number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. 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 the rule in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

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 May 26, 1999. 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 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the **Federal Register** on July 1, 1982.

Dated: February 23, 1999.

Felicia Marcus,

Regional Administrator, Region IX.

Part 52, Chapter I, Title of 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(254)(i)(C) and (c)(254)(i)(D) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(254) * * *

(i) * * *

(C) Santa Barbara County Air Pollution Control District.

(*1*) Rule 102 amended on April 17, 1998.

(D) South Coast Air Quality Management District.

(*1*) Rule 102 amended on June 13, 1997.

* * * * *

[FR Doc. 99–7422 Filed 3–25–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300820; FRL–6069–5]

RIN 2070–AB78

Quinclorac; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of quinclorac, 3,7-dichloro-8-quinoline carboxylic acid in or on wheat and sorghum. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 26, 1999. Objections and requests for hearings must be received by EPA on or before May 26, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300820], 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–300820], 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 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of 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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300820]. No Confidential Business

Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, 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, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703 305–6224, miller.joanne @epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 2, 1998 (63 FR 66535) (FRL–6043–2), 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) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) 7F4870 for a tolerance by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709–3528. This notice included a summary of the petition prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.463 be amended by establishing tolerances for residues of the herbicide quinclorac 3,7-dichloro-8-quinoline carboxylic acid, in or on the raw agricultural commodities wheat and sorghum as follows: 0.5 part per million (ppm) (wheat grain), 0.1 ppm (wheat straw), 1.0 ppm (wheat forage), 0.5 ppm (wheat hay), 0.75 ppm (wheat germ), 6.0 ppm (sorghum, grain, grain), 3.0 ppm (sorghum, grain, forage), 1.0 ppm (sorghum, grain, stover) and 1,200 ppm (aspirated grain fractions). Based on the estimated dietary burden from the established tolerances and the proposed uses in this petition the following revised tolerances are also established: fat of cattle, goats, hogs, horses and sheep at 0.7 ppm and the meat byproducts of cattle, goats, hogs, horses and sheep at 1.5 ppm.

I. Background and Statutory Findings

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

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

II. 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 quinclorac and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of 3,7-dichloro-8-quinoline carboxylic acid on the raw agricultural commodities wheat and sorghum as follows: 0.5 ppm (wheat grain), 0.1 ppm (wheat straw), 1.0 ppm (wheat forage), 0.5 ppm (wheat hay), 0.75 ppm (wheat germ), 6.0 ppm (sorghum, grain, grain), 3.0 ppm (sorghum, grain, forage), 1.0 ppm (sorghum, grain, stover) and 1,200 ppm (aspirated grain fractions). Based on the estimated dietary burden from the established tolerances and the proposed uses in this petition the following revised tolerances are also established: fat of cattle, goats, hogs, horses and sheep at 0.7 ppm and the 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 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 quinclorac are discussed in this unit.

1. Acute toxicology studies place technical-grade quinclorac in Toxicity Category III for all routes of exposure. It is a dermal sensitizer.

2. A 21–day dermal toxicity study in NZ White rabbits was conducted at doses of 0, 200 or 1,000 milligrams/kilograms/day (mg/kg/day). No dermal or systemic toxicity was seen following 21 daily dermal applications of quinclorac at doses of 0, 200, or 1,000 mg/kg/day. The no observed adverse effect level (NOAEL) is greater than 1,000 mg/kg/day.

3. A 13–week feeding study in mice was conducted at doses of 0, 4,000, 8,000, or 16,000 ppm; equivalent to 0, 1,000, 2,202 or 4,555 mg/kg/day for males and 0, 1,467, 2,735 or 5,953 mg/kg/day for females. The lowest observed adverse effect level (LOAEL) is 1,000 mg/kg/day for males and 1,467 mg/kg/day for females based on decreased body weight gains in males and females (17.6 and 18.7%, respectively).

4. A 13–week feeding study in mice was conducted at doses of 0 or 500 ppm (equivalent to 0 or 75 mg/kg/ day). The NOAEL is 75 mg/kg/day.

