§ 186.1300 [Removed]

b. Section 186.1300 is amended by transferring the text to § 180.379 and redesignating it as paragraph (a)(3) and § 186.1300 is removed.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300580; FRL–5755–1]

RIN 2070–AB78

Fenpropathrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropathrin in or on cottonseed at 1.0 parts per million (ppm), peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by products and eggs at 0.05 ppm, and in the processed products cottonseed oil at 3.0 ppm. It also removes time limitations for tolerances for residues of fenpropathrin on the same commodities that expire on November 15, 1997. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

In addition, this regulation removes a feed additive tolerance for cottonseed hulls at 2.0 ppm. Originally, a feed additive tolerance existed for cottonseed soapstock at 2.0 ppm. In the November 14, 1994 **Federal Register** (59 FR 56454), which extended the time-limitation for these tolerances, the Agency inadvertently changed the expression from cottonseed soapstock to cottonseed hulls. Because a tolerance for cottonseed hulls was never intended, the Agency is removing the tolerance with this regulation. Also, the Agency no longer considers cottonseed soapstock to be a significant feed commodity. Under present residue chemistry guidelines, a tolerance for cottonseed soapstock is no longer required. Therefore, with this regulation, the tolerance for cottonseed soapstock is also removed.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before Jnauary 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300580], 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–300580], 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 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–300580]. 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: Beth Edwards, 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) 305–5400, e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On April 14, 1993, EPA established time-limited tolerances under section 408 and 409 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of fenpropathrin on cottonseed; meat, meat byproducts, and fat of cattle, goats, hogs, horses, poultry, and sheep; milk fat; eggs; a food additive tolerance in or on cottonseed oil; and a feed additive tolerance in or on cottonseed soapstock (58 FR 19357). On September 27, 1995, EPA established time-limited tolerances for residues of fenpropathrin on strawberries and tomatoes (60 FR 49793)(FRL–4979–1). On July 31, 1996, EPA established time-limited tolerances for residues of fenpropathrin on peanut hay and nutmeat (61 FR 39887)(FRL–5385–1). These tolerances expire on November 15, 1997. Valent U.S.A., on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide fenpropathrin in the commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of the registration. Valent U.S.A. also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of September 25, 1997 (62 FR 50337)(FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 2F4144, 3F4186, and 4F4327) for tolerances by Valent U.S.A. Corporation, 1333 North California Blvd., Walnut Creek, CA 94596–8025. This notice included a summary of the petitions prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.466 be amended by removing the time limitation for tolerances for residues of the insecticide and pyrethroid fenpropathrin, in or on cottonseed at 1.0 parts per million (ppm), peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by-products and eggs at 0.05 ppm, and in the processed products cottonseed oil at 3.0 ppm and cottonseed soapstock at 2.0 ppm.

The basis for time-limited tolerances that expire November 15, 1997 was given in the October 20, 1993 issue of the **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage

pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

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 percent 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 hundredfold MOE is based on the same rationale as the hundredfold 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 database, 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.

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 fenpropathrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for residues of fenpropathrin on cottonseed at 1.0 parts per million (ppm), peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by-products and eggs at 0.05 ppm, and in the processed product cottonseed oil at 3.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 fenpropathrin are discussed below.

1. Acute toxicity studies with technical fenpropathrin: Oral LD_{50} in the rat is 54.0 milligram/kilogram (mg/kg) for males and 48.5 (mg/kg) for females - Toxicity Category I; dermal LD_{50} is 1,600 mg/kg for males and 870 mg/kg for females - Category II; acute inhalation (impossible to generate sufficient test article vapor or aerosol to elicit toxicity) - Category IV; primary eye irritation (no corneal involvement, mild iris and conjunctival irritation) - Category III; and primary dermal irritation (no irritation) - Category IV. Fenpropathrin is not a sensitizer.

