Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–4878; e-mail address: *huber.david@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA published the direct final rule and companion proposed rule for approval of the use of three additional analytical methods for compliance determinations of uranium in drinking water in the **Federal Register** on June 2, 2004 (69 FR 31008 and 31068). In the companion proposal, EPA proposed the approval of three methods that use an inductively coupled plasma mass spectrometry (ICP–MS) technology. Specifically, EPA proposed the approval of ICP–MS methods published by EPA, ASTM International, and the Standard Methods Committee (EPA 200.8, ASTM D5673–03, and SM 3125) for compliance determinations of uranium in drinking water. The proposed approval of the three ICP–MS methods did not affect approval of the 15 methods currently specified at 40 CFR 141.25(a) for compliance determinations of uranium.

In the companion proposed rule (69 FR 31068) section of the June 2, 2004, EPA invited comment on the substance of the direct final rule and stated that if adverse comments were received by July 2, 2004, the direct final rule would not become effective and a notice would be published in the **Federal Register** to withdraw the direct final rule before the August 31, 2004, effective date. The EPA subsequently received comment on the proposed rule.

List of Subjects for 40 CFR Part 141

Environmental protection, Chemicals, Incorporation by reference, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: August 5, 2004.

Benjamin H. Grumbles,

Acting Assistant Administrator, Office of Water.

[FR Doc. 04–19334 Filed 8–24–04; 8:45 am]

BILLING CODE 6560–50–P≤

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0168; FRL–7369–1]

Folpet; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerance for residues of folpet in or on hops to delete the footnote stating that there are no registrations for the use of folpet on hops in the United States. The Interregional Research Project Number 4 (IR-4), requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 25 2004. Objections and requests for hearings, identified by docket identification (ID) number OPP–2004–0168, must be received on or before October 25, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP–2004–0168. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Crystal Mall #2, Rm. 1801, South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7740; e-mail address: *giles-parker.cynthia@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of May 7, 2003 (68 FR 24467) (FRL–7305–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E6310) by IR-4, Center for Minor Crop Pest Management, Rutgers, The State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petition prepared by IR-4, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.191 be amended by establishing a tolerance for residues of the fungicide folpet, N-(trichloromethylthio)phthalimide, in or on U.S. grown hop, dried cones at 120 parts per million (ppm). EPA has

previously established a tolerance for folpet on hops in the **Federal Register** of March 5, 2003 (68 FR 10377) (FRL–7296–2). That tolerance applies to all hops in interstate commerce in the U. S. no matter what country the hops originate from. Nonetheless, because at the time that tolerance was established there was no registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, for use of folpet on hops, that fact was noted, as is EPA's general practice, in the tolerance regulation. A FIFRA registration has since been applied for and EPA plans to approve that registration simultaneous with promulgation of this final rule. This final rule amends the folpet tolerance to delete the statement regarding the lack of a FIFRA registration. Further, this action re-examines the safety determination for folpet because the prior action assumed that folpet would not be used on hops in the United States.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish or amend 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. . . .''

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 of FFDCA 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) 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of folpet on hop, dried cones at 120 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by folpet as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the March 5, 2003 **Federal Register** document (OPP–2003–0075). There have been no changes in the toxicological profile since the March 5, 2003 **Federal Register** document (OPP–2003–0075) and, therefore, the Agency will not repeat the entire table in this final rule but refers to the original document.

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 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.

