a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Regional Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a 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)and 7410(k)(3).

C. 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 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 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.

D. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

E. 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 September 29, 1997. 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, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements.

Dated: July 9, 1997.

Michael V. Peyton,

Acting Regional Administrator.

Part 52 of chapter I, title 40, 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. 7401–7671q.

Subpart RR—Tennessee

2. Section 52.2220, is amended by adding paragraph (c)(155) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(155) Revisions to Tennessee state implementation plan submitted to EPA by the State of Tennessee on April 30, 1996, regarding emission standards and monitoring requirements for additional control areas.

(i) Incorporation by reference.

Tennessee Division of Air Pollution Control Regulations, Chapter 1200–3–19, adopted September 7, 1988.

(ii) Other material. None.

* * * * *

[FR Doc. 97–20056 Filed 7–29–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300519; FRL–5732–1]

RIN 2070–AB78

Buprofezin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of buprofezin and its metabolite BF 12 in or on citrus; dried citrus pulp; cotton seed; cotton gin byproducts; milk; and cattle, sheep, hogs, goats, and horse meat, fat, and meat by-products . This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cotton in Arizona and California, and on citrus in California. This regulation establishes maximum permissible levels for residues of buprofezin in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on July 31, 1998.

DATES: This regulation is effective July 30, 1997. Objections and requests for hearings must be received by EPA on or before September 29, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300519], 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–300519], must also be submitted to:

Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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. 1132, 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@epamail.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 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–300519]. 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: Andrea Beard, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9356, e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for combined residues of the insecticide buprofezin, in or on citrus fruit at 2.0 part per million (ppm); dried citrus pulp at 10 ppm; cotton seed at 1.0 ppm; cotton gin byproducts at 20 ppm; milk at 0.03 ppm; and cattle, sheep, hogs, goats, and horse meat and fat at 0.02 ppm, and meat by-products at 0.5 ppm. These tolerances will expire and are revoked on July 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL-5572-9).

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

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

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

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

II. Emergency Exemptions for Buprofezin on Citrus and Cotton and FFDCA Tolerances

Requests were received from Arizona and California for use of two insect growth regulators, buprofezin and pyriproxyfen (residues and associated risk assessments of pyriproxyfen are addressed in a separate **Federal Register** document. See July 25, 1997 issue of the **Federal Register**) for control of a recently introduced strain or species of sweetpotato whitefly, which has had devestating effects on cotton and various vegetable crops in the southwest for the past several years. This newer strain of whitefly, often referred to as the silverleaf whitefly, appears to be capable of quickly developing resistance, and is resistant to available alternative controls. Use of two chemicals was approved because the use patterns of each only allow one application, which will not be sufficient to control whitefly populations throughout the season.. EPA has authorized under FIFRA section 18 the use of buprofezin on cotton for control of whiteflies in Arizona and California. After having reviewed the submission, EPA concurs that emergency conditions exist.

A request was recieved from California for use of buprofezin and imidacloprid on citrus to control red scale, which has developed resistance in some localized citrus-producing areas of California, causing significant losses to the affected citrus producers. Over the past several years, control of scale in citrus has required increasing amounts of pesticide applications due to the resistance development. A pesticide with a different mode of action is required, and California has requested the use of two materials based on the ability of this pest to quickly develop resistance. After having reviewed the submission, EPA concurs that an emergency condition exist, and has authorized the use of buprofezin on citrus for control of red scale in California under FIFRA section 18.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of buprofezin in or on citrus and cotton commodities, milk, and meat. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting

food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on July 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on citrus fruit and dried pulp, cotton seed, cotton gin byproducts, meat, and milk after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether buprofezin meets EPA's registration requirements for use on citrus and cotton or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of buprofezin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Arizona and California to use this pesticide on these crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for buprofezin, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enactment of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this

assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants, less than 1 year old) was not regionally based.

IV. 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 buprofezin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of buprofezin and its metabolite BF 12 on citrus fruit at 2.0 ppm; dried citrus pulp at 10 ppm; cotton seed at 1.0 ppm; cotton gin byproducts at 20 ppm; milk at 0.03 ppm; and cattle, sheep, hogs, goats, and horse meat and fat at 0.02 ppm, and meat by-products at 0.5 ppm; . EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by buprofezin are discussed below.

1. *Acute toxicity*. EPA has selected the developmental NOEL of 200 mg/kg/day from a rat developmental study, for the acute dietary endpoint; at the LOEL of 800 mg/kg/day, decreased fetal body weight and delayed ossification was observed. The population subgroup of concern is females 13+ years of age.

