VI. Paperwork Reduction Act of 1995

The agency has determined that this final rule contains no additional collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 900 is amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

2. Section 900.12 is amended by revising paragraphs (b)(5) and (e)(5)(vii)(A) to read as follows:

§ 900.12 Quality standards.

* * * * *

(b) * * *

(5) *Light fields.* For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

* * * * *

(e) * * *

(5) * * *

(vii) * * *

(A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

* * * * *

Dated: April 7, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–9222 Filed 4–13–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300830; FRL–6071–3]

RIN 2070–AB78

Pyriproxyfen (2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyriproxyfen in or on pome fruits, walnuts and apple pomace, wet. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 14, 1999. Objections and requests for hearings must be received by EPA on or before June 14, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300830], 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–300830], 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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–300830]. 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 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: Rm. 222, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6411, tavano.joseph@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 27, 1998 (63 FR 14926) (FRL–5579–6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP 7F4882) for tolerance by Valent U.S.A. Corporation, 1333 N. California Blvd., Walnut Creek, CA 94596 This notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.510 be amended by establishing a tolerance for residues of the insecticide, pyriproxyfen, in or on pome fruits, walnuts and apple pomace, wet at 0.2, 0.02 and 0.8 part per million (ppm) respectively.

I. Background and Statutory Findings

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. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

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 pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of pyriproxyfen on pome fruits, walnuts and apple pomace, wet at 0.2, 0.02 and 0.8 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 pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine are discussed in this unit.

1. *Acute toxicity.* Acute toxicity studies with technical pyriproxyfen: Oral LD_{50} in the rat is >5,000 milligram/kilogram (mg/kg) for males and females - Toxicity Category IV; dermal LD_{50} in the rabbitat >2,000 mg/kg - Toxicity Category IV; inhalation LC_{50} in the rat is >1.3 mg/L (highest dose attainable) - Toxicity Category III; primary eye irritation in the rabbit (mild irritatant) - Toxicity Category III; primary dermal irritation in the rabbit (not an irritant: non-irritating to the skin under conditions of test))- Toxicity Category IV. Pyriproxyfen is not a sensitizer.

2. *Subchronic toxicity.* In the subchronic feeding study in rats, the no-observed effect level (NOAEL) was 27.68 mg/kg/day. The lowest oberved effect level (LOAEL) was 141.28 mg/kg/day, based upon higher mean total cholesteral and phospholipids, decreased mean RBCs, hematocrit and hemoglobin counts and increased relative liver weight.

In the subchronic feeding study in dogs, the NOAEL was 100 mg/kg/day and the LOAEL was 300 mg/kg/day. The effects were based on increased absolute and relative liver weight in males and hepatocellular hypertrophy in females. These findings were also observed at 1,000 mg/kg/day and may represent adaptive changes at both 300 mg/kg/day and the limit dose of 1,000 mg/kg/day.

In a 21-day dermal study in rats, the NOAEL for systemic effects was >1,000 mg/kg/day (limit dose). The LOAEL for systemic effects was not established in this study. No dermal or systemic toxicity was observed at any dose tested.

3. *Chronic toxicity/carcinogenicity.* In a 1-year chronic feeding study in dogs, the NOAEL was 100 mg/kg/day. The LOAEL was 300 mg/kg/day based on decreased weight gain, increased absolute and relative liver weight, mild anemia, increased cholesterol and triglycerides.

The oncogenicity study in mice the NOAEL and LOAEL for systemic toxicity in males are 600 ppm and 3,000 ppm, respectively, based on an renal lesions in males. The technical grade test material was given to male and female CD-1 mice in diet for 18 months at 0, 120, 600, or 3,000 ppm. No statistically significant increase in tumor incidence relative to controls were observed in either sex at any dose up to 3,000 ppm HDT.

In the chronic feeding/oncogenicity study in rats, the NOAEL (systemic) was 35.1 mg/kg/day and the LOAEL (systemic) was 182.7 mg/kg/day. The technical grade test material was administered to male and female Sprague-Dawley rats in diet for 24 months at 0, 120, 600, or 3,000 ppm. A decrease of 16.9% in body weight gain in females at 3,000 ppm 182.7 mg/kg/day was basis for the systemic LOAEL.

4. *Developmental toxicity.* In the developmental study in rabbits, the maternal NOAEL/LOAEL for maternal toxicity were 100 and 300 mg/kg/day based on premature delivery/abortions, soft stools, emaciation, decreased activity and bradypnea. The developmental NOAEL was determined to be 300 mg/kg/day and developmental LOAEL was determined to be undetermined; no dose related anomalies occurred in the 4 remaining litters studied at 1,000 mg/kg/day.