Three other types of safety factors (SF) or UFs may be used: ''Traditional UFs;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X SF that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional UF or a special FQPA SF).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional UF factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA SF or the default FQPA SF is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for folpet used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FOLPET FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = 10 milligrams/kilograms/day (mg/kg/day) UF = 100 Acute RfD = 0.1 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ Special FQPA SF = 0.1 mg/kg/day	Rabbit developmental toxicity LOAEL = 20 mg/kg/day based on increase in number of fetuses and litters with hydrocephaly and related malformations.
Acute dietary (general population including infants and children)	An appropriate endpoint attributable to a single dose was not identified for the general population including infants and children for this risk assessment in the toxicological database.		
Chronic dietary (all populations)	NOAEL = 9 mg/kg/day UF = 100 Chronic RfD = 0.09 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD ÷ Special FQPA SF = 0.09 mg/kg/day	Combined chronic toxicity/carcinogenicity study in rats LOAEL = 35 mg/kg/day based on hyperkeratosis/acanthosis and ulceration/erosion of the non-glandular stomach in males and females.
Short-term dermal (1 to 30 days)	Dermal (or oral) study NOAEL = 10 mg/kg/day. (dermal absorption rate = 2.7%)	LOC for MOE = 100 (Occupational and residential)	Rabbit development toxicity LOAEL = 20 mg/kg/day based on increase in number of fetuses and litters with hydrocephaly and related malformations.
Intermediate-term dermal (1 to 6 months)	NOAEL (developmental) = 10 mg/kg/day (dermal absorption rate = 2.7%	LOC for MOE = 100 (Occupational and residential)	Rabbit developmental study LOAEL = 20 mg/kg/day based on increase in number of fetuses and litters with hydrocephaly and related malformations.
Long-term dermal (> 6 months)	Dermal (or oral) study NOAEL = 9 mg/kg/day (dermal absorption rate = 2.7% when appropriate)	LOC for MOE = 100 (Occupational and residential)	Combined chronic toxicity/carcinogenicity study in rats LOAEL = 35 mg/kg/day based on hyperkeratosis/acanthosis and ulceration/erosion of the non-glandular stomach in males and females.
Short-term inhalation** (1 to 30 days)	NOAEL (developmental) = 10 mg/kg/day	LOC for MOE = 100 (Occupational and residential)	Rabbit developmental study LOAEL = 20 mg/kg/day based on increase in number of fetuses and litters with hydrocephaly and related malformations. ** Assume inhalation absorption rate = 100% of oral absorption.
Intermediate-term inhalation** (1 week to several months)	NOAEL (developmental) = 10 mg/kg/day	LOC for MOE = 100 (Occupational and Residential)	Rabbit Developmental Study LOAEL = 20 mg/kg/day based on increase in number of fetuses and litters with hydrocephaly and related malformations. ** Assume inhalation absorption rate = 100% of oral absorption.
Long-term inhalation** (several months to lifetime)	NOAEL = 9 mg/kg/day	LOC for MOE = 100 (Occupational and residential)	Combined chronic toxicity/carcinogenicity study in rats LOAEL = 35 mg/kg/day based on hyperkeratosis/acanthosis and ulceration/erosion of the non-glandular stomach in males and females. ** Assume inhalation absorption rate = 100% of oral absorption.
Cancer (oral, dermal, inhalation)	Folpet is a B2 carcinogen (probable human carcinogen) based on the increased incidences of adenomas and carcinomas in the duodenum of male and female mice in two strains (CD-1 and B6C3F1). The Q1* is 1.86 x 10^{-3} (mg/kg/day).		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.191) for residues of folpet, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from folpet in food as follows:

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.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which

