paragraph (a), and by removing and reserving paragraph (b) as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) * * *

Commodity	Parts per million
Date, dried fruit	1.0

(b) [Reserved]

* * * * *

[FR Doc. 03–5194 Filed 3–4–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0075; FRL–7296–2]

Folpet; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of folpet (N-(trichloromethylthio)phthalimide) in or on hop, dried cones. Makhteshim-Agan of North America Inc. 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 March 5, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0075, must be received on or before May 5, 2003.

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.**

FOR FURTHER INFORMATION CONTACT: Richard P. Keigwin, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–7618; e-mail address: *keigwin.richard@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:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in 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 Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0075. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* 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 at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_(_00.html,* a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of January 9, 2003 (68 FR 1182) (FRL–7287–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 2E6512) by Makhteshim-Agan of North America Inc., 551 Fifth Ave., Suite 1100 New York, NY 10176. That notice included a summary of the petition prepared by Makhteshim-Agan of North America Inc., 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 hop at 120 parts per million (ppm).

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....''

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 the 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 the 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 the FFDCA, for a tolerance for residues of folpet on hop, dried cones at 100 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 are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL = 160 milligrams/kilogram/day (mg/kg/day) LOAEL = 500 mg/kg/day based on 5 percent decrease in body weight
870.3150	90–Day oral toxicity in nonrodents	NOAEL = <790 mg/kg/day (lowest dose tested)(LDT) LOAEL = 790 mg/kg/day based on decreased weight gain in males and females, testicular atrophy in males
870.3200	28–Day dermal toxicity	NOAEL = 1 mg/kg/day LOAEL = 10 mg/kg/day based on dermal irritation;systemic toxicity as reduced body weight gain occurred only at doses greater than 10 mg/kg/day
870.3700	Prenatal developmental in rodents Crl: COBS-CD-(SD) BR strain.	Maternal NOAEL = 10 mg/kg/day LOAEL = 60 mg/kg/day based on reduced body weight Developmental NOAEL = 60 mg/kg/day LOAEL = 360 mg/kg/day based on possible incomplete ossification of one or both pubes and/or eschia
870.3700	Prenatal developmental in rodents CD Rats	Maternal NOAEL = 150 mg/kg/day LOAEL = 550 mg/kg/day based on decreased body weight gain, soft feces Developmental NOAEL = <150 mg/kg/day (LDT) LOAEL = 550 mg/kg/day based on small fetuses, reduced ossification of interparietal bone as well as increase in angulated ribs
870.3700	Prenatal developmental in nonrodents HY/CR Albino Rabbits	Maternal NOAEL = 40 mg/kg/day LOAEL = 160 mg/kg/day based on decrease in body weight gain and food consumption Developmental NOAEL = 10 mg/kg/day LOAEL = 40 mg/kg/day based on delayed ossification of sternebrae and lack of ossification of caudal vertebrae distal to caudal vertebra 15.
870.3700	Prenatal developmental in nonrodents NZW Rabbits	Maternal NOAEL = 10 mg/kg/day LOAEL = 20 mg/kg/day based on decreased food consumption & body weight gain during gestation. At 60 mg/kg/day, decreased food consumption & body weight gain, hydrocephalus and related skull malformations. Developmental NOAEL = 10 mg/kg/day LOAEL = 20 mg/kg/day based on Increased incidence of hydrocephalus & domed skull & irregularly shaped fontanelles
870.3800	Reproduction and fertility effects Charles River Rat	Parental/Systemic NOAEL = 19.1 mg/kg/day in males; 22.5 mg/kg/day in females LOAEL = 112 mg/kg/day in males and 134 mg/kg/day in females based on diffuse hyperkeratosis of the non-glandular epithelium of in both sexes of both generations. Reproductive NOAEL = 370 mg/kg/day in males; 436 mg/kg/day in females highest dose tested (HDT) Offspring NOAEL = 112 mg/kg/day in males and 134 mg/kg/day in females LOAEL = 370 mg/kg/day in males and 565 mg/kg/day in females based on lower pup body weights primarily in the F1 litter generation

