

(e) * * *

| Inert ingredients | Limits | Uses |
|--|--------|----------------|
| Tetraethoxysilane, polymer with hexamethyldisiloxane, 6,500 minimum number average molecular weight (in amu) (CAS Reg. No. 104133-09-7). | | Antifoam agent |

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 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301207; FRL-6818-8]

RIN 2070-AB78

Zeta-Cypermethrin and its Inactive R-isomers; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of zeta-cypermethrin and its inactive R-isomers in or on edible podded legume vegetables (Crop subgroup 6A) at 0.5 parts per million (ppm); succulent, shelled peas and beans (Crop subgroup 6B) at 0.1 ppm; dried, shelled peas and beans, except soybean (Crop subgroup 6C) at 0.05 ppm; soybean, seed at 0.05 ppm; fruiting vegetables, except cucurbits (Crop Group 8) at 0.2 ppm; sorghum, grain at 0.5 ppm; sorghum, forage at 0.1 ppm; sorghum, stover at 5.0 ppm; wheat, grain at 0.2 ppm; wheat, forage at 3.0 ppm; wheat, hay at 6.0 ppm; wheat, straw at 7.0 ppm; aspirated grain fractions at 10.0 ppm; meat of cattle, goats, hogs, horses, sheep at 0.2 ppm. FMC Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This document also corrects two errors that appeared in the codified text of a final rule issued for zeta-cypermethrin in the **Federal Register** of September 17, 2001. The amendatory language for that document should have included instructions removing the entry for milk and adding an entry for goat, fat, under the table in § 180.418(a)(2). This document corrects those errors.

DATES: This regulation is effective February 12, 2002. Objections and requests for hearings, identified by docket control number OPP-301207,

must be received by EPA on or before April 15, 2002.

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-301207 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6100; and e-mail address: larocca.george@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," "Regulations and Proposed Rules," 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/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301207. 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

In the **Federal Register** of November 8, 2000 (65 FR 66998) (FRL-6750-2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP) for a tolerance by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103. This notice included a summary of the petition prepared by FMC Corporation, 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 zeta-cypermethrin (-alpha-cyano(3-phenoxyphenyl) methyl (\pm)(*cis-trans* 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate in or on the following raw agricultural commodities:

PP 0F06207 proposed tolerances in or on the raw agricultural commodities wheat, grain at 0.15 ppm; wheat forage, at 2.5 ppm; hay at 6.0 ppm; wheat, straw at 6.5 ppm; wheat, bran at 0.20 ppm; sorghum, grain, at 0.50 ppm; sorghum, forage at 0.10 ppm; sorghum fodder at 1.5 ppm; tomatoes at 0.10 ppm; peppers at 0.30 ppm; peas and beans (dried, succulent, and edible podded) at 0.50 ppm; soybeans at 0.05 ppm; poultry, meat at 0.05 ppm; poultry, meat by-products at 0.05 ppm; poultry, fat at 0.05 ppm; eggs at 0.05 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.3 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.30 ppm; and milk, fat at 0.2 ppm (reflecting 0.01 ppm in whole milk).

Based on EPA's review, the petition was revised by the petitioner to: Propose tolerances of 0.5 ppm for edible podded legume vegetables (Crop subgroup 6A); propose tolerances of 0.1 ppm for succulent, shelled peas and beans (Crop subgroup 6B); propose tolerances of 0.05 ppm in or on dried, shelled peas and beans, except soybean (Crop subgroup 6C); propose tolerances of 0.05 ppm in or on soybean, seed; propose tolerances of 0.2 ppm in or on the fruiting vegetables, except cucurbits group (Crop group 8); propose tolerances of 0.5 ppm in or on sorghum, grain; propose tolerances of 0.1 ppm in or on sorghum forage; propose tolerances of 5.0 ppm in or on sorghum, stover; propose tolerances of 0.2 ppm in or on wheat, grain; propose tolerances of 3.0 ppm in or on wheat, forage; propose tolerances

of 6.0 ppm in or on wheat, hay; propose tolerances of 7.0 ppm in or on wheat straw; propose tolerances of 10.0 ppm in or on aspirated grain fractions; propose tolerances of 0.2 ppm in or on meat of cattle, goats, hogs, horses, and sheep.

Although EPA is requesting a number of changes to the initial petitions and Notice of Filings, the nature of the changes, i.e. clarification and correction of commodity terms, international harmonization of tolerances, reduction in tolerance levels are not considered significant nor do they alter the risk assessment. Therefore, EPA is issuing this as a final action.

