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 tolerances 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 actions 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 Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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 rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 8, 1998.

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. 346a and 371.

2. In § 180.516, by adding text to paragraph (b) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Apricots	5.0	12/31/99
Nectarines	5.0	12/31/99
Peaches	5.0	12/31/99
Plums	5.0	12/31/99

* * * * *

[FR Doc. 98–16677 Filed 6–23–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300675; FRL 5796–9]

RIN 2070–AB78

Tebufenozide; Benzoic Acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebufenozide in or on pecans and grapes, wine and a time-limited tolerance for residues of tebufenozide in or on pears. The time-limited tolerance for pears is being established to allow the use of tebufenozide on pears under an Experimental Use Permit. Rohm and Haas Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective June 24, 1998. Objections and requests for hearings must be received by EPA on or before August 24, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300675], 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–300675], 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–300675]. 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: Joseph M. Tavano, 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) 305–6411, e-mail: tavano.joseph@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 28, 1998 (63 FR 4252) [FRL 5763–6]; March 6, 1998 (63 FR 11240) [FRL 5777–5] and March 27, 1998 (63 FR 14926) [5577–6]. EPA, issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP) for tolerance by Rohm and Haas Company, 100 Independence mall west, Philadelphia, PA 19106–2399. These notices included a summary of the petitions prepared by Rohm and Haas Company, the registrant. There were no comments received in response to these notices of filing.

The petition requested that 40 CFR 180.482 be amended by establishing a tolerance for residues of the insecticide, tebufenozide, in or on pecans, grapes, wine and pears at 0.01, 0.5, and 1.0 part per million (ppm) respectively.

I. Risk Assessment and Statutory Findings

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. . . .''

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 was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of tebufenozide on pecans, grapes, wine and pears at 0.01, 0.5, and 1.0 ppm respectively. 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, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide are discussed below.

1. Acute toxicity studies with technical grade: Oral LD_{50} in the rat is > 5 grams for males and females - Toxicity Category IV; dermal LD_{50} in the rat is = 5,000 milligram/kilogram (mg/kg) for males and females - Toxicity Category III; inhalation LC_{50} in the rat is > 4.5 mg/l - Toxicity Category III; primary eye irritation study in the rabbit is a non-irritant; primary skin irritation in the rabbit > 5mg - Toxicity Category IV. Tebufenozide is not a sentizer.

2. In a 21–day dermal toxicity study, Crl: CD rats (6/sex/dose) received repeated dermal administration of either the technical 96.1% product RH-75,992 at 1,000 mg/kg/day Limit-Dose or the formulation 23.1% a.i. product RH-755,992 2F at 0, 62.5, 250, or 1,000 mg/kg/day, 6 hours/day, 5 days/week for 21 days. Under conditions of this study, RH-75,992 Technical or RH-75,992 2F demonstrated no systemic toxicity or dermal irritation at the highest dose tested 1,000 mg/kg/ during the 21–day study. Based on these results, the NOEL for systemic toxicity and dermal irritation in both sexes is 1,000 mg/kg/day highest dose tested (HDT). A lowest-observable-effect level (LOEL) for systemic toxicity and dermal irritation was not established.

3. A 1–year dog feeding study with a (LOEL) of 250 ppm, 9 mg/kg/day for male and female dogs based on decreases in RBC, HCT, and HGB, increases in Heinz bodies, methemoglobin, MCV, MCH, reticulocytes, platelets, plasma total bilirubin, spleen weight, and spleen/body weight ratio, and liver/body weight ratio. Hematopoiesis and sinusoidal engorgement occurred in the spleen, and hyperplasia occurred in the marrow of the femur and sternum. The liver showed an increased pigment in the Kupffer cells. The no-observed effect level (NOEL) for systemic toxicity in both sexes is 50 ppm (1.9 mg/kg/day).

4. An 18–month mouse carcinogenicity study with no carcinogenicity observed at dosage levels up to and including 1,000 ppm.

5. A 2–year rat carcinogenicity with no carcinogenicity observed at dosage levels up to and including 2,000 ppm (97 mg/kg/day and 125 mg/kg/day for males and females, respectively).

