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.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 15, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.472 is amended by revising the entries for ''cranberries,'' ''stone fruit, crop group 12,'' and ''prunes'' and adding commodities to the table in paragraph (b) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/ Revocation Date
Almond, hulls	4.0	12/31/03
Almond, nutmeat	0.05	12/31/03
* * * * *		
Cranberries	0.5	12/31/03
* * * * *		
Prunes	10.0	12/31/03
Stone fruit	3.0	12/31/03
* * * * *		

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[FR Doc. 01–27601 Filed 11–6–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301188; FRL–6807–1]

RIN 2070–AB78

Chlorothalonil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes a time-limited tolerance for combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on ginseng. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on ginseng. This regulation re-establishes a maximum permissible level for residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS-3701) in this food commodity. The tolerance will expire and is revoked on December 31, 2003.

DATES: This regulation is effective November 7, 2001. Objections and requests for hearings, identified by docket control number OPP–301188, must be received by EPA on or before January 7, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301188 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dan Rosenblatt, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number:(703) 308–9375; and e-mail address: rosenblatt.dan@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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180._00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301188. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is re-establishing a tolerance for combined residues of the fungicide chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on ginseng at 0.10 part per million (ppm). This tolerance will expire and is revoked on December 31, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Chlorothalonil on Ginseng and FFDCA Tolerances

Ginseng is a valuable root crop that is used as a health supplement in a variety of foods such as teas, wine, herbal medicines and gum. Ginseng is grown over multiple growing seasons, so disease control is necessary to ensure that the harvested roots and seeds are not damaged by intensifying disease pressure over successive seasons. Roots are not harvested until the plants are four years old. Growers are concerned about the damage that the fungal disease *Alternaria panax* causes to ginseng gardens. The fungus can produce leaf and stem blight which defoliates and diminishes the overall vigor of effected ginseng. These blights can result in high or complete yield loss of the harvested ginseng root.

Growers have typically relied upon mancozeb treatments to protect gardens against *Alternaria panax*. However, during the 2001 growing season, Wisconsin experienced significant precipitation and also hot humid conditions. This weather cycle further heightened the probability of significant disease pressure. At the same time, the rain events negated the effectiveness of the traditional control means, mancozeb. If applied prior to rain events, mancozeb will wash off of the ginseng plants. The Applicant identified a weather-stick formulation of chlorothalonil that has the characteristic of adhering strongly to the ginseng plants. Thus, on June 15, 2001, the Wisconsin Department of Agriculture, Trade, and Consumer Protection availed itself of its authority to declare a crisis situation under section 18, thereby permitting growers to immediately use a weather-stick formulation of chlorothalonil on ginseng.

EPA acknowledges that there are not sufficient registered alternatives and concurred on the crisis declaration by the State to control leaf and stem blight in ginseng.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of chlorothalonil in or on ginseng. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on ginseng after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not

exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether chlorothalonil meets EPA's registration requirements for use on ginseng or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of chlorothalonil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Wisconsin to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for chlorothalonil, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of chlorothalonil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on ginseng at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. 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 endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for 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 factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (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 $x10^{-6}$ 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 chlorothalonil used for human risk assessment is shown in the following Table 1.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CHLOROTHALONIL 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 general population including infants and children	LOAEL = 175 mg/kg/day UF = 300 Acute RfD =0.58 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF= 0.58 mg/kg/day	Subchronic Dietary - Rats LOAEL = 175 mg/kg/day based on increased cell proliferation correlated with histopathological lesions of degeneration of the proximal convoluted tubules and epithelial hyperplasia.
Chronic dietary all populations	NOAEL = 2 mg/kg/day UF = 100 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF= 0.02 mg/kg/day	Chronic Toxicity/Carcinogenicity Study - Rats LOAEL = 4 mg/kg/day based on increased kidney weights and hyperplasia of the proximal convoluted tubules in the kidneys as well asulcers and forestomach hyperplasia.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-term dermal (1 to 7 days) (Residential)	dermal (or oral) study NOAEL= 600 mg/kg/day (dermal absorption rate = 0.15%)	LOC for MOE = 100 (Residential)	21-Day Dermal Toxicity Study - Rats LOAEL = 600 mg/kg/day based on no treatment-related systemic toxicity in the highest dose tested.
Intermediate-termdermal (1 week to several months) (Residential)	dermal (or oral) study NOAEL = 600 mg/kg/day (dermal absorption rate = 0.15%	LOC for MOE = 100 (Residential)	21-Day Dermal Toxicity Study - Rats LOAEL = 600 mg/kg/day based on no treatment-related systemic toxicity in the highest dose tested.
Cancer (oral, dermal,inhalation)	$Q^* = 7.66 \times 10^{-3}$ (mg/kg/day)$^{-1}$		Chronic toxicity/carcinogenicity study in rats. Findings based on evidence of increased incidence of renal adenomas, carcinomas and adenomas/carcinomas combined in rats and mice following chronic dosing at 15 and 175 milligram/kilograms/day (mg/kg/day), as well as increased incidence of forestomach carcinomas in CD-1 mice and papillomas and/or carcinomas combined in Fisher 344 rats. A 3/4 scaling factor was applied to the Q*.
Cancer (oral, dermal, inhalation)	NOAEL = 1.5 mg/kg/day	LOC for MOE = 9,500	Cell proliferation study in rats; LOAEL = 15 mg/kg/day based on toxic response of the kidney and forestomach.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