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 zeta-cypermethrin and its inactive *R*-isomers on edible podded legume vegetables (Crop subgroup 6A) at 0.5 ppm; succulent, shelled peas and beans (Crop subgroup 6B) at 0.1 ppm; dried, shelled peas and beans, except soybean (Crop subgroup 6C) at 0.05

ppm; soybean, seed at 0.05 ppm; fruiting vegetables, except cucurbits (Crop group 8) at 0.2 ppm; sorghum, grain at 0.5 ppm; sorghum, forage at 0.1 ppm; sorghum, stover at 5.0 ppm; wheat, grain at 0.2 ppm; wheat, forage at 3.0 ppm; wheat, hay at 6.0 ppm; wheat, straw at 7.0 ppm; aspirated grain fractions at 10.0 ppm; meat of cattle, goats, hogs, horses, sheep at 0.2 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by zeta-cypermethrin and its inactive *R*-isomers were discussed in detail in the **Federal Register** notice of September 17, 2001 (66 FR 47979) (FRL-6801-1). In that document (Unit III.), the toxicological profile for zeta-cypermethrin and cypermethrin was fully discussed. The observed health effects as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) were presented in tables sorted by the EPA Guideline number for each study type. The presentation of the toxicological profile for zeta-cypermethrin in the September 17, 2001 **Federal Register** remains current and can, therefore, be referenced as background in relation to the tolerances being established with this document.

Zeta-cypermethrin is an enriched isomer of cypermethrin. In order to select toxicity endpoints for the purposes of risk assessment, bridging data on zeta-cypermethrin were submitted so that the toxicity of zeta-cypermethrin could be compared with that of cypermethrin and the data bases could be combined to form one complete data base for both chemicals. In the selection of toxicity endpoints, studies conducted with zeta-cypermethrin were used wherever possible.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes

used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ($RfD = NOAEL/UF$). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL/exposure$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific

circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve.

To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure}/\text{exposures}$) is calculated. A summary of the toxicological endpoints for zeta-cypermethrin and its inactive R-isomers used for human risk assessment was presented in Table 3 in Unit III.B. of the **Federal Register** of September 17, 2001 (66 FR 47979) (FRL-6801-1). The selected hazard endpoints used in the risk assessment to support the tolerances published on September 17, 2001, remain current. Therefore, the same toxicological dose and hazard endpoints are used in the risk assessment for the tolerances established through this rulemaking. For this reason, the detailed table listing the selected endpoints is not being republished with this final rule. Refer to the September 17, 2001 **Federal Register** cited above to review the hazard endpoints selected for zeta-cypermethrin.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.418) for the residues of zeta-cypermethrin and its inactive R-isomers, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from zeta-cypermethrin and its inactive R-isomers in food as follows:

Zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin. Both cypermethrin and

zeta-cypermethrin are mixtures of eight isomers, with the active components consisting of the S-enantiomers ("S" configuration at the cyano bearing carbon). The two differ in that cypermethrin has a 50:50 R/S ratio whereas zeta-cypermethrin is enriched in the S-enantiomers with a ratio of 90:10 of the S/R. The enriched isomer formulation provides for similar insect control but at lower use rates. Since use of both cypermethrin and zeta-cypermethrin result in human exposure to the same eight isomers, dietary and non-dietary (residential) aggregate risk assessment was conducted by adding the uses of the two chemicals.

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues and 100% crop treated have been used in these analyses for all commodities having either established or proposed tolerances of cypermethrin or zeta-cypermethrin. In cases where a commodity has an established tolerance for cypermethrin and a proposed tolerance for zeta-cypermethrin, the larger of the two values was used in the assessment. DEEM default processing factors were used for all commodities in this assessment. All exposures are Tier 1 estimates that are extremely conservative and likely overestimate actual dietary exposure.

