been impracticable. The details of the event were not finalized with sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date.

Background and Purpose

The marine event requiring this regulation is the Riverfest powerboat/pylon races on the river. Event sponsors expect between 25,000 and 50,000 spectators. The City of Clarksville sponsors this event. Spectators will be able to view the event from areas designated by the sponsor.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary because of the event's short duration.

Small Entities

The Coast Guard finds that the impact on small entities, if any, is not substantial. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq) that this temporary rule will not have a significant economic impact on a substantial number of small entities because of the event's short duration.

Collection of Information

This rule contains no information collection requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq).*

Federalism Assessment

The Coast Guard has analyzed this action in accordance with the principles and criteria of Executive Order 12612 and has determined that this rule does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2–1, paragraph (34)(h) of Commandant Instruction M16475.1C this rule is excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements.

Temporary Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations, is amended as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35

2. A temporary § 100.35–T08–058 is added to read as follows:

§ 100.35–T08–058 Cumberland River at Clarksville, Tennessee.

(a) *Regulated Area:* A regulated area is established on all waters of the Cumberland River between mile 125.5 and mile 127.0.

(b) *Special Local Regulation:* All persons and/or vessels not registered with the sponsors as participants or official patrol vessels are considered spectators. The ''official patrol'' consists of any Coast Guard, public, state or local law enforcement and/or sponsor provided vessels assigned to patrol the event.

(1) No spectators shall anchor, block, loiter in, or impede the through transit of participants or official patrol vessels in the regulated area during effective dates and times, unless cleared for such entry by or through an official patrol vessel.

(2) When hailed and/or signaled by an official patrol vessel, a spectator shall come to an immediate stop. Vessels shall comply with all directions given: failure to do so may result in a citation.

(3) The Patrol Commander is empowered to forbid and control the movement of all vessels in the regulated area. The Patrol Commander may terminate the event at any time it is deemed necessary for the protection of life and/or property and can be reached on VHF–FM Channel 16 by using the call sign ''PATCOM''.

(c) *Effective Date:* This section is effective on September 13, 1998 from 9 a.m. until 5 p.m.

Dated: August 27, 1998.

Paul J. Pluta,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. 98–24422 Filed 9–10–98; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300706; FRL–6025–6]

RIN 2070–AB78

Cypermethrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cypermethrin (±) alpha-cyano-(3-phenoxyphenyl)methyl (±) *cis, trans*-3(2,2-dichloroethyenyl)-2,2-dimethylcyclopropane carboxylate in or on the commodity green onion at 6.0 parts per million (ppm). 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.

DATES: This regulation is effective September 11, 1998. Objections and requests for hearings must be received by EPA on or before November 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300706], 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–300706], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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

of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300706]. 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: Sidney Jackson, 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) 305–7610, e-mail: jackson.sidney@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 19, 1998 (63 FR 13404) (FRL–5776–6), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), announcing the filing of a pesticide petition (PP 5E4463) for tolerance by the Interregional Research Project (IR-4). This notice included a summary of the petition prepared by FMC Corporation, 1735 Market St., Philadelphia, PA 19103, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.418 be amended by establishing a tolerance for residues of the insecticide cypermethrin (±) alpha-cyano-(3-phenoxyphenyl)methyl (±) *cis, trans*-3(2,2-dichloroethyenyl)-2,2-dimethylcyclopropane carboxylate in or on the commodity green onion at 6.0 ppm.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate

protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of cypermethrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of cypermethrin on green onions at 6.0 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 cypermethrin are discussed below.

1. *Acute toxicity*. The required battery of acute toxicity studies has been submitted and found adequate. The findings were as follows: oral toxicity, lethal dose $(LD)_{50}$ > 263 milligram/kilogram (mg/kg); dermal toxicity, LD_{50} > 2,460 mg/kg; inhalation toxicity lethal concentration $(LC)_{50}$, 2.5 mg/liter (L); primary eye irritation--Toxicity Category III; primary dermal irritation --Toxicity Category IV. Cypermethrin is considered to be a dermal sensitizer.

