with.'' Any such use of methyl bromide would subject the resulting product to the labeling rule. Similarly, any product ''containing'' methyl bromide, as that phrase is defined by the labeling rule, is subject to the rule.

III. Submission to Congress and the General Accounting Office

The Congressional Review Act (''Act''), 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule.

IV. Additional Information

For more information on methyl bromide, please contact the Stratospheric Protection Hotline at 1–800–296–1996, Monday–Friday, between the hours of 10:00 a.m. and 4:00 p.m. (EST). **Federal Register** publications can be ordered from the Government Printing Office Order Desk (202) 783–3238; the citation is the date of publication. Each of the final rules referred to in this Notice may also be retrieved from EPA's Ozone Depletion World Wide Web site, at http://www.epa.gov/docs/ozone/ .

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: May 8, 1998.

Richard D. Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 98–12851 Filed 5–14–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300640; FRL–5784–8]

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 peppers (bell and non-bell) . 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 peppers (bell and non-bell). This regulation establishes a maximum permissible level for residues of tebufenozide in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on September 30, 1999.

DATES: This regulation is effective May 15, 1998. Objections and requests for hearings must be received by EPA on or before July 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300640], 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–300640], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, 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 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300640]. 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: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367, e-mail: ertman.andrew@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 a tolerance for residues of the insecticide tebufenozide, in or on peppers (bell and non-bell) at 0.5 part per million (ppm). This tolerance will expire and is revoked on September 30, 1999. 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 Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum published in the **Federal Register** of November 13, 1996 (61 FR 58135) (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 Exemption for Tebufenozide on Peppers (Bell and Non-bell) and FFDCA Tolerances

The applicant indicates that emergency conditions exist because beet armyworm (BAW) populations have demonstrated resistance to registered insecticides. The survival rate of the pest has been furhter compounded by a mild winter and unusually dry, hot weather which has increased. Naturally occurring epizootics require cool, wet conditions to have their greatest impact on this pest. The applicant also notes that there are unusually large numbers of BAW and damage due to BAW in peppers could result in a 50% yield loss without the use of an effective pesticide. EPA has authorized under FIFRA section 18 the use of tebufenozide on peppers (bell and non-bell) for control of beet armyworm in Texas. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebufenozide in or on peppers (bell and non-bell). In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on September 30, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on peppers (bell and non-bell) 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 peppers (bell and non-bell) 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 Texas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption 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. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

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

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

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure

that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute'', ''short-term'', ''intermediate term'', and ''chronic'' risks. These assessments are defined by the Agency as follows.

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

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

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

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

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

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

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of 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 peppers (bell and non-bell) at 0.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

1. *Acute toxicity*. No acute dietary risk endpoint was identified by the Agency, therefore this risk assessment is not required.

2. *Short - and intermediate - term toxicity*— i. *Short-term*. NOEL = 1,000 milligrams/kilogram/day (mg/kg/day). Concerning short-term dermal toxicity, the Agency noted that in a 21–day dermal toxicity study in rats there was no systemic toxicity observed at 1,000 mg/kg/day, the highest dose tested (HDT). This risk assessment is not required.

ii. *Intermediate-term*. The Agency did not identify an intermediate-term toxicology endpoint. Additionally, because there is no intermediate exposure scenario with this section 18 request, an intermediate-term risk assessment is not required.

3. *Chronic toxicity*. EPA has established the RfD for tebufenozide at 0.018 mg/kg/day. This RfD is based on a 1–year feeding study in dogs with a NOEL of 1.8 mg/kg/day. An uncertainty factor of 100 was used to account for both the interspecies extrapolation and intraspecies variability. The lowest-effect-level (LEL) of 8.7 mg/kg/day was based on hematopoietic findings (decreased red blood cells, hematocrit, hemoglobin levels, and increased heinz bodies, MCV, MCH, reticulocytes, and platelets).

4. *Carcinogenicity*. Tebufenozide has been classified as a Group E, ''no evidence of carcinogenicity for humans,'' chemical by the Agency.