2. *Chronic toxicity*. EPA has calculated a temporary RfD for buprofezin at 0.002 milligrams/kilogram/day (mg/kg/day). This RfD is based on the systemic lowest effect level (LEL) of 2.0 mg/kg/day (lowest dose tested) from a 2-year dog study (an NOEL was not established), and uses a thousandfold uncertainty factor); an extra factor of 10 was added to the standard hundredfold uncertainty factor since the RfD was based on an LEL (rather than an NOEL) and the database is lacking an adequate reproductive study). At the LEL, slight liver effects were observed.

3. *Carcinogenicity*. There is no concern for cancer risks identified by the EPA; data from available studies do not indicate a treatment-related tumor problem, and cancer risk endpoints have not been identified.

B. Exposures and Risks

1. *From food and feed uses.* Risk assessments were conducted by EPA to assess dietary exposures and risks from these section 18 uses of buprofezin 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 one day or single exposure. The acute dietary risk assessment (only contribution is tolerances in connection with this use on cotton) used tolerance-level residue values and assumed 100% of crop treated. The resulting high-end exposure estimate of 0.04 mg/kg/day results in a dietary MOE of 5,000 for the population subgroup of concern, females 13+ years old. This MOE is a conservative risk assessment; refinement using anticipated residue values and percent crop treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, the only refinement to the data estimates used was calculating anticipated residue levels for citrus commodities. For the other commodities, EPA used the very conservative assumptions that residues would occur in 100% of the U.S. cotton and livestock commodities at tolerance levels; and that the anticiated residues calculated would occur in 100% of the U.S. citrus crop. In actuality, under these exemptions, only a portion of the cotton crop in Arizona and California may potentially be treated; and a very small portion of the citrus crop in California (portions of Kerns and Tulare Counties only) may potentially be treated. Under these very conservative assumptions, these time-limited tolerances on citrus, cotton, and livestock commodites result in an ARC that is equivalent to the following percentages of the RfD: U.S. Population, 23%; Non-Nursing Infants (<1 year old), 104%; Nursing Infants, 23%; Children (1-6 years old), 63%; Children (7-12 years old), 40%. Additional refinement using anticipated residue values for cotton and livestock commodities, and percent of crop treated would result in much lower dietary exposure estiomates, especially considering that this use is only for a small portion of the cotton grown in California and Arizona, and an extremely limited area of citrus in California only.

2. *From drinking water.* Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause buprofezin to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with buprofezin in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Buprofezin is not registered for any residential uses at this time. Therefore, no non-dietary, non-occupational exposure is antipated..

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

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether buprofezin 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, buprofezin 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 buprofezin has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* For the population of concern (females 13 years and older), the calculated MOE value (for food only) is 5,000. Although theoretically there is the potential for exposure to buprofezin in dringking water, EPA does not expect that exposure would result in an aggregate MOE (food blus water) that would exceed the levels of concern for acute dietary exposure.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to buprofezin from food will utilize 23 percent of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Non-nursing infants, < 1 year old, 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 buprofezin in drinking water and from non-dietary, non-occupational exposure, 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 from aggregate exposure to buprofezin residues.

Therefore, EPA concludes that there is reasonable certainty that no harm will result from exposure to buprofezin through these uses.

D. Aggregate Cancer Risk for U.S. Population

There is no concern for cancer risks identified by the EPA; data from available studies do not indicate a treatment-related tumor problem, and cancer risk endpoints have not been identified.

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

1. *Safety factor for infants and children*— a. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of buprofezin, EPA considered data from developmental toxicity studies in the rat and rabbit. EPA currently has an incomplete database (no adequate reproduction study) and no NOEL for the chronic study which was used to determine the temporary RfD. Therefore, a thousandfold margin/factor was applied to the chronic study which provides a reasonable certainty of safety for infants and children exposed to residues of buprofezin. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide xeposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and

children. Margins of safety are incorporated into EPA risk assessments either directly through use of a 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 hundredfold safety factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold safety 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 safety factor. As stated above, EPA currently has an incomplete database for buprofezin, and therefore an additional tenfold safety factor was added onto the standard hundredfold safety factor, providing a reasonable certainty of no harm to infants and children exposed to buprofezin through these uses.

b. *Developmental toxicity studies.* In the rat developmental toxicity study, the maternal (systemic) NOEL was 200 mg/kg/day, based on mortality, decreased pregnancy, and increased resorption rates, at the LOEL of 800 mg/kg/day. The developmental (fetal) NOEL was 200 mg/kg/day, based on the increased incidence of delayed ossifications and decreased pup weight at the LOEL of 800 mg/kg/day.

