Subpart G—Significant New Alternatives Policy Program

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Appendix I to Subpart G—Substitutes Subject to Use Restrictions, Listed in the April 26, 2000, Final Rule, Effective May 26, 2000

FIRE SUPPRESSION AND EXPLOSION PROTECTION—TOTAL FLOODING AGENTS

[Substitutes Acceptable Subject to Use Conditions]

End Use	Substitute	Decision	Conditions	Comments
Halon 1301 Total Flooding Systems.	IG–100	Acceptable	IG–100 systems should be designed to maintain an oxygen level of 10%. A design concentration of less than 10% may only be used in normally unoccupied areas and in areas where egress is possible within 30 seconds. If it is not possible to egress an area within one minute, IG–100 systems must be designed to maintain an oxygen level of 12% If the possibility exists for oxygen levels to drop below 10%, employees must be evacuated prior to such oxygen depletion.	IG–100 systems must include alarms and warning mechanisms. Workplace personnel and employees should not remain in or re-enter the area after system discharge (even if such discharge is accidental) without appropriate personal protective equipment. See additional comments 1, 2, 3.

Additional Comments:
1. Should conform with OSHA 29 CFR 1910, Subpart L, Section 1910.160.
2. Per OSHA requirements, protective gear (SCBA) should be available in the event personnel must re-enter the area.
3. EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protective equipment (*e.g.*, respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to EPA's regulation of halon substitutes.

FIRE SUPPRESSION AND EXPLOSION PROTECTION—STREAMING AGENTS

[Substitutes Acceptable Subject to Narrowed Use Limits]

End Use	Substitute	Decision	Limitations	Comments
Halon 1211 Streaming Agents.	HCFC Blend E ...	Acceptable	Nonresidential uses only	As with other streaming agents, EPA recommends that potential risks of combustion by-products be labeled on the extinguisher (see UL 2129). See additional comments 1, 2.

Additional Comments:
1. Discharge testing and training should be strictly limited only to that which is essential to meet safety or performance requirements.
2. The agent should be recovered from the fire protection system in conjunction with testing or servicing, and recycled for later use or destroyed.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300992; FRL–6554–4]

RIN 2070–AB78

Fenpropathrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fenpropathrin in or on the cucumber/squash crop subgroup. The Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 26, 2000. Objections and requests for hearings, identified by docket control number OPP–300992, must be received by EPA on or before June 26, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300992 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112	Crop production. Animal production.

Categories	NAICS codes	Examples of potentially affected entities
	311 32532	Food manufacturing. Pesticide manufacturing.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300992. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 3, 1999 (64 FR 679054) (FRL–6392–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP 9E6042) for tolerance by IR–4, Rutgers State University, North Brunswick, NJ 08902–3390. This notice included a summary of the petition prepared by Valent USA Company, 1333 North California Boulevard, Suite 600, Walnut Creek, CA 94596–8025, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.466 be amended by establishing a tolerance for residues of the insecticide fenpropathrin, (alpha-cyano-3-phenoxybenzyl 2,2,3,3- tetramethylcyclopropanecarboxylate), in or on the cucurbit vegetable group at 0.5 part per million (ppm). The petition was subsequently amended by IR–4 to propose a tolerance for the squash/cucumber subgroup at 0.5 ppm.

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

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

III. 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of fenpropathrin on the cucumber/squash crop subgroup at 0.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

B. Toxicological Endpoints

1. *Acute toxicity*. An acute reference dose (RfD) of 0.06 mg/kg/day was established based on clinical signs of neurotoxicity on the day of dosing in dams during a developmental toxicity study in rats. The no observed adverse effect level (NOAEL) was 6.0 milligrams/kilograms/day (mg/kg/day). An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variations) was used to determine the acute RfD. The acute Population Adjusted Dose (PAD) is equal to the acute RfD divided by the FQPA Safety Factor. Since the FQPA Safety Factor was reduced to 1X, the acute PAD is equal to the acute RfD.