2. In a subchronic oral toxicity study, rats were dosed at concentrations of 0, 3, 30, 100, 300, or 600 ppm in the diet. The lowest effect level (LEL) is 600 ppm (30 mg/kg/day) based on body weight reduction (female), body tremors, and increased brain (female) and kidney (male) weights. The NOEL is 300 ppm (15 mg/kg/day).

3. In a subchronic oral toxicity study, dogs were dosed at concentrations of 0, 250, 500, or 1,000 ppm in the diet. A 1,000 ppm dog was sacrificed moribund during the third week after having tremors and showing other signs of poisoning caused by the test article. Because of this death, the dose for this group was reduced to 750 ppm for the remainder of the study. The LOEL is 750 ppm (18.8 mg/kg/day) based on tremors. The NOEL is 500 ppm (12.5 mg/kg/day).

4. In a 21–day dermal toxicity study, rabbits were dosed 5 days/week for 3 weeks on abraded or unabraded skin at doses of 0, 500, 1,200, or 3,000 mg/kg/day. There were no dose-related effects on body weight, food consumption, clinical pathology, gross pathology, or organ weights. Trace or mild inflammatory cell infiltration was seen in the intact and abraded skin in all groups, including controls, and was attributed to the test article. The systemic NOEL is > 3,000 mg/kg/day. Local irritation only.

Although a 21–day dermal toxicity study in rabbits is available the Agency has determined that rats are the most sensitive species to ascertain the dermal toxicity potential of fenpropathrin. Therefore, the lack of a 21–day dermal study in rats is data gap. This study will be required under a special Data-Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data to support these tolerances and these additional studies are not expected to significantly change the risk assessment.

5. In a 1–year feeding study, dogs were dosed at 0, 100, 250, or 750 ppm in the diet. The systemic LEL is 250 ppm (6.25 mg/kg/day) based on tremors in all dogs. The neurologic NOEL is 100 ppm (2.5 mg/kg/day); the systemic NOEL is 100 ppm (2.5 mg/kg/day).

6. In a chronic feeding/carcinogenicity study, rats were dosed at 0, 50, 150, 450, or 600 ppm in the diet (0, 1.93, 5.71, 17.06, or 22.80 mg/kg/day in males, and 0, 2.43, 7.23, 19.45, or 23.98 mg/kg/day in females). There was no evidence of carcinogenicity at any dose up to and including 600 ppm (22.80 and 23.98 mg/kg/day in males and females, respectively). The systemic NOEL (male) is 450 ppm (17.06 mg/kg/day). The systemic NOEL (female) is 150 ppm (7.23 mg/kg/day); systemic LEL (male) is 600 ppm highest dose tested (HDT); 22.80 mg/kg/day) based on increased mortality, body tremors, increased pituitary, kidney, and adrenal weights. The systemic LEL (female) is 450 ppm (19.45 mg/kg/day) based on increased mortality and body tremors.

7. In a chronic feeding/carcinogenicity study, mice were dosed at 0, 40, 150, or 600 ppm in the feed (0, 3.9, 13.7, or 56.0 mg/kg/day in males, and 0, 4.2, 16.2, or 65.2 mg/kg/day in females). As expected, mortality was highest during the final quarter of the study, but the incidence was similar in all dosed and control groups. No other indications of toxicity or carcinogenicity were seen. The systemic NOEL is > 600 ppm (HDT; male/female, 56.0/65.2 mg/kg/day).

8. In a developmental toxicity study in rats, pregnant female rats were dosed by gavage on gestation days 6–15 at 0 (corn oil control) 0.4, 1.5, 2.0, 3.0, 6.0, or 10.0 mg/kg/day. The maternal no observed adverse effect level (NOAEL) is 6 mg/kg/day; maternal LEL is 10 mg/kg/day based on death, moribundity, ataxia, sensitivity to external stimuli, spastic jumping, tremors, prostration, convulsions, hunched posture, squinted eyes, chromodacryorrhea, and

lacrimation; developmental NOAEL is > 10 mg/kg/day.