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects Sprague-Dawley Rat	Parental/Systemic NOAEL = 35 mg/kg/day LOAEL = 160 mg/kg/day based on decreased weight gain in F1 offspring. Reproductive NOAEL = 35 mg/kg/day LOAEL = 160 mg/kg/day based on decreased fertility in males
870.4100	Chronic toxicity rodents Crl:CD(SD)BR albino rats	NOAEL = 10 mg/kg/day LOAEL = 40 mg/kg/day based on ulceration/erosion, hyperkeratosis of stomach in males and females
870.4100	Chronic toxicity rodents Fischer 344 Rat	NOAEL = 25 mg/kg/day LOAEL = 50 mg/kg/day based on hyperkeratosis of nonglandular epithelium of stomach in both sexes.
870.4100	Chronic toxicity rodents	NOAEL = 12 mg/kg/day in males; 15 mg/kg/day in females LOAEL = 81 mg/kg/day in males and 100 mg/kg/day in females based on an increase in incidence and severity of hyperkeratosis of the esophagus and nonglandular epithelium of the stomach.
870.4100	Chronic toxicity dogs	NOAEL = 10 mg/kg/day LOAEL = 60 mg/kg/day based on decreased food consumption & body weight gain; decreased serum cholesterol and serum proteins
870.4200	Carcinogenicity rats Crl:CD(SD)BR albino rats	NOAEL = Not achieved. LOAEL = 10 mg/kg/day on increased incidence of C-cell adenoma & carcinoma of thyroid in males & intrietical cell tumors of testes
870.4200	Carcino-genicity rats Fischer 344 Rat	NOAEL =50 mg/kg/day LOAEL = 100 mg/kg/day on increased benign fibroepithelial tumor of the mammary glands & C-cell adenoma of the thyroid No evidence of carcinogenicity
870.4200	Carcinogenicity mice B6C3F1 Strain	NOAEL = Not achieved. LOAEL = 150 mg/kg/day based on duodenal carcinoma and stomach papilloma both sexes; malignant lymphoma in high dose females only Evidence of carcinogenicity
870.4200	Carcinogenicity mice CD-1 Mice	NOAEL = Not achieved. LOAEL = 150 mg/kg/day based on a dose related increase in incidence of intestinal adenomas and adenocarcinomas in both sexes Evidence of carcinogenicity
870.5195	Mutagenic-Lymphoma Mutation in L5178Y/TK mouse lymphoma cells	Positive for forward mutations in L5178Y/TK mouse lymphoma cells. Higher concentration necessary in the presence of S-9 fraction
870.5275	Mutagenic-Sex Link Recessive in Drosophilia	Positive for sex linked recessive lethals
870.5300	Mutagenic-*In vivo* Cytogenetic toxicity in Mouse	No effect on the incidence of coat color spots - negative for mutations. Significant pup mortality at all doses levels. Decreased survival of pups during lactation. Increased melanocyte toxicity in pups at 4310 ppm, decreased weight gain in dams at 4310.
870.5300	Mutagenic-*In Vivo* Cytogenetic in Mouse	Decreases in the number and percentage of live born pups; maternal weight gain
870.5375	Mutagenic-Chromosome Aberration in Rats	Not a clastogen at the HDT. No measure of cytotoxicity in bone marrow. Dose used not supported by evidence that the HDT was a maximum tolerated dose.
870.5380	Cytogenetics Chromosome Aberration in Chinese hamster ovary cells	Folpet was tested up to toxicity in non-activated (2.5 µg/mL) & activated Chinese hamster ovary cells (CHO) (25.7 & 75.0 µg/mL) in 10 & 20 hour assays. Results: There was a 10-30 fold difference in toxicity sensitivity. The test article induced chromosomal aberrations at marginally cytotoxic concentrations of 0.75 µg/mL in the non-activated system, and 0.26 µg/mL in the 10 hour activ. assay, but required 25.0 µg/mL in the 20 hour activation assay.
870.5395	Mutagenic Micronucleus Assay in the Mouse (CD-1)	No evidence of mutagenicity.
870.5450	Mutagenic-Dominant Lethal Test in the Mouse	Negative for mutation

