

Commodity	Parts per million	Expiration/Revocation Date
* * * * *	* * *	
Blueberries .....	1.0	12/31/99
* * * * *	* * *	
Raspberries .....	1.0	12/31/99
* * * * *	* * *	

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-300763; FRL 6047-3]

RIN 2070-AB78

### Fenpropathrin; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for combined residues of fenpropathrin in or on soybeans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of fenpropathrin in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. The tolerance will expire and is revoked on June 30, 2000.

**DATES:** This regulation is effective January 20, 1999. Objections and requests for hearings must be received by EPA on or before March 22, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300763], 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-300763], 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 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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300763]. 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: Jacqueline Gwaltney, 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) 305-6792, e-mail: gwaltney.jackie@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues insecticide/fungicide/herbicide fenpropathrin, in or on soybeans at 0.1 part per million (ppm). This tolerance will expire and is revoked on June 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

### I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq.*, and the FIFRA, 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA

pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL 5572-9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

## II. Emergency Exemption for Fenpropathrin on Soybeans and FFDCA Tolerances

The Applicant stated that the two-spotted spider mite is a serious pest of soybeans in Delaware, and Maryland.

*Delaware.* During the 1997 field season in Delaware, fields were sprayed 3–5 times with dimethoate, Lorsban and Parathion. While dimethoate provided systemic activity, it has been ineffective in recent years due to reduced systemic activity when fields are drought stressed resulting in poor absorption and translocation of the chemical into the leaf tissue. The two-spotted spider mite may also be developing resistance to dimethoate. Since July 17, 1998, the mite population in Delaware has begun to explode in soybean fields and dimethoate applications have not provided control.

*Maryland.* Maryland's Emergency situation is very similar to Delaware. They too used dimethoate and Lorsban with control ranging from 0 to less than 30%. Maryland growers have experienced increasing problems with spider mites in soybean fields. In 1997, the mite population reached record high levels on more than 50% of the soybean acreage and caused significant losses in yield and increased production costs. Dimethoate has been the chemical of choice in Maryland because of its systemic and longer residual action. However, numerous control failures with dimethoate have been reported in 1997. Dimethoate has been ineffective in recent years due to reduced systemic activity when fields are drought stressed resulting in poor absorption and translocation of the chemical into the leaf tissue. In the Eastern Shore the problem is more intense, control failures are also believed to be the result of dimethoate-tolerant populations caused by repeated use of this product over the years. EPA has authorized under FIFRA section 18 the use of fenpropathrin on soybeans for control of two-spotted spider mite *Tetranychus urticae* in Delaware and Maryland. EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fenpropathrin in or on soybeans. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine

situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on June 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybeans after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

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

## III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of fenpropathrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues or residues of fenpropathrin on soybeans at 0.1 ppm. EPA's assessment

of the dietary exposures and risks associated with establishing the tolerance follows.

### A. Toxicological Profile

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

1. *Acute toxicity.* EPA has established the Reference dose (RfD) for fenpropathrin at 0.06 milligram/kilogram/day (mg/kg/day). This RfD is based on the risk assessment that was done for synthetic pyrethroids since fenpropathrin is a member of the synthetic pyrethroids class of pesticides.

2. *Chronic toxicity.* EPA has established the RfD for fenpropathrin at 0.025 mg/kg/day. Since fenpropathrin is a member of the synthetic pyrethroids class of pesticides, the RfD is based on the risk assessment that was done for synthetic pyrethroids.

### B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.180) for the combined residues of fenpropathrin, in or on a variety of raw agricultural commodities at levels ranging from 0.05 ppm in eggs to 20 ppm in peanut hay. In addition, time-limited tolerances have been established (40 CFR 190.466(b)) at 15 ppm in currants in conjunction with previous section 18 requests. Risk assessments were conducted by EPA to assess dietary exposures and risks from fenpropathrin as follows.

2. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary (food only) risk assessment used the Monte Carlo analysis and provides fenpropathrin levels on soybeans at 0.05 ppm and assumes that 1% of the total U.S. soybean acreage was treated. Although this level is half of the soybean tolerance, it is a reasonable estimate of anticipated residues based on tolerances for other synthetic pyrethroids. This should be viewed as a highly refined risk estimate. The risk assessment was applied to all groups. The exposure estimates for the U.S. population and certain subgroups are shown in Table 1.

TABLE 1. ACUTE DIETARY EXPOSURE SUMMARY

Population Subgroup <sup>1</sup>	Theoretical Maximum Residue Contribution, <sup>2</sup> mg/kg/day	% of RfD
U.S. Population (48 States).	0.010	17
All Infants (< 1 yr) .....	0.025	42
Nursing Infants (< 1 yr) ..	0.044	73
Children (1–6 yr) .....	0.020	33
Children (7–12 yr) .....	0.012	20
Females (13+) .....	0.007	12

<sup>1</sup> The subgroups listed above are: (1) the U.S. population (48 states), (2) infants and children, (3) females (13+ years of age), and (4) other subgroups (in this case, none) for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

<sup>2</sup> The theoretical maximum residue contribution is at the 99.9th percentile.

3. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA made a conservative assumption that 100% of soybeans and all other commodities having fenpropathrin tolerances will contain fenpropathrin residues. The existing fenpropathrin tolerances result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the percentages of the RfD shown in Table 2.

TABLE 2. CHRONIC DIETARY EXPOSURE SUMMARY

Population Subgroup <sup>1</sup>	Theoretical Maximum Residue Contribution, mg/kg/day	% of RfD
U.S. Population (48 States) All Seasons.	0.0026	10
U.S. Population (48 States) Autumn Season.	0.0028	11
Northeast Region .....	0.0027	11

TABLE 2. CHRONIC DIETARY EXPOSURE SUMMARY—Continued

Population Subgroup <sup>1</sup>	Theoretical Maximum Residue Contribution, mg/kg/day	% of RfD
Midwest Region .....	0.0027	11
Pacific Region .....	0.0027	11
Non-hispanic Other Than Black or White.	0.0030	12
All Infants (<1 yr) .....	0.0066	27
Non-nursing Infants (<1 yr).	0.0084	34
Children (1–6 yr) .....	0.0065	26
Children (7–12 yr) .....	0.0044	17
Females (13+ yr, Nursing)	0.0027	11

<sup>1</sup> The subgroups listed above are: (1) the U.S. population (48 states), (2) infants and children, and (3) other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

4. *From drinking water.* Fenpropathrin is relatively persistent and not mobile. There are no established Maximum Contaminant Levels or health advisory levels for fenpropathrin. Acute and chronic exposure to fenpropathrin residues in drinking water do not exceed EPA's level of concern.

5. *Acute exposure and risk.* Based on the acute dietary (food) exposure estimates, acute drinking water levels of concern (DWLOCs) for fenpropathrin were calculated and are summarized in Table 3. The acute exposure to fenpropathrin residues in drinking water do not exceed EPA's level of concern.

TABLE 3. DRINKING WATER LEVELS OF CONCERN FOR ACUTE DIETARY EXPOSURE

Population <sup>1</sup>	RfD, mg/kg/day	TMRC (Food Exposure), mg/kg/day	Max. Water Exposure <sup>2</sup> , mg/kg/day	DWLOC, <sup>3,4,5</sup> µg/L
U.S. Population (48 States) .....	0.06	0.0102	0.0498	1,700
Females, 13+ .....	0.06	0.0067	0.0533	1,600
Nursing Infants (< 1 yr) .....	0.06	0.0440	0.0160	160

<sup>1</sup> Populations listed are the U.S. population (48 states), females 13+ years, infants/children, and any subpopulations whose exposure exceeds that of the U.S. population (48 states). Within each subpopulation, the group with the highest exposure is listed.

<sup>2</sup> Maximum Water Exposure (mg/kg/day) = RfD (mg/kg/day) - TMRC from DEEM (mg/kg/day).