6. In a prenatal developmental toxicity study in Sprague-Dawley rats 25/group Tebufenozide was administered on gestation days 6–15 by gavage in aqueous methyl cellulose at dose levels of 50, 250, or 1,000 mg/kg/day and a dose volume of 10 ml/kg. There was no evidence of maternal or developmental toxicity; the maternal and developmental toxicity NOEL was 1,000 mg/kg/day.

7. In a prenatal developmental toxicity study conducted in New Zealand white rabbits 20/group Tebufenozide was administered in 5 ml/kg of aqueous methyl cellulose at gavage doses of 50, 250, or 1,000 mg/kg/day on gestation days 7–19. No evidence of maternal or developmental toxicity was observed; the maternal and developmental toxicity NOEL was 1,000 mg/kg/day.

8. In a 1993 two-generation reproduction study in Sprague-Dawley rats tebufenozide was administered at dietary concentrations of 0, 10, 150, or 1,000 ppm (0, 0.8, 11.5, or 154.8 mg/kg/day for males and 0, 0.9, 12.8, or 171.1 mg/kg/day for females). The parental systemic NOEL was 10 ppm (0.8/0.9 mg/kg/day for males and females, respectively) and the LOEL was 150 ppm (11.5/12.8 mg/kg/day for males and females, respectively) based on decreased body weight, body weight gain, and food consumption in males, and increased incidence and/or severity of splenic pigmentation. In addition, there was an increased incidence and severity of extramedullary hematopoiesis at 2,000 ppm. The reproductive NOEL was 150 ppm. (11.5/12.8 mg/kg/day for males and females, respectively) and the LOEL was 2,000 ppm (154.8/171.1 mg/kg/day for males and females, respectively) based on an increase in the number of pregnant females with increased gestation duration and dystocia. Effects in the offspring consisted of decreased number of pups per litter on postnatal days 0 and/or 4 at 2,000 ppm (154.8/171.1 mg/kg/day for males and females, respectively) with a NOEL of 150 ppm (11.5/12.8 mg/kg/day for males and females, respectively).

9. In a 1995 two-generation reproduction study in rats Tebufenozide was administered at dietary concentrations of 0, 25, 200, or 2,000 ppm (0, 1.6, 12.6, or 126.0 mg/kg/day for males and 0, 1.8, 14.6, or 143.2 mg/kg/day for females). For parental systemic toxicity, the NOEL was 25 ppm (1.6/1.8 mg/kg/day in males and females, respectively), and the LOEL was 200 ppm (12.6/14.6 mg/kg/day in males and females), based on histopathological findings (congestion and extramedullary hematopoiesis) in the spleen. Additionally, at 2,000 ppm (126.0/143.2 mg/kg/day in M/F), treatment-related findings included reduced parental body weight gain and increased incidence of hemosiderin-laden cells in the spleen. Columnar changes in the vaginal squamous epithelium and reduced uterine and ovarian weights were also observed at 2,000 ppm, but the toxicological significance was unknown. For offspring, the systemic NOEL was 200 ppm. (12.6/14.6 mg/kg/day in males and females), and the LOEL was 2,000 ppm (126.0/143.2 mg/kg/day in M/F) based on decreased body weight on postnatal days 14 and 21.

10. Several mutagenicity tests which were all negative. These include an Ames assay with and without metabolic activation, an in vivo cytogenetic assay in rat bone marrow cells, and *in vitro* chromosome aberration assay in CHO cells, a CHO/HGPRT assay, a reverse mutation assay with *E. Coli*, and an unscheduled DNA synthesis assay (UDS) in rat hepatocytes.

11. The pharmacokinetics and metabolism of tebufenozide were studied in female Sprague-Dawley rats (3–6/sex/group) receiving a single oral dose of 3 or 250 mg/kg of RH-5992,^{14}C labeled in one of three positions (A-ring, B-ring or *N*-butylcarbon). The extent of absorption was not established. The majority of the radiolabeled material was eliminated or excreted in the feces within 48 hours within 48 hours; small amounts (1 to 7% of the administered dose) were excreted in the urine and only traces were excreted in expired air or remained in the tissues. There was no tendency for bioacculmulation. Absorption and excretion were rapid.