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5500	Mutagenic-Reverse Mutation	Positive direct acting mutagen. Both batches tested were equally mutagenic. Effect of metabolic activation not assessed.
870.5500	Mutagenic-DNA Repair Test	Positive for DNA damage without metabolic activation.
870.5550	Unscheduled DNA Synthesis in WI 38 Fibroblasts:	Positive in the presence of metabolic activation only.
870.5500	Reverse Mutation	Positive for reverse mutations in *Salmonella* TA100, TA1535 & TA1538, & in *E. coli* WP2. Rat liver S-9 had no effect on mutagenicity
870.5575	Mutagenic-Recomb/ Convers Assay	Positive for recombinants with/without metabolic activity.
870.6200	Acute neurotoxicity screening battery	Not available.
870.6200	Subchronic neurotoxicity screening battery	Not available.
870.6300	Developmental neurotoxicity	Not available.
870.7485	Metabolism and pharmacokinetics	Doses: 50 and 5,000 ppm. Results: The 5,000 ppm level had been shown to cause the tumors in mice but not in rats. The studies suggested that folpet was tumorigenic in the mouse and not in the rat because: Greater intake in the mouse and greater target tissue exposure to active metabolites that the mouse could not detoxify; greater local effects on mouse upper gastrointestinal tract; and greater reliance by the mouse on glutathione for detoxification of folpet.
870.7485	Metabolism and pharmacokinetics	C^{14}-Folpet was administered orally to Sprague-Dawley rats in 3 studies: 1. Single dose of 10 mg/kg; 2. Single dose of 500 mg/kg; and 3. On day 15, 10 mg/kg of C^{14}-Folpet after 14 consecutive days of unlabeled folpet at 10 mg/kg. Samples were examined for radioactivity for up to 120 hours post C^{14}-dosing. Results: 1. Single C^{14}-Folpet at 10 mg/kg was absorbed > 90% of the dose, there was rapid urinary excretion and by 120 hours, there was little detactable radioactivity. 2. Single C^{14}-Folpet at 500 mg/kg was about 60% absorbed with the urinary excretion rate being slower that after the 10 mg/kg dose (possibly due to rate-limiting absorption). 3. Single C^{14}-Folpet at 10 mg/kg following 14 daily non-labeled doses of 10 mg/kg yielded results similar to those observed after a single c^{14} dose. 4. No accumulation of folpet was detected during the 5 days after dosing; concentrations of radioactivity in measured tissues were generally below the limit of detection at 10 mg/kg or were detected at very low levels at 500 mg/kg. 5. Phthalamic acid was determined to be the single active metabolite found in urine & it was suggested that its formation from Folpet may have been by trichloromethylthio groups loss and hydrolytic cleavage of the maleimide ring. At 10 mg/kg,the major fecal metabolite was phthalamic acid and at 500 mg/kg, the radioactivity was primarily associated with unchanged C^{14}-folpet (assumed to be unabsorbed test article).
870.7600	Dermal penetration	Doses: C^{14}-Folpet was administered dermally to male doses of 10, 1, 0.1, and 0.01 mg/rat (200 uL volume of test suspension to 18.9 cm2 of clipped skin) for up to 24 hours. Blood, urine, feces, carcass and skin radioactivity was measured (up to 24 hrs). Results: 1. Rapid absorption into the skin and carcass; 2. Low blood levels; 3. Primary excretion by urine with rate apparently inversely related to quantity applied; and 4. Minor bile involvement in excretion as little in feces.

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which 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 intra species differences.

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for folpet used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FOLPET FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.1 mg/kg/day	Developmental Toxicity Study in Rabbits LOAEL = 20 mg/kg/day based on an increased number of fetuses and litters with hydrocephaly and related skull malformations
Chronic Dietary (All populations)	NOAEL = 9 mg/kg/day UF = 100 Chronic RfD = 0.09 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.09 mg/kg/day	Chronic Toxicity Study in Rat LOAEL = 35 mg/kg/day based on hyperkeratosis/acanthosis and ulceration/erosion of non-glandular stomach epithelium in both sexes
Short-Term Dermal (1 to 7 days) (Residential)	oral study NOAEL= 10 mg/kg/day (dermal absorption rate = 2.7%)	LOC for MOE = 100 (Residential)	Developmental Toxicity Study in Rabbits LOAEL = 20 mg/kg/day based on an increased number of fetuses and litters with hydrocephaly and related skull malformations
Intermediate-Term Dermal (1 week to several months) (Residential)	oral study NOAEL = 10 mg/kg/day (dermal absorption rate = 2.7%	LOC for MOE = 100 (Residential)	Developmental Toxicity Study in Rabbits LOAEL = 20 mg/kg/day based on an increased number of fetuses and litters with hydrocephaly and related skull malformations
Short-Term Inhalation (1 to 7 days) (Residential)	oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental Toxicity Study in Rabbits LOAEL = 20 mg/kg/day based on an increased number of fetuses and litters with hydrocephaly and related skull malformations
Intermediate-Term Inhalation (1 week to several months) (Residential)	oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental Toxicity Study in Rabbits LOAEL = 20 mg/kg/day based on an increased number of fetuses and litters with hydrocephaly and related skull malformations
Cancer (oral, dermal, inhalation)	Cancer potency factor (Q1*) is 1.86×10^{-3}.		Based on increased incidences of adenomas and carcinomas in the duodenum of male and female mice in two strains