TABLE 1.—SUMMARY OF ACUTE DIETARY EXPOSURE, DIETARY EXPOSURE, AND RISK FOR ZETA-CYPERMETHRIN.

| Population Subgroup | Acute Dietary | |
|-----------------------|------------------------------|-------|
| | Dietary Exposure (mg/kg/day) | %aPAD |
| U.S. population | 0.021818 | 21.8 |
| Infants (<1 year old) | 0.024398 | 24.4 |
| Children (1-6 years) | 0.032668 | 32.7 |
| Females (13-50 years) | 0.020468 | 20.5 |

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA

1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for

the chronic exposure assessments: Tolerance-level residues and 100% crop treated have been used in these analyses for all commodities having either established or proposed tolerances of

cypermethrin or zeta-cypermethrin. For chronic risk assessments, residue estimates for foods (e.g., apples) or food-

forms (e.g., apple juice) of interest are multiplied by the averaged consumption estimate of each food/food-form of each

population subgroup. Exposure estimates are expressed in mg/kg bwt/day and as a percent of the cPAD.

TABLE 2.—SUMMARY OF CHRONIC DIETARY EXPOSURE AND RISK FOR ZETA-CYPERMETHRIN

| Population Subgroup | Chronic Dietary | |
|-----------------------|-------------------------------|-------|
| | Dietary Exposures (mg/kg/day) | %cPAD |
| U.S. population | 0.007442 | 2.4 |
| Infants (<1 year old) | 0.006485 | 10.8 |
| Children (1-6 years) | 0.014017 | 23.4 |
| Females (13-50 years) | 0.006513 | 10.9 |

As shown by the summarized acute and chronic results in Tables 1 and 2, all risk estimates fall below EPA's level of concern ($\geq 100\%$ PAD). All exposures are Tier 1 estimates that are extremely conservative and likely overestimate actual dietary exposure. Refinements to the analyses in the form of percent crop treated considerations and/or anticipated residues would likely reduce the exposure and risk estimates for zeta-cypermethrin.

iii. *Cancer.* Cypermethrin has been classified as a Category C, possible human carcinogen, based on an increased incidence of lung adenomas and adenomas plus carcinomas combined in female mice (Cancer Peer Review Committee, 1988). The evidence was not considered strong enough to warrant a quantitative estimation of human risk. Cypermethrin has not been classified under the more current, Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996). Because zeta-cypermethrin is an enriched isomer of cypermethrin, it is also classified as a Category C carcinogen and a RfD approach was recommended for human risk assessment purposes.

2. *Dietary exposure from drinking water.* Based on the available data, cypermethrin/zeta-cypermethrin is a moderately persistent chemical that primarily degrades by photolysis in water and biodegradation. Depending on the environmental circumstances, it may persist for periods of months post-treatment. Cypermethrin is tightly bound to soil particles and is not likely to move to ground waters. However, the degradate dichlorovinyl acid (DCVA) is mobile and likely to reach ground waters. Additional information about the mobility of this degradate has been requested. Cypermethrin can contaminate surface waters through spray drift. Under some conditions it may also have a potential for runoff into surface waters (primarily through

erosion), for several months post-application. Since zeta-cypermethrin is preferentially associated to the soils, the fraction of the chemical in the water column should be small. In addition, it is expected that treatment of drinking water would remove substantial portions of cypermethrin/zeta-cypermethrin present in water. Although the Agency has not addressed residues of DCVA in water, the Agency has concluded that DCVA does not need to be included in the dietary risk for food.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) 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 used are considered to be screening tools in the risk

assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) 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, and from residential uses. Since DWLOCs address total aggregate exposure to zeta-cypermethrin and its inactive R-isomers, they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models, the EECs of zeta-cypermethrin and its inactive R-isomers for acute exposures are estimated to be 8.9 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.46 ppb for surface water and 0.006 ppb for ground water. These values generally represent upper-bound estimates of the concentrations that might be found in surface water and ground water due to the use of cypermethrin on Brassica vegetables, which has the highest application rate among both cypermethrin and zeta-cypermethrin on all crops over which the chemicals are applied.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Zeta-cypermethrin and its inactive R-isomers is not registered for use on any sites that would result in residential exposure. However, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide

cypermethrin). The analytical method does not distinguish cypermethrin from zeta-cypermethrin, and the toxicological endpoints are the same. Therefore, dietary and non-dietary residential aggregate risk assessment is conducted by adding the uses of the two chemicals.

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 zeta-cypermethrin and its inactive R-isomers 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, zeta-cypermethrin and its inactive R-isomers 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 zeta-cypermethrin and its inactive R-isomers 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. Safety Factor for Infants and Children

1. *In general.* FFDC 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 on toxicity and exposure 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.