1. *Mechanistic data.* In a cell proliferation study, 28 male Fischer 344 rats received technical chlorothalonil (97.9%) in the diet at 175 mg/kg/day for up to 91 days. Mean labeling index was statistically increased in the kidneys of male rats treated with 175 mg/kg/day chlorothalonil at all scheduled sacrifice times. From Day 7 to Day 28, the increase in labeling index was relatively stable (approximately 10-fold over control), with a decrease to approximately 3.5-fold over control on Day 91. Increased cell proliferation correlated with histopathological lesions of degeneration of the proximal convoluted tubules and epithelial hyperplasia. The results of this study demonstrate a sustained cell proliferative response as a result of dietary administration of technical chlorothalonil at a dose of 175 mg/kg/day.

In another study, 96 male SPR rats were divided into test groups of 6 animals per group. Rats received technical chlorothalonil (98.98% a.i.) in the diet at dose levels of 0, 1.5, 15, or 175 mg/kg/day for either 7, 14, 21, or 28 days (total of 24 rats per time point). Histological examination of kidney and stomach tissue was performed for each group after the appropriate exposure. In addition, kidneys were subjected to PCNA staining and stomachs to BrdU staining, and the labeling index and labeling count of cell nuclei were performed. Duodenum was used as a negative control for PCNA and BrdU staining. Increased absolute and relative weight of the kidneys was observed at 175 mg/kg/day at all time points, and, in one animal, at 15 mg/kg/day on Day 28. Increased incidence of vacuolization of the epithelium of the proximal convoluted tubules was observed at all time points at 175 mg/kg/day on Days 7, 14, and 21 at 15 mg/kg/day. PCNA immunostaining of the proximal convoluted tubule epithelial cells showed increased labeling of cells at the 175 mg/kg/day dose level at all time points, and increased labeling at 15 mg/kg/day on Days 7, 14 and 21. BrdU labeling of the rat forestomach showed marked labeling at 175 mg/kg/day at all time points, and increased labeling on Day 28 at 15 mg/kg/day. The results of this study demonstrate a toxic response of the kidney and forestomach to repeated dietary administration of chlorothalonil at doses of 15 and 175 mg/kg/day.

2. *Summary of toxicological dose and levels of concern for SDS-3701 for use in human risk assessment.* There is no evidence of carcinogenicity for the SDS-3701 metabolite in either rats or mice. For the acute and chronic non-cancer exposure assessments, residues of SDS-3701 were combined with residues of chlorothalonil and the sum compared to chlorothalonil levels of concern (the LOAEL for acute dietary risk and the RfD for chronic non-dietary risk).

3. *Summary of toxicological dose and levels of concern for HCB for use in human risk assessment.* A summary of the toxicological endpoints for HCB used for human risk assessment is shown in the following Table 2.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR HCB 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
Chronic dietary all populations	NOAEL = 0.08 mg/kg/day UF = 100	Chronic RfD = 0.0008 mg/kg/day	130-week study in rats. Effects observed were hepatic centrilobular basophilic chromogenesis.