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.191) for the 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 one day or single exposure. The Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID™) analysis evaluated the individual food consumption as reported by respondents in the 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: Anticipated residues for most commodities and percent crop treated for many commodities. For hop, the dietary exposure analysis assumed tolerance level residues and 100 percent crop treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM FCID) analysis evaluated the individual food consumption as reported by respondents in the 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 chronic exposure assessments: Anticipated residues for most commodities and percent crop treated for many commodities. For hop, the dietary exposure analysis assumed tolerance level residues and 100 percent crop treated.

iii. *Cancer.* In conducting this cancer dietary risk assessment the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCID™) analysis evaluated the individual food consumption as reported by respondents in the 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 chronic exposure assessments: Anticipated residues for most commodities and percent crop treated for many commodities. For hop, the dietary exposure analysis assumed tolerance level residues and 100 percent crop treated.

iv. *Anticipated residue and percent crop treated (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 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 the 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.

The Agency did use anticipated residue calculations in conducting its risk assessment. These calculations are based upon submitted field trial data and could be further refined through the use of monitoring data.

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 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 the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows. The only registered food use of folpet in the United States is avocados grown in Florida. According to data available from the United States Department of Agriculture's National Agricultural Statistics Service, California accounted for 89 percent of avocado production in the United States, followed by Florida at nearly 11 percent and Hawaii at approximately 0.1 percent. Therefore, the Agency has assumed that only 11 percent of the U.S. avocado crop is treated with folpet. As stated earlier, for the hop use, the Agency assumed 100 percent crop treated even though imports of hop accounted for less than 50 percent of the crop consumed in the United States, based upon data available from the Hop Growers of American 2001 Statistical Report. For all other commodities (except hops and avocados), the Agency assumed a maximum percent crop treated value 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 United States Department of Agriculture for the years 1995 through 1999 and adjusted for the countries in which folpet is registered.

The Agency believes that the three conditions listed in Unit III. 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 also took into account the specific countries where folpet is registered. In the case of avocados, the Agency based its PCT estimate on the volume of the avocado crop grown in the United States, utilizing data from the U.S. Department of Agriculture. For all potentially-treated commodities, EPA used estimated maximum PCT assumptions in conducting both the acute and chronic dietary exposure assessments. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. 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

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

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to folpet they are further discussed in the aggregate risk sections in Unit III.E..

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of folpet for acute exposures are estimated to be 309 parts per billion (ppb) for surface water and 0.83 ppb for ground water. The EECs for chronic exposures are estimated to be 0.62 ppb for surface water and 0.83 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 as an additive in paints and stains for use both occupationally and by the homeowner. Four major exposure scenarios for homeowner handlers using folpet containing paints and stains labeled for pesticidal use and three major scenarios for homeowners using folpet containing products not labeled for pesticidal use were evaluated. The highest exposure level for combined inhalation and dermal exposures were based upon a homeowner applying a ready-to-use stain formulation with an airless sprayer. This exposure level was used to estimate the short- and intermediate-term risks for folpet.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether folpet has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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 estimate 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 the 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The data provided no indication of increased susceptibility in two prenatal developmental toxicity studies in rats following in utero or in the two (2) 2–generation reproduction studies in rats. Two developmental toxicity studies in rabbits are also available. In a study with New Zealand rabbits, folpet caused an increase in the incidence of hydrocephalus in fetuses and with the associated dome skull and irregularly-shaped fontanelles at the mid and high dose groups in the presence of maternal toxicity. Both fetal and litter incidences of this malformation were increased in a dose-related manner. There were no toxicological effects noted on litter size, resorptions, sex ratio, or number of skeletal malformations. For maternal toxicity, the NOAEL was 10 mg/kg/day and the LOAEL was 20 mg/kg/day, based on decreased body weight gain and food consumption. For developmental toxicity, the NOAEL was

10 mg/kg/day and the LOAEL was 20 mg/kg/day, based upon an increase in the number of fetuses and litters with hydrocephaly and related skull malformations. Although the developmental malformations (hydrocephaly) and associated maternal toxicity occur at similar doses, such effects are toxic manifestations as a result of exposure.