5. A 3–month feeding study in rats was conducted at doses of 0, 1,000, 4,000, or 12,000 ppm (0, 76.8, 302.3 or 929.9 mg/kg/day in males and 0, 86.7, 358, or 1,035.4 mg/kg/day in females). The NOAEL is 302 mg/kg/day(male); 358 mg/kg/day (female). The LOAEL is 930 mg/kg/day (male); 1035 mg/kg/day (female), based on decreased body weight gain, food consumption, and increased water intake in males and females, increased SGOT, SGPT and focal chronic interstitial nephritis in males.

6. A 1–year feeding study in dogs was conducted at doses of 0, 1,000, 4,000, or 12,000 ppm (0, 34, 142, or 513 mg/kg/day in males and 0, 35, 140, or 469 mg/kg/day in females). The NOAEL is 142 mg/kg/day (male); 140 mg/kg/day (female). The LOAEL is 513 mg/kg/day (male); 469 mg/kg/day (female), based on reduced body weight gain, increased liver and kidney weights, reduced food efficiency, reduced HgB, RBC, MCH, and MCV, and kidney degeneration.

7. A 2–year chronic/carcinogenicity study in rats at doses of 0, 1,000, 4,000, 8,000 or 12,000 ppm (0, 56, 186, 385, or 487 mg/kg/day in males and 0, 60, 235, 478, or 757 mg/kg/day in females). The NOAEL is 385 mg/kg/day (male); 478 mg/kg/day (female). The LOAEL is 487 mg/kg/day (male); 757 mg/kg/day (female), based on decreased body weight in females and increased incidence of pancreatic acinar cell hyperplasia in males.

8. An 18–month carcinogenicity study in mice was conducted at doses of 0, 250, 1,000, 4,000, or 8,000 ppm (0, 37.5, 150, 600, or 1200 mg/kg/day). The NOAEL is 37.5 mg/kg/day and the LOAEL is 150 mg/kg/day based on decreased body weight in both sexes.

9. A developmental toxicity study in rats was conducted at gavage doses of 0, 24.4, 146, or 438 mg/kg/day during gestation. The maternal toxicity NOAEL is 146 mg/kg/day. The maternal toxicity LOAEL is 438 mg/kg/day, based on increased mortality, decreased food consumption, and increased water consumption. The developmental toxicity NOAEL is equal to or greater than 438 mg/kg/day.

10. A developmental toxicity study in rabbits was conducted at gavage doses of 0, 70, 200, or 600 mg/kg/day during gestation. The maternal toxicity NOAEL is 70 mg/kg/day. The maternal toxicity LOAEL is 200 mg/kg/day, based on decreased body weight gains and food consumption. The developmental toxicity NOAEL is 200 mg/kg/day. The developmental toxicity LOAEL is 600 mg/kg/day, based on increased resorption rate, post-implantation loss, decreased number of live fetuses, and reduced fetal body weight.

11. A 2–generation reproduction study in rats was conducted at dietary levels of 0, 1,000, 4,000, or 12,000 ppm (0, 50, 200, 600 mg/kg/day). The parental toxicity NOAEL is 200 mg/kg/day. The parental toxicity LOAEL is 600 mg/kg/day, based on reduced body weight in both sexes during premating and lactating periods. The reproductive toxicity NOAEL is equal to or greater than 600 mg/kg/day. The developmental toxicity NOAEL is 200 mg/kg/day. The developmental toxicity LOAEL is 600 mg/kg/day, based on decreased pup weight and viability, and developmental delays.

12. A metabolism (biodisposition) study in rats was conducted at single oral doses of 15 or 600 mg/kg; and multiple doses of unlabeled quinclorac for 14 days followed by ^{14}C quinclorac. Quinclorac was rapidly absorbed and eliminated in the urine. Urinary elimination accounted for 91 to 98% of the dose, with 1 to 4% in the feces. None was demonstrated in the expired air.

13. Biliary excretion studies in rats were conducted at single oral doses of 15 or 600 mg/kg. Biliary excretion was significant (11.5 to 14.5% of the dose) in 600 mg/kg treated rats but was reabsorbed from the intestine and eliminated in the urine.

