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]

BILLING CODE 6560–50–F

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

ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300822]. 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: Cynthia Giles-Parker, Product Manager 22, 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. 249, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703 305–7740, giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 28, 1998 (63 FR 40273) (FRL–5799–3), 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 4G4276) for tolerance in connection with an Experimental Use Permit (EUP) for (4-aminophenyl) arsonic acid by Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234. This notice included a summary of the petition prepared by Fleming Laboratories, Inc., the registrant. There were comments received from two citrus growers supporting the approval of the EUP in order to further develop and test (4-aminophenyl) arsonic acid. Both growers are directors of consulting companies.

The petition requested that 40 CFR part 180 be amended by establishing a time-limited tolerance for residues of the plant growth regulator used as a ripening enhancement agent arsanilic acid [(4-aminophenyl) arsonic acid], in or on grapefruit at 0.5 part per million (ppm). The temporary tolerance on grapefruit is requested for fruit resulting from the experimental use of arsanilic acid to evaluate enhancement of ripening. The chemical will be tested on 50 acres of grapefruit in the state of Florida for a period of 2 years. This tolerance will expire on February 28, 2001.

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 arsanilic acid [(4-aminophenyl) arsonic acid] and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of (4-aminophenyl) arsonic acid in/on grapefruit at 2.0 ppm (not to exceed 0.7 ppm total arsenic). 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 arsanilic acid are discussed in this unit.

1. *Acute oral toxicity study*. Groups of Sprague-Dawley rats (5/sex) were given a single oral administration of arsanilic acid at doses of 500 (females), 750, 1,000, 1,250, or 1,500 milligrams/kilogram (mg/kg) (males). Clinical signs consisted of: piloerection, hypoactivity, soiled coat, hunched appearance, labored breathing, diarrhea, ataxia, subdued behavior, stained perigenital area, emaciation, and red nasal discharge. Oral LD_{50} results were as follows:

LD_{50} = 1,411 mg/kg (males)
LD_{50} = 976 mg/kg (females)
LD_{50} = 1,461 mg/kg (combined)

2. *Acute dermal toxicity study*. Groups of New Zealand White rabbits (5/sex/dose) were given a single dermal application of arsanilic acid at doses of 500, 1,000, or 2,000 mg/kg (Limit-Dose). Clinical signs of toxicity observed at all dose levels included: ataxia, diarrhea, dark urine, decreased defecation, convulsions, tremors, hindlimb paralysis, hyper salivation, vocalization, red eyes, piloerection, labored breathing, weight loss, hunched posture, and low food consumption primarily 2–8 days post-dosing. Dermal LD_{50} results were as follows:

LD_{50} = 922 mg/kg (males)
LD_{50} = 909 mg/kg (females)
LD_{50} = 921 mg/kg (combined)

3. *Acute inhalation toxicity study*. Groups of Sprague-Dawley rats (5/sex) were exposed to aerosol concentrations of arsanilic acid 99.5% at a maximum attainable analytical concentration of 5.3 mg/L for four hours. Rats exhibited respiratory depression, subdued appearance, and piloerection during exposure. Inhalation LC_{50} results were as follows:

LC_{50} > 5.3 mg/L (both sexes).

4. *Primary eye irritation study*. Arsanilic acid was instilled into the conjuctival sac of male New Zealand White rabbits. The results of this study indicate that arsanilic acid is a slight ocular irritant to rabbit.

5. *Primary dermal irritation study*. New Zealand White rabbits (6 males) were exposed to arsanilic acid on the intact skin for 4 hours. No erythema or edema was observed in any of the test animals. The primary Irritation Index is 0.0. The results of this study indicate that arsanilic acid is a non-irritant to the skin of rabbits.

6. *Dermal sensitization study*. The dermal sensitization potential of arsanilic acid was evaluated in 20 male Hartley guinea pigs receiving dermal applications of 0.5 mL of the test material at concentrations of 25%, 10%, 5%, or 2% w/v on three consecutive days for three weeks (Induction Phase), followed by a 25% w/v application to the original and virgin skin site four weeks later (Challenge Phase). None of the treated animals exhibited any irritation when challenged; the average skin reaction score for the virgin site was 0.0. Under the conditions of this

study, arsanilic acid 99.5% was not shown to be a sensitizer in guinea pigs.

