Approved: July 10, 2008.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

■ Accordingly, the interim final rule amending 38 CFR parts 17 and 59, which was published in the **Federal Register** at 66 FR 33845 on June 26, 2001, is adopted as a final rule with the following changes and with the final regulatory change made to § 59.50 that was effective on February 14, 2007 (72 FR 6959):

PART 59—GRANTS TO STATES FOR CONSTRUCTION OR ACQUISITION OF STATE HOMES

■ 1. The authority citation for part 59 continues to read as follows:

Authority: 38 U.S.C. 101, 501, 1710, 1742, 8105, 8131–8137.

■ 2. Amend § 59.20 by revising paragraph (a) to read as follows:

§ 59.20 Initial application requirements.

(a) For a project to be considered for inclusion on the priority list in § 59.50 of this part for the next fiscal year, a State must submit to VA an original and one copy of a completed VA Form 10–0388–1 and all information, documentation, and other forms specified by VA Form 10–0388–1 (these forms are available on the internet Web sites provided in § 59.170 of this part).

* * * * *

■ 3. Amend § 59.60 by revising paragraphs (a) and (b) to read as follows:

§ 59.60 Additional application requirements.

* * * * *

(a) Complete, updated Standard Forms 424 (mark the box labeled application and submit the information requested for an application), 424C, and 424D (these forms are available on the internet Web site provided in § 59.170 of this part), and

(b) A completed VA Form 10–0388–5 and all information and documentation specified by VA Form 10–0388–5 (this form is available on the internet Web site provided in § 59.170).

* * * * *

■ 4. Revise § 59.100 to read as follows:

§ 59.100 Payment of grant award.

The amount of the grant award will be paid to the State or, if designated by the State representative, the State home for which such project is being carried out or any other State agency or instrumentality. Such amount shall be paid by way of reimbursement, and in such installments consistent with the progress of the project as the Chief Consultant, Geriatrics and Extended Care, may determine and certify for payment to the appropriate Federal institution. Funds paid under this section for an approved project shall be used solely for carrying out such project as so approved. As a condition for the final payment, the State must comply with the requirements of this part based on an architectural and engineering inspection approved by VA, must obtain VA approval of the final equipment list submitted by the State representative, and must submit to VA a completed VA Form 10–0388–13 (this form is available on the internet Web site provided in § 59.170). The equipment list and the completed VA Form 10–0388–13 must be submitted to the Chief Consultant, Geriatrics and Extended Care (114), VHA Headquarters; 810 Vermont Avenue, NW.; Washington, DC 20420.

Authority: 38 U.S.C. 101, 501, 1710, 1742, 8105, 8131–8137

■ 5. Revise § 59.170 to read as follows:

§ 59.170. Forms.

All forms required by this part are available on the internet at ''*http://www.va.gov/forms/*'' for VA Forms and at ''*http://www.gsa.gov*'' for Standard Forms, or at the Veterans Health Administration, Room 789, 810 Vermont Ave., NW., Washington, DC 20420.

Authority: 38 U.S.C. 101, 501, 1710, 1742, 8105, 8131–8137, Section 2, 3, 4, and 4a of the Architectural Barriers Act of 1968, as amended, Pub. L. 90–480, 42 U.S.C. 4151–4157

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007-1191; FRL–8382–9]

Cymoxanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cymoxanil in or on bulb onion subgroup 3-07A; green onion subgroup 3-07B; leafy greens subgroup 4A; leaf petioles subgroup 4B; cilantro leaves; and caneberry subgroup 13-07A. The Interregional Research Project (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also deletes the tolerances for caneberry and head lettuce.

DATES: This regulation is effective October 8, 2008. Objections and requests for hearings must be received on or before December 8, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1191. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American

Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–1191 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 as required by 40 CFR part 178 on or before December 8, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–1191, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of March 12, 2008 (73 FR 13225) (FRL–8354–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 7E7282 and 7E7283) by IR-4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.503 be amended by establishing tolerances for residues of the fungicide cymoxanil, (2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide), in or on bulb vegetables group 3-07 at 1.1 parts per million (ppm); leafy greens subgroup 4A at 19 ppm; cilantro leaves at 19 ppm; caneberry subgroup 13-07A at 4 ppm (PP 7E7283); and leaf petioles subgroup 4B at 6.0 ppm (PP 7E7282). That notice referenced a summary of the petition prepared by IR-4 and DuPont, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Several comments were received from a private citizen objecting to the sale of the pesticide and animal testing. The Agency has received these same comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), 69 FR 63096-63098 (October 29, 2004) for the Agency's response to these objections.

