entries of taxable fuel after September 27, 2004.

§ 48.4081–3T [Removed]

■ **Par. 5.** Section 48.4081–3T is removed.

§ 48.4081–5 [Amended]

■ **Par. 6.** Section 48.4081–5 is amended by revising paragraph (a) to read as follows:

(a) *Overview.* This section sets forth requirements for the notification certificate under §§ 48.4081–2(c)(2)(ii), 48.4081–3(c)(2)(iii) and (iv), 48.4081–3(d)(2)(iii), 48.4081–3(e)(2)(iii), 48.4081–3(f)(2)(ii), and 48.4081–4(c) to notify another person of the taxable fuel registrant's registration status.

* * * * *

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 7.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 8.** In § 602.101, paragraph (b) is amended by removing the entry for § 48.4081–3T, and revising the entry for § 48.4081–3 in the table to read as follows:

§ 602.101 OMB control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
48.4081–3	1545–1270 1545–1418 1545–1897
* * * * *	

Kevin M. Brown,

Deputy Commissioner for Services and Enforcement.

Approved: July 16, 2007.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E7–14491 Filed 7–26–07; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2004–0257; FRL–8127–9]

Chlorthalonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on pea, edible podded. The Snowpea Commission of Guatemala requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 27, 2007. Objections and requests for hearings must be received on or before September 25, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2004–0257. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Tony Kish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–9443; e-mail address: *kish.tony@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2004–0257 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 September 25, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2004–0257, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 20, 2004 (69 FR 51672) (FRL–7674–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6795) by the Snowpea Commission of Guatemala, Guatemala City, Guatemala; GB Bioscience™ Corporation of Greensboro, NC serves as the agent for the Snowpea Commission of Guatemala. The petition requested that 40 CFR 180.275 be amended by establishing a tolerance for combined residues of the fungicide chlorothalonil, and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on pea, edible podded (to include snowpea, and sugar snap pea) at 5 parts per million (ppm). That notice included a summary of the petition prepared by GB Bioscience™ Corporation, the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see

• *http://www.epa.gov/oppfead1/trac/science*.

• *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

• *http://www.epa.gov/pesticides/trac/science/aggregate.pdf*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for the combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile on pea, edible podded at 5 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. Specific information on the studies received and the nature of the toxic effects caused by chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov*. The referenced document is available in Docket ID EPA–HQ–OPP–2004–0257.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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 variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at:

• *http://www.epa.gov/pesticides/health/human.htm*.

• *http://www.epa.gov/pesticides/facsheets/riskassess.htm*.

• *http://www.eap.gov/oppfead1/trac/science/*.

The chronic dietary endpoint used in this rule 0.003 milligrams/kilogram/day (mg/kg/day) is based on new toxicity data the Agency received, and is approximately 6.6 fold less than the endpoint of 0.02 mg/kg/day used in the chlorothalonil risk assessment for the April 1999 RED. The Agency has received and is reviewing additional information which could change this lower chronic dietary endpoint. A summary of the toxicological endpoints for chlorothalonil used for human risk assessment is shown in Table 1:

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

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	NOAEL= <0.9 mg/kg/day UF = 300 Chronic RfD = 0.003 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.003 mg/kg/day	*Rat Chronic* LOAEL = 0.9 mg/kg/day based on an increased incidence and severity of epithelial hyperplasia, hyperkeratosis and ulceration of the non-glandular region of the stomach in females
Short-Term Oral (1 to 7 days) (Residential)	Oral study NOAEL= <30.8 mg/kg/day	LOC for Margin of Exposure (MOE) = 1,000 (Residential)	*Rat Two-Generation* LOAEL = 30.8 mg/kg/day based on thickening and/or roughening of the forestomach with depressions in the epithelial aspect, and hyperplasia and hyperkeratosis of the non-glandular epithelium of the stomach
Short-Term Inhalation (1 to 30 days) (Residential)	Inhalation (or oral) study NOAEL= 30.8 mg/kg/day (inhalation absorption rate = 100%	LOC for MOE = 1,000 (Residential)	*Rat Reproduction Study* LOAEL = 30.8 mg/kg/day based on thickening and/or roughening of the forestomach with depressions in the epithelial aspect, and hyperplasia and hyperkeratosis of the non-glandular epithelium of the stomach
Intermediate-Term Inhalation (1-6 months) (Residential)	Oral study NOAEL = 30.8 mg/kg/day inhalation absorption rate = 100%	LOC for MOE = 1,000 (Residential)	*Rat Reproduction Study* LOAEL = 30.8 mg/kg/day based on thickening and/or roughening of the forestomach with depressions in the epithelial aspect, and hyperplasia and hyperkeratosis of the non-glandular epithelium of the stomach
Cancer (oral, dermal, inhalation)	NA	NA	*Classification*: ''Likely'' to be a human carcinogen by all routes of exposure. The Science Advisory Panel decision (6/30/98) supports the use of an MOE approach to adequately quantify cancer risk for chlorothalonil

