

List of Subjects in 40 CFR Part 180

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

Dated: July 2, 2007.

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. In § 180.564, paragraph (a) is revised and paragraph (b) is removed and reserved to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple, wet pomace	3.0
Alfalfa, forage	10
Alfalfa, hay	50
Cattle, fat	1.5
Cattle, meat	0.05
Cattle, meat byproducts	0.03
Corn, sweet, forage	10
Corn, sweet, kernel plus cob with husk removed	0.02
Corn, sweet, stover	15
Cotton, gin byproducts ...	15
Cotton, undelinted seed	2.0
Cranberry	0.90
Fruit, pome, except pear, group 11	1.0
Fruit, stone, group 12	0.90
Goat, fat	1.5
Goat, meat	0.05
Goat, meat byproducts ...	0.03
Grape	2.0
Grape, raisin	5.0
Hog, fat	1.5
Hog, meat	0.05
Hog, meat byproducts ...	0.03
Horse, fat	1.5
Horse, meat	0.05
Horse, meat byproducts	0.03
Milk	0.15

Commodity	Parts per million
Milk, fat	4.0
Okra	0.50
Pea, southern, seed	0.10
Peanut	0.01
Peanut, hay	40
Pear	0.20
Pear, oriental	0.20
Peppermint, tops	11
Sheep, fat	1.5
Sheep, meat	0.05
Sheep, meat byproducts	0.03
Soybean, aspirated grain fractions	45
Soybean, hulls	4.0
Soybean, seed	0.80
Spearmint, tops	11
Turnip, greens	12
Vegetable, <i>Brassica</i> , leafy, group 5	12
Vegetable, cucurbit, group 9	0.60
Vegetable, fruiting, group 8	0.50
Vegetable, leafy, except <i>Brassica</i> , group 4	14
Vegetable, tuberous and corm, subgroup 1-C	0.01

(b) *Section 18 emergency exemptions.*
[Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0331; FRL-8130-5]

Cymoxanil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cymoxanil in or on grape, hop, and caneberry. The Interregional Research Project (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 11, 2007. Objections and requests for hearings must be received on or before September 10, 2007, 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-2006-0331. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert

the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 Building), 2777 S. Crystal Drive, 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: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: brothers.shaja@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 an electronic copy of this **Federal Register** document through the electronic docket 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 the FFDCA, 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-2006-0331 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 September 10, 2007.

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-2006-0331, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 May 10, 2006, (71 FR 27247) (FRL-8067-5), and November 15, 2006, (71 FR 66522) (FRL-8101-8) EPA issued notices pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 5E7000 (grape and hop), and PP 6E7100 (caneberry) by the IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.503(a) be amended by establishing tolerances for residues of the fungicide cymoxanil, in or on grape (east of the Rocky Mountains) at 1.0 parts per million (ppm); hop, dried cones at 5.0 ppm; and caneberry at 4.0 ppm. These notices referenced a summary of the petitions prepared by Dupont, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received from a private citizen on the notice of filing for grape; and hop, dried cones. EPA's response to comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the 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 the 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...." These provisions were added to the FFDCA by

the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of the FFDCA, and the factors specified in 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 for the petitioned-for tolerance for residues of cymoxanil on grape at 0.10 ppm; hop, dried cone at 7.0 ppm; and caneberry at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

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-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2006-0331 in that docket. Please refer to the Human Health Risk Assessment for Cymoxanil for New section 3 Uses in/on Grapes (East of the Rocky Mountains); Hop, dried cones; and Caneberry Subgroup 13A on pages 16-19.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable uncertainty/safety factors. Short-term, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure ("MOE") called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for cymoxanil used for human risk assessment can be found at www.regulations.gov in the Human Health Risk Assessment for Cymoxanil for New section 3 Uses in/on Grapes (East of the Rocky Mountains); Hop, dried cone; and Caneberry Subgroup 13A, pages 19–20 in Docket ID EPA–HQ–OPP–2006–0331.

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(a)). 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 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. 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 for grape juice and raisin.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide CSFII. As to residue levels in food, EPA used tolerance level residues for all commodities except lettuce, hops and grapes. Average residues from field trials were used for lettuce, hops and grapes. DEEM 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. Exposure estimates were further refined using screening-level PCT (% CT) data for several registered commodities. For all other commodities, including the proposed new uses, 100 %CT was assumed.

iii. *Cancer.* EPA has classified cymoxanil as a "not likely" human carcinogen. Therefore, a cancer dietary exposure analysis was not performed.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the 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 pursuant to section 408(f)(1) require 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 section 408(b)(2)(E) of the FFDCA and authorized under section 408(f)(1) of the FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

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

- 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 such pesticide residue;
- The exposure estimate does not underestimate exposure for any significant subpopulation group; and
- Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not underestimate 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 section 408(b)(2)(F) of the FFDCA, 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%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions have been met. With respect to Condition 1, 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 2 and 3, 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 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 lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for cymoxanil in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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>.

The Agency calculated screening level surface and ground water estimates for cymoxanil using FQPA Index Reservoir Screening Tool (FIRST (version 1.0)), and SCI-GROW (Screening Concentration In GROund Water) models, respectively. The proposed application rates for use on grape and hop are higher than the rates evaluated previously. Estimated drinking water concentrations were estimated based on the newly proposed application rate for grape (0.25 lbs per acre, 10 times), which was the highest application rate reported for the new proposed uses.