Based upon review of the data supporting the petition, EPA has determined that the tolerance levels for bulb vegetables should be set as follows: bulb onion subgroup 3-07A at 0.05 ppm; green onion subgroup 3-07B at 1.1 ppm. The reasons for this change are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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) of FFDCA 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.''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 for the petitioned-for tolerances for residues of cymoxanil on bulb onion subgroup 3-07A at 0.05 ppm; green onion subgroup 3-07B at 1.1 ppm; leafy greens subgroup 4A at 19 ppm; leaf petioles subgroup 4B at 6.0 ppm; cilantro leaves at 19 ppm; and caneberry subgroup 13-07A at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing these 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. Specific information on the studies received and the nature of the adverse effects caused by cymoxanil as well as the no-observed-adverse-effect-levels (NOAELs) and the lowest-observed-adverse-effect-levels (LOAELs) from the toxicity studies can be found at *http://www.regulations.gov* in document *Cymoxanil; Human Health Risk Assessment for Proposed Uses on Bulb Vegetables (Crop Group 3-07), Leafy Greens (Subgroup 4A), and Leaf Petioles (Subgroup 4B)*, page 16 in docket ID number EPA–HQ–OPP–2007–1191.

Cymoxanil has low acute toxicity via oral, dermal, and inhalation routes of exposure. It is a mild skin irritant, not a skin sensitizer, and non-irritating to the eye. Systemic toxicity, as evidenced by decreased body weights, body weight gains, and food consumption, was observed in subchronic, chronic, developmental, reproductive and neurotoxicity studies across species. The dog appears to be the most sensitive species for cymoxanil-induced toxicity

with the thymus gland identified as a target organ in this species during subchronic and chronic exposures. No evidence of immunotoxicity was observed following subchronic exposure of rats up to 108 milligrams/kilograms/day (mg/kg/day) in males and 117 mg/kg/day in females (108/117 (M/F)) or mice up to 218/552 (M/F) mg/kg/day, respectively. In a 21–day dermal toxicity study in rats, no systemic toxicity was observed up to the limit dose. In a subchronic neurotoxicity study in rats, systemic toxicity was observed at 102/137 mg/kg/day (M/F); however, no neurotoxicity and/or neuropathology were observed up to 224/333 mg/kg/day (M/F; highest dose tested). In addition, no evidence of neurotoxicity was observed in the developmental toxicity studies in rats or rabbits, the 2-generation reproduction study in rats, the subchronic or chronic dog studies, or the 18–month mouse carcinogenicity study. However, in the combined chronic toxicity/carcinogenicity study in rats, clinical signs of hyperactivity and aggressiveness in males (≥30.3 mg/kg/day), as well as retinal atrophy in both sexes (≥30.3 mg/kg/day) were observed.

Increased susceptibility of rats and rabbits was observed following in utero exposure to cymoxanil. In acceptable developmental toxicity studies in both of these species, developmental effects were seen at doses below those that caused maternal toxicity. In the rat developmental toxicity studies, skeletal anomalies, delays in skeletal ossification, and/or increases in overall malformations were observed at lower doses than those at which maternal toxicity was observed. In a rabbit developmental study, increased skeletal malformations were observed at 8 mg/kg/day (LOAEL), which was also below the maternal NOAEL of 32 mg/kg/day. Cleft palate was also observed in fetuses at 32 mg/kg/day. In the first 2-generation reproduction toxicity study (1993), decreased pup viability (PND 0-4) was observed at maternally toxic doses. In a second 2-generation reproduction toxicity study (2001), decreased body weight was observed during lactation in both F_1 and F_2 offspring at a dose that was lower than that at which parental toxicity was observed. The increased susceptibility of offspring observed in this study was concordant with the results obtained in the developmental toxicity studies. In a developmental neurotoxicity study, offspring toxicity – adverse effects included decreased pup survival, decreased pup weight and body weight gain during early lactation, increases in morphometric measurements (anterior/posterior cerebrum for males, cerebellar height for females) at PND 79-83, and decreased retention in the water maze task for adult females – was observed at the same dose as maternal toxicity (slight decreases in body weight, body weight gain during gestation, and food consumption). The LOAEL for both maternal animals and offspring was 100 mg/kg/day. No residual uncertainties exist in the database for pre-/post-natal toxicity, and the endpoints selected for risk assessment are considered protective of effects observed in offspring in developmental and reproduction toxicity studies. The endpoints selected for risk assessment are further described in section 3.5 of the document: *Cymoxanil; Human Health Risk Assessment for Proposed Uses on Bulb Vegetables (Crop Group 3-07), Leafy Greens (Subgroup 4A), and Leaf Petioles (Subgroup 4B)*, page 13 in docket ID number EPA–HQ–OPP–2007–1191.