In the developmental study in rats, a maternal NOAEL/LOAEL were determined to be 100 mg/kg/day and 300 mg/kg/day, respectively. These findings were based on increased incidences in mortality and clinical signs at 1,000 mg/kg/day with decreased in food consumption, body weight, and body weight gain together with increases in water consumption at 300 and 1,000 mg/kg/day. The developmental NOAEL/LOAEL were 100 mg/kg/day and 300 mg/kg/day based on the increase of skeletal variations at 300 mg/kg/day and above.

5. *Reproductive toxicity.* In a 2-generation reproduction study in rats, the systemic NOAEL was 1,000 ppm (87 mg/kg/day). The LOAEL for sytemic toxicity was 5,000 ppm (453 mg/kg/day). Effects were based on decreased body weight, weight gain and food consumption in both sexes and both generations, and increased liver weights in both sexes associated with liver and kidney histopathology in males. The reproductive NOAEL was 5,000 ppm. A reproductive LOAEL was not established.

6. *Mutagenicity— Studies on gene mutation and other genotoxic effects.* In a Gene Mutation Assay (Ames Test)/ Reverse Mutation, finding was determined as negative for induction of gene mutation measured as the reversion to histine protrophy of 5 *S.typhimurium* strains and *E.Coli* WP2 uvra at doses from 10 to 5,000 µg/plate with and without S-9 activation. The highest dose was insoluble. A Gene Mutation assay in Mammalian Cells was found to be negative f or mutagencity in CHO (Chinese hamster ovary) V79 cells with and without metabolic activation yp to cytotoxic doses (300 µg/mL). In a Structural Chromosomal Aberration Assay *in vivo*, findings proved nonclastogenic in CHO cells both with and without S-9 activation up to cytotoxic doses 300 µg/mL. In Other Genotoxicity Assays, an increase in unscheduled DNA synthesis was not induced both with and without activation in HeLa cells exposed up to insoluble doses ranging to 6.4 µg/mL without activation and 51.2 µg/mL with activation.

7. *Metabolism*. The results of the metabolism studies are as follows: Acceptable Rats were orally dosed with ^{14}C-labeled pyriproxyfen at 2 or 1,000 mg/kg and at repeated oral doses 14 daily doses of unlabeled pyriproxyfen at 2 mg/kg followed by administration of a single oral dose of labeled pyriproxyfen at 2 mg/kg. Most radioactivity was excreted in the feces 81-92% and urine 5-12% over a 7 day collection period. Expired air was not detected. Tissue radioactivity levels were very low less than 0.3% except for fat. Examination of urine, feces, liver, kidney, bile and blood metabolites yielded numerous > 20 identified metabolites when compared to synthetic standards. The major biotransformation

reactions of pyriproxyfen include: (1) Oxidation of the 4′ - position of the terminal phenyl group; (2) Oxidation at the 5′ - position of pyridine; (3) Cleavage of the ether linkage and conjugation of the resultant phenols with sulfuric acid.

8. *Neurotoxicity.* Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental or reproductive studies performed with pyriproxyfen.

B. Toxicological Endpoints

1. *Acute toxicity.* An acute dietary dose and endpoint was not identified in the database. The Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

2. *Short- and intermediate-term toxicity.* Doses and endpoints were not identified for short and intermediate-term dermal and inhalation exposure. The Agency concludes that there are reasonable certainties of no harm from these exposures.

3. *Chronic toxicity.* EPA has established the RfD for pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine at 0.35 mg/kg/day. This Reference Dose (RfD) is based on a NOAEL of 35.1 mg/kg/day and an uncertainty factor (UF) of 100. The NOAEL was established from the combined chronic feeding/oncogenicity study in rats where the the LOAEL was 3,000 ppm, based on a 16.9% decrease in body weight gain in females when compared to controls.

4. *Carcinogenicity.* Pyriproxyfen is classified as Category E: not carcinogenic in two acceptable animal studies.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.510) for the residues of pyriproxyfen, in or on a variety of raw agricultural commodities. In todays action tolerances will be established for the residues of pyriproxyfen, in or on the raw agricultural commodities: pome fruits, walnuts and apple pomace, wet at 0.2, 0.02 and 0.8 ppm respectively. Risk assessments were conducted by EPA to assess dietary exposures from pyriproxyfen as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No acute dietary endpoint and dose was identified in the toxicology data base for pyriproxyfen, therefore the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk.* The chronic dietary exposure analysis from food sources was conducted using the RfD of 0.35 mg/kg/day. The RfD is based on the NOAEL of 35.1 mg/kg/day in male and female rats from the Chronic Feeding/Oncogenicity study in rats and an uncertainty factor of 100 applicable to all population subgroups.