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, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on a variety of raw agricultural commodities. Tolerances currently exist on almond; apricot; asparagus; banana; bean, dry; bean, snap; blueberry; broccoli; Brussels sprouts; cabbage; carrot; cauliflower; celery; cherry, sweet; cherry, tart; cocoa bean; coffee bean, corn, sweet; cranberry; cucumber; mango; melon; mushroom; nectarine; onion, dry bulb; onion, green; papaya; parsnip; passionfruit; peach; peanut; pepper, nonbell; pistachio; plum; plum, prune; potato; pumpkin; soybean; squash, summer; squash, winter; tomato; and various animal commodities for cattle; goat; hog; horse; milk; and sheep. There is also a time-limited tolerance on ginseng and tolerances with regional registration on filbert and mint, hay. Risk assessments were conducted by EPA to assess dietary exposures from chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure.

No such effects were identified in the toxicological studies for chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 3, chronic dietary-exposure assessment was refined by making use of anticipated residues derived from monitoring data from the Pesticide Data Program (PDP) and Food and Drug Administration surveillance monitoring, percent crop treated estimates, and the processing factors used in the Reregistration Eligibility Decision for Chlorothalonil (Document number EPA 738–R–99–004, April 1999). Drinking water was incorporated directly into the dietary assessment using the estimated maximum allowable Estimated Drinking Water Concentration (EDWC) of 42 ppb.

iii. *Cancer.* EPA has determined that a non-linear approach to cancer risk assessment is appropriate. Therefore the chronic RfD is considered to be protective for this effect.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA

relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins (DCIs) for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such DCIs will be required to be submitted no later than 5 years from the date of issuance of this tolerance. Mean anticipated residues were estimated from PDP monitoring data for apricot; asparagus; banana and plantain; bean, green; bean/pea, dry; broccoli, Brussels sprouts; carrot; cauliflower; celery; cherry; corn, sweet; cucumber; melon; milk; mushroom; nectarine, parsnip; peach; pepper, non-bell; potato; plum; pumpkin; prune; squash; and tomato. Mean anticipated residues were estimated from FDA monitoring data for blueberry; cabbage; cranberry; mango; onion, dry bulb; papaya; peanut; and soybean. Empirical processing factors were used for bean, green, cooked, canned, or frozen; cabbage; carrot, processed or cooked; cherry, processed; cocoa; coffee; cucumber, pickled; peach, cooked and canned; peanut, oil; pea, edible podded, cooked and processed; prunes; pumpkin; soybean, oil; squash, winter, cooked; and tomato, processed. Default processing factors were used for all other food commodities.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Almond, 100%; apricot, 10%; asparagus; 15%; banana and plantain, 100%; bean, green, 20%; bean/pea, dry, 1%; blueberry, 15%; broccoli, 10%; Brussels sprouts, 68%; cabbage, 40%; carrot, 45%; cattle, 100%; cauliflower, 10%; celery, 65%; cherry, 35%; cocoa, 100%; coffee, 100%; corn, sweet, 100%; cranberry, 100%; cucumber, 45%; filbert, 100%; ginseng, 100%; goat, 100%; hog, 100%; horse, 100%; mango, 100%; melon, cantaloupe, 60%; melon, honeydew, 18%; melon, watermelon and other, 84%; milk, 100%; mushroom, 100%; nectarine, 100%; onion, dry bulb, 50%; onion, green, 100%; papaya, 100%; parsnip, 100%; passionfruit, 100%; peach, 15%; peanut, 65%; pea, edible podded, 100%; pepper, non-bell, 100%; pistachio, 100%; potato, 60%; plum and prune, 5%; pumpkin, 40%; sheep, 100%; soybean, 100%; squash, 35%; and tomato, 45%.