Cymoxanil was not carcinogenic in rats and mice and is classified as ''not likely to be carcinogenic to humans.'' The available studies indicate that cymoxanil is not mutagenic in bacteria or cultured mammalian cells. There is, however, evidence of clastogenic activity and induction of unscheduled DNA synthesis *in vitro*. In contrast, cymoxanil was neither clastogenic nor aneugenic *in vivo* in mouse bone marrow cells and did not induce a genotoxic response in rat somatic or germinal cells. The negative results from the *in vivo* mouse bone marrow micronucleus assay support the lack of a carcinogenic effect in long-term rat and mouse feeding studies.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for cymoxanil used for human risk assessment can be found at *http://www.regulations.gov* in document *Cymoxanil; Human Health Risk Assessment for Proposed Uses on Bulb Vegetables (Crop Group 3-07), Leafy Greens (Subgroup 4A), and Leaf Petioles (Subgroup 4B)*, page 16 in docket ID number EPA–HQ–OPP–2007–1191.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to cymoxanil, EPA considered exposure under the petitioned-for tolerances as well as all existing cymoxanil tolerances in (40 CFR 180.503). EPA assessed dietary exposures from cymoxanil in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and 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. An acute endpoint of concern was not identified for the general U.S. population. Therefore, an acute dietary exposure assessment was performed only for Females 13-49 Years Old, based upon the NOAEL of 4 mg/kg/day from the rabbit developmental toxicity study. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels

in food, EPA assumed that cymoxanil residues were present in all registered and proposed food commodities at tolerance levels, and 100 percent crop treated (PCT) for all commodities. Dietary Exposure Evaluation Model (DEEM) version 7.81 default processing factors were used for all registered and proposed commodities except grapes. Processing factors for grape juice (1.4x) and raisins (1x) were derived from grape processing data.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance level residues or anticipated residues (field trial residues) and PCT. Anticipated residues were calculated from average field trial data for cilantro leaves, chive, grape, green onion, hops, leaf petioles, and leafy greens. DEEM 7.81 default processing factors were used for all commodities except grapes. Processing factors for grape juice (1.4x) and raisins (1x) were derived from grape processing data.

iii. *Cancer*. Cymoxanil was not carcinogenic in rats and mice. EPA classified cymoxanil as ''not likely'' to be a human carcinogen; therefore a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: Cucumber, head lettuce, pepper, potato, and tomato at 10%; pumpkin, squash, and watermelon at 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which cymoxanil may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cymoxanil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cymoxanil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of cymoxanil for acute exposures are estimated to be 9.3 parts per billion (ppb) for surface water and 0.0018 ppb for ground water. EDWCs of cymoxanil for chronic exposures for non-cancer assessments are estimated to be 0.05 ppb for surface water and 0.0018 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 9.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 0.05 ppb was used to assess the contribution to drinking water.

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). Cymoxanil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a 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.''

EPA has not found cymoxanil to share a common mechanism of toxicity with any other substances, and cymoxanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cymoxanil does not have

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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is an indication of increased susceptibility of rats and rabbits to *in utero* exposure to cymoxanil. In several developmental toxicity studies in the rat and rabbit, developmental toxicity was observed at doses that were lower than those that caused maternal toxicity. In the rat developmental toxicity studies, skeletal anomalies, delays in skeletal ossification, and/or increases in overall malformations were observed at lower doses than those at which maternal toxicity was observed. However, in the developmental neurotoxicity study in rat, offspring toxicity was observed at the same dose as maternal toxicity. In one rabbit developmental study, increased skeletal anomalies were observed at 8 mg/kg/day (LOAEL), which was below the maternal NOAEL of 32 mg/kg/day. In a second rabbit developmental toxicity study, an increased incidence of visceral and skeletal anomalies was observed at 25 mg/kg bw/day; a maternal LOAEL was not observed in this study. In the 2-generation reproduction toxicity study, decreased pup body weight was observed at a lower dose than that which caused toxicity in adults.