In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions: 100% of pome fruits and walnuts having pyriproxyfen tolerances will contain pyriproxyfen residues and those residues will be at the level of the established tolerance. This results 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 pyriproxyfen tolerances (published and pending) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD: US. Population (48 states) 0.8%; Hispanics 1.0%; Non-hispanic blacks 0.9%; Non-hispanic other than black or white 1.2%; All infants (< 1 year) 1.1%; Nursing Infants (< 1 year old) 0.8%; Non-Nursing Infants (< 1 year old) 1.2%; Children (1-6 years old) 2.2%; Children (7-12 years old) 1.3%; Females (13+/nursing) 1.0%.

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.* As previously stated, no acute dietary endpoint was identified for assessment of acute dietary risk. Thus the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk.* Following OPP's Interim Approach for Addressing Drinking Water Exposure in Tolerance Decision making issued on 17-NOV-1997, the Generic Expected Environmental Concentration (GENEEC) model and the Screening Conccentration In Ground Water) (SCI-GROW) model were run to produce estimates of pyriproxyfen concentrations in surface and ground water respectively. The primary use of these models is to provide a coarse screen for sorting out pesticides for which OPP has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health drinking water levels of comparison (DWLOCs). A human health DWLOC is the concentration of a pesticide in drinking water which would result in unacceptable aggregate risk, after having already factored in all food exposures and other non-occupational exposures for which OPP has reliable data.

For chronic (non-cancer) exposure to pyriproxyfen in surface and ground water, the drinking water levels of concern are 12,000 µg/L for U.S. Population and 3,400 µg/L for children (1-6 yrs). To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to pyriproxyfen in drinking water. DWLOCs were then calculated using default body weights and drinking consumption figures.

Estimated average concentrations of pyriproxyfen in surface and ground water are 0.14 parts per billion (ppb) and 0.006 ppb, respectively. The estimated average concentrations of pyriproxyfen in surface and ground water are less than OPP's level of concern for pyriproxyfen in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account present uses and uses proposed in this action, OPP concludes with reasonable certainty that residues of pyriproxyfen in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

3. *From non-dietary exposure.* Pyriproxyfen is the active ingredient in many registered residential (indoor, non-food) products for flea and tick control. Formulations include foggers, aerosol sprays, emulsifiable concentrates, and impregnated materials (pet collars).

i. *Acute exposure and risk.* An acute dietary dose and endpoint was not identified. Thus the risk from aggregate exposure is considered to be negligible.

ii. *Chronic exposure and risk.* With the exception of the pet collar uses, consumer use of pyriproxyfen typically results in short-term, intermittent exposures. Hence, chronic residential post-application exposure and risk assessments were conducted to estimate the potential risks from pet collar uses.

The risk assessment was conducted using the following assumptions: application rate of 0.58 mg ai/day (product label), average body weight for a 1 to 6 year old child of 10 kg, the active ingredient dissipates uniformly through 365 days (the label instruct to change collar once a year), 1% of the

active ingredient is available for dermal and inhalation exposure per day. The assessment also assumes an absorption rate of 100%. This is a conservative assumption since the dermal absorption was estimated to be 10%.

The estimated chronic term MOE was 61,000 for children, and 430,000 for adults. An adequate MOE is 100. The risk estimates indicate that potential risks from pet collar uses do not exceed the Agency's level of concern.

iii. *Short- and intermediate-term exposure and risk.* The Agency concludes that there is reasonable certainty of no harm from short term and intermediate-term dermal and inhalation occupational and residential exposure due to the lack of significant toxicological effects observed.

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.''

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

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

1. *Acute risk.* An acute dietary dose and endpoint was not identified. Thus the risk from acute aggregate exposure is considered to be negligible.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has calculated that the percentage of the RfD that will be utilized by dietary (food) exposure to residues of pyriproxyfen is 0.8 percent for the U.S. Population. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years old). See discussion below. Chronic residential exposure to pyriproxyfen from pet collars is estimated to increase total pyriproxyfen exposure only marginally. Despite the potential for exposure to pyriproxyfen in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

This determination is based on a comparison of estimated concentrations of pyriproxyfen in surface and ground water to levels of concern for pyriproxyfen in drinking water. The estimates of pyriproxyfen in surface and ground water are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with the pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impact of pyriproxyfen in food and drinking water as part of the aggregate chronic risk assessment process.