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

Exposure Scenario	Dose used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	Q* = 1.02 $(mg/kg/day)^{-1}$		Carcinogenicity study in rodents. Based on increased tumor incidences in hamsters and rats. A 3/4 scaling factor was applied to the Q*.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.275) for the combined residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on a variety of raw agricultural commodities. Because it is a low consumption specialty crop, ginseng is not uniquely identified in the dietary exposure system the Agency uses to estimate food consumption behaviors in the U.S. Thus, there is not likely to be a measurable difference in the exposures and risks from chlorothalonil when ginseng is added into the exposure scenario. Also, there are not likely to be implications for livestock as ginseng is not a feed item. However, in connection with another registration action involving chlorothalonil, EPA recently completed a comprehensive risk assessment for chlorothalonil. These risk assessments were conducted by EPA to assess dietary exposures from chlorothalonil and its metabolite 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. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1977–1978–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: Each analysis assumes uniform distribution of chlorothalonil in the commodity supply. Acute dietary exposure was estimated based on the theoretical maximum residue contribution (TMRC) or anticipated residues for combined residues of chlorothalonil and SDS-3701. Percent crop treated and anticipated residue refinements were used.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Risk Evaluation System (DRES) was used. The following assumptions were made for the chronic exposure assessments: Tolerance level residues and percent of crop treated information were used in the analysis for chlorothalonil and SDS-3701. Anticipated residues were used in the chronic dietary exposure analysis from food for HCB.

iii. *Cancer.* In this analysis, dietary exposure from chlorothalonil was estimated based on anticipated residues (excluding meat and milk, eggs and poultry). Meat and milk, eggs and poultry were not included in this analysis since chlorothalonil residues are not expected in these commodities. SDS-3701 was not included in this analysis since it is not carcinogenic. The dietary exposure from food from HCB was estimated based on anticipated residues (includes meat and milk, eggs, and poultry). Since HCB is a contaminant in several other pesticides, an aggregate exposure assessment for HCB was conducted with food uses of chlorothalonil, pentachlorobenzene, picloram, and dacthal. HCB is present in five other food-use pesticides but at low levels which do not significantly add to the aggregate dietary exposure. Pentachlorobenzene (PCB) is also present in PCNB, and the Agency has concluded that the carcinogenic potential of PCB is comparable to HCB. In estimating dietary carcinogenic risk from HCB in these four pesticides, the Q* for PCB is assumed to be equal to that for HCB. The assumption was made that the impurities would occur on food commodities at the same ratio to the active ingredient as was present in the formulation applied to these crops. It is also assumed that the impurity would dissipate from the food commodity at an equal or greater rate than the active ingredient. The Agency believes these are reasonable assumptions because there are data from studies with chlorothalonil, picloram, and dacthal which support this approach.

iv. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) 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), 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) 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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as shown in the following Table 3.

TABLE 3.—ESTIMATION OF PERCENTAGE OF CROPS TREATED WITH CHLOROTHALONIL

Commodity	Processing Factors	Anticipated Residues (ppm)		% Crop Treated
		Chlorothalonil	HCB	
Apricots	None	0.0078	3.9×10^{-6}	35
Banana pulp	None	0.0005	0.3×10^{-6}	10
Beans, dry	None	0.0087	4.4×10^{-6}	2
Beans, snap	0.05 for all cooked canned or frozen beans	0.0133	6.7×10^{-6}	40
Broccoli	None	0.0015	0.8×10^{-6}	15
Brussels sprouts	None	0.0135	6.8×10^{-6}	42
Cabbage	0.2 for all food forms	0.0137	6.9×10^{-6}	50
Cabbage, Chinese	0.2 for all food forms	0.0116	5.8×10^{-6}	100
Cattle fat	None	0	1.65×10^{-4}	None
Cattle meat	None	0	1.24×10^{-5}	None
Cattle liver	None	0	8×10^{-6}	None
Cattle kidney	None	0	8×10^{-6}	None
Cocoa	0.1 for all food forms	0.05	2.5×10^{-6}	100
Cantaloupe	None	0.0191	9.6×10^{-6}	30
Carrots	0.005 for all cooked or processed food forms	0.0036	1.8×10^{-6}	35
Cauliflower	None	0.0115	5.8×10^{-6}	20
Celery	None	0.0874	43.7×10^{-6}	85
Cherries	0.05 for all processed food forms	0.002	1×10^{-6}	40
Cranberries	None	0.4125	206×10^{-6}	60
Coffee	0.1 for all food forms	0.20	1×10^{-4}	100
Corn, sweet	None	0.0002	0.1×10^{-6}	5
Cucumber	0.2 for cold-canned pickles; 0.04 for hot-canned pickles	0.0062	3.1×10^{-6}	35
Garlic	None	0.0005	0.3×10^{-6}	10
Honeydew	None	0.0033	1.7×10^{-6}	20
Nectarines	None	0.00175	0.9×10^{-6}	35
Onions, bulb	None	0.0033	1.7×10^{-6}	65