7. *Developmental toxicity battery* —i. *Rat study*. Pregnant Crl:CD rats (25/dose) were administered arsanilic acid via oral gavage at dose levels of 0, 10, 30, or 60 mg/kg/day during gestation days 6–15. The test material in the powder form was mixed with Mazola corn oil for administration to the test animals. Maternal toxicity was observed at the highest dose tested (60 mg/kg/day) in the form of soft stool, decreased defecation, mucoid feces and/or mucoid diarrhea, alopecia on the abdomen or thorax, and red material around the nose. At the 30 mg/kg/day doses, alopecia on the hindlimbs and abdomen was seen at an increased frequency when compared to controls. Mean body weights were significantly decreased at 60 mg/kg/day on gestation days 8, 9, and 1–14, with a loss in mean body weight gain seen during gestation days 6–9. At 30 mg/kg/day, mean body weights were significantly decreased on gestation days 7, 8, 12, 13, and 15; mean body weight gain was significantly decreased during days 6–16. At 60 mg/kg/day, a significant decrease in food consumption was noted throughout the treatment period followed by a significant recovery during the post-treatment period. In the 10 and 30 mg/kg/day dose groups, significant decreases in food consumption were noted throughout the treatment period when compared to controls. Arsanilic acid did not induce developmental toxicity at any of the doses tested. Based on these results, the following is concluded:

Maternal No observable adverse effect level (NOAEL) = 6 mg/kg/day

Maternal Lowest observable adverse effect level (LOAEL) = 30 mg/kg/day (based on decreased body weight gain and food consumption, and clinical signs)

Developmental NOAEL = 60 mg/kg/day Highest dose tested (HDT)

ii. *Rabbit study*. Arsanilic acid in carboxymethyl cellulose was administered by gavage to 20 New Zealand White female rabbits/dose at dose levels of 0, 1, 3, or 6 mg/kg/day from days 7 through 19 of gestation. Maternal clinical toxicity included slightly increased clinical signs (diarrhea, discolored feces, decreased defecation), decreased bodyweight gains, and decreased food consumption in the high-dose group. No treatment-related differences in clinical signs, bodyweight gain, or food consumption were observed in the mid- and low-dose groups. The numbers of corpora, total implantations, and viable fetuses were decreased in a dose-dependent fashion compared to concurrent controls, but were within historical control ranges. Pre-implantation losses were increased in a dose-dependent fashion; however, the standard deviations were large and historical control data were not provided. The extent of resorptions, post-implantation losses, and mean fetal weights were similar between control and treated groups. Although the observed maternal toxicity was marginal, the dose levels used in this developmental study were adequate. In a range finding study in which rabbits were dosed with arsanilic acid at 5–80 mg/kg/day from days 7–19 of gestation, all animals in the 20, 40 and 80 mg/kg/day groups and three animals in the 10 mg/kg/day group died, were euthanized, or aborted prior to the scheduled necropsy. Clinical signs, and differences in bodyweight gains and food consumption were detected in the 5 and 10 mg/kg/day groups. Based on these results, the following is concluded:

Maternal NOAEL = 3 mg/kg/day

Maternal LOAEL = 6 mg/kg/day (Based on clinical signs, decreased body weight gain, and decreased food consumption)

Developmental NOAEL ≥6 mg/kg/day (HDT)

8. *Mutagenicity battery* — i. *Ames study*. In two independently performed *Salmonella typhimurium*/mammalian microsome plate incorporation assays, strains TA1535, TA1537, TA98, and TA100 were exposed to 33, 100, 333, 1,000, 3,333, or 10,000 µg/plate arsanilic acid with or without S9 activation. The S9 fraction was prepared from Arochlor 1254-induced rat livers and arsanilic acid was delivered to the test system in dimethyl sulfoxide (DMSO). No cytotoxicity or mutagenicity was observed in any strain at any dose either in the presence or absence of S9 activation.