incorporates food consumption data as reported by respondents in the (United States Department of Agriculture) (USDA) 1994–1996 and 1998 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: A Tier 3 acute probabilistic dietary exposure analysis was performed. The assumptions for most commodities (apple and apple juice; cranberries; cucumbers; grapes, grape juice, wine, raisins; lettuce; melons; onions; strawberries; and tomatoes) were anticipated residue levels (incorporated into residue distribution files) and the percent crop treated (PCT) estimate for imported crops consumed in the U.S. PCT for imported commodities is estimated at a maximum of 1%, based on information derived through an analysis of import and domestic production data available from the USDA for the years 1995 through 1999, adjusted for the countries in which folpet is registered. For avocados, the assumptions of the acute dietary exposure analysis were anticipated residue levels and 11 PCT (Florida avocado acreage is 11% of the total U.S. avocado acreage as reported by USDA and assuming all the crop in Florida is treated is considered very conservative). For hops, the assumptions of the acute dietary analysis were tolerance level residues (120 ppm) and 100 PCT.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 3 chronic (non-cancer) dietary exposure analysis was performed. The assumptions for most commodities (apple and apple juice; cranberries; cucumbers; grapes, grape juice, wine, raisins; lettuce; melons; onions; strawberries; and tomatoes) were anticipated residue levels (incorporated into residue distribution files) and the PCT estimate for imported crops consumed in the U.S. (which is a maximum of 1%, based on information derived through an analysis of import and domestic production data available from the USDA for the years 1995 through 1999, adjusted for the countries in which folpet is registered). For avocados, the assumptions of the chronic dietary exposure analysis were anticipated residue levels and 11 PCT (because Florida avocado acreage is 11% of the total U.S. avocado acreage as reported by USDA). For hops, the assumptions of the chronic dietary analysis were tolerance level residues (120 ppm) and 100 PCT.

iii. *Cancer*. A Tier 3 chronic dietary exposure analysis was performed. The assumptions for most commodities (apple and apple juice; cranberries; cucumbers; grapes, grape juice, wine, raisins; lettuce; melons; onions; strawberries; and tomatoes) were anticipated residue levels (incorporated into residue distribution files) and the PCT estimate for imported crops consumed in the U.S. (which is a maximum of 1%, based on information derived through an analysis of import and domestic production data available from the USDA for the years 1995 through 1999, adjusted for the countries in which folpet is registered). For avocados, the assumptions of the chronic dietary exposure analysis were anticipated residue levels and 11 PCT (because Florida avocado acreage is 11% of the total U.S. avocado acreage as reported by USDA). For hops, the assumptions of the chronic dietary analysis were tolerance level residues (120 ppm) and 100 PCT.

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 chemicals that have been measured in food. If EPA relies on such information, EPA must 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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 the Agency can make the following findings: Condition 1, that 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows. As discussed in the Agency's March 5, 2003 final rule for folpet the only registered use of folpet in the United States is avocados grown in Florida. According to data available from the USDA's National Agricultural Statistics Service, California accounted for 89% of avocado production in the U.S. followed by Florida at nearly 11% and Hawaii at 0.1 %. Therefore, the Agency has assumed that only 11% of the U.S. avocado crop is treated with folpet (100% of the Florida grown avocados). For hops the Agency assumed 100 PCT (U.S. product and imported hops). For all other commodities (i.e., apple, cranberry, cucumber, grape, lettuce, melon, onion, strawberry, and tomato) based upon information derived through an analysis of import and domestic production data available from the USDA for the years 1995 through 1999 and adjusted for the countries in which folpet is registered.

The Agency believes that the three conditions listed Unit III.1.C.iv. 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. In using these data, the Agency took into account the specific countries where folpet is registered. In the case of avocados, the Agency based it's PCT estimate on the volume of crop grown in Florida based on data from the USDA. Therefore, the Agency has assumed that only 11% of the U.S. avocado crop is treated with folpet. For all other commodities (except hops and avocados), the Agency has assumed (see March 5, 2003 folpet final rule) a maximum PCT of 1% for each commodity (i.e., apple, cranberry, cucumber, grape, lettuce, melon, onion, strawberry, and tomato) based upon information derived through an analysis of import and domestic production data available from the USDA for the years 1995 through 1999 and adjusted for the countries in which folpet is registered.

For all potentially treated commodities the Agency used estimated maximum PCT assumptions in conducting both the acute and chronic dietary exposure assessments. The exposure estimates from this approach the Agency is reasonably certain,

represent the highest levels to which individuals could be exposed, and are unlikely 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 Subpopulation 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 folpet may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for folpet in drinking water (other than avocados in Florida all tolerances reflect imported commodities and monitoring data other than from Florida would probably not be useful). 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 physical characteristics of folpet.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (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. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 folpet they are further discussed in the aggregate risk Unit III.E.