TABLE 3.—ESTIMATION OF PERCENTAGE OF CROPS TREATED WITH CHLOROTHALONIL—Continued

Commodity	Processing Factors	Anticipated Residues (ppm)		% Crop Treated
		Chlorothalonil	HCB	
Onions, green and leeks	None	0.0262	13.1×10^{-6}	65
Papayas	None	0.005	2.5×10^{-6}	100
Parsnips	None	0.0052	2.6×10^{-6}	10
Passion fruit	None	3	1.5×10^{-3}	100
Peaches	0.02 for all cooked or canned food forms	0.0018	0.9×10^{-6}	35
Peanuts	0.5 for peanut oil	0.0045	2.3×10^{-6}	90
Plums	0.33 for dried prunes	0.0005	0.3×10^{-6}	10
Potatoes	None	0.0030	1.5×10^{-6}	30
Poultry fat	None	0	2.2×10^{-6}	None
Pumpkins	0.002 for raw pumpkin	0.0065	3.3×10^{-6}	30
Soybeans	0.5 for soybean oil	0.00005	2.5×10^{-8}	1
Squash	None for summer squash; 0.002 for raw winter squash; 0.001 for cooked winter squash	0.0058	2.9×10^{-6}	15
Tomatoes	0.25 for juice; 0.02 for paste, puree and catsup	0.0716	35.8×10^{-6}	70
Watermelons	None	0.0228	11.4×10^{-6}	55

The Agency believes that the three conditions listed above 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. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. 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 chlorothalonil may be applied in a particular area.

2. *Dietary exposure from drinking water*—i. *Ground water exposure - chlorothalonil and SDS-3701.* Exposure to chlorothalonil in drinking water is derived from the monitoring data. The metabolites (SDS-46851, SDS-47525, SDS-3701, and SDS-19221) were measured at a combined concentration of approximately 16 parts per billion (ppb) in Suffolk County, Long Island in 1981. Chlorothalonil itself has been detected in the Sates of California, Florida, Massachusetts, and Maine at levels typically below 1 ppb. These observations are predictable based on laboratory mobility studies and evidence of metabolite persistence. It is expected that the levels of chlorothalonil metabolites detected in the ground water in New York are relatively high compared to the country as a whole, because (a) they were the highest values reported in the data base, (b) potatoes are a major crop on Long Island, and (c) Long Island ground water is generally shallow and vulnerable. The Long Island values were used to represent a high-end potential exposure. In the absence of data demonstrating otherwise, this assessment is based on the conservative assumption that the detected metabolites of chlorothalonil have the same toxicity as the parent. As indicated above, this assessment relies on other conservative factors.

ii. *Surface water exposure chlorothalonil and SDS-3701.* Chlorothalonil can contaminate surface water at application via spray drift or after application through runoff and erosion. The intermediate soil/water partitioning of chlorothalonil indicates that its concentration is suspended and bottom sediment will be substantially greater than its concentration in water. The major degradate of chlorothalonil in the soil under aerobic conditions is SDS-3701. SDS-3701 appears to be more persistent and mobile than chlorothalonil, based on ground water detections. Substantial amounts of SDS-3701 could be available for runoff for longer periods than chlorothalonil, and SDS-3701 may be more persistent in water/sediment systems than chlorothalonil. The apparent greater mobility of SDS-3701 suggests that it exhibits lower soil/water partitioning than chlorothalonil. Therefore, the ratio of SDS-3701 runoff loss via dissolution in runoff to runoff loss via adsorption to eroding soil for SDS-3701 may be greater than for chlorothalonil. In addition, the ratios of concentrations dissolved in the water column to concentrations adsorbed to suspended and bottom sediment may be higher for SDS-3701 than for chlorothalonil. The Agency has be unable to calculate drinking water risk for SDS-3701 in surface water because no monitoring data were available.