2.*Chronic toxicity*. EPA has established the RfD for fenpropathrin at 0.025 mg/kg/day. This RfD is based on the observance of tremors in dogs in the 1-year oral feeding study. The NOAEL was 2.5 mg/kg/day. An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variation) was used to determine the chronic RfD. The chronic PAD is equal to the chronic RfD divided by the FQPA Safety Factor. Since the FQPA Safety Factor was reduced to 1X, the chronic PAD is equal to the chronic RfD.

3. *Carcinogenicity*. As no indication of carcinogenicity was seen in rats or mice, no carcinogenic endpoint was selected.

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. Permanent tolerances are established for the residues of fenpropathrin in/on pome fruit crop group at 5.0 ppm; grapes at 5.0 ppm and the processed product raisins at 10 ppm; citrus fruit crop group at 2.0 ppm and the processed product citrus oil at 75.0 ppm and dried citrus pulp at 4.0 ppm; head and stem brassica crop group at 3.0 ppm and the melons crop group at 0.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures 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. Tier 3 acute dietary exposure analyses for fenpropathrin were performed with the Dietary Exposure Evaluation Model (DEEM™) using field trial values and percent crop treated estimates. The acute risk was analyzed at the 99.9th percentile using the 1989–1992 food consumption survey. The U.S. population and population subgroups (with the exception of nursing infants, all infants, and children) acute dietary risk estimates are below EPA's level of concern. The acute dietary risk estimates for subgroups of nursing infants, all infants, and children were above EPA's level of concern. In the 1989–1992 survey, there is a consumption value associated with grapes which can be considered to be aberrant. There were only 4 nursing infants in the 1989–1992 survey who reportedly ate grapes. A single 10-month old nursing infant consumed 2/3 of a pound of grapes in 1 day. This is an unusually high quantity of grapes for an infant to consume in 1 day. Because of the aberrant data point, the acute dietary exposure analysis was conducted using the 1994–1996 food consumption survey.

ii. *Chronic exposure and risk*. A DEEM™ chronic dietary exposure analysis was performed using anticipated residues (field trial data) and percent crop treated data. The FQPA 10X safety factor was removed. As a result, the chronic PAD is equivalent to the chronic RfD: 0.025 mg/kg/day. Based on the 1989–1992 data base, the most highly exposed subgroup (children 1–6 years) utilized 9% of the chronic PAD. As a result, exposure to fenpropathrin of the U.S. population and all population subgroups is below EPA's level of concern.

2. *From drinking water*. Fenpropathrin is persistent and immobile. There are no established maximum contaminant level for residues of fenpropathrin in drinking water. Neither has any health advisory levels for fenpropathrin in drinking water been established.

The Agency lacks sufficient water-related exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenpropathrin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. The Agency is currently relying on GENEEC (Generic Estimated Environmental Concentration) and PRZM/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and SCI–GROW (Screening Concentration in Ground Water), which predicts pesticide concentrations in ground water. None of these models include consideration of the impact processing of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern. Since the models estimates are used as screening tools in the risk assessment process, the Agency does not use the estimates from GENEEC, PRZM/EXAMS and SCI–GROW to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOC) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. Different populations have different DWLOCs. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

The Agency used its SCI–GROW and GENEEC screening models and environmental fate data to determine the estimated environmental concentration (EEC) for fenpropathrin in ground water and surface water respectively. EPA reported ground water EEC of 0.006 parts per billion (ppb) and surface water EECs of 2.72 ppb (acute) and 0.34 ppb (chronic) for fenpropathrin.