Based on the Tier 1 FIRST and SCI-GROW models, the EECs of folpet for acute exposures are estimated to be 309 parts per billion (ppb) for surface water and 0.06 ppb for ground water. The EECs for chronic exposures are estimated to be 0.62 ppb for surface water and 0.06 ppb for ground 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).

Folpet is currently registered for use on the following residential non-dietary sites: Fungicide/preservative in wood sealants for use on exterior wood surfaces including residential/recreational decks and playsets, as well as siding, shingles, and fences. There are two wood preservative product registered that have residential use sites. The risk assessment was conducted using the following residential exposure assumptions: Residential handlers may receive short-term dermal and inhalation exposure to folpet when applying the ready-to-use formulations. Adults and children may be exposed to folpet residues from dermal contact with treated wood during post-application activities. In addition, toddlers may receive short- and intermediate-term oral exposure from incidental ingestion (i.e., hand-to-mouth) during post-application activities on treated decks or playsets.

Exposure and risk estimates of dermal and inhalation exposure for residential handlers were assessed using: An oral NOAEL of 10 mg/kg/day (LOAEL = 20 mg/kg/day based on the increase in number of fetuses and litters with hydrocephaly and related malformations). Because the endpoints are based on an oral study, the estimated dermal exposures were adjusted by applying a 2.7% dermal absorption rate, while absorption in the lung was assumed to be 100%. In addition, these endpoints are applicable to females 13+ years old; therefore, a 60–kg body weight was used in the calculations. The endpoints are the same for both dermal and inhalation exposure therefore, the individual dermal and inhalation MOEs were combined into a total MOE. The dermal endpoint used in the adult post-application exposure assessment is the same as that for residential handlers. To assess toddler incidental ingestion and dermal exposure, the maternal NOAEL (10 mg/kg/day) from the rabbit developmental toxicity study; based on a decrease in food consumption at the LOAEL of 20 mg/kg/day, was used for risk assessment purposes because it occurs at the same dose level as the developmental NOAEL (i.e., protective of developmental effects), is from the same study, and is more applicable to toddlers than hydrocephaly effects, which apply only to females of child-bearing age. In addition, using the maternal NOAEL for the toddler dermal assessment is more protective in that it allows for combination with the toddler incidental oral assessment, because they are compared to the same endpoint. The FQPA safety factor was reduced to 1X for the U.S. population and all population subgroups and for all exposure scenarios, thus, the target MOE for risk assessment purposes is 100.

To quantify cancer risk, the Q1* of 1.86×10^{-3} mg/kg/day^{-1} was multiplied by the estimated lifetime average daily doses from handler and post-application exposure. As with the non-cancer assessment, dermal doses were first adjusted for dermal absorption (i.e., 2.7%) because the Q1* is based on an oral study, while inhalation doses were assumed to be 100% absorbed. Cancer risks for residential handler and postapplication that exceed the range of 1 in 1 million are indicative of concern.

Handler exposures were previously assessed in the 1999 Reregistration Eligibility Decision (RED) for folpet. However, the assessment has been revised in this document to account for the possibility of the residential handler wearing short sleeves and short pants,

rather than the long sleeves/pants assumed for both occupational and residential handlers in the RED.

Dermal and inhalation daily doses for residential handlers were calculated for the wood sealant formulation using data for applying a paint or stain. The following handler scenarios were evaluated:

1. Application of ready-to-use wood sealant with a paint brush.

2. Application of ready-to-use wood sealant using an airless sprayer.

The calculated non-occupational handler MOEs are greater than the target of 100, and therefore, are not of concern to the Agency. The handler cancer risks range from 7.6E–08 to 1.0E–07, which also do not exceed the Agency's LOC.