<sup>3</sup> DWLOC(µg/L) = Max water exposure (mg/kg/day) \* body wt (kg) / (10–3 mg/µg) \* water consumed daily (L/day).

<sup>4</sup> HED Default body wts for males, females, and children are 70 kg, 60 kg, and 10 kg, respectively.

<sup>5</sup> HED Default Daily Drinking Rates are 2 L/Day for Adults and 1 L/Day for children.

6. *Chronic exposure and risk.* Based on the chronic dietary (food) exposure estimates, chronic DWLOCs for

fenpropathrin were calculated and are summarized in Table 4. The chronic exposure to fenpropathrin residues in

drinking water do not exceed EPA's level of concern.

TABLE 4. DRINKING WATER LEVELS OF CONCERN FOR CHRONIC DIETARY EXPOSURE

Population <sup>1</sup>	RfD, mg/kg/day	TMRC (Food Exposure), mg/kg/day	Max. Water Exposure <sup>2</sup> , mg/kg/day	DWLOC, <sup>3,4,5</sup> µg/L
U.S. Population (48 States) Autumn Season .....	0.025	0.0028	0.022	780
Females (13+ yr, Nursing) .....	0.025	0.0027	0.022	670

TABLE 4. DRINKING WATER LEVELS OF CONCERN FOR CHRONIC DIETARY EXPOSURE—Continued

Population <sup>1</sup>	RfD, mg/kg/day	TMRC (Food Exposure), mg/kg/day	Max. Water Exposure <sup>2</sup> , mg/kg/day	DWLOC, <sup>3,4,5</sup> µg/L
Non-nursing Infants (<1 yr) .....	0.025	0.0084	0.017	170
Non-hispanic Other Than Black or White .....	0.025	0.0030	0.022	770

<sup>1</sup> Populations listed are the U.S. population (48 states), females 13+ years, infants/children, and any subpopulations whose exposure exceeds that of the U.S. population (48 states). Within each subpopulation, the group with the highest exposure is listed.

<sup>2</sup> Maximum Water Exposure (mg/kg/day) = RfD (mg/kg/day) - TMRC from DEEM (mg/kg/day).

<sup>3</sup> DWLOC(µg/L) = Max water exposure (mg/kg/day) \* body wt (kg) / (10.3 mg/µg) \* water consumed daily (L/day).

<sup>4</sup>HED Default body wts for males, females, and children are 70 kg, 60 kg, and 10 kg, respectively.

<sup>5</sup> HED Default Daily Drinking Rates are 2 L/Day for Adults and 1 L/Day for children.

7. *From non-dietary exposure.* Fenpropathrin has no registered residential uses. There are registered uses for non-food sites, however, exposures are expected for workers only (i.e., greenhouse use).

8. *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 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. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Using the food exposure assumptions, and taking into account the completeness and reliability of the toxicity data, EPA concludes that dietary (food only) exposure to fenpropathrin will utilize 17% of the acute RfD for the U.S. population. In the

absence of additional safety factors, EPA generally has no concern for exposures below 100% of the RfD because the acute RfD represents the level at or below which an acute exposure will not pose an appreciable risk to human health. Despite the potential for exposure to fenpropathrin in drinking water and through occupational (e.g., commercial greenhouse) use, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

2. *Chronic risk.* Using the food exposure assumptions, and taking into account the completeness and reliability of the toxicity data, EPA concludes that dietary (food only) exposure to fenpropathrin will utilize 10% of the chronic RfD for the U.S. population. In the absence of additional safety factors, EPA generally has no concern for exposures below 100% of the RfD because the chronic 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 fenpropathrin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. The non-food sites (e.g., greenhouse uses) for which fenpropathrin is registered would not fall under a chronic scenario. There is a reasonable certainty that no harm will result to the U.S. population from chronic aggregate exposure to fenpropathrin residues.

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. No endpoint was selected for short- and intermediate-term dermal or inhalation exposures. This risk assessment is not required.

3. *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 fenpropathrin residues.

*D. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children—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 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to pre- and post-natal 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 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.