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. 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.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

The modeling showed that chronic drinking water levels of chlorothalonil from the most intensive use (i.e., sodfarms) would, in combination with other exposures, raise a risk of concern. EPA believes that this modeling estimate significantly overstates exposure not only because its surface water model is generally conservative, but due to several factors unique to this risk assessment. First, the EDWC for chlorothalonil and its major metabolite was estimated using the mobility factor for chlorothalonil's major metabolite, which is considered more mobile than the parent. EPA does not have a method to calculate model input values for mobility of combined toxic residues; therefore, the most conservative value was used for the model. Second, EPA assumed use of maximum sodfarm application rates, application intervals, and agronomic practices which are not always employed. Third, EPA assumed that 100% of a watershed consists of sodfarm turf, compared with recent preliminary data showing that 50% or less is a more realistic number. Fourth, EPA assumed that all sodfarms in any given watershed area would be treated with chlorothalonil in the same season, and at the same time, which is unlikely to occur. Despite EPA's conclusion that the predicted EDWC overstates exposure, EPA conducted a sensitivity analysis to determine what sodfarm usage rate would lower predicted drinking water levels by a sufficient amount to eliminate any risk concerns. EPA's analysis showed that the maximum allowable EDWC to be 42 ppb, and that reducing the maximum application rate for sodfarms from 26 lbs of active ingredient/acre/year to 13 lbs active ingredient/acre/year would result in acceptable EDWC of less than 42 ppb. This reduction in the maximum sodfarm application rate is being incorporated on all affected chlorothalonil product labels.

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: Golf courses and additive for paints. The risk assessment was

conducted using the following residential exposure assumptions: There is potential for residential exposure from treated golf courses and from using treated paint. All other turf uses involving chlorothalonil exposure to toddlers and children have been canceled. EPA has determined that there is no hazard via the dermal route; therefore, quantification of a dermal risk assessment is not required. Inhalation post-application exposures for golf courses were not assessed since inhalation exposures are thought to be negligible in outdoor post-application scenarios. Consequently, only inhalation and incidental oral exposures from the use of treated paint were assessed. The short- and intermediate-term inhalation and incidental oral MOEs are greater than the target MOE of 1000 and, therefore, do not exceed EPA's level of concern (LOC).

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to chlorothalonil and any other substances and 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. In the chlorothalonil RED, chlorothalonil was grouped in the polychlorinated fungicide class of pesticides. Other members of this class include hexachlorobenzene (HCB), pentachlorophenol (PCP), and pentachloronitrobenzene (PCNB). This is considered a weak classification, with the only point of commonality is that they are polychlorinated compounds used as fungicides. Available data do not support a finding for a common mechanism of toxicity for chlorothalonil and the other pesticides in the polychlorinated fungicide class. Chlorothalonil produces renal (kidney) tubular adenomas and carcinomas and papillomas of the stomach in rats. Chlorothalonil also produces gastric lesions and kidney toxicity due to perturbation of mitochondrial respiration. The other pesticides in the class do not have the same toxic effects and do not have the same mode of action.For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. EPA has concluded that there is no increased susceptibility following prenatal or postnatal exposure to chlorothalonil in rats. There is equivocal evidence of increased susceptibility in rabbits; however, the degree of concern for prenatal susceptibility is low. There is a well-defined NOAEL in the rabbit developmental toxicity study protecting from these effects. In addition, developmental effects were observed in only one of the two developmental toxicity studies conducted in the same strain of rabbit at the same dose levels. Therefore, based on overall weight-of-evidence, EPA concluded that there is no increased susceptibility following exposure to chlorothalonil or its 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite.

3. *Conclusion*. There is a complete toxicity data base for chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The acute, subchronic, developmental, reproduction and chronic studies were sufficient to determine whether human hazard could exist within the context of dose, duration, timing, and route-of-exposure. The uncertainty factor used in determining the chronic reference dose (cRfD) was 300 (10X for interspecies animal-to-human extrapolation; 10X for intraspecies human variations; and 3X for use of a LOAEL instead of a NOAEL). The uncertainty factor of 3X for use of the LOAEL instead of the NOAEL is considered appropriate because an increased incidence and severity of epithelial hyperplasia, hyperkeratosis and ulceration of the non-glandular region of the stomach in females were seen in few animals and were minimal in severity and observed in one sex only. The chlorothalonil FQPA safety factor was reduced to 3X for chronic risk assessment but retained at 10X for residential assessments. The data from the chronic toxicity study in rats show that a 3X factor in the chronic risk assessment is protective of infants and children despite the lack of a NOAEL in that study. As to the residential risk assessment, there are insufficient reliable data to conclude that a reduction of the 10X FQPA safety factor is safe for infants and children given the lack of a NOAEL in the study upon which the residential risk assessment is based. Other than the lack of NOAELs in these two critical studies, other considerations raise no concern for the safety of infants and children. Specifically, (1) the hazard and exposure databases are complete; (2) there are low concerns for prenatal and/or postnatal toxicity; (3) there are no residual uncertainties with regard to prenatal and/or postnatal toxicity; and (4) there are no neurotoxic concerns.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. No acute effects were identified in the toxicological studies for chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile; therefore, a quantitative acute dietary exposure assessment is unnecessary. In the 1999 Chlorothalonil Registration Elibibility Document, the acute RfD was based on the results of a of 90–day study in rats in which gastric renal lesions were observed beginning at 7 days of continuous dosing. These type of lesions and in particular, the time frame at which they occurred (after 7 days of continuous high-dose administrations), do not meet the criteria of a single-dose effect.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile from food will utilize 3% of the cPAD for the U.S. population, 2% of the cPAD for all infants, and 8% of the cPAD for children 1-2 years old. There are no residential uses for chlorothalonil that result in chronic residential exposure to chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile. Based on approved use pattern, chronic residential exposure to residues of chlorothalonil are not expected. In addition, there is potential for chronic dietary exposure to chlorothalonil in drinking water. Analyses by the Agency indicate that 42 ppb is the maximum residue concentration (parent plus metabolite) in drinking water which results in acceptable levels of chronic aggregrate risk. However, as explained prior in Unit III.C.2., this 42 ppb EDWC is considered conservative. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CHLOROTHALONIL