TABLE 2.—EXPOSURE AND RISK FOR RESIDENTIAL HANDLERS

Scenarios for Residential Folpet Uses	Amount Used	Short-Term MOE	Intermediate-Term MOE	Total /MOE	Cancer Risk
Apply sealant with a paint brush	5 gal/day	430	9,400	410	7.6E–08
Apply sealant with an airless sprayer	15 gal/day	420	1,100	300	1.0E–07

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.''

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 folpet and any other substances and folpet 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 folpet 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

Captan and folpet share a common metabolite, thiophosgene, which the Agency believes to be responsible for the carcinogenic effects of these compounds. Thiophosgene is a highly reactive, short-lived compound. Studies indicate that thiophosgene causes local irritation of the site with which it comes in contact, and is believed to cause tumors through irritation of the duodenum. Because they are so short-lived, thiophosgene residues cannot be quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet since the formation of thiophosgene may be different for both compounds. However, assuming that the carcinogenic effects observed in both pesticides are due solely to the metabolite thiophosgene, the Agency believes it is reasonable to add the estimated cancer risks from the individual aggregate risks from both folpet and captan to obtain a worst-case estimate.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA 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 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*—a. The Agency made a determination of susceptibility, as well as performed a degree of concern analysis regarding pre- and/or postnatal toxicity resulting from exposure to folpet. The Agency recommended that the FQPA safety factor be reduced to 1X based upon the following:

i. There was no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure in two developmental toxicity studies in the rat.

ii. There was no quantitative or qualitative evidence of enhanced susceptibility to the pups in two different two-generation reproduction studies in the rat.

iii. Although there was qualitative evidence of susceptibility in one developmental study in the rabbit (hydrocephaly (developmental LOAEL = 20 mg/kg/day; developmental NOAEL = 10 mg/kg/day)), and quantitative evidence of susceptibility in the other developmental study in the rabbit (delayed ossification (developmental LOAEL = 40 mg/kg/day; developmental NOAEL = 10 mg/kg/day)), the Agency determined that there is low concern for the observed susceptibility because:

- Clear NOAELs/LOAELs were established in these studies.
- There were inconsistencies in the results seen between these studies (hydrocephaly seen in one study was not seen in the other study).
- A conservative determination was made to use hydrocephaly as the endpoint for acute dietary, and short- and intermediate-term dermal and inhalation exposure scenarios, in spite of lack of replication of this effect.
- The dose selected for overall risk assessment would address the concerns for developmental toxicity seen in this species.
- The structure-activity relationship analysis showed that there was not evidence of increased susceptibility in rabbits following *in utero* exposure to captan, a structural analog of folpet.
- There are no other signs from the available toxicology database of a concern for neurotoxic effects.

b. Therefore, the Agency concluded that there is no residual uncertainty for prenatal and/or postnatal toxicity. The Agency also determined that a developmental neurotoxicity (DNT) study for folpet is not warranted based upon the following considerations:

i. The hydrocephalus seen in one fetus/1 litter at 20 mg kg/day in the presence of maternal toxicity was not seen at higher doses (40 or 160 mg/kg/day) in another study in the same strain of rabbit.

ii. No alterations to the fetal nervous system were seen in the developmental rat study at the same doses that induced hydrocephaly in the rabbits.

iii. Although there are no acute or subchronic neurotoxicity studies, there is no evidence of neurotoxicity or neuropathology in adult animals in any of the studies.

iv. The available data indicate that the DNT study would have to be tested at dose levels higher than 150 mg/kg/day, because no developmental toxicity was observed in rats at 2,000 mg/kg/day. In addition, given the results in the 2–generation reproduction study (NOAEL of 168 mg/kg/day), it is anticipated that in order to elicit any fetal nervous system abnormalities in the DNT study, the selected dose levels would have to be higher than 160 mg/kg/day.

v. Since the dose level selections for the DNT study would be greater than 160 mg/kg/day, the resultant NOAEL would be either comparable to, or higher than, the doses currently used in the risk assessment. The NOAEL of 10 mg/kg/day selected for the acute RfD and the residential exposure assessment are 17 times lower than the offspring NOAEL in the reproduction study. The NOAEL of 9 mg/kg/day selected for the chronic RfD is 19 times lower than the offspring NOAEL in the reproduction study. Therefore, it is unlikely that the DNT study would change the current doses used for overall risk assessments.