ii. *Mouse lymphoma mutation study*. There were two independently performed mouse lymphoma forward mutation assays. Target cells exposed to arsanilic acid at doses of 112, 225, 450, 900, or 1,800 µg/mL with or without S9 activation were evaluated in the initial assay. Non-activated 600, 900, 1,200, 1,500, or 1,800 µg/L or S9-activated 800, 1050, 1,300, 1,550, or 1,800 µg/mL were assessed in the confirmatory test. S9 activation was derived from Arochlor 1254-induced rat livers and the test material was delivered in DMSO. Arsanilic acid was positive with S-9 activation at 1,800 µg/mL in both independent trials. Under non-activated conditions, a positive response was observed only at high cytotoxicity (4% relative suspension growth) in the initial assay, and the confirmatory assay was negative. Although the mutation assay was repeated several times due to widely varying cytotoxicity data, the results were consistent between the two acceptable assays and could be at least partially explained by a steep cytotoxicity curve. Findings with the positive controls confirmed the sensitivity of the test system to detect mutagenesis. Colony sizing at the high dose indicated that the predominant mutations induced were large chromosome deletions.

iii. *Micronucleus assay study*. In a mouse micronucleus assay, groups of five CD-1 mice/sex/dose received single oral gavage administrations of 0, 100, 200, or 400 mg/kg/day arsanilic acid for three consecutive days. Dosing solutions of the test material were prepared in 0.5% carboxymethyl cellulose. Mortalities, other clinical signs of toxicity (piloerection, hunched appearance, hypothermia, and cyanosis), and target tissue cytotoxicity were observed in the high-dose group. There was, however, no significant increase in the micronucleated polychromatic erythrocytes in bone marrow cells harvested 24 or 48 hours post-treatment with the high dose or 24 hours post-administration of the mid or low doses.

9. *General metabolism study*. The study demonstrated that arsanilic acid is rapidly absorbed, distributed, and excreted following oral administration in pigs and roosters. In four pigs administered 1.9–3.1 mg/kg ^{14}C-arsanilic acid, total 3- or 4-day recovery of the radioactivity was 92.3–97% of the administered dose, with higher recovery in the urine (47.7–65.8% of the administered dose) than in the feces (18.2–42.2% of the administered dose). Data suggested that biliary excretions was a minor elimination route; only 4.7% of the administered dose was recovered in the bile of a pig 3 days after administration of ^{14}C-arsanilic acid, recovery of radioactivity in the excreta (63.4% of administered dose in urine, 26.6% in feces) was similar to that of the pigs; however, biliary excretion was not determined. Tissue distribution and bioaccumulation of arsanilic acid is low in pigs and roosters as indicated by low recoveries of radioactivity in tissues 3 or 4 days after oral administration. The metabolism of arsanilic acid does not appear to be extensive. Unmetabolized parent compound and the metabolite, *N*-acetylarsanilic acid, represented the highest amount of urinary radioactivity in pigs; therefore, the major biotransformation reaction of arsanilic acid in pigs appeared to be *N*-acetylation. Unmetabolized arsanilic acid was the only radioactive

component identified from the urine of roosters. Radioactivity in the feces was not characterized for pigs or roosters.