2. *Prenatal and postnatal sensitivity.* The data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to either zeta-cypermethrin or cypermethrin. In the prenatal

developmental toxicity studies in rats, there was no evidence of developmental toxicity at the highest doses tested (35 mg/kg/day). Maternal toxicity (decreased body weight gain (both chemicals), and food consumption, ataxia, urine and feces-stained for (zeta-cypermethrin) was observed at the LOAEL of 25 mg/kg/day. The maternal NOAELs were established at 12.5 mg/kg/day for zeta-cypermethrin and 17.5 mg/kg/day for cypermethrin. In the definitive rabbit developmental toxicity study conducted with cypermethrin, the maternal LOAEL was 450 mg/kg/day based on decreased body weight gain. No developmental toxicity was observed at dose levels up to 700 mg/kg/day. In the 2-generation reproduction study in rats conducted with zeta-cypermethrin, off-spring toxicity (decreased pup weight gain during lactation) was observed at the same treatment level which resulted in parental systemic toxicity (NOAEL: 27 mg/kg/day; LOAEL: 45 mg/kg/day). In the definitive multigeneration reproduction study conducted with cypermethrin, the parental NOAEL/LOAEL is lower than the pup NOAEL/LOAEL, both based on decreased in body weight gain (2.5/7.5 mg/kg/day for the parents versus 7.5/37.5 mg/kg/day for the pups).

3. *Conclusion.* There is a complete toxicity data base for zeta-cypermethrin and its inactive R-isomers and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The safety factor can be removed for zeta-cypermethrin and its inactive R-isomers because: (1) There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; (2) the requirement of a developmental neurotoxicity study is not based on criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a developmental neurotoxicity study - and a safety factor (e.g., neuropathy in adult animals; central nervous system malformation following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) and therefore does not warrant an FQPA safety factor; and (3) the dietary (food and drinking water) and non-dietary exposure assessment will not underestimate the potential exposures for infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a

point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking 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 and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to zeta-cypermethrin and its inactive R-isomers will occupy 22% of the aPAD for the U.S. population, 21% of the aPAD for females 13 years and older, 24% of the aPAD for infants (>1 year old), and 33% of the aPAD for children (1-6 years). In addition, there is potential for acute dietary exposure to zeta-cypermethrin and its inactive R-isomers in drinking water. After calculating DWLOCs and

comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100%

of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS

| Population Subgroup | aPAD (mg/kg) | %aPAD (Food) | Surface Water EEC (ppb) ¹ | Ground Water EEC (ppb) ¹ | Acute DWLOC (ppb) ² |
|----------------------------|--------------|--------------|--------------------------------------|-------------------------------------|--------------------------------|
| U.S. population | 0.10 | 22% | 8.9 | 0.006 | 2,700 |
| All infants (< 1 year old) | 0.10 | 24% | 8.9 | 0.006 | 760 |
| Children (1-6 years old) | 0.10 | 33% | 8.9 | 0.006 | 670 |
| Females (13-50 years old) | 0.10 | 21% | 8.9 | 0.006 | 2,400 |

¹ EECs resulting from the maximum proposed application rate (Cypermethrin on brassica vegetables).

² The acute DWLOC was calculated as follows: DWLOC (µg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption (L/day) x 0.001 mg/µg

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to zeta-cypermethrin and its inactive R-isomers from food will utilize 12% of the cPAD for the U.S. population, 11% of the cPAD for infants (<1 year old) and 23% of the cPAD for children (1-6 years). There are no residential uses for zeta-cypermethrin and its inactive R-isomers that result in chronic residential exposure to zeta-cypermethrin and its inactive R-isomers.

However, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin). The analytical method does not distinguish cypermethrin from zeta-cypermethrin, and the toxicological endpoints are the same. Therefore, dietary and non-dietary residential aggregate risk assessment is conducted by adding the use of the two chemicals. Based on the use pattern, chronic residential exposure to residues of zeta-

cypermethrin and its inactive R-isomers is not expected. In addition, there is potential for chronic dietary exposure to zeta-cypermethrin and its inactive R-isomers in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC(NON-CANCER) EXPOSURE TO ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS

| Population Subgroup | cPAD mg/kg/day | %cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|--------------------------|----------------|--------------|-------------------------|------------------------|---------------------|
| U.S. population | 0.06 | 12 | 0.46 | 0.006 | 1,900 |
| All infants (<1year old) | 0.06 | 11 | 0.46 | 0.006 | 540 |
| Children (1-6years old) | 0.06 | 23 | 0.46 | 0.006 | 460 |
| Females 13-50 years old | 0.06 | 11 | 0.46 | 0.006 | 1,600 |

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Zeta-cypermethrin and its inactive R-isomers is not registered for use on any sites that would result in residential exposure; however, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin). Cypermethrin registered residential uses constitute short- and intermediate-term exposure scenarios; endpoints have been selected for short- and intermediate-term incidental oral

and inhalation exposures, and the acceptable MOEs for short- and intermediate-term exposures are 100. Since the toxicological effects through the inhalation exposure route are similar to those toxicological effects through the oral routes, short-term aggregate risk assessment was conducted adding inhalation, oral non-dietary exposure, and average food and water exposure.