9. In a developmental toxicity study in rabbits, pregnant female New Zealand rabbits were dosed by gavage on gestation days 7 through 19 at 0, 4, 12, or 36 mg/kg/day. Maternal NOEL is 4 mg/kg/day; maternal LEL is 12 mg/kg/day based on grooming, anorexia, flicking of the forepaws; developmental NOEL is > 36 mg/kg/day (HDT).

10. A 3-generation reproduction study was performed in rats. Rats were dosed with fenpropathrin at concentrations of 0, 40, 120, or 360 ppm (0, 3.0, 8.9, or 26.9 mg/kg/day in males; 0, 3.4, 10.1, or 32.0 mg/kg/day in females, respectively). Parents (male/female): systemic NOEL = 40 ppm (3.0/3.4 mg/kg/day); systemic LEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors with spasmodic muscle twitches, increased sensitivity and maternal lethality; reproductive NOEL = 120 ppm (8.9/10.1 mg/kg/day); reproductive LEL = 360 ppm (26.9/32.0 mg/kg/day) based on decreased mean F_{1B} pup weight, increased F_{2B} loss. Pups (male/female): developmental NOEL = 40 ppm (3.0/3.4 mg/kg/day); developmental LEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors, increased mortality.

11. Studies on gene mutation and other genotoxic effects: An Ames Assay was negative for *Salmonella* TA98, TA100, TA1535, TA1537, and TA1538; and *E. coli* WP2uvrA (trp-) with or without metabolic activation; Sister Chromosome Exchange in CHO-K1 Cells - there were no increases in sister chromatid exchanges seen in the CHO-K1 cells treated with S–33206 or the DMSO vehicle; Cytogenetics *in vitro* (CHO/CA) - negative for chromosome aberrations (CA) in Chinese hamster ovary (CHO) cells exposed *in vitro* to toxic doses (≧ 30 µg/ml) without activation; and to limit of solubility (1,000 µg/ml) with activation; *In Vitro* Assay in Mammalian Cells - equivocal results - of no concern; DNA Damage/Repair in *Bacillus subtilis* - not mutagenic or showing evidence of DNA damage at ≤ 5,000 µg/paper disk.

12. In a metabolism study in rats, animals were dosed with radiolabelled S–3206 fenpropathrin by three protocols. They were dosed with S–3206 radiolabelled on either the alcohol or acid portion of the molecule (i.e. [alcohol-^{14}C]–S–3206 or [acid-^{14}C]–S–3206). In Experiment I, rats received 14 daily oral low-doses of 2.5 mg/kg/day of unlabelled S–3206 followed by a 15th dose of either the alcohol or acid radiolabelled S–3206. In Experiments II and III, groups of rats received a single dose of either of the two radiolabelled test articles at 2.5 mg/kg (II) or 25 mg/kg (III). No clinical signs were seen in any rats.

The major biotransformations included oxidation at the methyl group of the acid moiety, hydroxylation at the 4′-position of the alcohol moiety, cleavage of the ester linkage, and conjugation with sulfuric acid or glucuronic acid.

Four metabolites were found and characterized in the urine of rats dosed with alcohol-radiolabel. The major metabolites were the sulfate conjugate of 3-(4′-hydroxyphenoxy)benzoic acid and 3-phenoxybenzoic acid (22–44% and 3–9% of the administered dose, respectively). Eight metabolites were found in the urine of rats dosed with acid-radiolabel, but only four were characterized. The major urinary metabolites of the acid-labeled fenpropathrin were TMPA-glucuronic acid and TMPA-CH_2OH (11–26% and 6–10% of the administered dose, respectively). None of the parent chemical was found in urine.

The major elimination products in the feces included the parent chemical (13–34% of the administered dose) and four metabolites. The fecal metabolites (and the percentage of administered dose) included CH_2OH-fenpropathrin (9–20%), 4′-OH-fenpropathrin (4–11%), COOH-fenpropathrin (2–7%), and 4′-OH-CH_2OH-fenpropathrin (2–7%).

13. No neurological studies are available. These studies will be required under a special Data Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change this risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of a NOEL of 6.0 mg/kg/day based on clinical signs of neurotoxicity on day one of dosing in dams from developmental toxicity study in rats.