2. *Genotoxicity*. The Agency has reviewed several mutagenicity studies. Types include an Ames mutagenicity assay; a dominant lethal study, a mouse lymphoma mutagenicity assay, a Chinese hamster ovary/hypoxanthine quanine phosphoribose transferase (CHO/HGPRT) assay, and a bone marrow cytogenic study. The data base for mutagenicity is considered to be adequate. Based on the available mutagenicity studies, there are no concerns for mutagenicity.

3. *Reproductive and developmental toxicity*— i. *Developmental toxicity study in the rat*. Cypermethrin was administered by gavage to rats at dose levels of 0, 17.5, 35, or 70 mg/kg/day on days 6-15 of gestation. The maternal lowest-observed effect level (LOEL) is 35 mg/kg/day, based on bodyweight. The maternal NOEL is 17.5 mg/kg/day. The developmental LOEL was > 70 mg/kg/day. The developmental NOEL is > 70 mg/kg/day.

ii. *Developmental toxicity study in the rabbit*. Cypermethrin was administered to 20 New Zealand White rabbits per dose group by gavage at dose levels of 0, 100, 450, or 700 mg/kg/day from days 7 through 19 of gestation. The test animals were sacrificed on day 29 of gestation. The maternal LOEL was 450 mg/kg/day, based on bodyweight gain. The maternal NOEL was 100 mg/kg/day. There were no indications of developmental toxicity. The NOEL and LOEL for developmental toxicity was > 700 mg/kg/day.

iii. *Three-generation reproduction study in rats*. Cypermethrin was administered to rats at dose levels of 0, 50, 150, or 1,000/750 ppm (reduced to 750 ppm after 12 weeks because of severe neurological symptoms). These dose levels correspond to 2.5, 7.5, or 50/37.5 mg/kg/day. Three successive generations were produced, each consisting of two separate breedings to produce six sets of litters. The LOEL is 150 ppm (7.5 mg/kg/day) based on consistent decreased bodyweight gain in both sexes. The NOEL was 50 ppm (2.5 mg/kg/day).

4. *Subchronic toxicity*. The data base for subchronic toxicity is considered to be complete except for a series 82-4 subchronic inhalation toxicity study of 90-days duration. This study is required if inhalation exposure is for periods greater than 21-days.

i. *A 21-day dermal study in the rabbit*. Cypermethrin was applied at dose levels of control, 2, 20, or 200 mg/kg/day applied in 20% weight/weight (w/w) basis PEG 300 with daily applications

for 3 weeks for a total of 15 applications. The LOEL is 200 mg/kg/day based on liver effects. The NOEL is 20 mg/kg/day.

ii. *A 21-day inhalation study in the rat*. Cypermethrin was administered to rats by nose only exposure at concentrations of 0, 0.01, 0.05, or 0.25 mg/L for 6 hours per day, 5 days per week for total of 15 exposures. The LOEL was 0.05 mg/L based mainly on bodyweight decrease. The NOEL was 0.01 mg/L.

5. *Chronic toxicity/carcinogenicity*—i. *Chronic oral study in the dog.* Cypermethrin was administered to beagle dogs at dose levels of 0, 1, 5, or 15 mg/kg/day for 52 weeks. The LOEL was 5 mg/kg/day based on gastrointestinal effects. The NOEL is 1 mg/kg/day.

ii. *Carcinogenicity study in the mouse*. Cypermethrin was administered to mice at dose levels of control-1, control-2, 100, 400, and 1,600 ppm (corresponding to 0, 0, 14, 57, or 229 mg/kg/day) for 97 weeks for males and 101 weeks for females. The LOEL was 400 ppm (57 mg/kg/day) based on liver weight. The NOEL was 100 ppm (14 mg/kg/day). This study was determined to be positive for induction of benign alveologenic neoplasms.

iii. *Chronic feeding/carcinogenicity study in the rat*. Cypermethrin was administered to rats at dose levels of control-1, control-2, 20, 150, or 1,500 ppm (corresponding to 0, 1, 7.5, or 75 mg/kg/day) for 2 years. The LOEL is 1,500 ppm (75 mg/kg/day) based on body weight. The NOEL was 150 ppm (7.5 mg/kg/day). Cypermethrin was not considered to be oncogenic in this study. A possible association with increased testicular interstitial tumors was not considered definite.