B. 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. A permanent tolerance has been established for the residues of tebufenozide in/on walnuts at 0.1 ppm. A permanent tolerance at 1.0 ppm has also previously been established for imported apples. Time limited tolerances have been established on apples and on associated animal commodities, cottonseed at 0.2 ppm, leafy vegetables (except brassica) at 5.0 ppm, brassica (cole) leafy vegetables at 5.0 ppm, sugar beets at 0.3 ppm, sugarcane at 0.03 ppm, and turnip tops at 5.0 ppm. A time limited tolerance for peppers (bell and non-bell) had been established at 0.5 ppm, however this tolerance expired on February 28, 1998. 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 one day or single exposure. Since an acute dietary endpoint has not been identified in the toxicology database, an assessment of acute dietary risk was not conducted for this section 18 request.

ii. *Chronic exposure and risk*. In conducting this exposure assessment, EPA has made very conservative assumptions -- 100% of sugarcane and all other commodities having tebufenozide tolerances will contain tebufenozide residues and those residues would be at the level of the tolerance -- which result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment. The existing tebufenozide tolerances (published, pending, and including the necessary section 18 tolerances) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Population Subgroup	TMRC food (mg/kg/day)	%RfD
U.S. Population - 48 States	0.005516	31%
Nursing Infants (<1 year old)	0.007384	41%
Non-Nursing Infants (<1 year old)	0.014348	80%
Children (1–6 years old)	0.010646	59%
Children (7–12 years old)	0.007595	42%
Non-Hispanic Blacks	0.006063	34%
Non-Hispanic Others	0.007358	41%
Western Region	0.006033	34%

The subgroups listed above are: (a) the U.S. population (48 States); (b) those for infants and children; and, (c) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 States).

For chronic dietary risk to tebufenozide, the population subgroup with the largest percentage of the RfD occupied is non-nursing infants (<1 year old) at 80% of the RfD.

2. *From drinking water.* Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. There is no established Maximum Contaminant Level (MCL) for residues of tebufenozide in drinking water. No drinking water Health Advisories have been issued for tebufenozide. There is no entry for tebufenozide in the ''Pesticides in Groundwater Database'' (EPA 734–12–92–001, September 1992).

Chronic exposure and risk. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause 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.

3. *From non-dietary exposure.* Tebufenozide is not currently registered for any indoor or outdoor residential uses; therefore, no non-dietary residential exposure is anticipated.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better

determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether 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.

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

1. *Acute risk.* Since no acute endpoint was identified for tebufenozide, no acute risk assessment is required.

2. *Chronic risk.* Using the conservative exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary (food only) exposure to tebufenozide will utilize 31% of the RfD for the U.S. population. The Agency 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 (food and water) to exceed 100% of the RfD. Since there are no non-dietary non-occupational exposure scenarios for tebufenozide, there are no additional exposure from those routes. The Agency concludes that there is a reasonable certainty that no harm will result from aggregate chronic exposure to tebufenozide residues.

3. *Short- and intermediate-term risk.* Since there were no toxicity endpoints identified by the Agency for tebufenozide and no indoor/outdoor residential uses, no short- or intermediate-term risk assessment was required.

D. Aggregate Cancer Risk for U.S. Population

Since tebufenozide has been classified as a Group E chemical, ''no evidence of carcinogenicity for humans,'' no cancer risk assessment was required.

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 two-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 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 factor.

ii. *Developmental toxicity studies*— a. *Rats.* In a developmental toxicity study in rats, the maternal (systemic) NOEL was 250 mg/kg/day. The LOEL was 1,000 mg/kg/day, based on decreased body weight and food consumption. The developmental (pup) NOEL was > 1,000 mg/kg/day (HDT).

b. *Rabbits.* In a developmental toxicity study in rabbits, the maternal and developmental NOELs were >1,000 mg/kg/day (HDT).