2. *Short - and intermediate - term toxicity.* toxicity. A short- and intermediate-term risk assessment is not required for fenpropathrin. There was no systemic toxicity at 3,000 mg/kg/day in a 21–day study in rabbits.

3. *Chronic toxicity*. EPA has established the RfD for fenpropathrin at 0.025 mg/kg/day. This RfD is based on the 1–year toxicity study in dogs with a NOEL of 2.5 mg/kg/day (tremors) with an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in any of the chronic studies. Fenpropathrin has not yet been classified.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.466) for the residues of fenpropathrin, in or on a variety of raw agricultural commodities. These are cottonseed (1.0 ppm), strawberries (2.0 ppm), and tomatoes (0.6 ppm); in the fat of cattle, goats, hogs, horses, and sheep at 1.0 ppm; in the meat of cattle, goats, hogs, horses and sheep at 0.1 ppm; in the meat byproducts of cattle, goats, hogs, horses and sheep at 0.1 ppm; milkfat at 2.0 ppm (reflecting 0.08 ppm in whole milk); and poultry fat, meat, meat byproducts, and eggs at 0.05 ppm. A food additive tolerance for residues of fenpropathrin on cottonseed oil at 3.0 ppm has been established under 40 CFR 185.3225. A feed additive tolerance for residues of fenpropathrin on cottonseed soapstock at 2.0 ppm has been established under 40 CFR 186.3225. Risk assessments were conducted by EPA to assess dietary exposures and risks from fenpropathrin 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. The acute dietary exposure assessment used Monte Carlo modeling incorporating anticipated residues and percent crop treated refinements. The acute dietary Margin of Exposure (MOE) calculated at the 99.9th percentile for the most highly exposed population subgroup (children 1–6 years old) is 803. The MOE calculated at the 99.9th percentile for the general U.S. population is 2,108. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater. Therefore, the acute dietary risk assessment for fenpropathrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk*. The RfD used for the chronic dietary analysis is 0.025 mg/kg/day. The chronic dietary exposure assessment used anticipated residues and percent crop treated information. The risk assessment resulted in use of 0.1% of the RfD for the U.S. population and 0.2% of the most highly exposed population subgroup (non-Hispanic other than black or white).

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA is June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent of crop treated refinements. The chronic dietary risk assessment used

percent crop treated information and anticipated residues.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a timeframe it deems appropriate. Section 408(b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for fenpropathrin were derived from Federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. 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. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water.* Since fenpropathrin is applied outdoors to growing agricultural crops, the potential exists for fenpropathrin or its metabolites to reach ground or surface water that may be used for drinking water. Fenpropathrin is extremely insoluble in water (14 ppb), with a high octanol/water partitioning coefficient (K_{OW} 1.19×10^5) and a relatively short soil half-life for parent and environmental metabolites. Estimates of fenpropathrin drinking water concentrations were generated with the PRZM I and EXAMS computer models. Based on these analyses, the contribution of water to the dietary risk estimate is negligible. Therefore, EPA concludes that together these data indicate that residues are not expected to occur in drinking water.

i. *Acute exposure and risk.* The acute drinking water MOEs, calculated at the 99.9th percentile, are 5,756 and 3,007 for the U.S. population and non-nursing infants < 1 year old, respectively.

ii. *Chronic exposure and risk.* The chronic drinking water risk assessment resulted in use of 0.3% and 1.6% of the RfD for the U.S. population and non-nursing infants < 1 year old, respectively.

3. *From non-occupational non-dietary exposure.* Fenpropathrin has no other uses, such as indoor pest control, homeowner or turf, that could lead to unique, enhanced exposures.

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 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 fenpropathrin 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, fenpropathrin 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 fenpropathrin has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and water. The acute aggregate MOE calculated at the 99.9th percentile for the U.S. population is 1,543. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency concludes that there is a reasonable certainty that no harm will result from acute aggregate exposure to fenpropathrin residues in food and drinking water.