Since all the acceptable MOEs are at the same level, the aggregate risks for population subgroup can be estimated by calculating aggregate Margin of Exposure values (MOE_{aggregate}).

$$MOE_{aggregate} = 1/MOE_I + 1/MOE_D + 1/$$

$MOE_O + 1/MOE_{food} + 1/MOE_{water}$ where I = inhalation, D = dermal (no dermal endpoints were selected), O = non-dietary oral, MOE_{food} = average food from the chronic DEEM analysis.

As residue values in water from monitoring data are not available, therefore, as with the acute dietary aggregate risk estimate for the short- and intermediate-term aggregate risk assessments, the DWLOCs have to be back calculated. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,500 for adult males, 1,700 for

adult females, 830 for a child, and 1,700 for infants. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and

compared to the EECs for chronic exposure of zeta-cypermethrin and its inactive R-isomers in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA

does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS

| Population Subgroup | Aggregate MOE (Food + Residential) | Aggregate Level of Concern (LOC) | Surface Water EEC (µg/L) | Ground Water EEC (µg/L) | Short-Term DWLOC (µg/L) |
|---------------------|------------------------------------|----------------------------------|--------------------------|-------------------------|-------------------------|
| Adult male | 1,300 | 100 | 0.46 | 0.006 | 3,300 |
| Adult female | 1,500 | 100 | 0.46 | 0.006 | 2,800 |
| Child | 600 | 100 | 0.46 | 0.006 | 830 |
| Infants | 1,000 | 100 | 0.46 | 0.006 | 910 |

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Zeta-cypermethrin and its inactive R-isomers is not registered for use on any sites that would result in residential exposure; however, cypermethrin does have indoor and outdoor residential uses (zeta-cypermethrin is an enriched-enantiomer version of the insecticide cypermethrin). Cypermethrin registered residential uses constitute short- and intermediate-term exposure scenarios; endpoints have been selected for short- and intermediate-term incidental oral and inhalation exposures, and the acceptable MOEs for short- and

intermediate-term exposures are 100. Since the toxicological effects through the inhalation exposure route are similar to those toxicological effects through the oral routes, short-term aggregate risk assessment was conducted adding inhalation, oral non-dietary exposure, and average food and water exposure.

Since all the acceptable MOEs are at the same level, the aggregate risks for the population subgroups can be estimated by calculating aggregate Margin of Exposure values (MOE_{aggregate}). $MOE_{aggregate} = 1/MOE_I + 1/MOE_D + 1/MOE_O + 1/MOE_{food} + 1/MOE_{water}$.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that

food and residential exposures aggregated result in aggregate MOEs of 640 for adult males, 740 for adult females, 300 for child, and 530 for infants. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of zeta-cypermethrin and its inactive R-isomers in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO ZETA-CYPERMETHRIN AND ITS INACTIVE R-ISOMERS

| Population Subgroup | Aggregate MOE (Food + Residential) | Aggregate Level of Concern (LOC) | Surface Water EEC µg/L | Ground Water EEC µg/L | Intermediate-Term DWLOC µg/L |
|---------------------|------------------------------------|----------------------------------|------------------------|-----------------------|------------------------------|
| Adult male | 640 | 100 | 0.46 | 0.006 | 1,500 |
| Adult female | 740 | 100 | 0.46 | 0.006 | 1,300 |
| Child | 300 | 100 | 0.46 | 0.006 | 330 |
| Infant | 530 | 100 | 0.46 | 0.006 | 410 |