A total of 11 metabolites, in addition to the parent compound, were identified in the feces; the parent compound accounted for 96 to 99% of the administered radioactivity in the high dose group and 35 to 43% in the low dose group. No parent compound was found in the urine; urinary metabolites were not characterized. The identity of several fecal metabolites was confirmed by mass spectral analysis and other fecal metabolites were tentatively identified by cochromatography with synthetic standards. A pathway of metabolism was proposed based on these data. Metabolism proceeded primarily by oxidation of the three benzyl carbons, two methyl groups on the B-ring and an ethyl group on the A-ring to alcohols, aldehydes or acids. The type of metabolite produced varies depending on the position oxidized and extent of oxidation. The butyl group on the quaternary nitrogen also can be leaved (minor), but there was no fragmentation of the molecule between the benzyl rings.

No qualitative differences in metabolism were observed between sexes, when high or low dose groups were compared or when different labeled versions of the molecule were compared.

12. The absorption and metabolism of tebufenozide were studied in a group of male and female bile-duct cannulated rats. Over a 72 hour period, biliary excretion accounted for 30%[M] to 34%[F] of the administered dose while urinary excretion accounted for ≈ 5% of the administered dose and the carcass accounted for < 0.5% of the administered dose for both males and females. Thus systemic absorption (percent of dose recovered in the bile, urine and carcass] was 35%[M] to 39%[F]. The majority of the radioactivity in the bile (20% [M] to 24% [F]) of the administered dose] was excreted within the first 6 hours postdosing indicating rapid absorption. Furthermore, urinary excretion of the metabolites was essentially complete within 24 hours postdosing. A large amount [67%(F) to 70% (M)] of the administered dose was unabsorbed and excreted in the feces by 72 hours. Total recovery of radioactivity was 105% of the administered dose.

A total of 13 metabolites were identified in the bile; the parent compound was not identified i.e. unabsorbed compound nor were the primary oxidation products seen in the feces in the pharmacokinetics study. The proposed metabolic pathway proceeded primary by oxidation of the benzylic carbons to alcohols, aldehydes or acids. Bile contained most of the other highly oxidized products found in the feces. The most significant individual bile metabolites accounted for 5% to 18% of the total radioactivity (F and/or M). Bile also contained the previously undetected (in the pharmacokinetics study] ''A'' Ring ketone and the ''B'' Ring diol. The other major components were characterized as high molecular weight conjugates. No individual bile metabolite accounted for > 5% of the total administered dose. Total bile radioactivity accounted for ≈ 17% of the total administered dose.

No major qualitative differences in biliary metabolites were observed between sexes. The metabolic profile in the bile was similar to the metabolic profile in the feces and urine.

B. Toxicological Endpoints

1. *Acute toxicity*. Toxicity observed in oral toxicity studies were not attributable to a single dose (exposure). No neuro or systemic toxicity was observed in rats given a single oral administration of Tebufenozide at 0, 500, 1,000, or 2,000 mg/kg. 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. Thus the risk from acute exposure is considered negligible.

2. *Short - and intermediate - term toxicity*. No dermal or systemic toxicity was seen in rats receiving 15 repeated dermal applications of the technical (97.2%) product at 1,000 mg/kg/day (Limit- Dose) as well as a formulated (23% a.i) product at 0, 62.5, 250, or 1,000 mg/kg/day over a 21–day period (MRID 42991507). The HIARC noted that in spite of the hematological effects seen in the dog study, similar effects were not seen in the 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. This risk is considered to be negligable.

3. *Chronic toxicity*. EPA has established the RfD for tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide at 0.018 mg/kg/day. This RfD is based on a NOEL of 1.8 mg/kg/day and an uncertainty factor (UF) of 100. The NOEL was established from the chronic toxicity study in dogs where the NOEL was 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 8.7 mg/kg/day. EPA determined that the 10 x factor to protect children and infants as required by FQPA should be removed. Therefore, the RfD remains the same at: 0.018 mg/kg/day. An UF of 100 is supported by the following factors.

(i) Developmental toxicity studies showed no increased sensitivity in fetuses when compared to maternal animals following *in utero* exposures in rats and rabbits.

(ii) Multi-generation reproduction toxicity studies in rats showed no increased sensitivity in pups as compared to adults and offspring.

(iii) There are no data gaps.