2. *Chronic risk.* Using the Anticipated Residue Contribution (ARC) exposure assumptions described above, EPA has concluded that aggregate exposure to fenpropathrin from food and water will utilize 0.4% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants < 1 year old. EPA generally has no concern for exposures below 100% of the RfD

because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fenpropathrin residues.

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. Based on fenpropathrin not being registered for residential uses, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern (MOE less than 100), and that there is a reasonable certainty that no harm will result from aggregate exposure to fenpropathrin residues.

E. Aggregate Cancer Risk for U.S. Population

This chemical has not yet been classified; however, there is no evidence of carcinogenicity in any of the chronic studies. EPA believes that this pesticide does not pose a significant cancer risk.

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 fenpropathrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 3-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

ii. *Developmental toxicity studies.* See Toxicological Profile in Unit II. A. of this preamble.

iii. *Reproductive toxicity studies.* See Toxicological Profile in Unit II. A. of this preamble.

iv. *Pre- and post-natal sensitivity.* There is no evidence of additional sensitivity to young rats or rabbits following pre- or postnatal exposure to fenpropathrin.

v. *Conclusion.*The data base related to pre- and post-natal sensitivity is complete. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* The aggregate acute MOE calculated at the 99.9th percentile for children age 1–6 is 719. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to fenpropathrin through food and drinking water.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to fenpropathrin from food and water will utilize 1.6% of the RfD for non-nursing infants. 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 concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fenpropathrin residues.

4. *Short- or intermediate-term risk.* Based on fenpropathrin not being registered for residential uses, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is a reasonable certainty that no harm will result.

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism In Plants and Animals

Metabolism studies have been conducted on pinto beans, tomatoes, apples, cotton and tomato. In the earlier studies, the parent compound was found to be the major residue; remaining residues were characterized but not identified. The apple metabolism study was deemed fully adequate because the majority of the residue was the parent compound. The cotton temporary tolerances were established with an expiration date because the petitioner had indicated that a new cotton metabolism study would be conducted to further elucidate the nature of radioactive residues in cotton commodities. In both recent plant metabolism studies, on cotton and tomatoes, it has been concluded that the residue of concern is the parent compound fenpropathrin per se.

Metabolism studies with goats and poultry dosed with radiolabeled fenpropathrin were submitted with PP7F03485/FAP7H05527. The majority of the residue in muscle, fat, and milk and eggs was found to be the parent compound, fenpropathrin. The residue in kidney and liver consisted mainly of various metabolites. Livestock metabolites, with the possible exception of TMPA lactone, have also been

identified in rat metabolism studies and their contributions to the overall toxicity of fenpropathrin have been considered. For the apple and pear tolerances, the levels of the metabolites in livestock were low enough not to be included in the tolerance expression.

B. Analytical Enforcement Methodology

Residues of fenpropathrin in peanut raw agricultural and processed commodities were determined using analytical method RM–22–4 Gas Chromatography with Electron Capture Detection (GC/ECD). An EPA trial of method RM–22–4 for fenpropathrin residues in/on apples and method RM–22A–1 for residues of fenpropathrin in meat and milk has been successfully conducted. In addition, recovery of fenpropathrin was tested through FDA multiresidue methods and fenpropathrin was found to be completely recovered by the PAM I Section 302 method (Luke method); thus a confirmatory method is available.

C. Magnitude of Residues

1. *Plant commodities—field trial studies*. For the purposes of dietary risk assessment, residue data generated from residue field trials conducted at maximum application rates and minimum pre-harvest intervals were used to estimate chronic and acute dietary exposure to potential residues of fenpropathrin. For chronic dietary exposure analyses, mean anticipated residue values were calculated, substituting one-half the limit of detection for those samples for which residues were reported as non-detectable. For acute dietary exposure analyses, the entire range of field trial residue data which reflected the current labeled maximum rate and minimum PHI for single serving commodities were used (Tier 3 modeling, as outlined in ''Final Office Policy for Performing Acute Dietary Exposure Assessment,'' D. Edwards, June 13, 1996.) For those foods considered to be blended, mean field trial residues were calculated, substituting the full limit of detection for those samples for which residues were reported as non-detectable (Tier 2 modeling) used residue distributions from field trial studies.