2. *Developmental toxicity studies*—i. *Rats*. In the developmental study in rats, the maternal (systemic) no observed adverse effect level (NOAEL) was 6 mg/kg/day. The maternal lowest adverse effect level (LOAEL) of 10 mg/kg/day was based on death, moribundity, ataxia, hypersensitivity, spastic jumping, tremors, prostration, convulsions, hunched posture, squinting eyes, chromodacryorrhea, and lacrimation. The developmental (fetal) NOAEL was >10 mg/kg/day, the highest dose tested (HDT).

ii. *Rabbits*. In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 4 mg/kg/day. The maternal LOAEL of 12 mg/kg/day was based on anorexia, grooming, and flicking of the forepaws. The developmental (fetal) NOAEL was >36 mg/kg/day at the HDT.

3. *Reproductive toxicity study*—*Rats*. In the 3-generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 3 mg/kg/day. The parental (systemic) LOAEL of 8.9 mg/kg/day was based on body tremors with spasmodic muscle twitches, increased sensitivity and maternal lethality. The developmental NOAEL was 3.0 mg/kg/day. The developmental LOAEL of 8.9 mg/kg/day was based on body tremors and increased pup mortality. The reproductive NOAEL was 8.9 mg/kg/day. The reproductive LOAEL of 26.9 mg/kg/day was based on decreased F<sup>1</sup>B pup weight and increased pup loss in the F<sup>2</sup>B generation.

4. *Conclusion*. There is a complete toxicity database for fenpropathrin and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

5. *Acute risk*. Using the food exposure assumptions described above (Acute Dietary Risk), and taking into account the completeness and reliability of the toxicity data, EPA concludes that dietary (food only) exposure to fenpropathrin will utilize 73% of the acute RfD for the U.S. population subgroup nursing infants (< 1 yr). This is the maximally exposed subgroup in the infants and children categories. In the absence of additional safety factors, EPA generally has no concern for exposures below 100% of the RfD because the acute RfD represents the level at or below which an acute exposure will not pose an appreciable risk to human health. Despite the potential for exposure to fenpropathrin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

6. *Chronic risk*. Using the food exposure assumptions described above (Chronic Dietary Risk), and taking into

account the completeness and reliability of the toxicity data, EPA concludes that the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of fenpropathrin ranges from 9.6% for nursing infants (<1 yr) up to 34% for non-nursing infants (< 1 yr). In the absence of additional safety factors, 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 fenpropathrin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. The non-food sites (e.g., greenhouse use) for which fenpropathrin is registered would not fall under a chronic scenario.

7. *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 fenpropathrin residues.

#### IV. Other Considerations

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5229).

#### A. Magnitude of Residues

Crop residue studies of fenpropathrin in/on soybeans were not available for review. In lieu of soybean residue data, EPA considered residue data from grapes and peanuts. Pyrethroid insecticides are non-systemic; therefore, residues of fenpropathrin in soybean seed are not expected to be as high as those on "exposed" crop commodities (e.g., grapes). Because of this, EPA also used data from other pyrethroid insecticides (fenvalerate, lambda-cyhalothrin, permethrin, tralomethrin) that are registered for use on soybeans to determine the appropriate tolerance for soybean seed. Residue data from the above-ground parts of peanut commodities were used to determine appropriate tolerances for soybean forage and hay. Because a soybean processing study was not available for review, the maximum theoretical concentration factors were used to derive tolerances for the soybean processed commodities aspirated grain

fractions, meal, hulls, and refined oil from the soybean seed tolerance.

Residues of fenpropathrin are not expected to exceed the following values for soybean:

- Aspirated grain fractions—20 ppm
- Soybean, forage—15 ppm
- Soybean, hay—20 ppm
- Soybean, seed—0.1 ppm

or the following values for processed soybean commodities:

- Soybean, hulls—1.0 ppm
- Soybean, meal—0.2 ppm
- Soybean, oil, refined—1.5 ppm

Existing tolerances for fenpropathrin in animal commodities are listed in 40 CFR 180.466. Secondary residues in animal commodities are not expected to exceed existing tolerances.