In the developmental and postnatal studies for which there is increased susceptibility, the effects are well characterized and conservative NOAELs were established for developmental and offspring effects. In addition, the doses selected for risk assessment are based on the lowest NOAELs from the developmental and reproductive toxicity studies, where appropriate, and are protective of any potential pre- and post-natal effects. Therefore, there are low levels of concern and no residual uncertainties for pre- and post-natal toxicity.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for acute risk determination. That decision is based on the following findings:

i. The toxicity database for cymoxanil is complete for dietary risk assessment and includes a developmental neurotoxicity study.

ii. Although there is evidence of increased susceptibility in the prenatal developmental studies in rats and rabbits, there have not been any residual uncertainties identified after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of cymoxanil. The degree of concern for pre-and/or postnatal toxicity is low.

iii. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues, and DEEM default processing factors for all registered and proposed commodities. The chronic dietary food assessment was performed incorporating tolerance levels or anticipated residues (field trial residues) and PCT (potatoes, head lettuce, peppers, tomatoes, watermelon, cucumber, pumpkin, and summer and winter squash). EPA believes that the PCT estimates used are based on reliable data because PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cymoxanil in drinking water. These assessments will not underestimate the exposure and risks posed by cymoxanil.

EPA has retained the 10X FQPA safety factor for assessing risk from chronic dietary exposure to cymoxanil because the LOAEL from the chronic toxicity study in the dog was used to assess chronic dietary risk.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. An acute dietary exposure assessment was performed for females 13-49 years old only, since an acute endpoint of concern was not identified for the general U.S. population. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure to cymoxanil from food and water will occupy 89% of the aPAD for females 13-49 years old, the only population subgroup of concern.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cymoxanil from food and water will utilize 74% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. For the general U.S. population, chronic exposure to cymoxanil from food and water will utilize 48% of the cPAD. There are no residential uses for cymoxanil.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cymoxanil is not registered for any use patterns that would result in residential exposure. Therefore, the short- or intermediate-term aggregate risk is the sum of the risk from exposure to cymoxanil through food and water and will not be greater than the chronic aggregate risk.

4. *Cancer*. Because cymoxanil was not carcinogenic in rats and mice, EPA concludes that the cancer risk to humans from exposure to cymoxanil is negligible.

5. *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, or to infants and children from aggregate exposure to cymoxanil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography with ultra violet detection (HPLC/UV) and HPLC/MS (mass spectroscopy)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no CODEX maximum residue levels established for cymoxanil on any of the commodities for which the tolerances are being established.

C. Response to Comments

Comments were submitted by a private citizen who opposed the establishment of cymoxanil tolerances for the following reasons:

1. The availability of numerous products previously registered for the same purpose as the new uses of cymoxanil supported by these tolerances, and

2. Cymoxanil is toxic to aquatic plants, bees, and birds, and therefore has potentially harmful effects on the environment.

These comments are considered irrelevant because the safety standard for approving tolerances under section 408 of the FFDCA focuses on potential harm to human health and does not permit consideration of effects on the environment or the availability of other registered products. Environmental effects were closely considered in EPA's decision to register cymoxanil under the Federal Insecticide, Fungicide, and Rodenticide Act.

D. Revisions to Petitioned-For Tolerances

Because there is a wide variability in the field trial residues, EPA has concluded that a group tolerance for bulb vegetables is not supported by the available data. Therefore, EPA has determined that the proposed tolerance level for bulb vegetables of 1.1 ppm should be revised as follows: Bulb onion subgroup 3-07A at 0.05 ppm; green onion subgroup 3-07B at 1.1 ppm.

V. Conclusion

Therefore, tolerances are established for residues of cymoxanil, (2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide), in or on bulb onion subgroup 3-07A at 0.05 ppm; green onion subgroup 3-07B at 1.1 ppm; leafy vegetables subgroup 4A at 19 ppm; cilantro leaves at 19 ppm; leaf petioles subgroup 4B at 6.0 ppm; and caneberry subgroup 13-07A at 4.0 ppm. Additionally, the existing entries for ''Caneberry'' and ''Lettuce, head'' are deleted.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: September 29, 2008.

