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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 2, 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, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: June 17, 1997.

A. Stanley Meiburg,

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)(147) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(147) Addition of a new chapter 1200–3–23 ''Visibility Protection'' to the Tennessee Air Pollution Control Regulations submitted by the Tennessee Department of Environment and Conservation on February 9, 1993, and December 19, 1994.

(i) Incorporation by reference.

(A) Chapter 1200–3–23 ''Visibility Protection,'' effective July 24, 1994.

(ii) Other material. None.

* * * * *

[FR Doc. 97–17183 Filed 7–1–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300500; FRL–5719–9]

RIN 2070-AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the insecticide tebufenozide in or on the following raw agricultural commodities: apples; apple pomace; cottonseed, undelinted; cottonseed meal; cottonseed oil; cottonseed hulls, cotton gin byproducts; milk; meat, meat fat, and meat by-products of cattle, sheep, and goats; and horse meat in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of tebufenozide on apples in Pennsylvania, New Jersey, Virginia, West Virginia, Michigan and New York. This regulation establishes maximum permissible levels for residues of tebufenozide on the above raw agricultural commodities pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and be revoked on June 30, 1998.

DATES: This regulation becomes effective July 2, 1997. Objections and requests for hearings must be received by EPA on or before September 2, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300500], 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–300500], must 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–300500]. 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: Pat Cimino, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308-8328, e-mail: cimino.pat@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 residues of the insecticide tebufenozide (benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide) in or on apples at 1.0 part per million (ppm); apple pomace at 2.0 ppm; cottonseed, undelinted at 0.2 ppm; cottonseed meal at 0.5 ppm; cottonseed oil at 1.3 ppm; cottonseed hulls at 0.8 ppm; cotton gin byproducts at 4.0 ppm; milk at 0.05

ppm; meat of cattle, sheep, goats, and horses at 0.02 ppm; fat of cattle, sheep, and goats at 0.10 ppm; meat by-products (except liver kidney) of cattle, sheep, and goats at 0.10 ppm; liver of cattle, sheep, and goats at 1.0 ppm; and kidney of cattle, sheep, and goats at 0.02 ppm. These tolerances will expire and be revoked by EPA on June 30, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance 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 FFDCA, 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under 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 Tebufenozide on Apples and FFDCA Tolerances

Between February 13 and April 24, 1997, the New Jersey Department of Environmental Protection, Virginia Department of Agriculture and Consumer Affairs, New York Department of Environmental Conservation, and Pennsylvania, West Virginia, and Michigan Departments of Agriculture requested a specific exemption under FIFRA section 18 for the use of tebufenozide on apples to control tufted apple bud moth in PA, NJ, VA and WV and oblique banded leafroller in NY and MI. These pests are becoming increasingly resistant to registered pesticide alternatives and growers are experiencing both quality and yield losses from infestations. The registered alternative products do not provide control of these pests and lack of a viable alternative is responsible for growing levels of economic loss over the last several years. Growers will experience significant economic loss if these pests are not controlled. After having reviewed their submissions, EPA concurs that emergency conditions exist.

Between March 18 and June 20, 1997, the Texas, South Carolina, Louisiana, Florida, Mississippi, Arkansas, Alabama, Georgia and New Mexico Departments of Agriculture requested a specific exemption under FIFRA Section 18 for the use of tebufenozide on cotton to control beet armyworm in cotton. This pest is resistant to control by currently registered products and growers have experienced significant economic losses from infestations of this pest. After having reviewed their submissions, EPA concurs that emergency conditions exist.

As part of its assessment of these applications for emergency exemption, EPA assessed the potential risks presented by residues of tebufenozide on apples. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for tebufenozide will permit the marketing of apples treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e) as provided in section 408(l)(6). Although these tolerances will expire and be revoked by EPA on June 30, 1998, under FFDCA section 408(l)(5), residues of tebufenozide not in excess of the amount specified in the tolerances remaining in or on apples, milk, meat, meat fat and meat by-products after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. 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.