10. *Subchronic battery (90–day dog) study*. Arsanilic acid was administered to four beagle dogs/sex/dose group at dietary concentrations of 0, 50, 100 or 200 ppm (equivalent to 0, 1.5, 3.2 or 6.9 mg/kg/day in males and 0, 1.7, 3.1 or 6.8 mg/kg/day in females) for 13 weeks. Because a NOAEL was not established in males of this initial phase, an add-on phase was conducted in which arsanilic acid was administered to four males/dose group at dietary concentrations of 0, 10 or 25 ppm (equivalent to 0, 0.3 or 0.7 mg/kg/day). In the initial phase, the kidney was the target organ, based on microscopic kidney alterations in all treated males and all 200 and 100 ppm group females. The incidence and severity of kidney alterations increased with dose. All treated male groups and both 100 and 200 ppm female groups had at least one animal whose kidneys displayed tubule regeneration, tubule dilatation, chronic inflammation, interstitial fibrosis, and papillary necrosis. Kidneys of all 200 ppm group dogs had a granular/pitted/rough appearance, irregular shape, dilated pelvis, pale material, pale area, and/or enlarged size. The severity of the kidney alterations ranged from slight in the 50 ppm group males to almost severe in the 200 ppm group males and females. Renal function was impaired in the 200 ppm male and female treatment groups, based on increased urea nitrogen at Weeks 4, (138–207%), 8 (78–92%), and 13 (78–128%) compared to the control values, and increased creatinine levels (1.0–1.3 mg/dL) compared to the control and the 50 and 100 ppm group dogs (0.7–0.9 mg/dL) at Weeks 4, 8, and 13. Though not statistically significant, all treated male groups had absolute and relative (to body weight) kidney weights around 20% higher than those of the control group. On the other hand, the 200 ppm group males and females were anemic, based on 11–16% decreased mean erythrocyte counts, hemoglobin, and hematocrit relative to the control values at Weeks 8 and 13; the decreases were significant ($p \leq 0.05$) except for erythrocyte counts in males and hemoglobin in females. No treatment-related effects were seen in the 50 ppm group females. In the add-on phase, the 25 and 10 ppm group males were not adversely affected by treatment and there were no treatment-related differences in hematology or clinical chemistry. In both phases, no animals died and there were no treatment-related differences in appearance, behavior, body weights, body weight gains, food consumption, ophthalmology, and absolute or relative remaining organ weights. Based on these results, the following is concluded:

NOAEL = 0.7 mg/kg/day (males)

NOAEL = 1.7 mg/kg/day (females)

LOAEL = 1.5 mg/kg/day (males - based on microscopic kidney alterations)

LOAEL = 3.1 mg/kg/day (females - based microscopic kidney alterations)

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary exposure, a maternal NOAEL of 6 mg/kg/day was selected from a developmental toxicity study in rats. The observed effects at the LOAEL of 30 mg/kg/day were decreased body weight gain and food consumption and clinical signs. Using an uncertainty factor of 100, the acute dietary reference dose (Acute (RfD)) is 0.06 mg/kg/day. The additional 10x FQPA safety factor for infants and children was removed.

2. *Short - and intermediate-term toxicity*. For non-dietary short-term dermal exposure, an endpoint of 6 mg/kg/day was selected. This endpoint was selected based on the developmental toxicity study in rats and it was assumed that dermal absorption was 5%. For non-dietary intermediate-term dermal exposure, an endpoint of 0.7 mg/kg/day was selected. The result was selected based on the 13-week feeding study in dogs and it was assumed that dermal absorption was 5%.

3. *Chronic toxicity*. EPA has established the RfD for arsanilic acid at 0.0007 mg/kg/day. This RfD is based on 13-week dog study that had NOAELs of 0.7 mg/kg/day for males and 1.7 mg/kg/day for females and an uncertainty factor of 1000. The uncertainty factor was calculated based on extrapolation from a subchronic dog study to a chronic scenario. The LOAEL (1.5 mg/kg/day (males)/3.1 mg/kg/day (females)) caused microscopic kidney alterations.

4. *Carcinogenicity*. There is no endpoint. This chemical has not been classified yet.

C. Exposures and Risks

1. *From food and feed uses*. Currently, there are no tolerances established for residues of arsanilic acid in or on any raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from arsanilic acid as follows:

i. *Acute dietary (food only) exposure and risk (Acute RfD = 0.06 mg/kg/day)*. 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.

A Tier 1 acute Dietary Exposure Evaluation Model (DEEM) analysis was performed reflecting the Theoretical Maximum Residue Concentration (TMRC). The DEEM detailed acute analysis estimates of the distribution of single-day exposures for the overall United States (U.S.) population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–91 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of arsanilic acid in the commodity supply.