In order to determine the critical period of treatment for the occurrence of hydorcephaly and other treatment-related fetal anomalies observed in the above study, another developmental toxicity study was conducted with the same strain of rabbit with the highest dose group (60 mg/kg/day) receiving folpet on gestation days 7-9, 10-12, 13-15, or 16-18. The incidence of hydrocephalus was higher than historical or concurrent controls, but lower than in the previous study. The maternal toxicity noted was a dose-related decreased food consumption and variable decrease in body weight gain. Significantly increased incidence of irregularly-shaped fontanelles and slightly increased incidences of angulated hyoid alae were noted in the 60 mg/kg/day dose group.

In a second rabbit developmental toxicity study, HY/CR strain rabbits received folpet on gestation days 7 through 19. For maternal toxicity, the NOAEL was 40 mg/kg/day and the LOAEL was 160 mg/kg/day, based on decreased body weights and food consumption as well as clinical signs. For developmental toxicity, the NOAEL was 10 mg/kg/day and the LOAEL was 40 mg/kg/day, based on delayed ossification of the sternebrae. There was no evidence of hydrocephaly observed in this study at dose levels greater than in the previous study.

In addition, the Agency examined the available studies for captan, the structural analog of folpet, and determined that there was no indication of increased susceptibility of rabbits or hamsters to pre- or post-natal exposure to captan. In prenatal developmental toxicity studies in rabbits and hamsters and reproduction studies in the rat, all conducted using captan as the test material, toxicity to the offspring occurred at equivalent or higher doses than maternal toxicity.

3. *Conclusion*. i. There is a complete toxicity data base 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 upon the following weight-of-the-evidence considerations:

a. There was no evidence of quantitative or qualitative susceptibility in two developmental toxicity studies in the rat;

b. There was no evidence of enhanced suspectibility to the pups in two different 2–generation reproduction studies in the rat;

c. Folpet is not a cholinesterase inhibitor and, therefore, comments made at the June 26-27, 2002 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) meeting on the Determination of the Appropriate FQPA Safety Factor(s) in the Organophosphorous Pesticide Cumulative Risk Assessment: Susceptibility and Sensitivity to the Common Mechanism, Acetylcholinesterase Inhibition should not influence this uncertainty factor decision.

d. There is inconsistency between the two available developmental toxicity studies in the rabbit. When tested at lower doses, there is a concern for hydrocephaly. However, when this study was repeated in the same strain of rabbit at higher dose levels, no evidence of hydrocephaly was observed. Nevertheless, for purposes of risk assessment, the Agency has selected the developmental NOAEL of 10 mg/kg/day from the rabbit developmental study in which hydrocephaly was observed as the endpoint for evaluating acute risk.

e. Other than the one rabbit developmental toxicity study, there are no other signs from the available toxicology database of a concern for neurotoxic effects.

f. Furthermore, the Agency's exposure assumptions are conservative. The assessment assumes that all hops consumed in the United States are treated with folpet. In addition, the analysis presumes that all avocados grown in Florida are treated with this fungicide. The percent crop treated data for the imported commodities assumed that all crop exported to the U.S. from countries in which folpet is registered are treated with this chemical. Therefore, a figure of 1% crop treated was assumed for the following commodities: Apple, cranberry, cucumber, grape, lettuce, melon, onion, strawberry, and tomato.

ii. The Agency has also determined that a developmental neurotoxicity study for folpet is not warranted based upon the following considerations:

a. Although hydrocephalus was observed in one developmental toxicity study in the rabbit, it occurred at maternally toxic doses and was only seen in one species;

b. No alterations to the fetal nervous system were seen in the developmental rat studies at the same doses that induce hydrocephaly in rabbits;

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

d. The available data indicate that the developmental neurotoxicity 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 developmental neurotoxicity study, the selected dose levels would have to be higher than 160 mg/kg/day.