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

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 walnuts at 0.1 ppm and apples at 1.0 ppm. Numerous section 18 tolerances have been established at levels ranging from 0.3 ppm in sugar beet roots to 5.0 ppm in turnip tops. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide 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. Toxicity observed in oral toxicity studies were not attributable to a single dose (exposure). No Neuro or systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 mg/kg. 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. This risk is considered to be negligable.

ii. *Chronic exposure and risk*. The RfD used for the chronic dietary analysis is 0.018 mg/kg/day. In conducting this exposure assessment, EPA has made very conservative assumptions 100% of pecans and wine and sherry and and pears 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, HED is taking into account this conservative exposure assessment. The existing tebufenozide tolerances published, pending, and including the necessary section 18 tolerance(s) resulted in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD: U.S. Population (31% of RfD); Nursing Infants (<1 year old) (41% of RfD); Non-Nursing Infants (<1 year old) (80% of Rfd); Children (1–6 years old) (60% of RfD); Children (7–12 years old) (43% of Rfd); Females (13 + years old, nursing) (31% of RfD); Males (13–19 years old) (28% of RfD); Non-Hispanic Blacks (34% of RfD); Non Hispanic Others (42% of RfD) Western Region (35% of RfD). The subgroups listed above are: (1) the U.S. population (48 States); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 States).

2. *From drinking water*— i. *Acute exposure and risk*. Because no acute dietary endpoint was determined, the Agency concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

ii. *Chronic exposure and risk*. Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile.Under certain conditions tebufenozide appears to have the potential to contaminate ground and surface water through runoff and leaching; subsequently potentially contaminating drinking water.There are no established Maximum Contaminant Levels (MCL) for residues of tebufenozide in drinking water and no Health Advisories (HA) have been issued for tebufenozide therefore these could not be used as comparative values for risk assessment. Therefore, potential residue levels for drinking water exposure were calculated using GENEEC (surface water) and SCIGROW (ground water) for human health risk assessment. Because of the wide range of half-life values (66–729 days) reported for the aerobic soil metabolism input parameter a range of potential exposure values were calculated. In each case the worst case upper bound exposure limits were then compared to appropriate chronic drinking water level of concern (DWLOC). In each case the calculated exposures based on model data were below the DWLOC.

3. *From non-dietary exposure*. Tebufenozide is not currently registered for use on any residential non-food sites. Therefore there is no chronic, short- or intermediate-term exposure scenario.

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, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide 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, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide 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, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide has a common mechanism of toxicity with other substances.

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

1. *Acute risk*. Since no acute toxicological endpoints were established, no acute aggregate risk exists.

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. 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. The modeling data for tebufenozide indicate levels less than OPP's DWLOC. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. There are no registered residential uses of tebufenozide. Since there is no potential for exposure to tebufenozide from residential uses, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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. Since there are currently no registered indoor or outdoor residential non-dietary uses of tebufenozide and no short- or intermediate-term toxic endpoints, short- or intermediate-term aggregate risk does not exist.

E. Aggregate Cancer Risk for U.S. Population

Since, tebufenozide has been classified as a Group E, ''no evidence of carcinogenicity for humans,'' this risk does not exist.

F. 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, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide, 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 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 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 (HGT)

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*. In a 1993 two-generation reproduction study in Sprague-Dawley rats, tebufenozide was administered at dietary concentrations of 0, 10, 150, or 1,000 ppm (0, 0.8, 11.5, or 154.8 mg/kg/day for males and 0, 0.9, 12.8, or 171.1 mg/kg/day for females). The parental systemic NOEL was 10 ppm (0.8/0.9 mg/kg/day for males and females, respectively) and the LOEL was 150 ppm (11.5/12.8 mg/kg/day for males and females, respectively) based on decreased body weight, body weight gain, and food consumption in males, and increased incidence and/or severity of splenic pigmentation. In addition, there was an increased incidence and severity of extramedullary hematopoiesis at 2,000 ppm. The reproductive NOEL was 150 ppm. (11.5/12.8 mg/kg/day for males and females, respectively) and the LOEL was 2,000 ppm (154.8/171.1 mg/kg/day for males and females, respectively) based on an increase in the number of pregnant females with increased gestation duration and dystocia. Effects in the offspring consisted of decreased number of pups per litter on postnatal days 0 and/or 4 at 2,000 ppm (154.8/171.1 mg/kg/day for males and females, respectively) with a NOEL of 150 ppm (11.5/12.8 mg/kg/day for males and females, respectively)