The acute exposure estimates at the 99.9 percentile and their associated percentage of the acute reference dose (% Acute RfD) for the general U.S. population and those populations within subgroups with the highest exposure were calculated. None of the subgroups exceed 100% of the acute RfD. The exposure estimates were as follows (from highest to lowest): U.S. population (Spring) at 4% with 0.0026 mg/kg/day, children (1–6 years) at 4% with 0.0021 mg/kg/day, males (20+ years) at 4% with 0.0021 mg/kg/day, U.S. population (48 states) at 3% with 0.0019 mg/kg/day, females (13+ years, nursing) at 3% with 0.0020 mg/kg/day and infants with no exposure. Therefore, the risk from acute dietary exposure (food only) does not exceed the level of concern.

ii. *Chronic dietary (food only) exposure and risk (chronic RfD = 0.0007 mg/kg/day)*. The chronic exposure estimates and their associated percentage of the chronic reference dose (% Chronic RfD) for the general U.S. population and those populations within subgroups with the highest exposure were calculated. None of the subgroups exceed 100% of the Chronic RfD. The exposure estimates were as follows (from highest to lowest): U.S. Population (Winter) at 5% with 0.000033 mg/kg/day, seniors (55+ years) at 5% with 0.000035 mg/kg/day, U.S. population (48 states) at 3% with 0.000018 mg/kg/day, females (20+ years, not pregnant, not nursing) at 3% with 0.000024 mg/kg/day, children (7–12 years) at 2% with 0.000012 mg/kg/day, and infants with no exposure. Therefore, the risk from chronic dietary exposure (food only) does not exceed the level of concern.

2. *From drinking water*. Tentative summary data show that arsanilic acid is persistent in soil and water, as evidenced by 1) its stability in water, 2) spectroscopic inference of stability

against photolytic breakdown in water and soil, and 3) aerobic and anaerobic soil ''half-lives'' roughly estimated to be about 600 and 900 days, respectively. All degradates were accounted for, but not identified, as they are, individually, less than 2% of the applied radioactivity. However, as arsanilic acid slowly and inevitably degrades, various arsenic containing moieties may enter the complex, natural, arsenic biogeochemical cycle. In general, chemicals in the cycle include highly toxic inorganic arsenicals and moderately toxic organic arsenicals. These associated chemicals are slowly produced in relatively low concentrations and, except for repeated annual applications, would eventually be converted to near background levels of locally dominant arsenic containing species in the various environmental compartments (soil, water, air).

Although arsanilic acid is highly water soluble (approximately 5,000 ppm), this property is attenuated in the environment by the compound's intermediate sorption to, or reaction with, soil mineral and/or organic constituents (apparent or effective K_{oc} values ranging from approximately 4,000 to 11,000 mL/g; desorption coefficients are significantly higher). With the combination of persistence and intermediate mobility, arsanilic acid has potential for runoff into surface water, with comparable amounts partitioned to runoff water and eroding soil. For exposure to nontarget organisms, surface water screening level concentrations based on GENEEC model are 22 and 37 ppb for acute (instantaneous) effects and 8.3 and 14 ppb for chronic (56–day value) effects for use on pink/red and white grapefruit varieties, respectively.

In most areas of the U.S., leaching of arsanilic acid to groundwater is not expected to be significant. However, in the proposed growing areas of Florida, groundwater contamination could be problematic if application of this compound becomes widespread. Sandy soils, shallow depth to groundwater, Karst strata and groundwater-surface water interaction zones present a special situation for which SCI-GROW, the current groundwater screening model, is not well-suited and may be not be sufficiently conservative. The groundwater concentration estimated from SCI-GROW is 0.080 ppb for pink/red and 0.13 ppb for white grapefruit varieties. USGS NAWQA monitoring data for Dade County, Florida, reveal concentrations of total arsenic in shallow groundwater over 1,000 times the maximum contaminant level (MCL) of 50 ppb, far above the SCI-GROW prediction. The extent and possible sources and reasons for this contamination are under investigation at this time. Arsenicals such as MSMA and cacodylic acid are among possible sources.

The water solubility (polarity) of arsanilic acid would indicate little tendency for bioconcentration. The reported sorption to soil, which serves as a measure of potential bioconcentration for many compounds, indicates that some bioconcentration may occur. With this indication, and because of arsanilic acid's persistence and potential for toxic concentrations in south Florida water bodies and sediment, the Agency has recommended that additional bioconcentration studies using oysters as the test organism be conducted. This study is needed to show whether arsanilic acid is likely to concentrate in shellfish, snails, etc., at levels which would pose dietary risks to aquatic wildlife, including habituating birds and mammals.