In the rabbit developmental study, the maternal (systemic) NOEL was 50 mg/kg/day, based on decreased body weight and food consumption and possibly increased fetal loss at the LOEL of 250 mg/kg/day. The developmental (fetal) NOEL was 250 mg/kg/day highest dose tested.

c. *Reproductive toxicity study.* While a 2-generation rat reproductive study was submitted, it does not satisfy guideline requirements for a reproductive study, and is considered a data gap in the buprofezin database.

d. *Pre- and post-natal sensitivity.* The toxicology database is currently incomplete for evaluating post-natal, but not pre-natal, risks to infants and children. Based on the results of the rat developmental toxicity study, an acute dietary risk assessment was conduected for females 13+ years of age. The MOE of 5,000 obtained for this risk assessment demonstrates that acute developmental (pre-natal) risks are low.

e. *Conclusion.* The rat reproductive study is a data gap and a tenfold modifying factor has been added to the usual hundredfold uncertainty factor for a total uncertainty factor of 1,000 in calculation of the RfD. This additional uncertainty factor provides a reasonable certainty of safety for infants and children exposed to dietary residues of buprofezin.

2. *Acute risk.* The acute, aggregate dietary MOE of 5,000 which was calculated for females 13+ years old, accounts for both maternal and fetal exposure. The large aggregate MOE calculated provides assurance that there is a reasonable certainty of no harm to infants and children.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to buprofezin from food will utilize from 23% of the RfD for the subgroup nursing infants, to 104% of the RfD for the subgroup, non-nursing infants (< 1 year old). 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. Although the percentage of the RfD utilized is 104% for Non-nursing infants, this estimate was arrived at using extremely conservative assumptions, and is an overestimate of the actual risk. If further refinement of the estimates, as described above, were used, the dietary exposure estimates would be considerably lower. EPA does not expect that aggregate exposure will exceed 100% of the RfD for any of the infant and children population subgroups. Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, EPA concludes that there is reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to buprofezin residues.

V. Other Considerations

A. Metabolism In Plants and Animals

For the puposes of these uses under section 18, the nature of the residues in plants and animals is adequately undersotood. The residue of concern is the parent buprofezin BF 01, 2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one] only.

B. Analytical Enforcement Methodology

Adequate methodology is available to enforce these tolerances. The methodology for buprofezin and its mtebolites is summarized in the following reports: ''Determination of Buprofezin and BF 12 Residues in Cottonseed and Gin Trash,'' method BF-01-96; ''Determination of Residues of Buprofezin and the Metabolite BF 12 in Beef Tissues via Solid Phase Extraction and Gas Chromatography With MS Detection,'' method BF-05-97; ''Determination of BF 02 Residues in Beef Tissues by Gas Chromatography Using Nitrogen Phosphorus Detection,'' method BF-06-97; ''An Analytic Method for the Determination of Residues of Buprofezin at Estimated Tolerance Levels in Almonds, Cotton Seed, Citrus (lemons), and Grapes by Gas Chromatography Using Nitrogen Phosphorous Detection,'' method BF-09-97; AgrEvo Corporation, Wilmington, Delaware.

C. Magnitude of Residues

Residues of buprofezin are not expected to exceed the following, as a result of these emergency exemption uses: 2.0 ppm in citrus fruit; 10 ppm in dried citrus pulp; 1.0 ppm in cotton seed; 20 ppm in cotton gin byproducts; 0.03 ppm in milk; 0.02 ppm in meat and fat, and 0.5 ppm in meat byproducts, of cattle, sheep, hogs, goats, and horses.

D. International Residue Limits

There are no maximum residue levels (MRLs) established for buprofezin on any cotton or livestock commodities, and Canadian or Mexican MRLs established for buprofezin in/on citrus. A temporary Codex MRL of 0.3 mg/kg has been established for buprofezin on oranges.