3. *Short- and intermediate-term risk.* No significant toxicological effects were observed in the animal studies that could be attributed to short- or intermediate-term exposure. Thus, the risk from short- and intermediate-term exposure is negligible.

4. *Aggregate cancer risk for U.S. population.* Pyriproxyfen is classified as Category E: not carcinogenic in two acceptable animal studies.

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

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

1. *Safety factor for infants and children*— i. In assessing the potential for additional sensitivity of infants and children to residues of pyriproxyfen, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 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.* In the rat developmental study, the developmental NOAEL was 100 mg/kg/day and the maternal NOAEL was 100 mg/kg/day. Therefore, there was no prenatal developmental toxicity in the presence of maternal toxicity. Similarly in rabbits, the prenatal developmental NOAEL was 300 mg/kg/day and the maternal NOAEL was 300 mg/kg/day. Therefore, prenatally exposed fetuses were not more sensitive to the effects of pyriproxyfen than maternal animals.

iii. *Reproductive toxicity study.* In the rat reproduction study, the parental NOAEL of 1,000 ppm was identical to the pup NOAEL of 1,000 ppm and decreased body weight was seen in both pup and parental animals. This finding demonstrates that there are no extra sensitivities with respect to pre- and post-natal toxicity between adult and infant animals.

iv. *Pre- and post-natal sensitivity.* The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to in utero and postnatal exposure to pyriproxyfen.

v. *Conclusion.* The 10X factor for infants and children (as required by FQPA) was removed, since there was no special sensitivity for infants and children and the data base is complete. For chronic dietary risk assessment, a UF of 100 is adequate for protection from exposure to pyriproxyfen.

2. *Acute risk.* An acute dietary dose and endpoint was not identified. Thus the risk from acute aggregate exposure is considered to be negligible.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyriproxyfen from food will utilize 2.2% of the RfD for infants and

children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to pyriproxyfen in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.* Short-term and intermediate-term dermal and inhalation risks are judged to be negligible due to the lack of significant toxicological effects observed.

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

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is understood. Acceptable metabolism studies using ^{14}C-labeled pyriproxyfen (phenyl and pyridyl rings) have been performed in apple RACs and cotton RACs. Metabolism of pyriproxyfen in apples proceeds through hydroxylation and cleavage of the phenoxy ether linkage. Primary metabolites formed are further metabolized to more polar products by oxidation or conjugation reactions. Similar metabolic pathways were observed for the metabolism of pyriproxyfen in cotton, goats, and hens.

The HED Metabolism Assessment Review Committee (MARC) has determined that there are no pyriproxyfen metabolites of toxicological or regulatory concern in plants thus, tolerances based on the parent only are appropriate.

There are no poultry feed items associated with pome fruits and walnuts. Therefore, no secondary residues are expected to occur in poultry eggs, fat, meat, and meat byproducts as a result of the proposed uses on pome fruits and walnuts.

Valent submitted data from studies investigating the metabolism of Ph-^{14}C uniformly ring labeled and Py-^{14}C in pyridine ring 2 and 6 positions pyriproxyfen in lactating goats. Two goats were fed 10 ppm of the Ph-^{14}C pyriproxyfen daily for 5 days, while two other goats were fed 10 ppm of the Py-^{14}C pyriproxyfen daily for 5 days, with 1 control goat. Urine, feces and milk samples were obtained twice daily. After sacrifice at 6 hours after last dose, samples of blood, heart, kidneys, liver, loin muscle, rear leg muscle, omental and perirenal fat, gastrointestinal tract and contents were collected for ^{14}C analysis.

The majority (62-76%) of the ^{14}C-pyriproxyfen ingested by goats was excreted in urine and feces, with residue levels in feces being higher than in urine. Approximately 25 to 32% of the administered ^{14}C-pyriproxyfen was found in goat tissues, with the large majority located in the gastrointestinal tract. These studies show that metabolism of phenyl-^{14}C pyriproxyfen in goats proceeds through hydroxylation of the phenoxyphenyl and pyridyl rings, sulfation of the 4′-OH phenoxyphenyl moiety, and cleavage of the ether linkage. Metabolism of pyridyl-^{14}C pyriproxyfen in goats proceeds through hydroxylation of the phenoxyphenyl and pyridyl rings, sulfation of the 4′-OH phenoxyphenyl moiety, cleavage of the ether linkage and oxidation of the side chain. Therefore the nature of the residue in ruminants is adequately understood.

