(address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry and Environmental Review Team, FDA, to the Division of Petition Control, FDA, ''DPC Request to Identify and Address Unresolved Issues in the Pending Acrylamide Petitions,'' August 7, 1997.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' *Chemical Safety Regulation and Compliance*, edited by F. Homburger, and J. K. Marquis, New York, NY, pp. 24–33, 1985.

3. Memorandum from the Chemistry and Environmental Review Team, FDA, to the Division of Petition Control, FDA, ''Exposure to Acrylamide From the Use of the Sodium Salt of Copolymers 2-Acrylamido-2-Methylpropanesulfonic Acid and Acrylamide,'' February 3, 1999.

4. Johnson, K. A., Gorzinski, S. J., Bodner, K. M., Campbell, R. A., Wolf, C. H., Friedman, M. A., and Mast, R. W., ''Chronic Toxicity and Oncogenicity Study on Acrylamide Incorporated in the Drinking Water of Fischer 344 Rats,'' *Toxicology and Applied Pharmacology*, 85:154–168, 1986.

5. Memorandum from the Division of Petition Control, FDA, to the Quantitative Risk Assessment Committee, FDA, ''Estimation of Upper-Bound Risk for Acrylamide Exposure Resulting From the Use of Acrylamide Polymer with Sodium 2-Acrylamido-2-Methylpropanesulfonate—FAP 6B3940,'' March 3, 1999.

6. Memorandum of Conference, FDA, CFSAN, Washington, DC, Cancer Assessment Committee Meeting on Acrylamide, February 13 and June 6, 1985, May 31, 1996.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.180 is amended in the table in paragraph (b)(2) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 176.180 Components of paper and paperboard in contact with dry food.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
Acrylamide polymer with sodium 2-acrylamido-2-methylpropane-sulfonate (CAS Reg. No. 38193–60–1)	For use at a level not to exceed 0.015 weight percent of dry fiber.
* * *	* * * *

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31700 Filed 12–7–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300947; FRL–6390–9]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of tebufenozide in or on soybeans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective December 8, 1999. Objections and requests for hearings, identified by docket control number OPP–300947, must be received by EPA on or before February 7, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300947 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9367; and e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially

affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300947. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the insecticide tebufenozide, in or on soybeans at 2.0 part per million (ppm). This tolerance will expire and is revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Tebufenozide on Soybeans and FFDCA Tolerances

The state of Louisiana declared a crisis for the use of tebufenozide on soybeans to control fall armyworms due to lack of efficacy of currently labeled products. EPA has authorized under FIFRA section 18 the use of tebufenozide on soybeans for control of fall armyworms in Louisiana.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebufenozide in or on soybeans. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybeans after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether tebufenozide meets EPA's registration requirements for use on soybeans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of tebufenozide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Louisiana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional

information regarding the emergency exemption for tebufenozide, contact the Agency's Registration Division at the address provided under ''FOR FURTHER INFORMATION CONTACT.''

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of tebufenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tebufenozide on soybeans at 2.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

B. Toxicological Endpoint

1. *Acute toxicity*. No toxicological endpoint has been identified for acute toxicity. Toxicity observed in oral toxicity studies were not attributable to a single dose (exposure). No neurological or systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 milligrams/kilograms/day (mg/kg/day). No maternal or developmental toxicity was observed following oral administration of tebufenozide at 1,000 mg/kg/day (limit-dose) during gestation to pregnant rats or rabbits.

2. *Short- and intermediate-term toxicity.* No toxicological endpoints have been identified for short- and intermediate-term toxicity. No dermal or systemic toxicity was seen in rats administered 15 dermal applications at 1,000 mg/kg/day (limit dose) over 21 days with either technical tebufenozide or 23% active ingredient formulation. Despite hematological effects seen in the dog study, similar effects were not seen in these rats receiving the compound via the dermal route indicating poor dermal absorption. Also, no developmental endpoints of concern were evident due to the lack of developmental toxicity in either rat or rabbit studies.

3. *Chronic toxicity*. EPA has established the reference dose, or RfD, for tebufenozide at 0.018 mg/kg/day. This RfD is based on the no observable adverse effect level (NOAEL) of 1.8 mg/kg/day based on growth retardation, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen and liver at the lowest observable adverse effect level (LOAEL) of 8.7 mg/kg/day. An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variability) was applied to the NOAEL of 1.8 mg/kg/day to calculate the RfD of 0.018 mg/kg/day.