The South Florida Water Management District (SFWMD) summarized chlorothalonil detections in samples collected every 2 to 3 months from surface water sites within the SFWMD from November 1988 through November 1993. Approximately 810 samples (30 sampling intervals x 27 sites sampled/interval) were collected during that time. Chlorothalonil was detected in 25 samples at concentrations ranging from 0.003 ppb to 0.35 ppb. Six of the samples had concentrations greater than 0.01 ppb.

iii. *Ground and surface water exposure HCB and PCB.* HCB and pentachlorobenzene are present in ground water and surface water from sources other than current usage of contaminated pesticides, including manufacturer of solvents and tires, incineration of wastes, and coal combustion. HCB and PCB are persistent and relatively immobile in the environment; the major route of dissipation is through sorption to soil, sediment, and suspended particulates in water. HCB and PCB contamination of ground water sources is relatively unlikely due to the high binding potential of both compounds. Detections of HCB in ground water generally have ranged between 0.0002 to 0.100 ppb. Based on monitoring data and fate properties, it seems unlikely that long-term HBC and PCB concentration in surface water would exceed 10 parts per trillion (ppt) (0.01 ppb).

Surface water detection shows much more variability than concentrations in ground water and have been measured at up to 750 ppb. These values appear to include sorbed HCB. The HCB concentration which actually appear to be dissolved in the water are generally less than 0.001 ppb. Great Lakes region concentrations generally ranged from 0.00002 to 0.0001 ppb. When concentrations exceeded this range, they appeared to be related to industrial areas or areas of historic contamination (more than 20 years ago). Concentrations of PCB in surface water have ranged between 0.00002 and 0.0001 ppb. Concentrations of HCB and PCB in drinking water can be greatly reduced through treatment with activated granular charcoal.

Higher concentrations of HCB and PCB have been reported in surface and ground water, but tend to be related to hazardous waste, landfill sites, and suspended sediment. The U.S. Department of Health and Human Services in 1996 estimated that the average exposure in the United States from drinking HCB contaminated water is 0.00085 µg/kg/year (-0.000082 ppb). Since potential exposures are generally so low, and because pesticides are just one source of HCB and PCB in drinking water, the Agency concluded that there are insufficient data to quantify risk and that drinking water risk estimates from HCB in pesticides do not exceed the Agency's level of concern.

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).

Chlorothalonil is currently registered for use on the following residential non-dietary sites: Home vegetable gardens, ornamentals, paint, stain, and wood preservatives. The risk assessment was conducted using the following exposure assumptions: The Agency completed an exposure assessment for uses of chlorothalonil as an additive contained 40.4% active ingredient for use in caulks, sealants, polymer lattices, grouts, joint compounds, and paper coatings. All relevant occupational and residential exposures were considered. Data were not available to estimate application and post application exposure and risk for primary and secondary homeowner exposure. Primary homeowner exposure occurs in individuals who use or install chlorothalonil-containing material; secondary residential exposure occurs when other individuals live and work in places where chlorothalonil-containing materials have been used. For these exposures, no risk assessment could be conducted, but the Agency believes that secondary and homeowner exposures to these products by themselves are generally lower than primary occupational application exposures.

Since other residential risks could not be quantified, risk concerns and uncertainties about exposure resulted in the following agreements with the registrants. To mitigate potential residential exposure concerns and uncertainties about the packaging and concentration of chlorothalonil additives for paint, the registrants have agreed that chlorothalonil mildewicidal additives must be labeled to prohibit sale over-the-counter in retail outlets. The registrants have committed to

working with the Agency to develop measures for the protection of employees of paint sales outlets who mix mildewicidal additives into paint for sale. To mitigate potential residential exposure concerns and uncertainties about the in-container preservative use of chlorothalonil, particularly because the chlorothalonil content of products in which the preservative is used may not be known to the purchaser, and because such preservatives may be used in paints intended for use by children, the registrants have agreed that the in-container preservative use of chlorothalonil is prohibited.

The contact rate for activities with ornamentals (5,800 cm^2/hr) is based on a study by Brouwer et al., in which chlorothalonil was applied to carnation sprays and carnations grown for cut flowers. Rates for dermal contact with treated turf by adults (1,000 cm^2/hr)and toddlers (8,700 cm^2/hr) are based on EPA estimates for low exposure activities. Contact rates for hand-to-mouth transfer by toddlers (1.56 events/hour), ingestion of treated grass by toddlers (25 cm^2/day, and ingestion of soil from treated areas by children (100 mg/day) are default values which originate with high-end exposure scenarios. For the cancer risk estimates, the Agency assumed that activities with ornamentals occur 4 days per year for 50 years, and that an application is made once a year, for adults in dermal contact with treated turf, that contact occurred 40 days per year for 50 years, and that three applications were made each year. The Agency also assumed that reentry occurred on the day of treatment.

