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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301088; FRL–6759–4]

RIN 2070–AB78

Chlorothalonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS–3701) in or on almonds (nutmeats), almond hulls, asparagus, mangoes, non-bell peppers, and pistachios. In addition, tolerances for the metabolite SDS–3701 are established for milk and meat commodities. ISK Biosciences Corporation and the Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 12, 2001. Objections and requests for hearings, identified by docket control number OPP–301088, must be received by EPA on or before May 11, 2001.

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 VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301088 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703–305–7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	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 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/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301088. 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, Crystal 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

In the **Federal Register** of February 13, 1997 (PP 5F4558) (62 FR 6780) (FRL–5587–3), April 2, 1997 (PP 6F4676) (62 FR 15700) (FRL–5594–9), July 11, 1997 (PP 6F4611) (62 FR 37246) (FRL–5723–1), and September 17, 1997 (PP 2E4042, 2E4018 and 6E4672) (62 FR 48849) (FRL–5735–8), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP) for tolerances by ISK Biosciences Corporation, 15966 Heisley Road, P.O. Box 8000, Mentor, OH 44061–8000 and Interregional Research Project Number 4 (IR–4), New Jersey Agricultural Experimental Station, P.O. box 231, Rutgers University, New Brunswick, NJ 08903. These notices included a summary of the petition prepared by ISK Biosciences Corporation and IR–4, the registrants. The active ingredient has since been transferred to GB Biosciences Corporation, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–5458. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.275 be amended by establishing tolerances for combined residues of the fungicide chlorothalonil, tetrachloroisophthalonitrile and its metabolite, 4-hydroxy-2,5,6-trichloroisopthalonitrile (SDS–3701), in or on almonds (nutmeats) at 0.05 part per million (ppm), almond hulls at 1.0 ppm, asparagus at 0.1 ppm, mangoes at 1.0 ppm, non-bell peppers at 5 ppm, and pistachios at 0.2 ppm, and for residues of the metabolite SDS–3701 in or on the following milk and meat commodities: fat of cattle, hogs, goats, horses, and sheep at 0.1 ppm; kidney of cattle, hogs, goats, horses and sheep at 0.5 ppm; meat byproducts (mbyp) (except kidney) of cattle, goats, hogs, horses and sheep at 0.05 ppm and meat of cattle, goats, hogs, horses, and sheep at 0.03 ppm and milk at 0.1 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) 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....''

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).

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of chlorothalonil and its metabolite SDS–3701 in or on almonds (nutmeats) at 0.05 ppm, almond hulls at 1.0 ppm, asparagus at 0.1 ppm, mangoes at 1.0 ppm, non-bell peppers at 5 ppm, and pistachios at 0.2 ppm, and for residues of the metabolite SDS–3701 in or on the following milk and meat commodities: fat of cattle, hogs, goats, horses, and sheep at 0.1 ppm; kidney of cattle, hogs, goats, horses and sheep at 0.5 ppm; meat byproducts (mbyp) (except kidney) of cattle, goats, hogs, horses and sheep at 0.05 ppm and meat of cattle, goats, hogs, horses, and sheep at 0.03 ppm and milk at 0.1 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 chlorothalonil, SDS–3701, the major metabolite of chlorothalonil, and hexachlorobenzene (HCB), an impurity in chlorothalonil and other pesticide products, are discussed in the following Table 1 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; CHLOROTHALONIL AND SDS–3701