iii. *Reproductive toxicity study— Rats.* In a multigeneration reproductive toxicity study in rats, the parental (systemic) NOEL was 0.85 mg/kg/day. Splenic pigmentation changes and extramedullary hematopoiesis occurred at the LOEL of 12.1 mg/kg/day (Female, Male; F_0, F_1). In addition to these effects, decreased body weight gain and food consumption occurred at 171.1 mg/kg/day. The reproductive (pup) NOEL was 125 mg/kg/day. The reproductive LOEL of 171.1 mg/kg/day, based on a slight increase in the number of pregnant females that either did not deliver or had difficulty and had to be sacrificed (F_1). Additionally at the LOEL, in F_1 dams, 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 F_1 and on LD's 0 and 4 to 80% for the second generation.

iv. *Pre- and post-natal sensitivity*— a. *Pre-natal sensitivity.* The developmental NOELs of >1,000 mg/kg/day (HDT) from the developmental toxicity studies in rats and rabbits demonstrate that there is no developmental (prenatal) 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.

b. *Post-natal sensitivity.* 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 post-natal sensitivity for infants and children in comparison to other exposed groups.

2. *Acute risk.* Since no acute endpoint was identified for tebufenozide, no acute risk assessment is required.

3. *Chronic risk.* Using the conservative exposure assumptions described above, HED has concluded that the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of tebufenozide ranges from 41% for nursing infants (< 1 year old) up to 80% for non-nursing

infants (< 1 year old). Despite the potential for exposure to tebufenozide in drinking water, HED does not expect the aggregate exposure (food and water) to exceed 100% of the RfD. Taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, HED 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

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

B. Analytical Enforcement Methodology

The Rohm and Haas Analytical Method TR 34–93–119 (HPLC/UV), should be adequate to determine residues of tebufenozide per se in/on peppers.

C. Magnitude of Residues

Residues of tebufenozide per se are not expected to exceed 0.5 ppm in or on peppers as a result of this section 18 use.

D. International Residue Limits

There are currently no CODEX, Canadian, or Mexican listings for tebufenozide residues, therefore there are no harmonization issues for this action.

VI. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in peppers (bell and non-bell) at 0.5 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 July 14, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as 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–300640] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

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

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that

there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 5, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

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

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

2. In § 180.482, in paragraph (b) by revising the entry for ''Peppers'' in the table to read as follows:

§180.482 Tebufenozide; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * *	* *	* *
Peppers	0.5	9/30/99
* * *	* *	* *

* * * * *

[FR Doc. 98–12718 Filed 5–14–98; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[FCC 97–218]

Forfeiture Proceedings; Correction

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations (47 CFR Part 1), which were published in the **Federal Register** of August 14, 1997, (62 FR 43474). The regulations related to Practice and Procedure for Guidelines for Assessing Forfeitures.

DATES: Effective on May 15, 1998.

FOR FURTHER INFORMATION CONTACT: Deborah Hannah, Compliance and Information Bureau, (202) 418–1168, email dhannah@fcc.gov.

SUPPLEMENTARY INFORMATION:

Background

The final rule regulations that are the subject of this correction amended the Commission's rules to incorporate a note to the rule the Commission's policy statement regarding forfeitures.

Need for Correction

As published, the final regulations contain an error which may prove to be misleading and need to be clarified.

List of Subjects in 47 CFR Part 1

Penalties.

Accordingly, 47 CFR Part 1 is corrected by making the following correcting amendment:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. 151, 154, 303, and 309(j); unless otherwise noted.

§ 1.80 [Corrected]

2. In § 1.80, in note to paragraph (b)(4), page 112, the first column, line 27, remove the figure ''$27,500'' and add, in its place, ''$275,000''.

Federal Communications Commission.

Pamera D. Hairston,

Chief, Compliance Division.

[FR Doc. 98–12904 Filed 5–14–98; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–16; RM–9213]

Radio Broadcasting Services; Three Rivers, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document dismisses a petition filed by Live Oak Broadcasting proposing the allotment of Channel 265A to Three Rivers, Texas. *See* 63 FR 07360, February 13, 1998. Petitioner failed to filed comments indicating its continuing interest in applying for Channel 265A at Three Rivers, Texas, if allotted. Therefore, we have dismissed the petition for rule making by Live Oak Broadcasting. With this action, this proceeding is terminated.

EFFECTIVE DATE: June 15, 1998.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 98–16, adopted April 22, 1998, and released May 1, 1998. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of