EPA has calculated DWLOCs for both acute and chronic risks. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from DEEM) was subtracted from the acute PAD to obtain the acceptable acute exposure to fenpropathrin in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM) was subtracted from the chronic PAD to obtain the acceptable chronic (non-cancer) exposure to fenpropathrin in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

i. *Acute exposure and risk*. The drinking water EEC for dietary exposures at the 99.9th percentile exceeds the DWLOC for the population subgroups all infants, nursing infants, and children 1–6 years. The DWLOCs, which were calculated based on the exposure values at the 99.5th percentile of exposure for nursing infants and at the 99.75th percentile of exposure for all infants and for children 1–6 years, were above the drinking water EEC. The same is true for the DWLOCs calculated based on the 99.9th percentile exposure values from the 1994–1996 food consumption survey. For the reasons discussed in Unit C.1.i. EPA has chosen to use data from the 1994–1996 food consumption survey for these three population subgroups (and for this risk assessment only). Although the dietary exposure estimates are highly refined, EPA notes that 100% crop treated was used for the following crops: cucurbit group, grapes, pome fruit group, citrus group, and head and stem Brassica vegetable subgroup. Based on percent crop treated values for registered uses, the percent crop treated for these uses will probably be significantly less than 100%.

ii.*Chronic exposure and risk*. EPA generally reduces GENEEC model values by a factor of 3 when determining whether or not a chronic level of comparison has been exceeded. If the GENEEC model value is ≤ 3 times the DWLOC, the pesticide is considered to have passed the screen and no further assessment is needed.

Based on the chronic dietary (food) exposure estimates, chronic DWLOC for

fenpropathrin have been calculated. The lowest DWLOC is 230 ppb for both nursing infants and children 1–6 years. The highest EEC for fenpropathrin in surface water is from the application of fenpropathrin to pears and citrus fruits (0.34 ppb) and is substantially lower than the DWLOCs calculated. Therefore, chronic exposure to fenpropathrin residues in drinking water are not expected to exceed EPA's level of concern.

3. *From non-dietary exposure*. There are no residential or non-occupational uses for fenpropathrin; therefore residential exposures are not expected.

4. *Cumulative exposure to substances with a 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 information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. For this risk assessment, the acute aggregate risk is equivalent to the risk from (food + water). Using the 1994–96 food consumption survey, it is estimated that acute exposure to fenpropathrin from food for the most highly exposed population subgroup, children (1–6 years), will utilize 76% of the acute PAD at the 99.9 percentile of exposure (see discussion in Unit III.C.). An acute dietary exposure (food + water) of 100% or less of the acute PAD is needed to protect the safety of all population subgroups. The EECs of fenpropathrin in surface and ground water for acute exposure are below the DWLOCs. Thus, the acute aggregate risk of exposure to fenpropathrin from food and drinking water is below EPA's level of concern for the U.S. population and all population subgroups.

2. *Chronic risk*. For this risk assessment, the chronic aggregate risk is equivalent to the risk from (food + water). Chronic residential exposure to fenpropathrin residues is not expected. In addition, no chronic dermal or inhalation endpoints were identified. As discussed above, EPA has concluded that exposure to fenpropathrin from food for the most highly exposed subgroup (children 1–6 years) will utilize 9% of the chronic PAD. EPA generally has no concern for exposure below 100% of the chronic PAD because the chronic PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The highest EEC for fenpropathrin in drinking water (0.34 ppb) is substantially lower than the lowest DWLOC (230 ppb). Therefore, chronic aggregate risk does not exceed EPA's level of concern.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Since there is no expected residential exposure to residues of fenpropathrin, the short- and intermediate-term aggregate risk does not exceed EPA's level of concern.

4. *Aggregate cancer risk for U.S. population*. The Agency has determined that there is no evidence of carcinogenicity in studies in either the mouse or rat.

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

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

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of 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 gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

ii. *Developmental toxicity studies*. In 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 NOAEL is 6 mg/kg/day; maternal LOAEL 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. There were no developmental effects observed under the conditions of the study.