EPA has determined that the 10X factor to account for enhanced susceptibility of infants and children (as required by FQPA) can be removed, and therefore, the chronic Population Adjusted Dose (cPAD), is 0.018 mg/kg/day, which is the same as the RfD. For purposes of this risk assessment, the term cPAD will be used instead of RfD. The determination that the 10X factor be removed is based on the results of reproductive and developmental toxicity studies. No evidence of additional sensitivity to young rats or rabbits was observed following prenatal or postnatal exposure to tebufenozide.

4. *Carcinogenicity*. Tebufenozide is classified as Group E (no evidence of carcinogenicity in humans).

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.482) for the residues of tebufenozide, in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of tebufenozide on apples, berries, canola, cotton, cranberries, fruiting vegetables, leafy vegetables, milk, mint, pears, pecans, pome fruit, sugarcane, turnips, walnuts and livestock commodities of cattle, goats, hogs, horses, and sheep. Additionally, time-limited tolerances associated with emergency exemptions have been established for poultry, eggs, peanuts, rice, and sweet potatoes. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebufenozide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. Toxicity observed in oral toxicity studies were not attributable to a single dose or 1 day exposure. Therefore, no toxicological endpoint was identified for acute toxicity and no acute dietary risk assessment is needed.

ii. *Chronic exposure and risk.* The Agency conducted a chronic dietary exposure analysis and risk assessment. The chronic analysis for tebufenozide used a cPAD of 0.018 mg/kg/day. The analysis evaluated individual food consumption as reported by respondents in the USDA 1989-92 Continuing Surveys of Food Intake by Individuals and accumulates exposure to the chemical for each commodity. Tolerance level residues and some percent crop treated (PCT) assumptions were made for the proposed commodities to estimate the Anticipated Residue Concentration (ARC) for the general population and subgroups of interest. The percent of the cPAD that would exceed the Agency level of concern would be 100%. The existing tebufenozide tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in a ARC that is equivalent to percentages of the cPAD below 100% for all subgroups U.S. population, 14% and non-nursing infants (<1 year old), the most highly exposed subgroup, 44%.

Section 408(b)(2)(F) states that the Agency may use data on the actual PCT for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

Estimates of PCT were used for the following crops. In all cases the maximum estimate was used:

Crops	Average	Maximum
Almonds	<1%	<1%
Apples	1%	2%
Beans/Peas, Dry	0%	1%
Cabbage, Fresh	2%	3%
Cole Crops	1%	2%
Cotton	1%	4%
Pears	<5%	
Spinach, Fresh	2%	3%
Spinach, Processed	20%	29%
Sugarcane	3%	5%
Walnuts	10%	16%

The Agency believes that the three conditions, discussed in section 408(b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. 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 the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which tebufenozide may be applied in a particular area.

2. *From drinking water.* The Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for tebufenozide. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on Generic Expected Environmental Concentration (GENEEC) and EPA's Pesticide Root Zone Model (PRZM/EXAMS) for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. None of these models include consideration of the impact processing of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern. For the proposed uses, based on the GENEEC and SCI-GROW models, the chronic drinking water concentration value are estimated to be 29 ppb for surface water and 1 pbb for ground water.

In the absence of monitoring data for pesticides, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to tebufenozide they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Tebufenozide is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore, EPA expects only dietary and occupational exposure from the use of tebufenozide.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether 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. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* As discussed above, no toxicological endpoint was identified for acute toxicity. Therefore, no acute aggregate risk assessment is needed.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 14% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure, non-nursing infants (<1 year old) will utilize 44% of the cPAD. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD 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, after calculating DWLOCs and comparing them to conservative model estimates of concentrations of tebufenozide in surface and ground water (29 ppb and 1 ppb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Tebufenozide is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore no short- and intermediate-term aggregate risk assessments are needed.

4. *Aggregate cancer risk for U.S. population.* Tebufenozide is classified as Group E (no evidence of carcinogenicity in humans).

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebufenozide residues.