For residential post-application exposures related to the use of chlorothalonil on turf and ornamentals, short- and intermediate-term MOEs ranged from 14 to 26,000. Only the MOEs for toddlers exposed to treated turf were at a risk level of concern at which the EPA typically takes regulatory action. To address this risk, the registrants have agreed to delete the home lawn use from their manufacturing-use and end-use products registered solely for this use. When considering the elimination of the home lawn use of chlorothalonil, EPA had determined that residential post-application exposures to toddlers exposed to treated turf do not exceed EPA's level of concern.

A summary of the residential post-application scenarios and cancer risks from chlorothalonil is shown in the following table 4.

TABLE 4.—SURROGATE RESIDENTIAL POST-APPLICATION SCENARIOS AND CANCER RISKS FROM CHLOROTHALONIL

Exposure Activity/Crop or Target	Application Rate (lb ai/acre)	DFR (µg/cm^2)	LADD* (mg/kg/day)	Cancer Risk (Based on Q*)
Ornamentals (Transplanting/Pruning/Bundling Flowers)	0.183	0.41	2.5E-6	2.0E-9
	8.7	20	1.3E-5	9.6E-8
	15.7	35	2.3E-5	1.8E-7
Vegetables (Harvesting)	0.183	0.41	4.6E-7	3.5E-9
	0.74	1.7	1.9E-6	1.4E-8
	8.7	20	2.2E-5	1.7E-7
Adult Dermal Contact with Turf	8.7	20	3.3E-5	2.5E-7
	11.8	26	4.4E-5	3.4E-7
	15.7	35	5.5E-5	4.2E-7

* Lifetime average daily dose.

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

EPA does not have, at this time, available data to determine whether chlorothalonil 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, chlorothalonil 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 chlorothalonil 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).

C. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* The developmental and reproductive data for chlorothalonil indicate that there is no evidence of increased sensitivity to chlorothalonil from prenatal and postnatal exposures. In the rat developmental toxicity study, the developmental NOAEL and LOAEL were based on an increase in total resoprtions per dam with a related increase in post-implantation loss. These observations occurred at a dose (400 mg/kg/day) which produced increased mortality and reduced body weight gain in maternal animals. No developmental toxicity was observed in

the rabbit developmental toxicity study, and no maternal toxicity was observed at the highest dose tested (20 mg/kg/day).

iii. *Conclusion*. There is a complete toxicity data base for chlorothalonil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because no reproductive effects were observed in any study and developmental effects occurred only in the presence of significant maternal toxicity. HCB was not considered in this evaluation of the special sensitivity of infants and children. HCB will be considered at a future date when the Agency is better equipped to understand the implications of FQPA for HCB, which is a common contaminant of at lest nine other pesticides and which also enters the environment from non-pesticidal sources.

D. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the estimated MOEs from exposure to chlorothalonil and SDS-3701 residues from food and water do not exceed the Agency's LOC. A summary of the aggregate risk assessment for acute exposure to chlorothalonil is shown in the following Table 5.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CHLOROTHALONIL AND SDS-3701

Population Subgroup	LOC for MOE	MOE
Food - U.S. Population	300	1,166
Food - Infants <1 year old	300	875
Food - Children (1-6 years)	300	875
Food - Females (13+ years)	300	1,750
Food - Males (13+ years)	300	1,750
Drinking water (ground water) - Children	300	110,000
Drinking water (ground water) - Adults	300	380,000
Drinking water (surface water) - Children	300	50,000,000
Drinking water (surface water) - Adults	300	175,000,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to chlorothalonil and SDS-3701 from food will utilize 34% of the cPAD for the U.S. population and 68% of the cPAD for children. Based on the use pattern, chronic residential exposure to residues of chlorothalonil is not expected. EPA does not have chronic non-cancer concerns for HCB in chlorothalonil. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The estimated MOEs from residential uses ranged from 310 for adults transplanting, pruning or bundling flowers to 110,000 for infants ingesting paint chips. Though residential exposure could occur with the use of chlorothalonil, the potential short- and intermediate-term exposure were not aggregated with chronic food and water exposures because the toxic effects are different. Therefore, based on the best available data and current policies, potential risks do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. HCB and pentachlorobenzene are present in ground water and surface water from sources other than current usage of contaminated pesticides, including manufacturing of solvents and tires, incineration of wastes, and coal combustion. Both are persistent and relatively immobile in the environment; the major route of dissipation is through sorption to soil, sediment, and suspended particulates in water.