2. *Animal commodities*. For chronic dietary analyses, dietary burdens were calculated using mean field trial residues, adjusted for percent of crop treated and applying appropriate processing factors, for all feed items. For acute dietary analyses, mean field trial residues (with no adjustment for percent of crop treated) were used for those feed items that are processed or blended, while the highest field trial residue values were used for the remaining feed items.

The secondary residue levels in animal tissues were then calculated by multiplying the total dietary burden by the tissue-to-feed ratio calculated from the lactating ruminant or laying hen feeding studies.

D. International Residue Limits

Codex Maximum Residue Limits (MRLs) for fenpropathrin have been established which are in harmony with the U.S. tolerances for cottonseed (1.0 ppm). Codex MRLs have been established which exceed the U.S. tolerances for cattle meat byproducts (0.05 vs. 0.02 ppm), cattle meat (0.5 vs. 0.02 ppm), whole milk (0.1 vs 0.02 ppm), and tomatoes (1.0 vs. 0.6 ppm). Codex MRLs have been established which are below their U.S. counterparts for eggs (0.01 vs 0.02 ppm) and poultry meat byproducts (0.01 vs. 0.02 ppm).

There are differences between the section 408 tolerances and the Codex MRL values for secondary residues in animal products. These differences are mainly caused by differences in the methods used to calculate animal feed dietary exposure. The only substantial difference between the U.S. tolerance and the Codex MRL value is for tomatoes. The JMPR (Joint Meeting on Pesticide Residues) reviewer required that the MRL exceed the highest field residue, and rounded to unity. The EPA reviewer agreed with Valent that one set of field residue samples was possibly comprised by the presence of a high rate processing treatment nearby. High outliers were ignored, and the tolerance was set at 0.6 ppm.

No Canadian MRLs have been established for residues of fenpropathrin. Mexico has established a tolerance for residues of fenpropathrin on cottonseed (1.0 ppm) which is in harmony with the U.S. tolerance.

IV. Conclusion

Therefore, these tolerances are established for residues of fenpropathrin in cottonseed at 1.0 ppm, peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by-products and eggs at 0.05 ppm, and in the processed products cottonseed oil at 3.0 ppm.

In addition to the tolerances being amended, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerances that now appear in § 185.3225 with the tolerances in § 180.466 and is removing the tolerances under § 185.3225 and § 186.3225.

Originally, the tolerance under § 186.3225 was for cottonseed soapstock at 2.0 ppm. In the **Federal Register** of November 14, 1994 (59 FR 56454)(FRL–4919–3) which extended the time-limitation for these tolerances, the Agency inadvertently changed the expression from cottonseed soapstock to cottonseed hulls. Because a tolerance for cottonseed hulls was never intended, the Agency is removing the tolerance by this regulation. Also, the Agency no longer considers cottonseed soapstock as a significant feed commodity. Under present residue chemistry guidelines, a tolerance for cottonseed soapstock is no longer required. Therefore, with this regulation, the tolerance for cottonseed soapstock is also removed.

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 January 26, 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 Records and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300580] (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 1132 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 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 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 a petition 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 General Accounting Office

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

List of Subjects

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, Feed additives, Pesticides and pests.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.466, is revised to read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the pesticide chemical fenpropathrin (alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetramethylcyclopropanecarboxylate) in or on the following agricultural commodities:

Commodity	Parts per million
Cattle, fat	1.0
Cattle, mbyp	0.1
Cattle, meat	0.1
Cottonseed	1.0
Cottonseed, oil	3.0
Eggs	0.05
Goats, fat	1.0
Goats, mbyp	0.1
Goats, meat	0.1
Hogs, fat	1.0
Hogs, mbyp	0.1
Hogs, meat	0.1
Horses, fat	1.0
Horses, mbyp	0.1
Horses, meat	0.1
Milkfat (reflecting 0.08 ppm in whole milk).	2.0
Peanut, hay	20.0
Peanut, nutmeat	0.01
Poultry, fat	0.05