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

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In prenatal developmental toxicity studies in rats and rabbits, there was no evidence of maternal or developmental toxicity; the maternal and developmental NOELs were 1,000 mg/kg/day (highest dose tested).

iii. *Reproductive toxicity study.* In 2-generation reproduction studies in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals.

iv. *Prenatal and postnatal sensitivity.* The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to tebufenozide. No maternal or developmental findings were observed in the prenatal developmental toxicity studies at doses up to 1,000 mg/kg/day in rats and rabbits. In the 2-generation reproduction studies in rats, effects occurred at the same or lower treatment levels in the adults as in the offspring.

v. *Conclusion.* There is a complete toxicity data base for tebufenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to tebufenozide. Based on this, EPA concludes that reliable data support the use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* No toxicological endpoint was identified for acute toxicity. Therefore, no acute aggregate risk assessment is needed.

3. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 44% of the cPAD for infants and 29% of the cPAD for children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD 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, after calculating DWLOCs and comparing them to conservative model estimates of concentrations of tebufenozide in surface and ground water (29 ppb and 1 ppb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk.* Tebufenozide is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore no short- and intermediate-term aggregate risk assessments are needed.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebufenozide residues.

V. Other Considerations

A. Metabolism in Plants and Animals

The residue of concern in plants is adequately understood and is tebufenozide *per se.* The qualitative nature of the residues in animals is also adequately understood based on acceptable poultry and ruminant metabolism studies. For animals, EPA has concluded that the residues of regulatory concern are tebufenozide and its metabolites benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-((4-carboxymethyl)benzoyl)hydrazide), benzoic acid, 3-hydroxymethyl,5-methyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, the stearic acid conjugate of benzoic acid, 3-hydroxymethyl, 5-methyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and benzoic acid, 3-hydroxymethyl-5-methyl-1-(1,1-dimethylethyl)-2-(4-(1-hydroxyethyl)benzoyl)hydrazide.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (for example, gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Residues of tebufenozide *per se* are not expected to exceed 2.0 ppm on soybeans as a result of this section 18 use.

D. International Residue Limits

There are currently no Canadian, or Mexican listings for tebufenozide residues. Codex maximum residue levels (MRLs) have been set for tebufenozide at 0.1 ppm for rice (husked), 0.05 ppm for walnuts, and 1 ppm for pome fruits.

VI. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in soybeans at 2.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the

old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300947 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 7, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–300947, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. 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) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to

include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

IX. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 17, 1999.

Peter Caulkins,

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. 321(q), (346a) and 371.

2. In § 180.482, by adding alphabetically to the table in paragraph (b), the following commodity to read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
* *	* *	*
Soybeans	2.0	12/31/01
* *	* *	*

* * * * *

[FR Doc. 99–31547 Filed 12–7–99; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 51

[CC Docket Nos. 96–45 and 96–98; FCC 99–86]

Implementation of the Local Competition Provisions of the Telecommunications Act of 1996; Deaveraged Rate Zones for Unbundled Network Elements

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: This document announces the lifting of the stay of the Commission's rule requiring each state to establish at least three geographic rate zones for unbundled network elements and interconnection.

DATES: Section 51.507(f), published at 61 FR 45476 (Aug. 29, 1996), is effective on May 1, 2000.

FOR FURTHER INFORMATION CONTACT: Neil Fried, Attorney, Common Carrier Bureau, Competitive Pricing Division, (202) 418–1520.

SUPPLEMENTARY INFORMATION: The Commission stayed the effectiveness of section 51.507(f) of its rules on May 7, 1999. See Deaveraged Rate Zones for Unbundled Network Elements, CC Docket No. 96–98, Stay Order, 14 FCC Rcd. 8300 (1999); 64 FR 32206 (June 16, 1999). The Commission stated that the stay would remain in effect until six months after the Commission released its order in CC Docket No. 96–45 finalizing and ordering implementation of high-cost universal service support for non-rural LECs. The Commission adopted on Nov. 2, 1999, its order in CC Docket No. 96–45 finalizing and ordering implementation of intrastate high-cost universal service support for non-rural LECs. See Federal-State Joint Board on Universal Service, CC Docket No. 96–45, Ninth Report and Order and Eighteenth Order on Reconsideration, FCC 99–306 (rel. Nov. 2, 1999). Consequently, as stated in the Nov. 2 order, the stay of section 51.507(f) shall be lifted on May 1, 2000. By that date, states are required to establish different rates for interconnection and UNEs in at least three geographic areas pursuant to section 51.507(f) of the Commission's rules.

List of Subjects in 47 CFR Part 51

Communications common carriers, Deaveraged rate zones, Interconnection, Local competition, Pricing of elements, Telecommunications, Unbundled network elements.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 99–31496 Filed 12–7–99; 8:45 am]

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