5. *Aggregate cancer risk for U.S. population.* Cypermethrin/zeta-cypermethrin has been classified as a Category C carcinogen, based on an increased incidence of lung adenomas and adenomas plus carcinomas combined in female mice. However, the

evidence was not considered strong enough to warrant a quantitative estimation of human risk. An RfD approach was recommended for human risk assessment purposes. Dietary risk concerns due to long-term consumption of zeta-cypermethrin are adequately

addressed in the chronic exposure analysis. For the U.S. population only 11% of RfD is occupied by chronic food and water exposure.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general

population, and to infants and children from aggregate exposure to zeta-cypermethrin and its inactive R-isomers residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of cypermethrin residues in plants and animal products in PAM II (Method 1). This method involves initial acetone-hexane extraction, followed by partitioning with water. The organic layer is evaporated, then redissolved in cyclohexane-methylene chloride and passed through a gel permeation column. The eluate is evaporated, redissolved in hexane and passed through a Florisil column. Cypermethrin residues are analyzed by gas chromatography (GC) with an electron capture detector (ECD). Since zeta-cypermethrin is an isomer enriched form of cypermethrin and the zeta-cypermethrin is an enriched form of cypermethrin, and the PAM II method is not stereospecific, this method is considered adequate for enforcement of the proposed tolerances of zeta-cypermethrin.

B. International Residue Limits

There are no specific Codex maximum residue limits (MRLs) for zeta-cypermethrin, but there are Codex MRLs for cypermethrin. The proposed or recommended U.S. tolerances for residue zeta-cypermethrin in/on soybean seeds (0.05 ppm), eggs (0.05 ppm), dried shelled peas and beans (0.05 ppm), and meat byproducts (0.05 ppm) are equivalent to their respective Codex MRLs. The recommended U.S. tolerance for fruiting vegetables (0.2 ppm) is also equivalent to the Codex MRL for egg plants, but is lower than Codex MRLs for tomatoes and peppers (0.5 mg/kg). Recommended U.S. tolerances for meat (cattle, goats, hogs, horses, and sheep) and sorghum stover will be increased to 0.2 and 5.0 ppm, respectively to match their equivalent Codex MRLs. The recommended U.S. tolerances for milk and wheat hay and straw are higher than their equivalent Codex MRLs and cannot be harmonized. The recommended U.S. tolerance for succulent shelled peas and beans cannot be harmonized with the Codex MRLs for common beans and peas since the crop groups are defined differently. The Codex definitions are based on the crop being a pea or a bean, whereas the U.S. groups are based on whether the raw agricultural commodity is shelled or the pod is consumed.

V. Conclusion

Therefore, the tolerance is established for residues of zeta-cypermethrin and its inactive R-isomers, Z-cypermethrin (S-cyano (3-phenoxyphenyl) methyl (+/-) (*cis-trans* 3-(2,2-dichloro, in or on edible podded legume vegetables (Crop subgroup 6A) at 0.5 ppm; succulent, shelled peas and beans (Crop subgroup 6B) at 0.1 ppm; dried, shelled peas and beans, except soybean (Crop subgroup 6C) at 0.05 ppm; soybean, seed at 0.05 ppm; fruiting vegetables, except cucurbits (Crop group 8) at 0.2 ppm; sorghum, grain at 0.5 ppm; sorghum, forage at 0.1 ppm; sorghum, stover at 5.0 ppm; wheat, grain at 0.2 ppm; wheat, forage at 3.0 ppm; wheat, hay at 6.0 ppm; wheat, straw at 7.0 ppm; aspirated grain fractions at 10.0 ppm; meat of cattle, goats, hogs, horses, sheep at 0.2 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-301207 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 April 15, 2002.

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, 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, 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, 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-301207, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 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 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 issues(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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or 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). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure

“meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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: January 23, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.418 is amended by removing the entire entries for “hogs, meat” and “milk”; alphabetically adding 15 commodities; and revising

the entries for "cattle, meat," "goat, meat" "horse, meat," and "sheep, meat," in the table in paragraph (a)(2) to read as follows:

§ 180.418 Cypermethrin and anisomer zeta-cypermethrin; tolerances for residues.