Commodity	Parts per million
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	1.0
Sheep, mbyp	0.1
Sheep, meat	0.1
Strawberry	2.0
Tomato	0.6

(b) *Section 18 emergency exemptions.* [Reserved]

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

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

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.3225 [Removed]

b. By removing § 185.3225 *Fenpropathrin*.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348 and 701.

§ 186.3225 [Removed]

b. By removing § 186.3225 *Fenpropathrin*.

[FR Doc. 97–31102 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPTS–50621C; FRL–5757–6]

RIN 2070–AB27

Dipropylene Glycol Dimethyl Ether; Final Significant New Use Rule; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: EPA issued a document (FR Doc. 97–29153) in the **Federal Register** of November 4, 1997, adding a significant new use rule (SNUR) for the chemical substance described as dipropylene glycol dimethyl ether (DGDE), which was the subject of premanufacture notice (PMN) P–93–507. The CAS No. listed for DGDE in the rule was incorrect. This document corrects that CAS No.

DATES: Effective on November 26, 1997.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a document (FR Doc. 97–29153) in the **Federal Register** of November 4, 1997 (62 FR 59579) (FRL–5745–1), stating that the CAS No. for DGDE was 11109–77–4. This document correctly changes the CAS No. from 11109–77–4 to 111109–77–4.

On page 59583, in the first column, in § 721.3550, in paragraph (a), in the fifth line, ''CAS No. 11109–77–4'' should read ''CAS No. 111109–77–4''.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 19, 1997.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 97–31130 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF DEFENSE

48 CFR Part 231

[DFARS Case 97–D312]

Defense Federal Acquisition Regulation Supplement; Allowability of Costs for Restructuring Bonuses

AGENCY: Department of Defense (DoD).

ACTION: Interim rule with request for comments.

SUMMARY: The Director of Defense Procurement has issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to prohibit use of DoD funds to reimburse a contractor for costs paid by the contractor to an employee for a bonus or other payment in excess of the normal salary paid to the employee, when such payment is part of restructuring costs associated with a business combination. This rule implements Section 8083 of the Fiscal Year 1998 Defense Appropriations Act.

DATES: Effective date: November 26, 1997.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before January 26, 1998, to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments to: Defense Acquisition Regulations Council, Attn: Ms. Sandra G. Haberlin, PDUSD (A&T) DP (DAR), IMB 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telefax number (703) 602–0350.

E-mail comments submitted over the Internet should be addressed to: dfars@acq.osd.mil

Please cite DFARS Case 97–D312 in all correspondence related to this issue. E-mail comments should cite DFARS Case 97–D312 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra G. Haberlin, (703) 602–0131.

SUPPLEMENTARY INFORMATION:

A. Background

This interim rule amends paragraph (f) (1) of DFARS 231.205–6, Compensation for personal services, to implement Section 8083 of the Fiscal Year 1998 Defense Appropriations Act (Pub. L. 105–56). Section 8083 prohibits DoD from using fiscal year 1998 funds to reimburse a contractor for costs paid by the contractor to an employee for a bonus or other payments in excess of the normal salary paid by the contractor to the employee, when such payment is part of restructuring costs associated with a business combination. Similar provisions were contained in the Fiscal Year 1996 and Fiscal Year 1997 Defense Appropriations Acts (Pub. L. 104–61 and Pub. L. 104–208, respectively).

B. Regulatory Flexibility Act

The interim rule is not expected to have a significant economic impact on a substantial umber of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because most contracts awarded to small entities use simplified acquisition procedures or are awarded on a competitive, fixed-price basis, and do not require application of the cost principle contained in this rule. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subpart also will be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite 5 U.S.C. 601, *et seq.* (DFARS Case 97–D312), in correspondence.