In a 1995 two-generation reproduction study in rats, tebufenozide was administered at dietary concentrations of 0, 25, 200, or 2,000 ppm (0, 1.6, 12.6, or 126.0 mg/kg/day for males and 0, 1.8, 14.6, or 143.2 mg/kg/day for females). For parental systemic toxicity, the NOEL was 25 ppm (1.6/1.8 mg/kg/day in males and females, respectively), and the LOEL was 200 ppm (12.6/14.6 mg/kg/day in males and females), based on histopathological findings (congestion and extramedullary hematopoiesis) in the spleen. Additionally, at 2,000 ppm (126.0/143.2 mg/kg/day in M/F), treatment-related findings included reduced parental body weight gain and increased incidence of hemosiderin-laden cells in the spleen. Columnar changes in the vaginal squamous

epithelium and reduced uterine and ovarian weights were also observed at 2,000 ppm, but the toxicological significance was unknown. For offspring, the systemic NOEL was 200 ppm. (12.6/14.6 mg/kg/day in males and females), and the LOEL was 2,000 ppm (126.0/143.2 mg/kg/day in M/F) based on decreased body weight on postnatal days 14 and 21.

iv. *Pre- and post-natal sensitivity*. The toxicology data base for tebufenozide is complete and includes acceptable developmental toxicity studies in both rats and rabbits as well as a two two-generation reproductive toxicity studies in rats.

The EPA determined that 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 two two-generation reproduction studies in rats, effects occurred at the same or lower treatment levels in the adults as in the offspring.

2. *Acute risk*. Since no acute toxicological endpoints were established, no acute aggregate risk exists.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide from food will utilize from 31% of the RfD for the U.S. population to 80% of the RfD for non-nursing infants less than 1 year old. The potential for exposure to tebufenozide in drinking water does not exceed EPA's level of concern. There are currently no tebufenozide residential or non-dietary exposure scenarios. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide residues.

4. *Short- or intermediate-term risk*. Since no short- and intermediate-term toxicological endpoints were established by EPA, no acute aggregate risk exists.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residues of tebufenozide in/on plants is adequately understood. The residue of concern for both regulatory (tolerance expression) and risk assessment purposes is the parent compound, tebufenozide *per se*.

There are no animal feed items associated with pecans. According to information supplied by the petitioner, wine grapes and wine grape processing commodities are not items of animal feed in Europe. Therefore, a discussion of potential transfer of secondary residues to animal commodities is not germane to these actions.

B. Analytical Enforcement Methodology

A HPLC/UV analytical method, *Enforcement Residue Analytical Method for RH-5992 in Pecans with HPLC-MS Confirmation* is adequate for enforcement purposes in pecans. A successful Agency validation for an analytical method to detect residues of tebufenozide *per se* has been conducted by ACL/BEAD.

The method used in the analysis of the total residue of concern in the European field residue trials in wine, Method AL 013/92–0, was developed by Rohm and Haas and independently validated. In the validation of this method, at levels from 0.01 to 0.5 ppm in wine recoveries ranged from 84 to 109%; in grapes at levels of 0.02 to 1.0 ppm recoveries ranged from 77 to 128%. The limit of quantitation was given as 0.02 ppm for grapes and 0.01 ppm for wine. The method is different from those validated for domestic commodities but was determined to be adequate for data collection.

C. Magnitude of Residues

Adequate residue data were provided to support tolerances of 0.01 ppm for pecans and 0.5 ppm for grapes, wine and a time-limited tolerance for pears.

There are no pecan or pear processed comodities of regulatory concern. In those instances when treated grapes were vinified, residues of tebufenozide in the aged wine were a third to a half of those in the treated grapes. The maximum residue found in the wine treated at label rates was 0.3 ppm; therefore, a tolerance for wine grapes would suffice for the wine made from them.