#### V. Conclusion

Therefore, the tolerance is established for combined residues or residues of fenpropathrin in soybeans at 0.1 ppm.

#### VI. Objections and Hearing Requests

The new FFDC 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 March 22, 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 above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if

the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

#### **VII. Public Record and Electronic Submissions**

EPA has established a record for this rulemaking under docket control number [OPP-300763] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:  
 opp-docket@epamail.epa.gov.

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

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

address in "ADDRESSES" at the beginning of this document.

#### **VIII. Regulatory Assessment Requirements**

##### *A. Certain Acts and Executive Orders*

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

In addition, since tolerances and exemptions that are established under FFDCA section 408 (l)(6), 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 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.

##### *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 to 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.

**IX. Submission to Congress and the Comptroller General**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: January 6, 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. 346a and 371.

2. In §180.466, by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

**§180.466 Fenpropathrin; tolerances for residues.**

\* \* \* \* \*

(b)\* \* \*

Commodity	Parts per million	Expiration/Revocation Date
* * *	*	*
Soybean, forage ...	15	6/30/00
Soybean, hay .....	20	6/30/00
Soybean, hulls .....	1.0	6/30/00
Soybean, meal .....	0.2	6/30/00
Soybean, oil, re-fined.	1.5	6/30/00
Soybean, seed .....	0.1	6/30/00

\* \* \* \* \*

[FR Doc. 99-1254 Filed 1-19-99; 8:45 am]

BILLING CODE 6560-50-F

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 71**

[Airspace Docket No. 98-ACE-51]

**Amendment to Class E Airspace; Belle Plaine, IA**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Direct final rule; request for comments.

**SUMMARY:** This action amends the Class E airspace area at Belle Plaine Municipal Airport, Belle Plaine, IA. The FAA has developed Global Positioning System (GPS) Runway (RWY) 17 and GPS RWY 35 Standard Instrument Approach Procedures (SIAPs) to serve Belle Plaine Municipal Airport, IA. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate these SIAPs and for Instrument Flight Rules (IFR) operations at this airport. The enlarged area will contain the new GPS RWY 17 and GPS RWY 35 SIAPs in controlled airspace.

In addition, the Class E airspace area is revised to indicate a minor revision to the Airport Reference Point (ARP) coordinates, and is included in this document. The intended effect of this rule is to provide controlled Class E airspace for aircraft executing GPS RWY 17 and GPS RWY 35 SIAPs, revise the ARP coordinates, and to segregate aircraft using instrument approach procedures in instrument conditions from aircraft operating in visual conditions.

**DATES:** This direct final rule is effective on 0901 UTC, May 20, 1999.

Comments for inclusion in the Rules Docket must be received on or before March 4, 1999.

**ADDRESSES:** Send comments regarding the rule in triplicate to: Manager, Airspace Branch, Air Traffic Division, ACE-520, Federal Aviation Administration, Docket Number 98-ACE-51, 601 East 12th Street, Kansas City, MO 64106.

The official docket may be examined in the Office of the Regional Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours

in the Air Traffic Division at the same address listed above.

**FOR FURTHER INFORMATION CONTACT:** Kathy Randolph, Air Traffic Division, Airspace Branch, ACE-520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, MO 64106; telephone: (816) 426-3408.

**SUPPLEMENTARY INFORMATION:** The FAA has developed GPS RWY 17 and GPS RWY 35 SIAPs to serve the Belle Plaine Municipal Airport, Belle Plaine, IA. The amendment to Class E airspace at Belle Plaine, IA, will provide additional controlled airspace at and above 700 feet AGL in order to contain the new SIAPs within controlled airspace, and thereby facilitate separation of aircraft operating under Instrument Flight Rules.

In addition, the Class E airspace area is amended to indicate the revised ARP coordinates. The amendment at Belle Plaine Municipal Airport, IA, will provide additional controlled airspace for aircraft operating under IFR, and revise the ARP coordinates. The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9F, dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

**The Direct Final Rule Procedure**

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment