acid in drinking water as a contribution to chronic aggregate exposure and does not result in an unacceptable level of chronic aggregate human health risk estimate at this time.

3. *From non-dietary exposure.* There are no registered uses which will result in non-dietary, non-occupational exposure to 3,7-dichloro-8-quinoline carboxylic acid.

4. *Cumulative exposure to substances with 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 3,7-dichloro-8-quinoline carboxylic acid 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, 3,7-dichloro-8-quinoline carboxylic acid 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 3,7-dichloro-8-quinoline carboxylic acid has a common mechanism of toxicity with other substances. For more 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. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute risk.* Using the conservative TMRC exposure assumptions already described, and taking into account the completeness and reliability of the toxicity data, EPA has calculated that the high end exposure to 3,7-dichloro-8-quinoline carboxylic acid residues in food will utilize 13% of the acute RfD for females 13+ years of age/nursing, the most highly exposed subpopulation of the females 13+ subgroup, which is the only subgroup of concern for acute dietary risk. The DWLOC was back-calculated as described previously, and residues of 3,7-dichloro-8-quinoline carboxylic acid which may be present in drinking water are far below the DWLOC for females 13+ years of age/nursing. Thus, EPA does not expect the acute aggregate exposure (food plus water) to exceed 100% of the acute RfD. EPA generally has no concern for acute exposures below 100% of the acute RfD, when the FQPA safety factor has been removed, as is the case here. Based on all these considerations, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. adult population from acute aggregate exposure to 3,7-dichloro-8-quinoline carboxylic acid residues.

2. *Chronic risk.* Using the conservative TMRC exposure assumptions already described, and taking into account the completeness and reliability of the toxicity data, EPA has calculated that dietary exposure to 3,7-dichloro-8-quinoline carboxylic acid residues in food will utilize 17% of the chronic RfD for non-hispanic others which, for 3,7-dichloro-8-quinoline carboxylic acid, is the most highly chronically exposed subgroup of the U.S. adult population. DWLOCs were back-calculated as described previously, and residues of 3,7-dichloro-8-quinoline carboxylic acid which may be present in drinking water are far below the DWLOCs for U.S. adult populations, including non-hispanic others. Thus, EPA does not expect the chronic aggregate exposure (food plus water) to exceed 100% of the chronic RfD. EPA

generally has no concern for chronic exposures below 100% of the chronic RfD (when the FQPA safety factor has been removed, as is the case here) because the chronic RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Under current EPA guidelines, non-dietary uses of 3,7-dichloro-8-quinoline carboxylic acid do not constitute a chronic exposure scenario, and thus are not a factor in chronic aggregate risk. Based on all these considerations, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. adult population from chronic aggregate exposure to 3,7-dichloro-8-quinoline carboxylic acid residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposures take into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses that may result in non-dietary, non-occupational exposure. Such exposure to 3,7-dichloro-8-quinoline carboxylic acid is not expected and endpoints for short- and intermediate-term exposures have not been selected. Thus, short- and/or intermediate-term risk assessments are not required.

4. *Aggregate cancer risk for U.S. population.* After considering an equivocal increase of acinar cell adenomas of the pancreas in male Wistar rats, 3,7-Dichloro-8-quinoline carboxylic acid was classified as a "Group D -- not classifiable as to human carcinogenicity" chemical.

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 3,7-dichloro-8-quinoline carboxylic acid 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 3,7-dichloro-8-quinoline carboxylic acid, EPA considered data from developmental toxicity studies in the rat and rabbit 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.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor. In the case of 3,7-dichloro-8-quinoline carboxylic acid, for purposes of these section 18 exemption uses, the FQPA 10X safety factor to protect infants and children in cases of enhanced susceptibility was removed for the following reasons: (a) the toxicology data base is complete; (b) there is no evidence of susceptibility in rat or rabbit developmental studies, or in the rat 2-generation reproduction study; (c) in the standard toxicity tests there is no indication of neurotoxicity that would warrant follow-up testing; (d) non-dietary, non-occupational exposures are not expected; and, (e) only limited dietary exposure is expected from these section 18 uses on wheat and grain sorghum. EPA concludes that reliable data support use of a 100-fold margin of exposure/uncertainty factor, for the purposes of these section 18 exemptions, to protect infants and children.

ii. *Developmental toxicity studies— a. Rats.* In a developmental toxicity study, 3,7-dichloro-8-quinoline carboxylic acid 3,7 (96.5% a.i.), was administered to twenty-five female Wistar rats by gavage at dose levels of 0, 24.4, 146, and 438 mg/kg/day from gestational days 6-15, inclusive.