- (a) * * *
- (2) * * *

| Commodity | Parts per million |
|--|-------------------|
| * * * | * * * |
| Aspirated grain fractions | 10.0 ppm |
| Cattle, meat | 0.2 ppm |
| Dried, shelled peas and beans, except soybean (Crop subgroup 6C) | 0.05 ppm |
| Edible podded legume vegetables (Crop subgroup 6A) | 0.5 ppm |
| Fruiting vegetables, except cucurbits (Crop Group 8) | 0.2 ppm |
| Goat, fat | 1.00 ppm |
| Goat, meat | 0.2 ppm |
| Hog, meat | 0.2 ppm |
| Horse, meat | 0.2 ppm |
| Sheep, meat | 0.2 ppm |
| Sorghum, forage ... | 0.1 ppm |
| Sorghum, grain | 0.5 ppm |
| Sorghum, stover ... | 5.0 ppm |
| Soybean, seed | 0.05 ppm |
| Succulent, shelled peas and beans (Crop subgroup 6B) | 0.1 ppm |
| Wheat, forage | 3.0 ppm |
| Wheat, grain | 0.2 ppm |
| Wheat, hay | 6.0 ppm |
| Wheat straw | 7.0 ppm |

* * * * *

[FR Doc. 02-2611 Filed 2-11-02; 8:45 am]

BILLING CODE 6560-50-S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 52

[CC Docket No. 99-200; CC Docket No. 96-98; FCC 01-362]

Numbering Resource Optimization

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Federal Communications Commission (FCC or Commission) continues to develop, adopt and implement a number of strategies to ensure that the numbering resources of the North American Numbering Plan (NANP) are used efficiently, and that all carriers have the numbering resources they need to compete in the rapidly expanding telecommunications marketplace.

DATES: Effective March 14, 2002, except for §§ 52.19(c)(3)(i) and 52.19(c)(4), which contain information collection requirements that have not been approved by OMB. The Commission will publish a document in the **Federal Register** announcing the effective date.

ADDRESSES: Federal Communications Commission, Secretary, 445 12th Street, SW., Room TW-B204F, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Sanford Williams, (202) 418-2320 or e-mail at swilliam@fcc.gov or Jennifer Gorny at (202) 418-2320 or jgorny@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Third Report and Order and Second Order on Reconsideration in CC Docket No. 96-98 and CC Docket No. 99-200 (Third Report and Order)*, adopted on December 12, 2001, and released on December 28, 2001. The full text of this document is available for inspection and copying during normal business hours in the Commission Reference Center, 445 12th Street, SW., Washington, DC 20554. The complete text may also be obtained through the World Wide Web at <http://www.fcc.gov/Bureaus/CommonCarrier/Orders>, or may be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 202-863-2893, facsimile 202-863-2898, or via e-mail at qualexint@aol.com.

Synopsis of the Third Report and Order and Second Order on Reconsideration in CC Docket No. 96-98 and CC Docket No. 99-200

1. With the rules adopted in the *Third Report and Order*, the Commission creates national standards to address numbering resource optimization. The *Third Report and Order*, among other things: (1) Declines to require paging providers and providers that do not have local number portability (LNP) and are operating outside the top 100 metropolitan statistical areas (MSA) to participate in thousands-block number pooling; (2) lifts the ban on service-specific and technology-specific

overlays (collectively, specialized overlays or SOs), and provides that the Commission will consider petitions filed by state commissions for authority to implement SOs on a case-by-case basis; (3) subjects carriers that violate numbering requirements or fail to cooperate with an auditor conducting a "for cause" or random audit to the denial of requests for numbering resources; (4) allows incumbent local exchange carriers (LECs) subject to rate-of-return or price cap regulation to recover their carrier-specific costs directly related to national thousands-block number pooling through the existing cost recovery mechanisms of rate-of-return or price cap adjustments, and allows all other carriers to recover their carrier-specific costs related to pooling in any manner allowed under the Act; and (5) clarifies that all non-exempt carriers operating within the top 100 MSAs must be LNP-capable and must participate in thousands-block number pooling.

2. The *Third Report and Order* also finds that state commissions should be allowed to have password-protected access to the North American Numbering Plan Administration (NANPA) database to obtain data concerning area codes within their state.

3. The rules adopted herein facilitate increased carrier accountability and incentives to use numbers efficiently, and promote the judicious conservation of numbering resources.

Final Paperwork Reduction Analysis

4. This *Third Report and Order* contains some new and/or modified information collections, which will be submitted to OMB for approval, as prescribed by the Paperwork Reduction Act.

Final Regulatory Flexibility Analysis

5. As required by the Regulatory Flexibility Act, as amended, (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Second Report and Order, Order on Reconsideration in CC Docket No. 96-98 and CC Docket No. 99-200, and Second Further Notice of Proposed Rulemaking (Second Report and Order)*, 66 FR 9528 (Feb. 8, 2001). The Commission sought written public comment on the proposals in the *Second Report and Order*, including comment on the IRFA. No comments received addressed the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.