EPA has not made any decisions about whether tebufenozide meets the requirements for registration under FIFRA section 3 for use on apples or whether permanent tolerances for tebufenozide for apples would be appropriate. This action by EPA does not serve as a basis for registration of tebufenozide by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any States other than Pennsylvania, New Jersey, Virginia, West Virginia, New York or Michigan to use this product on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR 180.166. For additional information regarding the emergency exemptions for tebufenozide, 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. For many of these 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. For shorter term risks, EPA calculates a 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 100-fold MOE is based on the same rationale as the 100-fold 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 relationships. 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.

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. 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 reliable federal and private market basket survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using the upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group.

IV. Aggregate Risk Assessments 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.

A. Toxicological Profile

1. *Acute toxicity.* No acute toxicological effects of concern were identified by the Agency.

2. *Short- and intermediate-term toxicity.* No short- or intermediate-term toxicological effects of concern were identified by the Agency.

3. *Chronic toxicity.* The RfD for tebufenozide is 0.018 milligrams(mg)/kilogram(kg)/day and is based on a 1-year feeding study in dogs with a NOEL of 1.8 mg/kg/day and an uncertainty factor of 100. Decreased red blood cells, hematocrit, and hemoglobin and increased heinz bodies, reticulocytes, and platelets were observed at the lowest-observed effect level (LOEL) of 8.7 mg/kg/day.

4. *Cancer.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), the Agency has classified tebufenozide as a Group ''E'' chemical (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in a 2-year rat study and an 18-month mouse study.

B. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

A permanent tolerance of 0.1 ppm has been established for residues of tebufenozide in or on walnuts and an apple import tolerance has been established. Tebufenozide is not registered for indoor or outdoor residential uses.

1. *Acute exposure.* 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. No acute toxicological effects of concern have been identified for tebufenozide and an acute risk assessment is not required.

2. *Chronic exposure.*—i. *Dietary-food exposure.* In conducting exposure assessments for this section 18 request, EPA used tolerance level residues and assumed that 100% of the crop would be treated with the pesticide (TMRC worst-case analysis assumptions, as described above).

ii. *Drinking water exposure.* Environmental fate data submitted to the Agency suggest that tebufenozide is moderately persistent to persistent and mobile and could potentially leach to groundwater and runoff to surface water under certain environmental conditions.

No Maximum Concentration Level or Health Advisory Level has been established for residues of tebufenozide in drinking water. There is no entry for

tebufenozide in the ''Pesticides in Groundwater Database'' (EPA 34-12-92-001, Sept. 1992).

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 consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause tebufenozide 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 tebufenozide 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.

iii. *Non-dietary, non-occupational exposure.* Non-dietary, non-occupational exposure is not expected because tebufenozide is not registered for indoor or outdoor residential uses.

C. 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 tebufenozide 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, tebufenozide 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 tebufenozide has a common mechanism of toxicity with other substances.

D. Safety Determinations for U.S. Population

1. *Acute risk.* No acute toxicological effects of concern have been identified for tebufenozide and an acute risk assessment is not required.

2. *Short- and intermediate-term risk.* Because no toxicity concerns have been identified by the Agency for short- or intermediate-term exposure to tebufenozide and no indoor or outdoor residential uses are registered, a short- or intermediate-term aggregate risk assessment is not required.

3. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, EPA has concluded that chronic aggregate exposure to tebufenozide from food will utilize 31% of the RfD for the U.S. population. Aggregate exposure to tebufenozide from food utilizes <81% of the RfD for all major identifiable subgroups, including 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 tebufenozide in drinking water, 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 chronic aggregate exposure to tebufenozide residues.

E. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. 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 MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under

existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety.

Based on current toxicological data requirements, the data base for developmental and reproductive studies for tebufenozide is complete. The data indicate that there are no special pre- or post-natal toxicity concerns for infants and children and that the standard uncertainty factor is adequate to protect the safety of infants and children.

Developmental toxicity was not observed in developmental studies using rats and rabbits. The NOEL for developmental effects in both rats and rabbits was 1,000 mg/kg/day (HDT), which is the limit dose for testing in developmental studies.

1. *Developmental toxicity studies.*—i. *Rat developmental toxicity.* The maternal (systemic) NOEL was 250 mg/kg/day and the LOEL was 1,000 mg/kg/day based on decreased weight gain and food consumption. The developmental (pup) NOEL was >1,000 mg/kg/day, the highest dose tested (HDT).

ii. *Rabbit developmental toxicity.* The maternal (systemic) and developmental (pup) NOELs were >1,000 mg/kg/day (HDT).