Since there are no pecan or pear animal feed items and according to information supplied by the petitioner, wine grapes and wine grape processing commodities are not items of animal feed in Europe, no secondary residues in animals are expected.

D. International Residue Limits

There are currently no CODEX, Canadian, or Mexican listings for tebufenozide residues in or on pecans or pears, therefore there are no harmonization issues for these crops.

Maximum residue levels (MRL) of 0.5 ppm have been established for wine grapes in France, Italy, and Germany. The tolerance of 0.5 ppm in or on wine grapes is in harmony with these MRLs.

E. Rotational Crop Restrictions

Since pecans, grapes, and pears are not rotated to other crops, a discussion of tebufenozide accumulation in rotational crops is not germane to this action.

IV. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in pecans, grapes, wine, and pears at 0.01, 0.5, and 1.0 ppm respectively.

V. 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 August 24, 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 Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300675] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 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.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any 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 on the basis of petitions under FFDCA section 408(d), such as the tolerances 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 actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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 the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated:June 12, 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, by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

§180.482 Tebufenozide; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	* * * *	
Grapes, wine [1]	0.5	NA
Pears	1.0	2001
Pecans	0.01	NA

Commodity	Parts per million	Expiration/Revocation Date
* * *	* * * *	

[1] There are no U.S. registrations on grapes as of June 24, 1998.

[FR Doc. 98–16822 Filed 6–23–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300627; FRL–5777–7]

RIN 2070–AB78

Recodification of Certain Tolerance Regulations

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is issuing this technical amendment to consolidate parts 185 and 186 pesticide tolerance regulations into part 180. This recodification is consistent with the Food Quality Protection Act which places all pesticide tolerances under section 408 of the Federal Food, Drug, and Cosmetic Act, thus eliminating the distinction between pesticide tolerances for raw and processed foods.

DATES: This regulation becomes effective June 24, 1998.

FOR FURTHER INFORMATION CONTACT: By mail, Joseph Nevola, Special Review Branch (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: 3rd Floor, Crystal Station, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8037; e-mail: nevola.joseph@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Pesticide tolerance regulations promulgated under sections 408 and 409 of the Federal Food, Drug, and Costmetic Act (FFDCA), 21 U.S.C. 346a and 348, appear in parts 180, 185 and 186 of title 40 of the Code of Federal Regulations. Part 180 contains pesticide tolerance regulations for pesticide chemical residues in raw agricultural commodities. Such regulations were promulgated under FFDCA section 408. Parts 185 and 186 contain food additive regulations for pesticide chemical residues in processed food. These regulations were promulgated under FFDCA section 409.

The Food Quality Protection Act (FQPA) was signed into law in August of 1996. Under section 408(j) of the FFDCA, as amended by the FQPA, all pesticide tolerances established under FFDCA section 409 were deemed to be tolerances under FFDCA section 408. Since there is no longer a statutory reason for the separation of these tolerances into different parts of the CFR, as a part of the routine process of issuing new and revised tolerances, EPA is consolidating certain sections of the regulations in parts 185 and 186 into 40 CFR part 180. Although the tolerances are being restructured to fit into part 180, no substantive changes are being made. The tolerance regulations in parts 185 and 186 are being redesignated as follows:

Old CFR section	New CFR section
185.425	180.519
185.2900	180.520
185.3475	180.521
185.3480	180.522
185.4025	180.523
185.4200	180.524
185.5300	180.525
186.5400	185.526

This action is being taken pursuant to EPA's authority under FFDCA section 408(e)(1)(C) to issue regulations implementing the requirements of section 408. Because this regulation involves a technical change to existing regulations and has no substantive impact, EPA for good cause finds that it would be in the public interest to promulgate this regulations without issuing a notice of proposed rulemaking under section 408(e)(2).

I. Regulatory Assessment Requirements

This final rule does not impose any requirements. It only implements technical amendments to the Code of Federal Regulations (CFR), by recodifying certain tolerances that have already been established under FFDCA section 408. Basically, this notice simply consolidates the tolerances, which currently appear in two separate parts of the CFR (i.e., 40 CFR parts 185 and 186), into a single part (i.e., 40 CFR part 180). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). For the same reason, it does not require any action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). In addition, since this type of action does not require any proposal, no action is needed under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.).

II. 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 the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.