3. *From non-dietary exposure.* Arsanilic acid is not registered for use on residential non-food sites.

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.'

Arsanilic acid is a member of the of the arsonic acid group of arsenical herbicides (Ware, G.W. 1994. The Pesticide Book, 4th edition). EPA does not have, at this time, available data to determine whether the arsonic acid group 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, the arsonic acid group 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 arsanilic acid 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. Population

1. *Acute risk (food + water).* The acute risk for ''food only'' does not exceed the level of concern. The lowest acute drinking water level of comparison (DWLOC) was for the infants/children subgroup at 580 µg/L. The maximum surface water screening level concentration for acute effects is 37 µg/L. Therefore, acute exposure to residues of arsanilic acid should not exceed the level of concern.

2. *Chronic risk (food + water + residential).* There are no current registered residential uses. The chronic drinking water level of comparison (DWLOC) for the U.S. population is 23 µg/L. The lowest DWLOC was for the infants/children subgroup at 7 µg/L. The highest surface water screening level concentration for chronic effects is 14 µg/L. However, the Agency believes that the GENEEC model overstimates average residues in drinking water at least 3-fold. Therefore, chronic exposure to residues of arsanilic acid should not exceed the level of concern.

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. Arsonic acid has no registered residential uses. Therefore, short- and intermediate-term aggregate risk assessments were not performed.

4. *Aggregate cancer risk for U.S. population*. Aggregate cancer risk was not determined since cancer studies are not required for pesticides to be tested under an Experimental Use Permit (EUP).

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 residues of arsanilic acid.

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 arsanilic 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 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 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. *Conclusion*. There is a complete toxicity database for an EUP for arsanilic acid and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Therefore, the additional 10x FQPA safety factor for infants and children was removed.

2. *Acute risk*. The acute risk for ''food only'' does not exceed the level of concern. The lowest acute DWLOC was for the infants/children subgroup at 580 µg/L. The maximum surface water screening level concentration for acute effects is 37 µg/L. Therefore, acute exposure to residues of arsanilic acid should not exceed the level of concern.

3. *Chronic risk*. Using the conservative exposure assumptions described in this unit, EPA has concluded that aggregate exposure to arsanilic acid from food will utilize 4% 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 arsanilic acid in drinking water (see discussion under U.S. population), EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to arsanilic acid residues.

4. *Short- and intermediate 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. Arsanilic acid has no registered residential uses. Therefore, short- and intermediate-term aggregate risk assessments were not performed.

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 arsanilic acid residues.

III. Other Considerations

A. Metabolism In Plants and Animals

An interim report from a study examining the metabolism and distribution of arsanilic acid in grapefruit showed that arsanilic acid and eleven metabolites were found in water extracts of the peel, pulp, and juice fractions of the grapefruit. These compounds account for 83% of the total radioactive residue (TRR) in/on grapefruit. The remaining residues occur as organo-, acid-, or base-soluble components. Identification of the metabolites is underway and one has been tentatively identified as *N*-acetyl arsanilic acid. The majority of the residues occur as arsanilic acid in/on the peel (26% TRR), as Metabolite II in the pulp (3.8% TRR), and as Metabolite I in the juice (7.3% TRR). On a whole-fruit basis, 29% of the TRR was unmetabolized arsanilic acid with four metabolites of potential concern (≥ 10% TRR) making up 51% of the TRR. The nature of the residues in plants is not adequately understood. However, for purposes of this EUP only, arsanilic acid per se will be considered the residue of concern.