3. *Conclusion*. There is a complete toxicity database for folpet and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency has determined that the FQPA safety factor can be reduced to 1X based on the weight of the evidence considerations.

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 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/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*. The Agency identified an aPAD for females 13 to 50 years old based on an increase in number of fetuses and litters with Hydrocephaly and related malformations in the rabbit developmental toxicity study at a LOAEL of 20 mg/kg/day (NOAEL = 10 mg/kg/day, UF = 100X, FQPA SF = 1X). An aPAD was not identified for the general population. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to folpet will occupy 6.4% of the aPAD for females 13 to 50. In addition, there is potential for acute dietary exposure to folpet in drinking water. No drinking water monitoring data are available for folpet, in fact it is only used in Florida on avocados. SCI-GROW and FIRST models were used to calculated EECs for this fungicide. Tier 1 (SCI-GROW) modeling estimates that folpet residues in ground water are not likely to exceed 0.06 ppb. Tier 1 (FIRST) surface water modeling for folpet residues predicts the peak (acute) EEC is not likely to exceed 309 ppb. After calculating DWLOCs for acute exposure to females 13–50 years old 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 Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FOLPET FOR FEMALES 13–50 YEARS OLD (AN aPAD WAS NOT IDENTIFIED FOR THE GENERAL POPULATION.)

Population Subgroup/	aPAD (mg/kg/day)	% aPAD/mg/kg//day/(Food)	Surface Water EEC/(ppb)	Ground Water EEC/(ppb)	Acute DWLOC/(ppb)
Females 13 to 50 years	0.10	0.0064	309	0.094	2800

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to folpet from food will utilize <1% of the cPAD for the U.S. population and all population subgroups. Based the use pattern, chronic residential exposure to residues of folpet is not expected. In addition, there is potential for chronic dietary exposure to folpet in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FOLPET

Population/Subgroup	cPAD/mg/kg/day	mg/kg/day/(Food)	Surface Water EEC/ (ppb)	Ground Water EEC/ (ppb)	Chronic/DWLOC (ppb)
U.S. population	0.09	0.000039	0.62	0.06	3,100
All infants	0.09	0.000045	0.62	0.06	900
Children 1–2	0.09	0.000107	0.62	0.06	900
Children 3–5	0.09	0.00009	0.62	0.06	900

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

Folpet is currently registered for uses that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for folpet.

Dermal NOAELs are based on a developmental effect (an increased number of fetuses and litters with hydrocephaly and related skull malformations), and the incidental oral NOAEL is based on a maternal effect (a decrease in food consumption). These effects were observed at the maternal or developmental LOAEL of 20 mg/kg/day (NOAEL = 10 mg/kg/day, UF = 100, FQPA SF = 1X) in the developmental toxicity study in rabbits. However, as in the post-application assessment, to assess toddler incidental ingestion and dermal exposure, the NOAEL based on the maternal decrease in food consumption was used because this effect is relevant to the population being assessed and the dose level is numerically equivalent to the dose level for the developmental NOAEL.

In the residential assessment, the highest adult exposure scenario (inhalation and dermal) was a residential handler applying a wood preservative with 0.66% active ingredient (ai) (EPA Reg. No. 577–539) to a deck or playset. The highest child exposure scenario (dermal and incidental oral) is a toddler being exposed while mulling around on the deck/playset after the wood preservative formulation has dried (24 hours after application). Exposure from these scenarios, in addition to background exposure from food and water, were used to estimate the short- and intermediate-term aggregate risk to adults and children from folpet. For adults and children, all exposure routes were combined.