e. Since the dose level selections for the developmental neurotoxicity 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 reference dose and the residential exposure and risk assessments is seventeen times lower than the offspring NOAEL in the reproduction study. The NOAEL of 9 mg/kg/day selected for the chronic reference dose is nineteen times lower than the offspring NOAEL in the reproduction study. Therefore, it is unlikely that the developmental neurotoxicity study would change the current doses used for overall risk assessments.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values

as used by the 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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to folpet will occupy <1 % of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to folpet in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FOLPET

Population Subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females, 13-49 years old	0.1	<1	309	0.83	2,800

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 less than 1% of the cPAD for all population subgroups within the United States. 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 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	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.09	<1%	0.62	0.83	3,100
All Infants	0.09	<1%	0.62	0.83	900
Children, 1-2 years	0.09	<1%	0.62	0.83	900
Females, 13-49 years	0.09	<1%	0.62	0.83	2,700
Adults, 50+ years	0.09	<1%	0.62	0.83	3,100

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

Folpet is currently registered for use 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 and intermediate-term exposures for folpet.

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 370. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term and intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of folpet in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term or intermediate-term aggregate exposures to exceed the Agency's level of concern, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENTS FOR SHORT-TERM AND INTERMEDIATE-TERM EXPOSURES TO FOLPET

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	DWLOC (ppb)
Females, 13-49 years	370	100	0.62	0.83	2,200

4. *Aggregate cancer risk for U.S. population.* The aggregate cancer risk (food plus residential) from exposure to folpet is estimated to be 7.2 x 10^{-8}. Assuming a negligible risk level of 1.0 x 10^{-6}, the cancer DWLOC would be 15 ppb. Based on the FIRST and SCI-GROW models the EECs for chronic exposures to folpet are estimated to be 0.62 ppb for surface water and 0.83 ppb for ground water, significantly lower than the DWLOC.

As discussed in Unit III.C.4., 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 estimate cancer risks from the individual aggregate risks from both folpet and captan to obtain a worst-case estimate.

For captan, the estimated cancer risk for the U.S. population from exposure to food only is 1.26 x 10^{-7}. As discussed above, the estimate cancer risk (food only) from exposure to folpet is 7.2 x 10^{-8}. If these two risk estimates are added together, the total estimated cancer risk is 2.0 x 10^{-7}. Assuming a negligible cancer risk in the range of 1.0 x 10^{-6} to 3.0 x 10^{-6}, the smallest cancer DWLOC would be 11 ppb. Based on the FIRST and SCI-GROW models the EECs for chronic exposures to folpet are estimated to be 0.62 ppb for surface water and 0.83 ppb for ground water. The EECs for chronic exposure to captan are estimated to be 4 ppb for surface water and 1 ppb for groundwater. The combined EECs for chronic exposure to captan plus folpet are 5 ppb for surface water and 2 ppb for groundwater, both below the DWLOC of 11 ppb.

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 chromatography/electron capture detector (GC/ECD) analytical method is available for enforcing tolerances of folpet in or 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 MRLs exist for folpet on hop.

V. Conclusion

Therefore, the tolerance is established for residues of folpet, (N–(trichloromethylthio)phthalimide), in or on hop, dried cones at 120 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the 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–2003–0075 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 May 5, 2003.

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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov,* or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0075, 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 Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov.* Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. 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 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under 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. 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 the 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: February 25, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.191 is amended:

i. By designating the existing text as paragraph (a) and adding a heading, and alphabetically adding a commodity to the table in newly designated paragraph (a); and

ii. By adding and reserving with headings paragraphs (b), (c), and (d) to read as follows:

§ 180.191 Folpet; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * *	* *
Hop, dried cones	120[1]
* * *	* *

1 There are no U.S. registrations on hop, dried cones as of February 14, 2003

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 03–5192 Filed 3–4–03; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

Radio Broadcasting Services; Clarendon, TX

CFR Correction

In Title 47 of the Code of Federal Regulations, Parts 70 to 79, revised as of October 1, 2002, in § 73.202(b), on page 108, the Table of FM Allotments is amended under Texas by adding Clarendon, Channel 257C2.

[FR Doc. 03–55507 Filed 3–4–03; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1080–AI17

Endangered and Threatened Wildlife and Plants; Final Rule to List the Columbia Basin Distinct Population Segment of the Pygmy Rabbit (*Brachylagus idahoensis*) as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine endangered status for the Columbia Basin distinct population segment of the pygmy rabbit (*Brachylagus idahoensis*) pursuant to the Endangered Species Act of 1973, as amended (Act). This population consists of fewer than 30 wild individuals in Douglas County, Washington, and a small captive population.