6. *Metabolism*. Studies in rats, dogs, and mice are available to support the requirement of metabolism in mammals. Studies show that cypermethrin is readily absorbed from the gastrointestinal tract and extensively metabolized. It is mostly excreted in the urine. No additional data are required.

7. *Neurotoxicity*. Additional data considered by the Agency included an acute delayed type neurotoxicity in hens, an acute neurotoxicity screening study in rats with a NOEL of 30 mg/kg and a LOEL of 100 mg/kg, and a subchronic neurotoxicity screening study in rats with a NOEL of 31 mg/kg/day and a LOEL of 77 mg/kg/day. Additional data will be required under a special Data Call-In (DCI) letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking EPA has a sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. To assess risk from acute dietary exposure, the Agency used a NOEL of 1.0 mg/kg/day based on increased incidence of passage of liquid stools at 5 mg/kg/day and above starting the first weeks of dosing in a chronic-dog study. A MOE of 100 is required

2. *Short - and intermediate - term toxicity.* To assess risk from (non-food) short- and intermediate-term dermal exposure, the Agency used a NOEL of 5 mg/kg/day from the chronic-dog study, incorporating 25% dermal absorption. A dermal absorption rate of 25% was derived based on the weight-of-evidence available for structurally related pyrethroids. For exposure via inhalation, the Agency used a NOEL of 0.01 mg/L from the 21-day inhalation study in rats.

3. *Chronic toxicity*. EPA has established the RfD for cypermethrin at 0.01 mg/kg/day. This RfD is based on a NOEL of 1.0 mg/kg/day from the chronic-dog study with an uncertainty factor of 100.

4. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992) the Carcinogenicity Peer Review Committee (CPRC) has classified cypermethrin as a Group C chemical, possible human carcinogen, based on increased incidence of lung adenomas in female mice, but did not recommend assignment of a cancer potency factor (Q*1) for a linear quantitative cancer risk assessment. Instead, the CPRC recommended the RfD approach. Based on the CPRC's recommendation that the RfD approach be used to assess dietary cancer risk, a quantitative linear dietary cancer risk assessment was not performed. Human health risk concerns due to long-term consumption of cypermethrin residues are adequately addressed by the dietary risk evaluation chronic exposure analysis using the RfD.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.418) for residues of cypermethrin in or on a variety of raw agricultural commodities. Tolerances currently exist for residues of cypermethrin on cottonseed; pecans; lettuce, head; onions, bulb; cabbage; *Brassica*, head and stem; *Brassica*, leafy and livestock commodities of cattle, goats, hogs, horses, and sheep as well as this pending tolerance for green onions. For the purposes of dietary risk assessment, residue data generated from residue field trials conducted at maximum application rates and minimum preharvest intervals were used. To assess secondary exposure from edible animal commodities, animal dietary burdens were calculated using mean field trial residue, adjusted for percent crop treated and applying appropriate processing factors for all feed items. Risk assessments were conducted by EPA to assess dietary exposures and risks from cypermethrin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary exposure assessment used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinement. The acute exposure via dietary intake for the U.S. Population is estimated at 0.004438 mg/kg/day. The acute dietary risk estimated by MOE at the 99.9th percentile for the U.S. population is 225. The acute dietary exposure for children is 0.005465 mg/kg/day with a resulting MOE of 183. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater.

ii. *Chronic exposure and risk*. The chronic dietary exposure assessment incorporated anticipated residues, tolerance values, FDA and PDP monitoring data, and percent crop treated information. The RfD used was 0.01 mg/kg/day. For the U.S. population, the exposure was estimated at 0.000025 mg/kg/day. The risk assessment resulted in use of 0.3% of the RfD. For children, the exposure was estimated at 0.000042 mg/kg/day, which uses 0.4% of the RfD.

Section 408(b)(2)(E) of the FFDCA authorizes EPA to consider available data and information on the anticipated residue levels of pesticides 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 five 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 time frame 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: (a) 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; (b) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (c) 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 cypermethrin were derived from federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by these 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 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 section 408(f) of the FFDCA requiring submission of data on anticipated residues in conjunction with approval of the registration under FIFRA.