Study Type	Results
21–Day dermal toxicity in rats-chlorothalonil	Dermal NOAEL = <60 mg/kg/day based on dermal irritation and lesions; Systemic LOAEL = 600 mg/kg/day.
Prenatal developmental in rodents -chlorothalonil	Maternal NOAEL = 100 mg/kg/day; LOAEL = 400 mg/kg/day based on increased mortality and reduced body weight gain. Developmental LOAEL = 400 mg/kg/day based on an increase total resorptions and resorptions per dam with a related increase in post-implantation loss. No decrease in litter size was reported.
Prenatal developmental in nonrodents - SDS–3701	Maternal NOAEL = 1 mg/kg/day; LOAEL = 2.5 mg/kg/day based on increase in maternal death and abortion. Developmental NOAEL = 5 mg/kg/day, the highest dose tested. No developmental toxicity observed.
Reproduction and fertility effects - chlorothalonil	Parental/Systemic NOAEL = <38 mg/kg/day; LOAEL = 38 mg/kg/day based on hyperplasia of renal and forestomach tissues. Offspring toxicity NOAEL = 115 mg/kg/day; LOAEL = 234 mg/kg/day based on lower neonatal body weights by day 21.
Carcinogenicity rats - chlorothalonil	NOAEL = 2 mg/kg/day; LOAEL = 4 mg/kg/day based on increased kidney weights as well as ulcers and forestomach hyperplasia. Renal tubular adenomas and carcinomas were seen in male Fisher 344 rats at 15 and 175 mg/kg/day and in females at 175 mg/kg/day. The incidence of forestomach papillomas and carcinomas was increased at 175 mg/kg/day in males and at both 15 and 175 mg/kg/day in females.
Carcinogenicity rats - chlorothalonil	NOAEL = <40 mg/kg/day; Chronic hyperplasia of cortical tubules and pelvic/papillary epithelium, tubular cysts were found at all dose levels. Renal adenomas and carcinomas as well as stomach papillomas were also present at all dose levels. Female rat renal (adenomas and/or carcinomas) tumor rates were 0/60 in the control, 2/60 at 40 mg/kg/day, 7/61 at 80 mg/kg/day, and 19/59 at 175 mg/kg/day.
Carcinogenicity mice - chlorothalonil	NOAEL = <112.5 mg/kg/day; Bone marrow and spleen red pulp hyperplasia, increased kidney weights with surface irregularities, pelvic dilation, cysts and nodules, and stomach /esophageal hyperplasia were found at all dose levels (equivalent to 112.5, 225, or 450 mg/kg/day) in CD–1 mice.
Carcinogenicity rats - SDS–3701	NOAEL = 3.0 mg/kg/day; LOAEL = 10 mg/kg/day based on reduced body weight. There was no evidence of carcinogenicity in either sex of Sprague-Dawley rats.
Carcinogenicity mice - SDS–3701	LOAEL = <54 mg/kg/day based on increased liver-to-body weight ratios in males. There was no evidence of carcinogenicity in either sex of CD–1 mice.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY; CHLOROTHALONIL AND SDS–3701—Continued

Study Type	Results
Gene Mutation	In light of considerable body of evidence from acceptable whole animal testing, it is concluded that chlorothalonil is also not calstogenic or aneugenic in rats, mice or Chinese hamsters.
Cytogenetics	A weak positive response was seen under non-activated conditions in an *in vivo* cytogenetic CHO assay and in the subchronic phase of an *in vivo* bone marrow Chinese hamster cytogenetic assay.
Metabolism and pharmacokinetics	Oral absorption was low (approximately 33% of the administered dose). Peak blood levels were considered low (less than 1% of the dose present in blood). Elimination was primarily by the gastrointestinal tract, with 80 – 90% in feces and approximately 15 – 20% was observed in bile.
Dermal penetration	An upper limit of 0.15% of chlorothalonil that contacts the skin during a workday is estimated to be absorbed. The dermal absorption rate is calculated using the lowest LOAEL from the subchronic oral dosing studies in rats, the oral absorption rate obtained from the rat metabolism study and the LOAEL from the 21–day dermal toxcity study.
Cell proliferation study in male Fisher 344 rats - chlorothalonil	LOAEL = 175 mg/kg/day based on increased cell proliferation correlated with histopathological lesions of degeneration of the proximal convoluted tubules and epithelial hyperplasia.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the 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 ariations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. In the case of acute dietary risk, effects were seen at the only dose tested in the subchronic dietary toxicity study in rats; therefore, no NOAEL was identified. Since the LOAEL was used for acute dietary risk assessment, an additional UF of 3X was added to the conventional UF of 100X for a total UF of 300X.