Maternal toxicity, observed at 438 mg/kg/day, was manifested as increased mortality, decreased food consumption (10-15%) and increased water consumption (31-54%) during the dosing and/or gestation period. The maternal LOEL is 438 mg/kg/day. The maternal NOAEL is 146 mg/kg/day.

No developmental toxicity was observed. The LOEL for developmental

toxicity is >436 mg/kg/day. The developmental NOEL is  $\geq$ 436 mg/kg/day.

b. *Rabbits*. In a developmental toxicity study, 3,7-dichloro-8-quinoline carboxylic acid (98.3% a.i.), was administered to fifteen female Himalayan rabbits by gavage at dose levels of 0, 70, 200, or 600 mg/kg/day from gestational days 7-19, inclusive.

Maternal toxicity, observed at 200 mg/kg/day, was manifested as decreased body weight gain (36%) and food consumption (13%) during the dosing period. Additional findings noted at 600 mg/kg/day included increased mortality, water consumption (7% over entire gestation), increased incidence of clinical signs (reduced/no defecation, diarrhea, apathy and poor general state) and discoloration of the kidney. The maternal LOEL is 200 mg/kg/day. The maternal NOEL is 70 mg/kg/day.

Developmental toxicity, observed at 600 mg/kg/day, consisted of increased rate of resorption and post-implantation loss, a decrease in the number of live fetuses, and reduced fetal body weight. The NOEL for developmental toxicity is 200 mg/kg/day.

iii. *Reproductive toxicity study—Rats*. In a 2-generation reproduction study, 3,7-dichloro-8-quinoline carboxylic acid ( $\geq$ 97.3% a.i.) was administered to Wistar rats (24/sex/group) at dietary levels of 0, 1,000, 4,000, or 12,000 ppm (0, 40, 160 or 480 mg/kg/day, respectively).

Evidence of toxicity was observed in the male and female parental rats of both generations at 12,000 ppm (480 mg/kg/day). It consisted of reduced body weight during the pre-mating (both sexes) and lactation period. In addition, increased incidence of interstitial nephritis was noted among females. The LOEL for parental systemic toxicity is 12,000 ppm (480 mg/kg/day) based on decreased body weight during pre-mating and lactation. There were no other systemic effects that could be attributed to treatment, nor was there any indication, at any treatment level, of an effect on the reproductive performance of the adults.

Treatment-related effects were observed in F<sub>1</sub> and F<sub>2</sub> offspring at 12,000 ppm (480 mg/kg/day) which consisted of reduced pup viability, delay in growth and physical development (pinna unfolding, eye opening), and reduction in pup survival. Additionally, decreases in body weights of F<sub>1</sub> and F<sub>2</sub> pups were noted throughout lactation.

Systemic LOEL = 480 mg/kg/day for males and females, based upon decreased body weight during

pre-mating and lactation. Systemic NOEL = 160 mg/kg/day for males and females.

Developmental LOEL = 480 mg/kg/day, based on decreased pup viability, and pup weight, and delay in development (pinna unfolding and eye opening). Developmental NOEL = 160 mg/kg/day.

Reproductive LOEL = >480 mg/kg/day, based on lack of reproductive effects. Reproductive NOEL =  $\geq$ 480 mg/kg/day.

iv. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for 3,7-dichloro-8-quinoline carboxylic acid is complete with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study. For purposes of these section 18 exemption requests, the FQPA 10X safety factor to protect infants and children in cases of enhanced susceptibility was removed, based on reasons given above.

2. *Acute risk*. This risk assessment was not conducted. EPA did not identify an appropriate endpoint which was applicable to infant and children population subgroups.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to 3,7-dichloro-8-quinoline carboxylic acid from food will utilize 34% of the RfD for children (1-6 years), the most highly exposed subpopulation of the infant and children subgroups. DWLOCs were back-calculated as described previously, and residues of 3,7-dichloro-8-quinoline carboxylic acid which may be present in drinking water are well below the DWLOCs for this population subgroup. Thus, EPA does not expect the chronic aggregate exposure (food plus water) to exceed 100% of the chronic RfD. EPA generally has no concern for exposures below 100% of the RfD (when the FQPA safety factor has been removed, as is the case here) because the chronic RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Under current EPA guidelines, non-dietary uses of 3,7-dichloro-8-quinoline carboxylic acid do not constitute a chronic exposure scenario, and thus are not a factor in chronic aggregate risk. Based on all these considerations, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to 3,7-dichloro-8-quinoline carboxylic acid residues.

4. *Short- or intermediate-term risk*. These risk assessments were not conducted. EPA did not identify endpoints for short- and intermediate-term exposures.

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 3,7-dichloro-8-quinoline carboxylic acid residues.