14. A plasma level study was conducted at single oral doses of 15, 100, 600, or 1,200 mg/kg; and a multiple dosing study at 15 and 600 mg/kg/day for 7 days. Mean ^{14}C residues were detected in plasma 30 minutes after dosing in single dose animals at 15, 100, and 600 mg/kg or 15 mg/kg/day for 7 days. Most of this radioactivity was the parent compound. Peak plasma levels of radioactivity in animals receiving 1,200 mg/kg and 600 mg/kg/day for 7 days were noted at 7 to 48 hours post-dosing.

15. Tissue level studies were conducted at daily oral doses of 15 mg/kg or 1,200 mg/kg for 7 days. In both studies, the highest concentration of radioactivity in tissues was found 30 minutes after administration of the final dose.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, an acute Reference Dose (RfD) of 2.0 mg/kg/day has been selected, based on the developmental NOAEL of 200 mg/kg/day, from the rabbit developmental toxicity study and an uncertainty factor of 100 (10X for inter-species differences and 10X for intra-species variability). The endpoint is based on increased incidence of fetal resorptions, decrease in the number of live fetuses, and reduced fetal body weight at the LOAEL of 600 mg/kg/day. The population subgroup at risk is females of child-bearing age (13+years). 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.* Short and intermediate-term toxicity endpoints are not established since no dermal or systemic toxicity was observed in a 21–day dermal toxicity study in New Zealand White rabbits.

3. *Chronic toxicity*. EPA has established the chronic RfD for quinclorac at 0.4 mg/kg/day. This RfD is based on decreased body weights in male and female mice observed in the mouse carcinogenicity study with a NOAEL of 37.5 mg/kg/day.

4. *Carcinogenicity*. After considering an equivocal increase of acinar cell adenomas of the pancreas in male Wistar rats, quinclorac is 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 a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from quinclorac 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 quinclorac. The analysis was conducted using the acute RfD of 2.0 mg/kg/day, based on increased incidence of fetal resorptions and post-implantation loss, decreased number of live fetuses and reduced fetal body weight observed in the rabbit developmental toxicity study. For the population subgroup of concern, females 13 years and older, the estimated 95th percentile of exposure occupies 0.4% of the acute RfD. The analysis is conservative since it assumes that 100% of wheat and sorghum - derived foods contain residues at the tolerance levels (0.5 and 6.0 ppm, respectively); tolerance level residues on all commodities with established quinclorac tolerances; and, 100% crop-treated.

ii. *Chronic exposure and risk.* A chronic dietary risk assessment was performed for quinclorac. The analysis used the chronic RfD of 0.4 mg/kg/day and assumed that 100% of wheat and sorghum - derived foods contain residues at tolerance levels (0.5 and 6.0 ppm, respectively); tolerance level residues on all commodities with established quinclorac tolerances; and, 100% crop-treated. Based on these assumptions, no more than 2% of the chronic RfD was occupied by any population subgroup.

2. *From drinking water.* No Maximum Contaminant Level or health advisory levels have been established for residues of quinclorac in drinking water. EPA used its SCI-GROW (Screening Concentration in Ground Water) screening model and environmental fate data to determine the estimated environmental concentration (EEC) for quinclorac in ground water. The GENEEC (Generic Estimated Environmental Concentration) screening model and environmental fate data were used to determine the EECs for quinclorac in surface water. EECs in ground water reflecting the maximum yearly application rate of 0.75 pounds of active ingredient per acre were 21 parts per billion (ppb;ug/L). EECs in surface water were 40 ppb for acute exposure scenarios and 38 ppb for chronic exposure scenarios. The computer generated EECs represent conservative estimates and should be used only for screening.

i. *Acute exposure and risk.* EPA has calculated a drinking water level of comparison (DWLOC) for acute

exposure to quinclorac in drinking water for the relevant population subgroup, females 13+ years of age. The DWLOC is 60,000 ug/L.