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 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 chlorothalonil used for human risk assessment is shown in the following Table 2:

TABLE 2.—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 = 1 aPAD = acute RfD/FQPA SF = 0.58 mg/kg/day	Subchronic dietary toxicity study in 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.

TABLE 2.—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
Chronic Dietary general population including infants and children	NOAEL= 2 mg/kg/day; UF = 100; Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.02 mg/kg/day	Chronic toxicity/ carcinogenicity study in rats LOAEL = 4 mg/kg/day based on increased kidney weights and hyperplasia of the proximal convoluted tubules in the kidneys as well as ulcers and forestomach hyperplasia.
Short–Term Dermal (1 to 7 days) (Residential)	dermal NOAEL = 600 mg/kg/day (dermal absorption rate = 0.15%)	LOC for MOE = 100 (Residential)	21–day dermal toxicity study in rats; LOAEL = 600 mg/kg/day based on No treatment-related systemic toxicity in the highest dose tested.
Intermediate-Term Dermal (1 week to several months) (Residential)	dermal NOAEL = 600 mg/kg/day (dermal absorption rate = 0.15%	LOC for MOE = 100 (Residential)	21–day dermal toxicity study in rats; LOAEL = 600 mg/kg/day based on no treatment-related systemic toxicity in the highest dose tested.
Short-, Intermediate, Long-Term Inhalation (Residential)	Oral NOAEL = 2 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Chronic toxicity/ carcinogenicity study in rats; LOAEL = 4 mg/kg/day based on increased kidney weights and hyperplasia of the proximal convoluted tubules in the kidneys as well as ulcers and forestomach hyperplasia.
Cancer (oral, dermal, inhalation)	$Q^* = 7.66 \times 10^{-3}$ (mg/kg/day)$^{-1}$		Chronic toxicity/ carcinogenicity study in rats 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 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 SPF 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 3:

TABLE 3.—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 Endpoint 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 feeding study in rats. Effects observed were hepatic centrilobular basophilic chromogenesis.
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^*.

C. 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 SDS–3701, in or on a variety of raw agricultural commodities. At levels ranging from 0.05 ppm in cocoa beans and bananas, edible pulp to 15 ppm in celery and papayas. Risk assessments were conducted by EPA to assess dietary exposures from chlorothalonil and its metabolite SDS–3701 in food as follows:

Food uses evaluated in the dietary (food) risk assessments were the published uses of chlorothalonil in 40 CFR 180.275 and pending uses. U.S. Food and Drug Administration monitoring data (1988–1993), USDA Pesticide Data Program (PDP) (1992–1994 partial), and field trial data are types of anticipated residue data provided for chlorothalonil and HCB. Anticipated residues were used for pending tolerances for pistachios (0.068 ppm), mangoes (0.3 ppm), asparagus (0.03 ppm) and non-bell peppers (5 ppm). Percent of crop treated information was used for most crops with established tolerances. Residues of HCB in plant commodities were estimated to be present at 0.05% of the residues of chlorothalonil. This level is equivalent to the maximum level of HCB that is allowed in formulations of chlorothalonil. In meat products, anticipated residues were estimated based on HCB feeding studies.

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 following assumptions were made for the acute exposure assessments: The computerized modeling system (Dietary Risk Evaluation System (DRES) was used to estimate acute dietary exposure. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977–1978 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to chlorothalonil for each commodity. 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.

ii. *Chronic exposure.*In conducting this chronic dietary risk assessment the computerized modeling system (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 described in the following Table 4:

TABLE 4.—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	6.9×1010^{-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
Cucumbers	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
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

TABLE 4.—ESTIMATION OF PERCENTAGE OF CROPS TREATED WITH CHLOROTHALONIL—Continued

Commodity	Processing factors	Anticipated Residues (ppm)		% crop treated
		Chlorothalonil	HCB	
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
Watermelon	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 of chlorothalonil have been found in ground water in Long Island, New York, and have been attributed to potato use. These 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 States 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 database, (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—chlorothlonil 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 was 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 27

surface water sites within the SFWMD from November 1988 through November 1993. Approximately 810 samples (30 sampling intervals × 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 ≥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 HCB and PCB concentrations in surface water would exceed 10 parts per trillion (ppt) (0.01 ppb).