**IV. Other Considerations**

*A. Metabolism In Plants and Animals*

The nature of the residue in/on rice is adequately understood. For purposes of these section 18s only, the nature of the residues in/on wheat and grain sorghum is considered to be adequately understood (by translation from rice). The residue-of-concern is 3,7-dichloro-8-quinoline carboxylic acid. The nature of the residue in animals is adequately understood. The residue-of-concern in animal commodities is 3,7-dichloro-8-quinoline carboxylic acid.

*B. Analytical Enforcement Methodology*

GLC/ECD is available BASF Method A8902, rice; BASF Method 268/1, animal and poultry tissues to enforce the tolerance expression. These methods have both undergone agency method trial validation and were found to be adequate to enforce the tolerances on rice and animal commodities, with a limit of determination of  $\leq$ 0.05 ppm. Recovery data submitted indicate that BASF Method A8902 is also suitable for wheat. The method should also be adequate for grain sorghum for purposes of this use.

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5229).

*C. Magnitude of Residues*

Residues of 3,7-dichloro-8-quinoline carboxylic acid are not expected to exceed the following levels as a result of this proposed section 18 use:

Grain sorghum, forage .....	5 ppm
Grain sorghum, grain .....	4 ppm
Grain sorghum, stover .....	1 ppm
Wheat, forage .....	5 ppm
Wheat, grain .....	4 ppm
Wheat, straw .....	1 ppm

Residues of 3,7-dichloro-8-quinoline carboxylic acid are not expected to exceed the following concentrations in wheat grain processed fractions as a result of this section 18 use:

Wheat, milled fractions .....	40 ppm
Aspirated grain fractions .....	800 ppm

Residues of 3,7-dichloro-8-quinoline carboxylic acid in animal commodities are not expected to exceed the following concentrations as a result of these section 18 uses:

Fat of cattle, goats, hogs, horses, and sheep .....	0.6 ppm
Fat of poultry .....	0.2 ppm
Meat by-products of cattle, goats, hogs, horses, and sheep .....	1.5 ppm

These time-limited tolerances are higher than the existing permanent tolerances (0.05 ppm) for residues (as specified in 40 CFR 180.463). The existing permanent tolerances for 3,7-dichloro-8-quinoline carboxylic acid residues in meat of cattle, goats, hogs, horses, poultry, and sheep (0.05 ppm); meat by-products of poultry (0.1 ppm); milk (0.05 ppm); and eggs (0.05 ppm) are sufficient for these section 18 uses.

#### D. International Residue Limits

There are no Codex or Mexican maximum residue limits (MRLs) established for 3,7-dichloro-8-quinoline carboxylic acid residues on wheat or grain sorghum.

#### E. Rotational Crop Restrictions

Restrictions for 3,7-dichloro-8-quinoline carboxylic acid use on wheat specify a plantback interval of not less than 10 months after application for all crops except flax and lentils, which have a 24-month interval. Similarly, restrictions for use on grain sorghum state a 10-month post-application interval for plantback of all crops except flax, peas, lentils, and sugar beets (24-month interval). Rotational crop tolerances are not needed with these plantback intervals.

#### V. Conclusion

Therefore, the tolerances are established for residues of 3,7-dichloro-8-quinoline carboxylic acid in wheat forage at 5 ppm, grain at 4 ppm, straw at 1 ppm, milled fractions at 40 ppm, aspirated grain fractions at 800 ppm; sorghum, grain at 4 ppm, grain forage at 5 ppm, grain fodder (stover) at 1 ppm; fat of cattle, goats, hogs, horses, and

sheep at 0.6 ppm; fat of poultry at 0.2 ppm; and meat byproducts of cattle, goats, hogs, horses, and sheep at 1.5 part per million (ppm).

#### VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by April 12, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ADDRESSES section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing

will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

#### VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300781] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia

address in ADDRESSES at the beginning of this document.

### VIII. Regulatory Assessment Requirements

#### A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides

the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

#### C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

### IX. 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 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**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects

##### 40 CFR Part 180

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

##### 40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: January 22, 1999.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

1. In part 180:
  - a. The authority citation for part 180 continues to read as follows:
 

**Authority:** 21 U.S.C. 346a and 371.
  - b. Section 180.463 is amended to read as follows:
    - i. By designating the existing text as paragraph (a)(1) and adding a heading to newly designated (a).
    - ii. By adding paragraph (b).
    - ii. By adding and reserving paragraphs (c) and (d) with headings to read as follows:

##### § 180.463 3,7-Dichloro-8-quinoline carboxylic acid; tolerances for residues.

- (a) *General.* (1) \* \* \*
- (b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide 3,7-dichloro-8-quinoline carboxylic acid in connection with use of the pesticide under FIFRA section 18 emergency exemptions granted by EPA.