HCB and PCB contamination of ground water sources is relatively unlikely due to the high binding potential of both compounds. Detections of HCB in ground water generally have ranged between 0.0002 to 0.100 µg/L. PCB levels in ground water at a hazardous waste site ranged from 0.001 to 62 µg/L.

Based on monitoring data and fate properties, it seems unlikely that long-term HCB and PCB concentrations in surface water would exceed 10 ppt (0.01 µg/L). As discussed previously, surface water detections show much more variability than concentrations in ground water but concentrations which actually appear to be dissolved in the water are generally less than 0.001 µg/L.

The upper bound carcinogenic risk from food uses of HCB for the general U.S. population was calculated using the following equation: HCB Upper Bound Cancer Risk = Dietary Exposure (ARC) x Q*, where the Q* of 1.02 mg/kg/day)-1, the upper bound cancer risk was calculated to be 2.4 x 10-7, contributed through all the published, pending and new uses for chlorothalonil.

The upper bound risk for HCB in chlorothalonil is in the range the Agency generally considers negligible for excess lifetime cancer risk. The exposure assessment for carcinogenic risk from HCB in chlorothalonil includes many a assumptions and uncertainties which impact the Agency's confidence in the calculated risk.

HCB is also a contaminant in several other pesticides, and an aggregate risk assessment for HCB from chlorothalonil and these other sources has been conducted. The exposure assessment for aggregate risk is subject to the same kinds of uncertainties and assumptions as the risk assessment for HCB in chlorothalonil. For some of the individual pesticide contributors, these

limitations impact the assessment to an even greater extent.

Four pesticides that are used on food/feed crops have been assessed for cancer risk due to contamination with HCB -- chlorothalonil, dacthal, picloram, and pentachlornitrobenzene (PCNB). Pentachlorobenzene (PCB) is also present in PCNB, and the Agency has concluded that the carcinogenic potential of PCB is comparable to HCB, based on the similarities of the chemical structures and toxicities of HCB and PCB. In estimated dietary risk from HCB in these four pesticides, the Q* for PCB is assumed to be equal to that for HCB.

HCB is also present in pentachlorophenol, but pentachlorophenol is not a food use pesticide and so that contaminant in pentachlorophenol does not contribute to aggregate dietary risk (the contribution to drinking water risk is discussed below). HCB and/or PCB is present in five other food-use pesticides, but at low levels which do not significantly add to the aggregate dietary exposure.

The estimated aggregate dietary cancer risk from HCB from all known pesticide sources is 1.34 x 10^{-6}. An additional 0.46 x 10^{-6} may be attributed to PCB for a total of 1.8 x 10^{-6}.

A summary of the cancer risks for chlorothalonil, HCB, and PCB are shown in the following Table 6.

Chemical	Q*	Upperbound Cancer Risk (Food)	Cancer MOE for food	Upper Bound Cancer Risk (Water)	Cancer MOE for Water
Chlorothalonil	0.00766	1.2 x 10^{-6}	9,500	8 x 10^{-9}	<1.5 million
HCB from Chlorothalonil	2.4 x 10^{-7}	Not applicable	5 x 10^{-9}	Not applicable	
HCB and PCB - all pesticide sources		1.8 x 10^{-6}	Not applicable	Does not exceed Agency's level of concern	Not applicable

EPA has estimated cancer risk using both the Q* and MOE approaches. Under the MOE approach, cancer risk is estimated at MOE = 9,500. At this time, EPA is not able to conclusively determine that chlorothalonil is a non-linear carcinogen nor to apply approved policy determinations on non-linear carcinogens to chlorothalonil, and so cannot determine whether the MOE of 9,500 represents an excess lifetime risk. Under the Q* approach, cancer risk is estimated at 1.2 x 10^{-6}. This figure is at a level which the EPA considers negligible for excess lifetime cancer risk estimates.