Surface water detections show much more variability than concentrations in ground water and have been measured at up to 750 ppb. These high values appear to include sorbed HCB. The HCB concentrations 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 residential exposure assumptions: The Agency completed an exposure assessment for uses of chlorothalonil as an additive containing 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 occur 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 product labels and have requested voluntary cancellation of their 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 5:

TABLE 5.—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	2.6E-7	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).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *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 database 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.

ii. *Prenatal and postnatal sensitivity.* The developmental and reproductive data for chlorothalonil indicate that there is no evidence of increased sensitivity to chlorothalonil from pre- or post-natal exposures. In the rat developmental toxicity study, the developmental NOAEL and LOAEL were based on an increase in total resorptions 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 database 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 least nine other pesticides and which also enters the environment from non-pesticidal sources.

E. 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 aggregrate risk assessment for acute exposure to chlorothalonil is shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CHLOROTHALONIL AND SDS–3701

Population Subgroup	LOC for MOE	MOE
Food - U.S. Population	300	1166
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	1750
Drinking water (ground water) - Children	300	110,000
Drinking water (ground water) - Adults Drinking water (surface water) - Children	300 300	380,000 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 combined residues of chlorothalonil and SDS–3701 from food and water 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 62.1 µg/L.

Based on monitoring data and fate properties, its 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 follow equation:

HCB Upper Bound Cancer Risk = Dietary Exposure (ARC) $\times$ Q^*

Based on Q^* of 1.02 $(mg/kg/day)^{-1}$, the upper bound cancer risk was calculated to be 2.4×10^{-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 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 estimating 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 the 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 pesticidal sources is 1.34×10^{-6}. An additional 0.46×10^{-6} may be attributed to PCB for a total of 1.8×10^{-6}.

A summary of the cancer risks for chlorothalonil, HCB, and PCB are shown in the following Table 7:

TABLE 7.—CANCER RISKS FOR CHLOROTHALONIL, HCB, AND PCB

Chemical	Q*	Upperbound cancer risk (food)	Cancer MOE for Food	Upperbound Cancer Risk (Water)	Cancer MOE for Water
Chlorothalonil	0.00766	$1.2 - 10^{-6}$	9,500	8×10^{-9}	<1.5 million
HCB from Chlorothalonil		2.4×10^{-7}	Not applicable	5×10^{-9}	Not applicable
HCB and PCB - all pesticide sources		1.8×10^{-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 point in 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 1.2×10^{-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 2.4×10^{-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 1.8×10^{-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 manufacuring-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.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available in PAM II for non-bell peppers and almonds. Residue analytical methods are available for purposes of reregistration. The Pesticide Analytical Manual (PAM) Vol. II lists Method I, a gas chromatography method with electron capture detection (ECD), for the enforcement of tolerances for plant commodities. Residue data for plant commodities were collected using methods based on the enforcement method. An acceptable enforcement method for residues of SDS–3701 tolerances for peanuts, potatoes, and tomatoes which is a modification of the current enforcement method is available. This method underwent successful validation and is suitable for enforcement of tolerances for SDS–3710 in meat and milk.

B. International Residue Limits

There are no Codex, Mexican or Canadian MRLs for almonds, almond hulls, asparagus, mango, and pistachio.

C. Conditions

All data pertaining to rotational crops have been evaluated and deemed adequate. In response to Agency evaluations of confined rotational crop data, there is a 12-month rotational crop restriction on all pertinent product labels. Available data indicate that only residue that was detected in rotated crops was the soil metabolite (SDS–46851). Because of the low toxicity of this metabolite, an exemption for the requirement of a tolerance for residues of the soil metabolite 2-carbamyl-2,4,5-trichlorobenzoic acid (SDS–46851) as inadvertent residues in rotated crops has been established (40 CFR 180.110).