To calculate the DWLOCs for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure from the DEEM (Dietary Exposure Evaluation Model) analysis was subtracted from the ratio of the acute RfD to obtain the acceptable acute exposure to quinclorac in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

For purposes of risk assessment, EPA used 40 ppb as the estimated maximum concentration of quinclorac in drinking water. The estimated maximum concentrations in water are less than EPA's level of concern (60,000 ppb) for quinclorac residues in drinking water as a contribution to acute aggregate exposure. Therefore, taking into account the use proposed in this action, EPA concludes with reasonable certainty that residues of quinclorac in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

ii. *Chronic exposure and risk*. EPA has calculated drinking water levels of comparsion (DWLOCs) for chronic exposure to quinclorac in drinking water. For chronic (non-cancer) exposure to quinclorac in drinking water, the drinking water levels of comparison are 14,000 ug/L and 3,900 ug/L for the U.S. population and the subgroup children (1–6 years old), respectively.

To calculate the DWLOCs for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from the DEEM analysis) was A subtracted from the chronic RfD to obtain the acceptable chronic (non-cancer) exposure to quinclorac in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

The estimated average concentration of quinclorac in drinking water is 38 ppb. The DWLOCs are 14,000 ppb for the U.S. population and 3,900 ppb for the subgroup, children (1–6 years old). The estimated average concentration of quinclorac in drinking water is less than EPA's level of concern for quinclorac in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account the use proposed in this action, EPA concludes with reasonable certainty that residues of quinclorac in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

3. *From non-dietary exposure.* Quinclorac is currently registered for use on the following residential non-food sites: residential lawns. The residential use on lawns poses the potential for dermal exposure for both children and adults and for oral exposure (incidental and/or hand-to-mouth ingestion) for children. However, since there was no observed dermal or systemic toxicity in a rabbit 21–day dermal study with quinclorac, short-, intermediate- or long-term dermal or inhalation endpoints are not being established. An acute dietary endpoint (applicable to the general population, including infants and children) is not being established since there was no observed toxicity in the database, from a single exposure. Thus, residential exposure risk assessments were not conducted.

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 quinclorac 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, quinclorac 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 quinclorac has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. For the population subgroup of concern, females 13+ years old, the acute dietary (food) exposure does not exceed 0.4% of the acute RfD. The drinking water level of comparison (DWLOC) for acute exposure to quinclorac residues is 60,000 ug/L for females (13+ years). The maximum estimated environmental concentration (EEC) of quinclorac in drinking water (40 ug/L) is less than EPA's level of concern for quinclorac in drinking water as a contribution to acute aggregate exposure. EPA concludes with reasonable certainty that residues of quinclorac in drinking water will not contribute significantly to the aggregate acute human health risk and that the acute aggregate exposure from quinclorac in food and water will not exceed the Agency's level of concern for acute dietary exposure.

2. *Chronic risk*. Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to quinclorac from food will utilize no more than 1% of the RfD for the U.S. adult population. The major identifiable subgroup with the highest aggregate exposure, infants or children is ''discussed below''. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to quinclorac in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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. The residential use on lawns poses the potential for dermal exposure for both children and adults and for oral exposure (incidental and/or hand-to-mouth ingestion) for children. However, risk assessments were not required for short- and intermediate-term aggregate exposures due to a lack of observed toxicity in the quinclorac database.

4. *Aggregate cancer risk for U.S. population*. Quinclorac is 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 to the adult U.S. population from aggregate exposure to quinclorac 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 quinclorac, 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 pre-and post-natal effects from exposure to the pesticide, information 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 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.

ii. *Pre- and post-natal sensitivity.* 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.

iii. *Conclusion*. There is a complete toxicity database for quinclorac and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Taking into account the completeness of the data base and the toxicity data regarding pre-and post-natal sensitivity, EPA concludes, based on reliable data, that use of the standard margin of safety will be safe for infants and children without addition of another tenfold factor.