Cancer risk for HCB is estimated at 2.4 x 10^{-7}, and EPA does not have cancer risk concerns for chlorothalonil alone. Although subject to considerable uncertainty, cancer risk from HCB from chlorothalonil and other pesticides, combined with cancer risk from the related contaminate PCB present in other pesticides, is estimated at 1.8 x 10^{-6}. a level at which the EPA typically takes regulatory action. To address this risk, the registrants of chlorothalonil have agreed that the level of HCB in all chlorothalonil products must be reduced to no greater than 0.004% (40 ppm). This is the lowest level that has been shown to be technologically feasible for chlorothalonil. All registrations are conditional on achieving this level, and failure to achieve this level will result in a suspension of manufacture or import of the subject products. In addition, registrants of chlorothalonil products will maintain approximately historic levels of production and import of chlorothalonil manufacturing use product to assure that chlorothalonil with higher levels of HCB will not be stockpiled and formulated. When this decrease in the amount of HCB is considered, EPA has determined that the cancer risk estimates do not exceed the level for regulatory action.

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 combined residues of chlorothalonil and SDS-3701 or from residues of the contaminant HCB.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology using gas chromotography is available to enforce the established tolerance expressions. The Pesticide Analytical Manual (PAM) vol. II lists Method I, a gas chromatography method with electron capture detection (ECD), for enforcement of tolerances for plant commodities. An acceptable enforcement method for residues of SDS-3701, a modification of the method for chlorothalonil, is also available.

B. International Residue Limits

There are no Canadian, Mexican, or Codex tolerances for chlorothalonil on ginseng.

VI. Conclusion

Therefore, the tolerance is re-established for combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on ginseng at 0.10 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301188 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 January 7, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in

the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301188, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. 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 FIFRA section 18 exemption under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled

Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 20, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.275 is amended by revising the entry for the commodity in the table in paragraph (b) to read as follows:

§ 180.275 Chlorothalonil; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
Ginseng	0.10	12/31/03

* * * * *

[FR Doc. 01–27602 Filed 11–6–01; 8:45 am]
BILLING CODE 6560–50–S

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1201

[STB Ex Parte No. 634]

Consolidated Reporting By Commonly Controlled Railroads

AGENCY: Surface Transportation Board, DOT.

ACTION: Final rule.

SUMMARY: The Board has concluded that consolidated financial reports should be filed for each group of railroads or railroad-related affiliates that operate as a single, integrated United States rail system whose cumulative annual operating revenues meet the Class I threshold of $250 million (in 1991 dollars).

EFFECTIVE DATE: January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Paul A. Aguiar, (202) 565–1527. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: On September 25, 2000, the Board proposed that commonly controlled railroads (and their railroad-related affiliates) whose combined annual operating revenues meet the $250 million threshold be required to file consolidated financial reports. *See* 65 FR 57650 (2000). The Board's objective was to gather more meaningful and accurate information on the large rail systems operating in the United States by conforming its regulatory reporting requirements as closely as practical to Financial Accounting Standards Board Statement No. 94, *Consolidation of All Majority-Owned Subsidiaries*. After evaluating the comments filed by interested parties, the Board has concluded that consolidated reports should be required for commonly controlled railroads that operate as a single, integrated United States rail system and whose cumulative operating revenues meet the Class I threshold. Accordingly, the Board will amend its regulations at 49 CFR part 1201 to reflect this change. A printed copy of the full Board decision served November 7, 2001 in this proceeding is available for a fee by contacting Da 2 Da Legal, Room 405, 1925 K Street, NW., Washington, DC 20006, telephone (202) 293–7776. The decision also is available for viewing and downloading via the Board's website at *www.stb.dot.gov*.

List of Subjects in 49 CFR Part 1201

Freight, Railroads, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, Title 49, part 1201 of the Code of Federal Regulations will be amended as follows:

PART 1201—[AMENDED]

1. The authority citation for Title 49, Part 1201 continues to read as follows:

Authority: 5 U.S.C. 553 and 49 U.S.C. 11142 and 11164.

2. Section 1–1 is amended by revising paragraph (b)(1) to read as follows:
1–1 Classification of Carriers. * * *

(b)(1) The class to which any carrier belongs shall be determined by annual carrier operating revenues after the railroad revenue deflator adjustment. Families of railroads operating within the United States as a single, integrated rail system will be treated as a single carrier for classification purposes. Upward and downward reclassification will be effected as of January 1 in the year immediately following the third consecutive year of revenue qualification.

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Decided: October 31, 2001.