V. Conclusion

Therefore, tolerances are established for combined residues of chlorothalonil, chlorothalonil and its metabolite SDS–3701, in or on almonds (nutmeats) at 0.05 ppm, almond hulls at 1.0 ppm, asparagus at 0.1 ppm, mangoes at 1.0 ppm, non-bell peppers at 5 ppm, and pistachios at 0.2 ppm, and for residues of the metabolite, 4-hydroxy-2,5,6 trichloroisopthalonitrile (SDS–3701), in or on the following milk and meat commodities: fat of cattle, hogs, goats, horses, and sheep at 0.1 ppm,; kidney of cattle, hogs, goats, horses and sheep at 0.5 ppm; mbyp (except kidney) of cattle, goats, hogs, horses and sheep at 0.05 ppm, meat of cattle, goats, hogs, horses, and sheep at 0.03 ppm and milk at 0.1 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 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–301088 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 11, 2001.

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 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.2. Mail your copies, identified by docket control number OPP–301088, 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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). 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 FFDCA section 408(d), 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.

VIII. 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: January 24, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.275 is amended by revising paragraph (a) introductory text and redesignating it as paragraph (a)(1); by adding in alphabetical order entries for ''almonds (nutmeat)''; ''almond hulls''; ''mango''; ''peppers, non-bell''; and ''pistachio'' to the table in newly designated paragraph (a)(1), and by adding new paragraph (a) (2) to read as follows:

§ 180.275 Chlorothalonil; tolerances for residues.

(a) *General*. (1) Tolerances are established for the fungicide chlorothalonil (tetrachloroisophthalonitrile) and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on the following food commodities.

Commodity	Parts per million
Almonds (nutmeats)	0.05
Almond hulls	1.0
Asparagus	0.1
* * * * *	
Mango	1.0
* * * * *	
Peppers, (non-bell[1])	5
* * * * *	
Pistachio	0.2
* * * * *	

[1]There are no U.S. registrations as of January, 2001.

(2) Tolerances are established for the metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile in or on the following food commodities.

Commodity	Parts per million
Cattle, fat	0.1
Cattle, kidney	0.5
Cattle, mbyp (except kidney)	0.05
Cattle, meat	0.03
Goat, fat	0.1
Goat, kidney	0.5
Goat, mbyp, (except kidney)	0.05
Goat, meat	0.03
Hog, fat	0.1
Hog, kidney	0.5
Hog, mbyp (except kidney)	0.05
Hog, meat	0.03
Horses, fat	0.1
Horses, kidney	0.5
Horses, mbyp (except kidney)	0.05
Horses, meat	0.03
Milk	0.1
Sheep, fat	0.1
Sheep, kidney	0.5
Sheep, mbyp (except kidney)	0.05
Sheep, meat	0.03

* * * * *

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413 and 422

[HCFA–1685–F2]

RIN 0938–AE79

Medicare Program; Payment for Nursing and Allied Health Education: Delay of Effective Date

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' published in the January 24, 2001 **Federal Register**, this action temporarily delays for 60 days the effective date of the rule entitled ''Payment for Nursing and Allied Health Education'' published in the January 12, 2001 **Federal Register** (66 FR 3358). That final rule sets forth in regulations Medicare policy for the payment of costs of approved nursing and allied health education programs and clarifies the payment methodology for certified registered nurse anesthetist education programs. To the extent that 5 U.S.C. section 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. section 553 (b) (A). Alternatively, HCFA's implementation of this rule without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. section 553 (b) (B) and 553 (d) (3), in that seeking public comment and delaying the effective date of this final rule is impracticable, and contrary to the public interest.

The temporary 60-day delay in the effective date is necessary to give Department officials the opportunity for further review and consideration of regulations that had been published in the **Federal Register** as of January 20, 2001 but had not yet taken effect as of that date, consistent with the Assistant to the President's memorandum of January 20, 2001. Given the imminence of the effective date, seeking prior public comment on this temporary delay would have been impracticable, as well as contrary to the public interest, in the orderly promulgation and implementation of regulations.

DATES: The effective date of the final rule, Payment for Nursing and Allied