Population/Subgroup	cPAD/mg/kg/day	%/cPAD/(Food plus water)	Surface Water EEC/(ppb)	Ground/Water EEC/(ppb)	Chronic/DWLOC (ppb)
U.S. Population	0.003	33	N/A (Not Applicable)	N/A	N/A
All infants (<1 year old)	0.003	99	N/A	N/A	N/A
Children 1-2 years old	0.003	52	N/A	N/A	N/A
Adults 20-49 years old	0.003	30	N/A	N/A	N/A

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

Chlorothalonil is currently registered for use that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term and intermediate-term exposures for chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 8,600 for adults 20-49 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food, water, and residential uses. Dietary exposure was calculated assuming residues in water of 42 ppb.

5. *Aggregate cancer risk for U.S. population.* EPA has determined that a non-linear approach to cancer risk assessment is appropriate and that the chronic RfD is considered to be protective for this effect.

6. *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 chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate residue analytical methods are available for purposes of registration. The Pesticide Analytical Manual (PAM) Vol. II lists Method I, a gas chromatography (GC) method with electron-capture detection (ECD), for the enforcement of tolerances for plant commodities.

B. International Residue Limits

There are no conflicts between existing U.S. tolerances and MRLs established by the CODEX Alimentarius Commission.

C. Response to Comments

One comment dated September 4, 2004, was received from B. Sachau. Ms. Sachau's comments regarding general exposure to pesticides contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to chlorothalonil, including all anticipated dietary exposures and other exposures for which there is reliable information. This comment, as well as her comments regarding animal testing, has been responded to by the Agency on several occasions. For example, January 7, 2005 (70 FR 1349) (FRL–7691–4) and October 29, 2004 (69 FR 63083) (FRL–7681–9).

V. Conclusion

Therefore, the tolerance is established for the combined residues of chlorothalonil, and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on pea, edible podded (includes snow pea and sugar snap pea) at 5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from*

Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled*Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 13, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.275 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows:

§180.275 Chlorothalonil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * *	*
Pea, edible podded	5
* * * *	*

* * * * *

[FR Doc. E7–14567 Filed 7–26–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

[CMS–4094–F5]

RIN 0938–AO83

Amendment to the Interim Final Regulation for Mental Health Parity

AGENCY: Centers for Medicare & Medicaid Services (CMS), DHHS.

ACTION: Amendment to interim final regulation.

SUMMARY: This document amends the interim final regulation that implements the Mental Health Parity Act of 1996 (MHPA) to conform the sunset date of the regulation to the sunset date of the statute under legislation passed on December 9, 2006.

DATES: *Effective date:* The amendment to the regulation is effective August 27, 2007.

Applicability dates: Under the amendment, the requirements of the MHPA interim final regulation apply to group health plans and health insurance coverage offered in connection with a group health plan during the period commencing August 27, 2007 through December 31, 2007.

FOR FURTHER INFORMATION CONTACT: Adam Shaw, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, at 1–877–267–2323, ext. 61091.

SUPPLEMENTARY INFORMATION:

I. Background

The Mental Health Parity Act of 1996 (MHPA) was enacted on September 26, 1996 (Pub. L. 104–204). MHPA amended the Public Health Service Act (PHS Act) and the Employee Retirement Income Security Act of 1974 (ERISA) to provide for parity in the application of annual and lifetime dollar limits on mental health benefits and the application of dollar limits on medical/surgical benefits. Provisions implementing MHPA were later added to the Internal Revenue Code of 1986 (Code) under the Taxpayer Relief Act of 1997 (Pub. L. 105–34).

The provisions of MHPA are set forth in Title XXVII of the PHS Act, Part 7 of Subtitle B of Title I of ERISA, and