The Columbia Basin pygmy rabbit is imminently threatened by recent decreases in its population size and distribution that have caused it to be susceptible to the combined influence of catastrophic environmental events, habitat degradation and fragmentation, disease, predation, demographic limitations, and loss of genetic heterogeneity. We find that these threats constitute a significant risk to the well-being of the Columbia Basin pygmy rabbit and, as such, make the protective measures afforded by the Act immediately available with publication of this final rule.

DATES: This rule becomes effective on March 5, 2003.

ADDRESSES: The complete file for this final rule is available for inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Upper Columbia Fish and Wildlife Office, 11103 East Montgomery Drive, Spokane, Washington 99206.

FOR FURTHER INFORMATION CONTACT: Christopher Warren, at the address listed above (telephone 509/891–6839; facsimile 509/891–6748; electronic mail: *chris_warren@fws.gov*).

SUPPLEMENTARY INFORMATION:

Background

The pygmy rabbit (*Brachylagus idahoensis*) is a member of the family Leporidae, which includes hares and rabbits. The species has been placed in a number of genera since it was first classified in 1891 as *Lepus idahoensis* (Washington Department of Fish and Wildlife (WDFW) 1995a). In 1904, it was reclassified and placed in the genus *Brachylagus.* In 1930, it was again reclassified and placed in the genus *Sylvilagus.* More recent examination of dentition (Hibbard 1963) and analysis of blood proteins (Johnson 1968) suggest that the pygmy rabbit differs significantly from species within either the *Lepus* or *Sylvilagus* genera. The pygmy rabbit is now generally considered to be within the monotypic genus *Brachylagus,* and classified as *B. idahoensis* (Green and Flinders 1980a; WDFW 1995a). There are no recognized subspecies of the pygmy rabbit (Dalquest 1948; Green and Flinders 1980a).

The pygmy rabbit is the smallest Leporid in North America, with mean adult weights from 375 to about 500 grams (0.83 to 1.1 pounds), and lengths from 23.5 to 29.5 centimeters (cm) (9.3 to 11.6 inches (in)) (Orr 1940; Janson 1946; Wilde 1978; Gahr 1993; WDFW 1995a; T. Katzner, Arizona State University, pers. comm. 2002). Females tend to be slightly larger than males. Pygmy rabbits undergo an annual molt. During summer, their overall color is slate-gray tipped with brown. Their legs, chest, and nape (back of neck) are tawny cinnamon-brown, their bellies are whitish, and the entire edges of their ears are pale buff. Their ears are short (3.5 to 5.2 cm (1.4 to 2.0 in)), rounded, and thickly furred outside. Their tails are small (1.5 to 2.4 cm (0.6 to 0.9 in)), uniform in color, and nearly unnoticeable in the wild (Orr 1940; Janson 1946; WDFW 1995a). The pygmy rabbit is distinguishable from other Leporids by its small size, short ears, gray color, small hind legs, and lack of white on the tail.

Pygmy rabbits are typically found in areas of tall, dense sagebrush (*Artemisia* spp.) cover, and are highly dependent on sagebrush to provide both food and shelter throughout the year (Orr 1940; Green and Flinders 1980a; WDFW 1995a). The winter diet of pygmy rabbits is comprised of up to 99 percent sagebrush (Wilde 1978), which is unique among Leporids (White *et al.* 1982). During spring and summer in Utah, their diet consists of roughly 51 percent sagebrush, 39 percent grasses (particularly native bunch-grasses, such as *Agropyron* spp. and *Poa* spp.), and 10 percent forbs (an herb other than grass) (Green and Flinders 1980b). There is evidence that pygmy rabbits preferentially select native grasses as forage during this period in comparison to other available foods. In addition, total grass cover relative to forbs and shrubs may be reduced within the immediate areas occupied by pygmy rabbits as a result of its use as a food source during spring and summer (Green and Flinders 1980b). The specific diets of pygmy rabbit populations likely change depending on the region occupied (T. Katzner, pers. comm. 2002).

The pygmy rabbit is believed to be one of only two Leporids in North America that digs its own burrows (Nelson 1909; Green and Flinders 1980a; WDFW 1995a), the other being the volcano rabbit (*Romerolagus diazi*) found in central Mexico (Durrell and Mallinson 1970). Pygmy rabbit burrows