The tolerances are specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	0.6	5/30/00
Cattle, mbyp	1.5	5/30/00
Goats, fat	0.6	5/30/00
Goats, mbyp	1.5	5/30/00
Hogs, fat	0.6	5/30/00
Hogs, mbyp	1.5	5/30/00
Horses, fat	0.6	5/30/00
Horses, mbyp	1.5	5/30/00
Poultry, fat	0.2	5/30/00
Sheep, fat	0.6	5/30/00
Sheep, mbyp	1.5	5/30/00
Sorghum, grain fodder (stover)	1	5/30/00
Sorghum, grain forage	5	5/30/00
Sorghum, grain, grain	4	5/30/00
Wheat, aspirated grain fractions	800	5/30/00
Wheat, forage	5	5/30/00
Wheat, grain	4	5/30/00
Wheat, milled fractions	40	5/30/00
Wheat, straw	1	5/30/00

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertent residues. [Reserved]

**PART 186—[AMENDED]**

2. In part 186:

a. The authority citation for part 186 continues to read as follows:

**Authority:** 21 U.S.C. 342, 348, and 371.

**§ 186.1860 [Partially Redesignated and Removed]**

b. Section 186.1860 is amended as follows:

i. By transferring the text of § 186.1860 to § 180.463, and redesignating it as paragraph (a)(2).

ii. By removing the remainder of § 186.1860.

[FR Doc. 99-3247 Filed 2-9-99; 8:45 am]

**BILLING CODE 6560-50-F**

**GENERAL SERVICES ADMINISTRATION**

**41 CFR Chapter 301**

[FTR Amendment 77—1998 Edition]

**RIN 3090-AG90**

**Federal Travel Regulation; Maximum Per Diem Rates**

**AGENCY:** Office of Governmentwide Policy, GSA.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Federal Travel Regulation (FTR) to make certain changes to the maximum per diem rates published elsewhere in this issue of the **Federal Register**. This rule adds Great Neck as a new per diem locality in New York and increases the maximum lodging amount in Fort Worth, Texas.

The General Services Administration (GSA), after an analysis of additional data, has determined that current lodging allowances for Great Neck (that part of Nassau County defined as the North Shore (up to and including Great Neck to the West and Oyster Bay to the East)), New York, and for Fort Worth (City limits of Fort Worth), Texas, do not adequately reflect the cost of lodging in those areas. To provide adequate per diem reimbursement for Federal employee travel to Great Neck, New York, the maximum lodging allowance is \$190 and the meals and incidental expenses (M&IE) rate is \$42, resulting in a maximum per diem rate of \$232. The maximum lodging allowance for the City of Fort Worth, Texas, is changed to \$94 and the M&IE rate remains at \$38, resulting in a maximum per diem rate of \$132.

**DATES:** This final rule is effective retroactive to January 1, 1999, and applies for travel performed on or after January 1, 1999.

**FOR FURTHER INFORMATION CONTACT:** Jim Harte, General Services Administration, telephone 202-501-1538.

**SUPPLEMENTARY INFORMATION:**

**A. Executive Order 12866**

GSA has determined that this final rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993.

**B. Regulatory Flexibility Act**

This final rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act does not apply.

**C. Paperwork Reduction Act**

The Paperwork Reduction Act does not apply because the final rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 501 *et seq.*

**D. Small Business Regulatory Reform Act**

This final rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

**List of Subjects in 41 CFR Chapter 301**

Government employees, Travel and transportation expenses.

For the reasons set forth in the preamble, under 5 U.S.C. 5701-5709, 41 CFR chapter 301 is amended as follows:

**CHAPTER 301—TEMPORARY DUTY (TDY) TRAVEL ALLOWANCES**

Appendix A to chapter 301 is amended by revising, under the State of New York, the entry for Great Neck, and by removing, under the State of Texas, the corresponding lodging, M&IE, and maximum per diem rates for Fort Worth and inserting in their places the following:

**APPENDIX A TO CHAPTER 301.—PRESCRIBED MAXIMUM PER DIEM RATES FOR CONUS**

Key City	Per diem locality, county and/or other defined location	Maximum lodging amount (includes applicable taxes)	+	M&IE rate	=	Maximum per diem rate
		(a)		(b)		(c)
*	*	*	*	*	*	*
NEW YORK						
*	*	*	*	*	*	*
Great Neck	That part of Nassau County defined as the North Shore (up to and including Great Neck to the West and Oyster Bay to the East).	190		42		232