An average food exposure was also used to estimate the short- and intermediate-term aggregate risk to adults and children from folpet. The highest average food exposures from the respective subpopulation groups were used, i.e. 0.000107 mg/kg/day for children (children 1–2 years), and 0.000039 mg/kg/day for adults (general U.S. population). The average food exposure for females 13 to 50 years (0.000032 mg/kg/day) was also considered, because the short- and intermediate-term dermal and inhalation developmental endpoint is particularly relevant to this subpopulation.

No drinking water monitoring data are available for folpet. SCI-GROW and FIRST models were used to calculate EECs for this fungicide. Tier 1 (SCI-GROW) modeling estimates that folpet residues in ground water are not likely to exceed 0.06 ppb micrograms (µg)/L). Additionally, Tier 1 (FIRST) surface water modeling for folpet residues predicts the annual average EEC is not likely to exceed 0.62 ppb.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 300. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of folpet in ground surface 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 LOC, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM AND INTERMEDIATE-TERM EXPOSURE TO FOLPET

Population/Subgroup	Aggregate/MOE/ (Food + Residential)	Aggregate LOC	Surface Water EEC/(ppb)	Ground Water EEC/ (ppb)	Short-Term DWLOC (ppb)
General U.S. population	300	100	0.62	0.06	2,300
Females 13 to 50 years	300	100	0.62	0.06	2,000
Children 1–2 years	160	100	0.62	0.06	3,700

4. *Aggregate cancer risk for U.S. population.* Chronic dietary and residential exposure are included in the aggregate cancer risk estimate. The residential exposure was calculated, as previously discussed, by averaging expected residential exposure over a lifetime (both handler dermal and inhalation and post-application dermal activities were included) as discussed in Unit III.C. Folpet and captan share a common metabolite, thiophosgene. Thiophosgene is highly reactive and severely irritating to mucus membranes and tissues it comes in contact with. Thiophosgene is believed to be responsible for the carcinogenic effects of these compounds. The carcinogenic effect of concern is gastrointestinal (GI) tract tumors from oral exposure to both folpet and captan. Therefore, the EPA believes it is reasonable to add the estimated cancer risks from the individual aggregate oral risks from both

folpet and captan to obtain a worst-case scenario. The Agency in fact used this approach when establishing the tolerance for hops previously (March 5, 2003 final rule). Dietary risks from both folpet and captan have not changed since the last risk assessment, and therefore the aggregate cancer assessment performed in the previous risk assessment has not changed (although the folpet EECs to which the aggregate cancer assessment is compared have changed, they do not impact the calculation, nor the conclusion).

Drinking water monitoring data are not available for folpet. SCI-GROW and FIRST models were used to calculate EECs for folpet in water. Tier 1 (SCI-GROW) modeling estimates that folpet residues in ground water, from the only U.S. registered use on avocados in Florida, are not likely to exceed 0.06 ppb (µg/L). Additionally, Tier 1 (FIRST) surface water modeling for folpet residues predicts the average annual (chronic-term) EEC is not likely to exceed 0.62 ppb (µg/L).

TABLE 6.—CANCER DWLOC CALCULATIONS (USING THE Q* APPROACH) FOR FOLPET

Population	Chronic Food/ Exposure/(mg/ kg/day)	Residential/Exposure/(mg/kg/ day)	Total. cancer exposure/(mg/ kg/day)	Ground Water EEC/(µg/L)	Surface Water EEC/(µg/L)	Cancer/DWLOC/ (µg/L)
U.S. population	0.000039	0.00017	0.00021	0.06	0.62	12

The dietary cancer risk estimate for folpet (food only) for the U.S. population is 7.2 x 10^{-8} and the cancer risk resulting from residential exposure is 3.1 x 10^{-7}. As shown in Table 6 of this unit, the DWLOC for assessing chronic (cancer) aggregate dietary risk is 12 µg/L. The SCI-GROW and FIRST chronic (cancer) EECs are less than the cancer DWLOC for folpet. Therefore, residues of folpet in drinking water will not contribute significantly to the aggregate chronic (cancer) human health risk, and thus, that the aggregate cancer risk from exposure to folpet is not of concern.