2. *Reproductive toxicity studies.—Rat reproduction toxicity.* In the two-generation reproductive toxicity study in the rat, the parental (systemic) NOEL was 0.85 mg/kg/day. Splenic pigmentation changes and extramedullary hematopoiesis occurred in the parents at the LOEL of 12.1 mg/kg/day (in males and females and in both generations). In addition to these effects, decreased body weight gain and food consumption occurred at 171.1 mg/kg/day.

The reproductive (pup) NOEL was 12.1 mg/kg/day and the LOEL was 171.1 mg/kg/day based on a slight increase, in both generations, in the number of pregnant females that did not deliver and a slight increase in the number of second generation pregnant females that had difficulty delivering and had to be sacrificed. Additionally, in second generation dams at the LOEL, the length of gestation increased and implantation sites decreased significantly. Finally, the number of pups per litter decreased on Lactation Day (LD) 4 to 90% of the controls for the first generation and on LD's 0 and 4 (80%) for the second generation. Because these reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest an increased post-natal sensitivity to children and infants (that infants and children might be more sensitive than adults) to tebufenozide exposure.

3. *Pre- and post- natal sensitivity.* The developmental (pup) NOELs of >1,000 mg/kg/day (HDT) from the rat and rabbit developmental toxicity studies demonstrate that there is no developmental (pre-natal) toxicity present for tebufenozide. Additionally, these developmental NOELs are greater than 500-fold higher than the NOEL of 1.8 mg/kg/day from the 1-year feeding study in dogs which was the basis of the RfD.

In the reproductive toxicity study in rats, the reproductive NOEL (12.1 mg/kg/day) is 14-fold higher than the parental NOEL (0.85 mg/kg/day) and indicates that post-natal toxicity in the reproductive studies occurs only in the presence of significant parental toxicity.

These developmental and reproductive studies indicate that tebufenozide does not have additional sensitivity for infants and children in comparison to other exposed groups.

4. *Acute risk.* No acute toxicological effects of concern have been identified for tebufenozide and an acute risk assessment is not required.

5. *Short- and intermediate-term risk.* Because no toxicity concerns have been identified by the Agency for short- or intermediate-term exposure to tebufenozide and no indoor or outdoor residential uses are registered, a short- or intermediate-term aggregate risk assessment is not required.

6. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that the percentage of RfD that will be utilized by dietary (food only) exposure to residues of tebufenozide ranges from 41% for nursing infants up to 80% for 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. Despite the potential for chronic exposure to tebufenozide in drinking water, 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 chronic aggregate exposure to tebufenozide residues.

V. Other Considerations

A. Metabolism in Plants and Animals

The metabolism in/on plants is adequately understood. The residue of concern is the parent compound, tebufenozide per se as specified in 40 CFR 180.482.

The metabolism in animals is not adequately understood; however, for purposes of these Section 18 exemptions only, the Agency considers the residue of concern to be the parent compound, tebufenozide per se. Estimates of secondary residues in ruminant tissues were extrapolated from data from a goat metabolism study submitted to support the import tolerance on apples. The recommended secondary ruminant tissue residues are based on high level dosing and maximum radioactive residues found in goat tissues and are likely conservative estimates of the actual residue levels that would occur in ruminants fed apple pomace containing tebufenozide residues.

B. Analytical Enforcement Methodology

The HPLC/UV method, TR 34-94-38 is adequate to detect residue so the parent compound in apples. At this time, there are no analytical methods available to the Agency to detect secondary residues in animal matrixes as a result of this use.

C. Magnitude of Residues

Residues of tebufenozide are not expected to exceed the following levels as a result of this use: 1.0 ppm in apples; 2.0 ppm in apple pomace; 0.05 ppm in milk; 0.02 ppm in meat of cattle, sheep, goat, and horse; 0.1 ppm in fat of cattle, sheep, and goats; 0.1 ppm in meat by-products (except liver and kidney) of cattle, sheep, and goats; 1.0 ppm in liver of cattle, sheep, and goat; and 0.02 ppm in kidneys of cattle, sheep, and goats.