Should future crop uses increase the maximum dietary burden in animals to the point that tolerances are needed in animal commodities, the residue of concern will be pyriproxyfen and the free and sulfate forms of 4′-OH-PYR.

B. Analytical Enforcement Methodology

The proposed enforcement methods for residues of pyriproxyfen on plant commodities has not been subjected to a complete Agency method validation at this time. The EPA validation laboratory at Beltsville is currently being relocated, and consequently, the laboratory is not operational at this time. The method trial requests have been received and a validation is scheduled. In the interim, EPA has conducted a preliminary review of the apple and walnut methods that indicates that they appears to be suitable for enforcement purposes pending the outcome of the actual method validation. Given that the registrant has provided concurrent fortification data to demonstrate that the methods are adequate for data collection purposes and has provided the Agency with a successful Independent Laboratory Validation, coupled with EPA's preliminary review, EPA concludes that the methods are suitable as enforcement methods to support tolerances associated with a conditional registration only. As a condition of the registration, the Agency will require successful method validations and the registrant will be required to make any necessary modifications to the methods resulting from the laboratory validation.

C. Magnitude of Residues

Adequate residue data were provided to support tolerances of 0.2 ppm forpome fruits and 0.02 ppm for walnuts.

Processing data provided for apples indicated concentration of residues in wet apple pomace. Based on the available field trial data the highest average field trial (HAFT) for apples is 0.16 ppm for residues of pyriproxyfen. The maximum pyriproxyfen residues in apple pomace based on the HAFT and the average concentration factor 4.9x would be 0.78 ppm. Therefore, the proposed tolerance of 0.8 ppm for pyriproxyfen residues in/on wet apple pomace is adequate.

There are no processed commodities associated with pears and walnuts andtherefore no tolerances for processed commodities are required.

A feeding study on lactating dairy cows was submitted. Using proposed tolerances for animal feed items, the calculated maximum theoretical dietary burdens for beef and dairy cattle are 1.69 and 1.29 ppm, respectively. Based on the dietary burdens, the dosing levels of 3, 9, and 30 ppm in the study represent 2x, 5x, and 18x the maximum theoretical dietary burden to beef cattle, and 2x, 7x, and 23x the maximum theoretical dietary burden to dairy cattle. Typically, tolerances are required on all animal commodities having detectable residue levels at a 10x dosing rate or below. For the computed MTDB of 1.69 ppm in beef cattle, this would include the 3 and 9 ppm dosing levels. The only commodity having detectable pyriproxyfen residues at these levels was fat: 0.01 - 0.03 ppm. Since the MTDB calculation is based on a nutritionally unbalanced diet and includes contributions from some animal feed items that are used only regionally, the Agency will not require the establishment of pyriproxyfen tolerances in fat at this time. However, should future new uses include additional animal feed items, tolerances on animal commodities will be needed.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for pyriproxyfen residues in/on pome fruits or walnuts. Therefore, international harmonization is not an issue at this time.

E. Rotational Crop Restrictions

The Agency has determined that rotational crop studies are not required for uses of pesticides on pome fruits or walnuts

IV. Conclusion

Therefore, the tolerances are established for residues of pyriproxyfen in pome fruits, walnuts and apple pomace, wet at 0.2 , 0.02, and 0.8 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 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 June 14, 1999, 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 under the ''ADDRESSES'' section (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 regulation. 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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300830] (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 Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition 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 specficed 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance/exemption 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 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.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by

statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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 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: March 30, 1999.

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

2. In § 180.510, paragraph (a), by alphabetically adding the following commodities to the table to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) * * *

Commodity	Parts per million
Apple, pomace, wet	0.8
* * * * *	* *
Pome fruits	0.2
Walnuts	0.02

* * * * *

[FR Doc. 99–9061 Filed 4-13-99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300839; FRL–6073–9]

RIN 2070–AB78

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of tebufenozide in or on Leafy and Brassica(cole) Vegetables and Fruiting Vegetables. Rohm and Haas Company requested these tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 14, 1999. Objections and requests for hearings must be received by EPA on or before June 14, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300839], 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 withthe Hearing Clerk identified by the docket control number, [OPP–300839], 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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