Based on the FIRST and SCI-GROW models, the estimated environmental concentrations (EECs) of cymoxanil for acute and chronic exposures are 0.019 parts per billion (ppb), and 0.0001 ppb, respectively for surface water. The EECs for groundwater (acute and chronic) are estimated to be 0.000003 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 0.019 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.0001 ppb was used to access 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 use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCFA 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cymoxanil and 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 not assumed that cymoxanil 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCFA provides that EPA shall apply an additional ("10X") 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 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is an indication of increased susceptibility (qualitative and quantitative) of rats and rabbits to *in utero* exposure to cymoxanil. In the rat developmental toxicity study, decreased fetal body weights and skeletal malformations were observed at 25 mg/kg/day LOAEL, which is below the maternal toxicity of 75 mg/kg/day LOAEL. In the rabbit developmental study increased skeletal malformations were observed at 8 mg/kg/day LOAEL, also below the maternal NOAEL of 32 mg/kg/day. In the 2-generation reproduction study there was an indication of increased qualitative susceptibility in the offspring, since there was decreased pup viability at a dose that produced less severe effects in maternal animals.

3. *Conclusion.* EPA has determined that reliable data show that it would be

safe for the infants and children FQPA safety factor to be reduced to 1X for acute dietary exposures. The EPA believes that this will be protective of infants and children based on the following findings:

- i. The toxicity database for cymoxanil is complete for dietary risk assessment.
- ii. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats and rabbits, the risk assessment team did not identify any residual uncertainties 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, tolerance-level residues, and DEEM default processing factors for all registered and proposed commodities. Conservative ground and surface water modeling estimates were also used and incorporated directly in the DEEM analysis. The Agency has determined with reasonable certainty that the identified assessment will not underestimate the exposure and risks posed by cymoxanil. However, the 10X FQPA safety factor was retained for chronic dietary exposure because a LOAEL was used to extrapolate a NOAEL for the chronic toxicity study in the dog.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate 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 LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure ("MOE") called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cymoxanil will occupy 72% of the aPAD for the population group (females 13–49 years old).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded

that exposure to cymoxanil from food and water will utilize 51% of the cPAD for children 1–2 years old, the subpopulation group with greatest exposure. There are no residential uses for cymoxanil that result in chronic residential exposure to cymoxanil.

3. *Short and intermediate-term risks.* Short and Intermediate-term aggregate exposures takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cymoxanil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* EPA has classified cymoxanil as a "not likely" human carcinogen. Therefore, cymoxanil is not expected to pose a cancer risk.

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 methodologies (high performance liquid chromatography with ultra violet detection (HPLC/UV) and (HPLC/MS) using (mass spectroscopy) on grape, caneberry, and hop, respectively) are available to enforce the tolerance expression. The methods 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 for CODEX maximum residue levels established for cymoxanil on grape; hop, dried cone; and caneberry.

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 in which the new cymoxanil tolerances are intended, and
2. Cymoxanil is toxic to aquatic plants, bees, and birds, and therefore has potential 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 harms to human health and does not permit consideration of effects on the environment or the availability of other registered products.

V. Conclusion

The proposed hop, dried cone tolerance was revised from 5.0 to 7.0 ppm based on submitted field trial residues. For grape, the proposed tolerance of 1.0 was lowered to 0.10 ppm. The residue field trials indicate 0.10 ppm as the appropriate regional tolerance for grape. Therefore, tolerances are established for residues of cymoxanil, 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide in or on grape (east of the Rocky Mountains) at 0.10 ppm; hop, dried cone at 7.0 ppm; and caneberry at 4.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866, 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) 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 the 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 the 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 6, 2000) do not apply to this rule. In addition, this 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: July 3, 2007.

Daniel J. Rosenblatt,

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 by revising the table in paragraph (a); and by adding text to paragraph (c) to read as follows:

§ 180.503 Cymoxanil, tolerance for residues.

(a) * * *

Commodity	Parts per million
Caneberry	4.0
Hop, dried cones	7.0
Lettuce, head	4.0
Lychee ¹	1.0
Potato	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.2

¹ There is no U.S. registration for lychee.

* * * * *

(c) *Tolerances with a regional registration.* Tolerances with a regional registration as defined in § 180.1(n) are established for the residues of the fungicide cymoxanil, 2-cyano -N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide) in or on the raw agricultural commodities:

Commodity	Parts per million
Grape	0.10

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0483; FRL-8131-6]

Chlorpropham, Linuron, Pebulate, Asulam, and Thiophanate-methyl; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking certain tolerances for the herbicides linuron and pebulate and the fungicide thiophanate-methyl. Also, EPA is modifying certain tolerances for the herbicides chlorpropham, linuron, asulam and the fungicide thiophanate-methyl. In addition, EPA is establishing new tolerances for the herbicides chlorpropham, linuron, asulam and the fungicide thiophanate-methyl. The

regulatory actions in this document are part of the Agency's reregistration program under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective July 11, 2007. Objections and requests for hearings must be received on or before September 10, 2007, 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-2006-0483. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Jane Smith, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0048; e-mail address: smith.jane-scott@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:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 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 an electronic copy of this **Federal Register** document through the electronic docket 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 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 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. 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-2006-0483 in the subject line on the first page of your submission. All requests must be in writing, and must be