The cancer risk estimate (food only) for the U.S. population (total) is 7.2 x 10^{-8} for folpet (food exposure = 0.000039 mg/kg/day) and 1.3 x 10^{-7} for captan (food exposure = 0.000053 mg/kg/day). The EECs for assessing chronic (cancer) aggregate dietary risk for folpet are 0.06 µg/L (for ground water) and 0.62 µg/L (for surface water). The EECs for assessing chronic (cancer) aggregate dietary risk for captan are 1 µg/L (for ground water) and 4 µg/L (for surface water).

TABLE 7.—CANCER DWLOC FOR AGGREGATE EXPOSURE TO FOLPET AND CAPTAN

Population	Aggregate/Cancer Risk	Max Water/Exposure[1]/(mg/kg/day)	Ground Water EEC/ (µg/L)	Surface Water EEC/(µg/L)	Cancer/DWLOC[2]/(µg/L)
U.S. population	2.0 x 10^{-7}	0.00032	0.06 (folpet) 1 (captan)	0.62 (folpet) 4 (captan)	11

[1] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Chronic Food Exposure).
[2] Cancer DWLOC (µg/L) = maximum water exposure (mg/kg/day) x body weight (kg), a 70 kg body weight and 2L water consumption were assumed. Water consumption (L) x 10^{-3} mg/µg.

The calculated DWLOC (calculated using the Q1* for captan 2.4 x 10^{-3} as this value is higher than that for folpet and results in a worst-case estimate of risk) for assessing chronic (cancer) aggregate dietary risk is 11 µg/L. The chronic (cancer) EECs are less than the EPA's level of comparison for folpet and captan residues in drinking water as a contribution to chronic (cancer) aggregate exposure. Therefore the Agency concludes with reasonable certainty that residues of folpet and captan in drinking water will not contribute significantly to the aggregate cancer human health risk from exposure to folpet and captan; and, that the aggregate exposure from folpet and captan residues in food and drinking water will not exceed the EPA's LOC for cancer risk for the U.S. population.

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, and to infants and children from aggregate exposure to folpet residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate gas chromotography/electron capture detector (GC/ECD) is available to enforce tolerances for folpet on plant commodities. 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

No CODEX Maximum Residue Level (MRL) exist for folpet on hops. A German MRL exists for folpet on hops at 120 ppm.

V. Conclusion

Therefore, the tolerance for residues of folpet, in or on hop, dried cone at 120 ppm is amended to delete the footnote stating that there are no registrations for use of folpet on hops in the United States.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2004–0168 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 October 25, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0168, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule amends a tolerance 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 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 amended 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. 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 section 408(n)(4) of FFDCA. 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. Congressional Review Act

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: August 12, 2004.

Lois Rossi,

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 180.191 is amended by revising the entry for ''Hops, dried cones'' in the table in paragraph (a) as follows:

§ 180.191 Folpet; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Hop, dried cones	120
* * * * *	

* * * * *

[FR Doc. 04–19036 Filed 8–24–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0212; FRL–7369–9]

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flumioxazin in or on almond, garlic, grape, onion, peppermint, pistachio, shallot, spearmint, sugarcane, and tuberous/corm vegetables (Subgroup 1C). Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 25, 2004. Objections and requests for hearings must be received on or before October 25, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket Identification (ID) number OPP–2004–0212. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *Miller.Joanne@epamail.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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 and Other Related Information?

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