2. *Acute risk.* Fetuses are addressed by examining exposure to the mother and those exposures are acceptable.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to quinclorac from food will utilize no more than 2% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to quinclorac in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *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 quinclorac residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants (sorghum grain, wheat, rice), ruminants, and poultry is adequately understood. The residue of concern is quinclorac per se.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas liquid chromotography with an electron capture detector) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

Residues of quinclorac 3,7-dichloro-8-quinoline carboxylic acid are not expected to exceed the following tolerances on the raw agricultural commodities wheat and sorghum as follows: 0.5 ppm (wheat grain), 0.1 ppm (wheat straw), 1.0 ppm (wheat forage), 0.5 ppm (wheat hay), 0.75 ppm (wheat germ), 6.0 ppm (sorghum, grain, grain), 3.0 ppm (sorghum, grain, forage), 1.0 ppm (sorghum, grain, stover) and 1200 ppm (aspirated grain fractions). Based on the estimated dietary burden from the established tolerances and the proposed uses in this petition the following revised tolerances are also established fat of cattle, goats, hogs, horses and sheep at 0.7 ppm and the meat byproducts of cattle, goats, hogs, horses and sheep at 1.5 ppm.

D. International Residue Limits

There are no Codex or Mexican maximum residue limits (MRLs) established for quinclorac residues on wheat or sorghum grain. Canada has an established MRL of 0.5 ppm for residues of quinclorac on ''wheat''. The tolerance BASF is proposing on wheat grain is in harmony with this MRL.

E. Rotational Crop Restrictions

The label restrictions are: Do not plant any crop other than wheat or sorghum grain for 309 days (10 months) following application. For flax, peas, lentils, and sugar beets, do not replant for 24 months.

IV. Conclusion

Therefore, the tolerances are established for residues of 3,7-dichloro-8-quinoline carboxylic acid in the raw agricultural commodities wheat and sorghum as follows: 0.5 ppm (wheat grain), 0.1 ppm (wheat straw), 1.0 ppm (wheat forage), 0.5 ppm (wheat hay), 0.75 ppm (wheat germ), 6.0 ppm (sorghum, grain, grain), 3.0 ppm (sorghum, grain, forage), 1.0 ppm (sorghum, grain, stover) and 1200 ppm (aspirated grain fractions). Based on the estimated dietary burden from the established uses in this petition the following revised tolerances are also established fat of cattle, goats, hogs, horses and sheep at 0.7 ppm and the meat byproducts of cattle, goats, hogs, horses and sheep at 1.5 ppm.

V. 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 May 26, 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 regulation. 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, CM #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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300820] (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 Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #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.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 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(d), such as the tolerance/exemption 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.

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 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: March 15, 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. 321(q), 346a and 371.

2. Section 180.463 is amended as follows:

a. By revising the section title to read as set forth below:

b. By alphabetically adding the entries aspirated grain fractions; sorghum, grain, forage; sorghum, grain, grain; sorghum, grain, stover; wheat forage; wheat germ; wheat grain; wheat hay; and wheat straw to the table in paragraph (a)(1) and;

c. By revising the entries for cattle, fat; cattle, mbyp; goats, fat; goats, mbyp; hogs, fat; hogs, mbyp; horses, fat; horses, mbyp; and sheep, fat; and sheep, mbyp to the table in paragraph (a)(1) as set forth below:

§ 180.463 Quinclorac; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of quinclorac (3,7-dichloro-8-quinoline carboxylic acid) in or the following food commodities:

Commodity	Parts per million
Aspirated grain fractions	1200
* * * * *	
Cattle, fat	0.7
Cattle, mbyp	1.5
* * * * *	
Goats, fat	0.7
Goats, mbyp	1.5
* * * * *	
Hogs, fat	0.7
Hogs, mbyp	1.5
* * * * *	
Horses, fat	0.7
Horses, mbyp	1.5
* * * * *	
Sheep, fat	0.7
Sheep, mbyp	1.5
* * * * *	
Sorghum, grain, forage	3.0
Sorghum, grain, grain	6.0
Sorghum, grain, stover	1.0
Wheat forage	1.0
Wheat germ	0.75
Wheat grain	0.5
Wheat hay	0.5
Wheat straw	0.1

* * * * *

[FR Doc. 99–7435 Filed 3–25–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300822; FRL–6069–7]

RIN 2070–AB78

Arsanilic acid [(4-aminophenyl) arsonic acid]; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of arsanilic acid [(4-aminophenyl) arsonic acid] in or on grapefruit. Fleming Laboratories, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire on February 28, 2001.

DATES: This regulation is effective March 26, 1999. Objections and requests for hearings must be received by EPA on or before May 26, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300822], 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–300822], 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 (CM #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