2. *From drinking water.* Studies show that cypermethrin is immobile in soil and does not leach into ground water. Drinking water residue levels were estimated using the PRZM1/EXAMS computer models in 1993 for comparative ecological risk assessment.

i. *Acute exposure and risk.* For the U.S. population, acute exposure is estimated at 0.000126 mg/kg/day (MOE = 7,965). For non-nursing infants < 1 year old, exposure is estimated at 0.000242 mg/kg/day (MOE= 4,138).

ii. *Chronic exposure and risk.* For the U.S. population, chronic exposure is estimated at 0.000005 mg/kg/day, or essentially 0% of the RfD. For non-nursing infants < 1 year old, exposure is estimated at 0.000021 mg/kg/day, or 0.2% of the RfD.

3. *From non-dietary exposure.* Cypermethrin is currently registered for use on the following residential non-food sites: lawns and carpet. Non-occupational exposure to cypermethrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. Using surrogate data and conservative exposure scenarios, the Agency has estimated combined inhalation, dermal, and oral non-dietary exposure.

4. *Short- and intermediate-term exposure and risk.* For the U.S. population, exposure is estimated at 0.0000515 mg/kg/day. For infants less than 1 year old, the exposure is estimated at 0.00259 mg/kg/day. It should be noted that carpet uses are considered short and intermediate term exposures because available data indicate that cypermethrin dissipates over time and is thus unavailable to contribute as chronic exposure and risk.

5. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Four members of the insecticide class pyrethroids produce a common metabolite known as DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid). These insecticides are cyfluthrin, cypermethrin, zeta-cypermethrin and permethrin. Although the residues of DCVA can be estimated, no toxicology data on the compound per se are available to directly conduct a hazard evaluation and thereby establish an appropriate endpoint for use in a joint risk assessment. To date, for the purpose of assessing the risk of the parent compound the toxicity of DCVA has been assumed to be equivalent to the parent compound. However, due to the different toxicological profiles of cyfluthrin, cypermethrin, permethrin, and zeta-cypermethrin, EPA does not believe that it would be appropriate to cumulate DCVA for these pesticides, or DCVA residues from one of these pesticides with the parent of another of these pesticides, in conducting the risk assessment for these pesticides. Accordingly, for the purposes of this tolerance action, EPA has not assumed that cypermethrin has a common mechanism of toxicity with other substances.

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

The Agency has determined that an aggregate systemic oral and dermal exposure risk assessment is not appropriate due to difference in the toxicity endpoints observed between the oral (neurotoxicity) and dermal (hepatotoxicity) routes. An aggregate oral and inhalation risk assessment is appropriate due to the similarity of toxicity (neurotoxicity) observed in rats via these routes.

1. *Acute risk.* Aggregate acute risk represents the sum of acute food and acute drinking water exposure. For cypermethrin, the aggregate acute exposure is estimated at 0.004564 mg/kg/day, with a resulting MOE of 219 for the adult U.S. population. EPA generally has no concern for acute risk when the MOE is greater than 100.

2. *Chronic risk.* Aggregate chronic exposure is the sum of chronic exposure from food and drinking water. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to cypermethrin from food and water will utilize 0.3% of the RfD for the U.S. population. 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.

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. For cypermethrin, exposure is estimated at 0.000082 mg/kg/day, with a resulting MOE of 61,000 for the U.S. population. EPA generally has no concern for short-term risks if MOEs are shown to be over 100.

E. Aggregate Cancer Risk for U.S. Population

Cypermethrin is classified as a weak Group C carcinogen based on the increased incidence of lung adenomas in female mice. An RfD approach was recommended for human risk assessment purposes. Therefore, a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of cypermethrin are adequately addressed in the chronic exposure analysis. For the U.S. population, less than 1% of the RfD is occupied by aggregate chronic food and water exposure.

F. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cypermethrin residues.