Donald R. Stubbs,

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), 346a and 371.

■ 2. Section 180.503 is amended in paragraph (a) by revising the introductory text, and in the table, by removing the entry for ''Lettuce, head'', revising the entry for ''Caneberry'' and alphabetically adding the following commodities to read as follows:

§180.503 Cymoxanil; tolerances for residues

(a) *General.* Tolerances are established for residues of the fungicide, cymoxanil, 2-cyano -N-[(ethylamino)carbonyl]-2-

(methoxyimino) acetamide, in or on the following food commodities:

Commodity	Parts per million
Caneberry, subgroup 13A-07	4.0
Cilantro, leaves	19
* * * * *	
Leafy greens, subgroup 4A	19
Leaf petioles, subgroup 4B	6.0
* * * * *	
Onion, bulb, subgroup 3-07A	0.05
Onion, green, subgroup 3-07B	1.1
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BILLING CODE 6560–50–S

OFFICE OF PERSONNEL MANAGEMENT

48 CFR Part 1633

RIN 3206–AL35

Federal Employees Health Benefits Acquisition Regulation: Board of Contract Appeals

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is adopting as final, without change, the proposed rule published April 7, 2008 to remove the designation of the Armed Services Board of Contract Appeals (ASBCA) from the Federal Employees Health Benefits Acquisition Regulation (FEHBAR).

DATES: Effective October 8, 2008.

FOR FURTHER INFORMATION CONTACT: For further information contact Marguerite Martel, Policy Analyst, at 202–606–1772 or e-mail: *marguerite.martel@opm.gov*.

SUPPLEMENTARY INFORMATION: OPM published a proposed rule to remove the designation of the ASBCA from the FEHBAR on April 7, 2008, at 73 FR 18729. No comments were received. Accordingly, OPM is adopting the proposed rule without change. The rule implements the provisions of the National Defense Authorization Act of 2006, which created the Civilian Board of Contract Appeals (CBCA) with authority extending to most civilian agencies, including OPM. The CBCA has now replaced the ASBCA as the venue for claims brought under the Act for the Federal Employees Health Benefits (FEHB) Program. OPM is updating the FEHBAR to eliminate reference to the ASBCA to reflect this change in the law.

Collection of Information Requirement

This rulemaking makes a minor clarifying amendment to the Federal Employees Health Benefits Acquisition Regulations. The rule does not impose information collection and recordkeeping requirements that meet the definition of the Paperwork Reduction Act of 1995's term ''collection of information,'' which means obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on ten or more persons, other than agencies, instrumentalities, or employees of the United States; or answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies with revenues of $11.5 million or less in any one year. This rulemaking affects FEHB Program carriers and their contractual arrangements that exceed the dollar threshold. Therefore, I certify that this regulation will not have a significant economic impact on a substantial number of small entities.

Regulatory Impact Analysis

We have examined the impact of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the RFA (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995, (Pub. L. 104–4), and Executive Order 13132. Executive Order 12866 (as amended by Executive Order 13258, which merely assigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). This rule is not considered a major rule, as defined in title 5, United States Code, section 804(2), because we estimate it will affect only FEHB carriers. Any resulting economic impact would not be expected to exceed the dollar threshold.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

List of Subjects in 48 CFR Part 1633

Government employees, Government procurement, Health insurance.

Office of Personnel Management.

Howard Weizmann,

Deputy Director.

■ Accordingly, under the authority of 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301 OPM is amending chapter 16 of title 48 of the Code of Federal Regulations by removing and reserving part 1633.

PART 1633—[RESERVED]

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OFFICE OF PERSONNEL MANAGEMENT

48 CFR Part 2133

RIN 3206–AL46

Federal Employees Group Life Insurance; Federal Acquisition Regulation: Board of Contract Appeals

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is adopting as final, without change, the proposed rule published April 7, 2008 to remove the designation of the Armed Services Board of Contract Appeals (ASBCA) from the Federal Employees Group Life Insurance Federal Acquisition Regulation (LIFAR).

DATES: Effective October 8, 2008.

FOR FURTHER INFORMATION CONTACT: For further information contact Marguerite