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 NOAEL is 4 mg/kg/day; maternal LOAEL is 12 mg/kg/day based on grooming, anorexia, flicking of the forepaws; developmental NOAEL is > 36 mg/kg/day highest dose tested. There were no developmental effects observed under the conditions of the study.

iii. *Reproductive toxicity study*. 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 NOAEL = 40 ppm (3.0/3.4 mg/kg/day). Systemic LOAEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors with spasmodic muscle twitches, increased sensitivity

and maternal lethality; reproductive NOAEL = 120 ppm (8.9/10.1 mg/kg/day). Reproductive LOAEL = 360 ppm (26.9/32.0 mg/kg/day) based on decrease mean F_{1B} pup weight, increased F_{2B} loss. Pups (male/female): Developmental NOAEL = 40 ppm (3.0/3.4 mg/kg/day). Developmental LOAEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors, and increased mortality.

iv. *Prenatal and postnatal sensitivity*. There is no evidence of sensitivity to young rats or rabbits following prenatal or postnatal exposure to fenpropathrin.

v. *Conclusion*. There is a complete toxicity data base for fenpropathrin, and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the above, EPA concludes that reliable data support use of the 100-fold uncertainty factor and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk*. (food + water) The percentages of the acute PAD utilized (by food alone) at the 99.9 percentile exposure are 56% for infants and 77% for children (1–6 years), the most highly exposed population subgroup. The EEC for fenpropathrin in drinking water is below the DWLOC. The Agency has no cause for concern if total acute exposure is 100% or less of the acute PAD. Therefore, the Agency has no acute aggregate concern due to exposure to fenpropathrin through food and drinking water.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fenpropathrin from food will utilize 5% of the RfD for infants and 9% of the RfD for children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fenpropathrin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. No uses of fenpropathrin have been identified for residential exposures, therefore, fenpropathin need not be evaluated for short- or intermediate-term risk resulting from residential exposure.

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

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants and animals is adequately understood.

B. Analytical Enforcement Methodology

EPA concludes that adequate methodology is available for enforcement of the proposed tolerances. Method RM–22–4 can be used for the analysis of fenpropathrin in cucurbits. Residues are extracted with acetone/hexane, cleaned up with silica gel and C18 Sep Pak chromatography and detection is by gas chromatography. The limit of detection is 0.01 ppm.

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Adequate residue field trials reflecting the prosed use rate were submitted to EPA to demonstrate that tolerances for cucumber/squash crop subgroup will not be exceeded when fenpropathrin products labeled for these uses are used as directed.

V. Conclusion

Therefore, the tolerance is established for residues of fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetra-methylcyclopropanecarboxylate), in or on the cucumber/squash crop subgroup at 0.5 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300992 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 26, 2000.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For

additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300992, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance 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) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final 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: April 11, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. In § 180.466, amend paragraph (a) by alphabetically adding the following entry to the table to read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Squash/cucumber subgroup ...	0.5
* * * * *	

* * * * *

[FR Doc. 00–10042 Filed 4–25–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300993; FRL–6554–6]

RIN 2070–AB78

Thiabendazole; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of the fungicide thiabendazol and its metabolites in or on lentils at 0.1 part per million (ppm) for an additional 20–month period. This tolerance will expire and is revoked on December 31, 2001. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on lentils. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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 the Federal Insecticide, Fungicide, and Rodenticide Act.

DATES: This regulation is effective April 26, 2000. Objections and requests for hearings, identified by docket control number OPP–300993, must be received by EPA on or before June 26, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300993 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9356; and e-mail address: beard.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300993. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA issued a final rule, published in the **Federal Register** of February 25, 1998 (63 FR 9435) (FRL–5767–6), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), it established a time-limited tolerance for the residues of thiabendazole and its metabolites in or on lentils at 0.1 ppm. Subsequently, EPA extended that tolerance, published in the **Federal Register** of December 4, 1998 (63 FR 66994) (FRL–6044–5) with an expiration date of April 30, 2000. EPA established the tolerance because 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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of thiabendazole on lentils for this year's growing season due to the situation remaining an emergency. The Applicants (Idaho, Washington, North Dakota, and Montana) state that the ascochyta blight fungus has only occurred in the United States in recent years, and presently available fungicides do not adequately control its spread in lentils, to prevent significant economic loss. Additionally, a recently-discovered sexually-reproducing strain is of even greater concern, as this sexual stage releases spores, capable of traveling long distances on the wind. This disease was