As part of the proposed EUP labeling, grapefruit treated with arsanilic acid will be restricted to fresh-market use only. Thus, animal metabolism studies are not required for establishment of the time-limited tolerances.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is not available to enforce the tolerance expression. A GC/ECD method is under development for the determination of arsanilic acid in whole grapefruit. This method currently demonstrates good extraction efficiency but suffers from poor reproducibility during derivatization and chromatography. The limit of quantitation for the method is expected to be 0.05 ppm arsanilic acid in whole grapefruit. For purposes of tolerance enforcement for this time-limited tolerance only, the Agency will accept a method for the analysis of whole-fruit total arsenic by atomic absorption. 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

Results of arsanilic acid field trial data are not yet available. The registrant has proposed a whole-fruit tolerance of 0.5 ppm arsanilic acid per se, based on data in the metabolic fate interim study summary. Because this value was obtained from a non-replicated, greenhouse study, the Agency believes that a tolerance of 0.5 ppm, as proposed by the registrant, is not adequately supported. Previously-submitted data indicate a tolerance of 2.0 ppm is appropriate. As a result of this EUP, residues of arsanilic acid are not expected to exceed 2 ppm in/on grapefruit. A time-limited tolerance should be established at this level. This tolerance is equivalent to 0.7 ppm arsenic, assuming arsanilic acid is the only source of arsenic. EPA is finalizing this tolerance using a tolerance level at variance with that requested in the petition based on consideration of all residue data available, the relatively low risk presented by this tolerance, and the limited exposure expected under the EUP connected with this tolerance.

Due to label restrictions, residues of arsanilic acid are not expected in the juice, oil, or dried pulp of treated grapefruit as no processed commodities are associated with this experimental use permit. Secondary residues of arsanilic acid are not expected in animal commodities as no feed items are associated with this experimental use permit due to label restrictions.

D. International Residue Limits

There are no Codex, Canadian, or Mexican tolerances established for arsanilic acid on grapefruit. Thus, international harmonization is not an issue for these time-limited tolerances.

E. Rotational Crop Restrictions

Grapefruit are not rotated to other crops, therefore, residues in or on rotational crops are not expected to occur.

IV. Conclusion

Therefore, the tolerance is established for residues of arsanilic acid in /on grapefruit at 2.0 ppm (not to exceed 0.7 ppm total arsenic).

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 ''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, 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–300822] (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 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(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 17, 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 180.550 is adding to read as follows:

§ 180.550 Arsanilic acid [(4-aminophenyl) arsonic acid]; tolerances for residues.

(a) *General.* A time-limited tolerance is established for residues of the plant growth regulator arsanilic acid [(4-aminophenyl) arsonic acid], in or on the following food commodities in connection with the use of the pesticide under section 5 experimental use permit. The tolerance will expire on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Grapefruit	2 ppm (not to exceed 0.7 ppm total arsenic)	2/28/01

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

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

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

[FR Doc. 99–7434 Filed 3–25–99; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 95

[WT Docket No. 95–102; FCC 98–293]

Establishing a Very Short Distance Two-Way Voice Radio Service

AGENCY: Federal Communications Commission.

ACTION: Final rule; petitions for reconsideration and clarification.

SUMMARY: This action denies two petitions for reconsideration and clarifies that, within the Family Radio Service (''FRS'') rules, an antenna must be non-detachable to be an ''integral antenna''.

EFFECTIVE DATE: November 9, 1998.

FOR FURTHER INFORMATION CONTACT: Joy Alford, Policy and Rules Branch, Public Safety and Private Wireless Division, Wireless Telecommunications Bureau at jalford@fcc.gov or (202) 418–0680.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Memorandum, Opinion and Order,* released on November 9, 1998. The full text of this *Memorandum, Opinion and Order* is available for inspection and copying during normal business hours in the FCC Reference Center, Room 239, 1919 M Street, NW, Washington, DC The complete text may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, Washington, DC 20036, telephone (202) 857–3800.

Summary of Memorandum Opinion and Order

1. On May 10, 1996, the Commission adopted a *Report and Order,* 61 FR 28768, June 6, 1996, 11 FCC Rcd 12977 (1996), in WT Docket No. 95–102 in which the Commission established the FRS, a very short distance, two-way voice personal radio service.

2. In a Petition for Reconsideration filed July 5, 1996, The Personal Radio Steering Group (PRSG) requests a series of additional rules and rule changes which it argues are primarily designed to provide greater assurance that the FRS is used for its intended purposes. It also expresses concern that some users of FRS units may not share spectrum responsibly with other users, and requests that we adopt rule changes to maintain the integrity of the FRS as