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

ii. *Developmental toxicity studies.* In the pre-natal developmental toxicity studies in rats and rabbits, there was no evidence of developmental toxicity at the highest dose tested (70 mg/kg/day in rats and 700 mg/kg/day in rabbits).

iii. *Reproductive toxicity study.* An acceptable 3-generation reproduction study in rats has been submitted. Offspring toxicity was observed only at the highest dietary level tested, (700/1,000 ppm; 50/37.5 mg/kg/day), while toxicity in parental animals was observed at the lower treatment levels. The parental systemic NOEL was 50 ppm (2.5 mg/kg/day) and the parental systemic LOEL was 150 ppm (7.5 mg/kg/day).

iv. *Pre- and post-natal sensitivity.* The developmental and reproductive toxicity data demonstrated no indications of increased pre- and post-natal sensitivity.

v. *Conclusion.* From available adequate data, there is no indication that the developing fetus or neonate is more sensitive than adult animals. No developmental neurotoxicity studies are being required at this time. A developmental neurotoxicity data requirement is an upper tier study and required only if effects observed in the acute and 90-day neurotoxicity studies indicate concerns for frank neuropathy or alterations seen in fetal nervous system in the developmental or reproductive toxicology studies. The FQPA conditional requirement of an additional tenfold margin of safety for pesticide residues be applied for infants and children to take into account potential pre-and post-natal toxicity was not imposed in this case. The Agency believes that reliable data support the use of the standard 100-fold uncertainty factor, and that a ten-fold (10x) uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* For children 1 to 6 years old, (most highly exposed subgroup), the aggregate acute exposure is estimated at 0.005572 mg/kg/day, with a resulting MOE of 179. EPA generally has no concern for MOEs over 100.

3. *Chronic exposure and risk.* Using the conservative exposure assumptions, EPA has concluded that aggregate exposure to cypermethrin from food and water is estimated at 0.000044 mg/kg/day for children 1 to 6 years old (the highly exposed subgroup) will utilize 0.4% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. *Short- or 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 short-term and intermediate-term residential exposure. The MOE for non-nursing infants < 1 year old (most highly exposed subgroup) is estimated at 1,900, well above MOE values of a MOE less than 100 which the Agency finds unacceptable.

Therefore, EPA concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to cypermethrin residues.

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.

H. 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 the program. Congress has allowed 3 years from 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 disruption effects.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of cypermethrin in plants and animals is adequately understood. Studies have been conducted to delineate the metabolism of radiolabelled cypermethrin in various crops all showing similar results. The residue that is regulated is the parent compound, cypermethrin.

B. Analytical Enforcement Methodology

Adequate enforcement methodology Gas Chromatography with Electron Capture Detection (GC/ECD) is available in PAM II for enforcement of the tolerance.

C. Magnitude of Residues

Residue data from field trial and the FDA monitoring program (1992-1995) and the PDP monitoring program (1994) were used to estimate chronic dietary exposure. For the chronic analyses, mean residues from FDA monitoring were used for letttuce and onions (dry bulbs). Residue field trial data were used for broccoli, cabbage, cotton, green onions, mustard greens, and pecans. For acute dietary exposure analysis, field trial residue data, along with percent crop treated were used in the Monte Carlo analysis.

D. International Residue Limits

There are no Codex Maximum Residue Limits (MRL) for cypermethrin on green onions.

IV. Conclusion

Therefore, the tolerance is established for residues of cypermethrin (±) alpha-cyano(3-phenoxyphenyl)methyl (±) *cis, trans* 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the raw agricultural commodity green onions at 6.0 ppm.

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 November 10, 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 CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300706] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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) (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).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (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 the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

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

C. Executive Order 13084

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

In addition, since these 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: August 31, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

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

2. In § 180.418, the table in paragraph (a)(1) is amended by alphabetically adding the commodity to read as follows:

§ 180.418 Cypermethrin; tolerances for residues.

(a)(1)* * *

Commodity	Parts per million
* * *	* *
Onions, green	6.0
* * *	* *

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[FR Doc. 98–24472 Filed 9–10–98; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300685; FRL–6017–9]

RIN 2070–AB78

Metolachlor; 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 metolachlor and its metabolites determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3- morpholinone, each expressed as the parent compound in or on grass forage and grass hay. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on grass grown for seed in Oregon. This