D. International Residue Limits

There are no Codex, Canadian, or Mexican international residue limits established for use of tebufenozide on apples.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of tebufenozide in/on the following: apples - 1.0 ppm; apple pomace - 2.0 ppm; cottonseed, undelinted - 0.2 ppm; cottonseed meal - 0.5 ppm; cottonseed oil - 1.3 ppm; cottonseed hulls - 0.8 ppm; cotton gin byproducts - 4.0 ppm; milk - 0.05 ppm; meat of cattle, sheep, goat, and horse - 0.02 ppm; fat of cattle, sheep, and goats - 0.1 ppm; meat by-products (except liver and kidney) of cattle, sheep, and goats - 0.1 ppm; liver of cattle, sheep, and goat - 1.0 ppm; and kidneys of cattle, sheep, and goats - 0.02 ppm.

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 2, 1997, file written objections to any aspect of this regulation (including the revocation provision) 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–300500] (including any comments and data submitted electronically). A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 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 Highway, Arlington, VA.

Electronic comments may be sent diectly to EPA:
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 tolerance under section 408 of the FFDCA and is in response to a petition received by the Agency requesting the establishment of such a tolerance. 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). In addition, 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, because tolerances that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rwule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Prior to the recent amendments to the FFDCA, however, EPA had treated such actions as subject to the RFA. The amendments to the FFDCA clarify that no proposed rule is required for such regulatory actions, which makes the RFA inapplicable to these actions. 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 (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

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 ofRepresentatives, 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: June 13, 1997.

James Jones,

Acting 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. Section 180.482 is amended as follows:

a. In paragraph (a) by adding a heading.

b. In paragraph (b) by revising the introductory text and alphabetically adding the entries to the table.

c. By adding the headings and reserving new paragraphs (c) and (d).

§ 180.482 Tebufenozide; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide benzoic acid in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Apple pomace	2.0	6/30/98
Apples	1.0	6/30/98
Cattle, fat	0.10	6/30/98
Cattle, kidney	0.02	6/30/98
Cattle, liver	1.0	6/30/98
Cattle, mbyp	0.10	6/30/98
Cattle, meat	0.02	6/30/98
Cotton gin byproducts	4.0	6/30/98
Cottonseed hulls	0.8	6/30/98
Cottonseed meal	0.5	6/30/98
Cottonseed oil	1.3	6/30/98
Cottonseed, undelinted	0.2	6/30/98
Goats, fat	0.10	6/30/98
Goats, kidney	0.02	6/30/98
Goats, liver	1.0	6/30/98
Goats, mbyp	0.10	6/30/98
Goats, meat	0.02	6/30/98
Horses, meat	0.02	6/30/98
* * * *	* *	*
Milk	0.05	6/30/98
* * * *	* *	*
Sheep, fat	0.10	6/30/98
Sheep, kidney	0.02	6/30/98
Sheep, liver	1.0	6/30/98
Sheep, mbyp	0.10	6/30/98
Sheep, meat	0.02	6/30/98
* * * *	* *	*

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

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

[FR Doc. 97–17370 Filed 7–1–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5850–1]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Cheshire Ground Water Contamination Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region I announces the deletion of the Cheshire Ground Water Contamination site from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR Part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the State of Connecticut have determined that the Site poses no significant threat to public health or the environment and, therefore, no further remedial measures pursuant to CERCLA are appropriate.

EFFECTIVE DATE: July 2, 1997.

FOR FURTHER INFORMATION CONTACT: Jane Dolan, Remedial Project Manager, U.S. EPA Region I (HBT), JFK Federal Building, Boston, MA 02203, (617) 573–9698.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Cheshire Ground Water Contamination Site, Cheshire, Connecticut.

A Notice of Intent to Delete for this site was published on March 21, 1997 (62 FR 13568). The closing date for comments on the Notice of Intent to Delete was April 21, 1997. EPA received no comments.

EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of the Hazardous Response Trust Fund (Fund-) financed remedial actions. Any site deleted from the NPL remains eligible for Fund-Financed remedial actions in the unlikely event that conditions at the site warrants such action. Section 300.425(e)(3) of the NCP states that Fund-Financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.