VI. Conclusion

Therefore, the tolerances are established for residues of buprofezin in the various commodities at the levels given as follows: 2.0 ppm in citrus fruit; 10 ppm in dried citrus pulp; 1.0 ppm in cotton seed; 20 ppm in cotton gin byproducts; 0.03 ppm in milk; 0.02 ppm in meat and fat, and 0.5 ppm in meat byproducts, of cattle, sheep, hogs, goats, and horses.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) 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 September 29, 1997, 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 above (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). 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 Confidential Business Information (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.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300519] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above 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 rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has 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 acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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: July 16, 1997.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority : 21 U.S.C. 346a and 371.

2. By adding § 180.511, to read as follows:

§ 180.511 Buprofezin; Tolerances for Residues.

(a) *General .*

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insect growth regulator buprofezin, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	0.02	July 31, 1998
Cattle, MBYP	0.5	July 31, 1998
Cattle, meat	0.02	July 31, 1998
Citrus fruit	2.0	July 31, 1998
Citrus, pulp, dried	10	July 31, 1998
Cotton seed	1.0	July 31, 1998
Cotton, gin byproducts	20	July 31, 1998
Goats, fat	0.02	July 31, 1998
Goats, MBYP	0.5	July 31, 1998
Goats, meat	0.02	July 31, 1998
Hogs, fat	0.02	July 31, 1998
Hogs, MBYP	0.5	July 31, 1998
Hogs, meat	0.02	July 31, 1998
Horses, fat	0.02	July 31, 1998
Horses, MBYP	0.5	July 31, 1998
Horses, meat	0.02	July 31, 1998
Milk	0.03	July 31, 1998
Sheep, fat	0.02	July 31, 1998
Sheep, MBYP	0.5	July 31, 1998
Sheep, meat	0.02	July 31, 1998

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

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

[FR Doc. 97–20061 Filed 7-29-97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPTS–50581E; FRL–5733–5]

Revocation of Significant New Use Rule for Certain Chemical Substances; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a document (FR Doc. 97–17178) in the **Federal Register** of July 2, 1997 (62 FR 35690) revoking two significant new use rules (SNUR). That document inadvertently contained an incorrect CFR section number. EPA intended to revoke the SNURs as stated in the preamble of the proposed revocation for these two substances (62 FR 6160, February 11, 1997) (FRL–5580–8). This action is necessary so that the correct SNURs are removed from part 721. Because this is a nonsubstantive change, notice and public comment are not required.

DATES: This document is effective on August 1, 1997.

FOR FURTHER INFORMATION CONTACT: Susan Hazen, Director, Environmental Assistance Division (TS–799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Room E–543A, 401 M St., SW., Washington, DC 20460; telephone: (202) 554–1404; TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a document (FR Doc. 97–17178) in the **Federal Register** of July 2, 1997 (62 FR 35690) (FRL–5715–3) inadvertently removing § 721.3020. This document correctly removes § 721.3060.

On page 35691, in the first column, amendatory item 2 should read: ''2. By removing § 721.3060.''

Dated: July 22, 1997.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 97–20062 Filed 7–29–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 36 and 54

[CC Docket No. 96–45; FCC 97–246]

Universal Service

AGENCY: Federal Communications Commission.

ACTION: Final rule; order on reconsideration; errata.

SUMMARY: On May 8, 1997, we adopted the Universal Service Report and Order (Order) implementing section 254 of the Communications Act of 1934, as amended (the Act). We reconsider on our own motion several issues with respect to school and library contracts, the school and library discount matrix, the method used to calculate the limit placed on the amount of corporate operations expense, the source of support and administration of support for high loop costs, and the new monitoring program and Monitoring Report. In addition, we reiterate our holdings in the Order with respect to the Commission's authority to assess universal service contributions from intrastate and interstate revenues, the Commission's authority to require any carrier to seek state authority to recover a share of its contribution through intrastate rates, section 254(k), and the Commission's review of decisions by state commissions not to waive the ''no-disconnect'' requirement for the Lifeline program. The intended effect of these rules is to implement fully the universal service provisions of the Act.

DATES: All policies and rules adopted herein shall be effective August 29, 1997, except for the amendments to § 54.500, which will take effect July 30, 1997.

FOR FURTHER INFORMATION CONTACT: Valerie Yates, Legal Counsel, Common Carrier Bureau, (202) 418–1500, or Sheryl Todd, Common Carrier Bureau, (202) 418–7400.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration adopted and released on July 10, 1997 and reflecting the changes included in errata released on July 14, 1997 and on July 24, 1997. The full text of the Order on Reconsideration and the errata is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M St., NW., Washington, DC.

Pursuant to the Telecommunications Act of 1996, the Commission released a Notice of Proposed Rulemaking and