organize comments by referencing the relevant part or section number.

- Explain why you agree or disagree: Suggest alternatives and substitute language.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Dated: November 26, 2008.

Robert J. Meyers,

Principal Deputy Assistant Administrator for Air and Radiation.

[FR Doc. E8–28675 Filed 12–2–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1106; FRL–8390–1]

Chlorothalonil; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish tolerances for combined residues of chlorothalonil and its 4-hydroxy metabolite in or on lychee and starfruit under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before February 2, 2009.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2007–1106, 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 Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility'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.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2007–1106. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either 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 Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying

information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

EPA on its own initiative, under section 408(e) of FFDCA, 21 U.S.C. 346a(e), is proposing to establish tolerances for combined residues of the fungicide, chlorothalonil, tetrachloroisophthalonitrile, and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on lychee at 15 parts per million (ppm) and starfruit at 3.0 ppm. The United States Department of Agriculture (USDA) requested that EPA establish these tolerances. Because USDA did not submit a petition in support of establishing these tolerances, EPA did not publish a Notice of Filing of a petition for these tolerances.

III. Aggregate Risk Assessment and Determination of Safety

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. * * *''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for tolerances for combined residues of chlorothalonil and its 4-hydroxy metabolite on lychee at 15 ppm and starfruit at 3.0 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances 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.

Chlorothalonil has low acute toxicity by the oral and dermal routes of exposure and is moderately toxic by the inhalation route. It is severely irritating to the eye and moderately irritating to the skin but is not a skin sensitizer.

Chlorothalonil causes gastric irritation upon ingestion. In a subchronic dog study, both males and females exhibited decreased body weights, body-weight gains and food consumption. In a chronic dog study, there was one death (female), decreased body-weight gain and food consumption, macroscopic and microscopic pathological findings in the stomach (including thickened appearance of the stomach and intra-epithelial nuclear pyknosis in the mucosal epithelium of the antrum of the stomach) and a very slight hypertrophy of the cells in the zona fasciculata of the adrenal glands. In a second chronic dog study, vacuolated epithelium of the kidney was observed. In a subchronic mouse study, chlorothalonil produced hyperplasia and hyperkeratosis of the squamous epithelium of the stomach. In a subchronic rat study, chlorothalonil increased relative kidney weights and produced dilated renal medullary tubules as well as hyperplasia and hyperkeratosis of the non-glandular area of the stomach. In rodent chronic toxicity studies, there was an increased incidence of epithelial hyperplasia of the limiting ridge and non-glandular region of the stomach in rats and mice.

There are two toxicology data sets, submitted by different basic registrants, available for chlorothalonil. There was no indication of a carcinogenic response in the rat chronic toxicity/carcinogenicity study from the newer data set; however, an increased incidence of renal adenomas and carcinomas and an increased incidence of papillomas and/or carcinomas of the forestomach were observed in both sexes of rats and mice with the older data set. The new carcinogenicity study in mice also demonstrates that chlorothalonil produces similar papillomas of the forestomach. Based on the increased incidence of renal adenomas and carcinomas observed in both sexes of rats and mice, the rarity of the tumor response in the kidney, and the increased incidence of papillomas and/or carcinomas of the forestomach in rats and mice, EPA classified chlorothalonil as a ''likely'' human carcinogen by all routes of exposure.

Several studies are available that address the mechanism of carcinogenicity of chlorothalonil. Based on the mechanistic data submitted for the kidney tumor response demonstrating a toxic response of the kidney and forestomach to repeated dietary administration of chlorothalonil, the mode of action for tumor induction of chlorothalonil is likely to be non-linear. With regard to the forestomach tumors, data submitted by the registrant showing cell proliferation and non-neoplastic pathology at doses near those producing a tumorigenic response also support a non-linear mode of action for chlorothalonil. Based on the weight of the evidence presented to the Agency, EPA has concluded that a non-linear risk assessment using a Margin of Exposure (MOE) approach is appropriate for chlorothalonil.

No developmental toxicity was observed in two rat developmental toxicity studies or in one of the two rabbit developmental toxicity studies available for chlorothalonil. In the other rabbit study, there was an increased incidence of thirteen ribs and reduced sternebrae in the absence of maternal toxicity. There was no evidence of reproductive toxicity in either rat reproduction study available for chlorothalonil.

There is no evidence that chlorothalonil causes neurotoxicity. There was no evidence of neuropathology, and there were no central nervous system (CNS) malformations, effects on brain weights, abnormal behavior or effects on offspring sexual maturation observed in the toxicity studies available for

chlorothalonil, including a subchronic neurotoxicity study in rats.

In a 90–day oral toxicity study in rats, a slight decrease in thymus weight was observed at the highest dose tested (HDT), a possible indication of immunotoxicity. However, since there were no histopathological findings noted in the thymus and no effects on the thymus observed in other subchronic or chronic/carcinogenicity studies in rats, EPA has concluded that the slight effect on thymus weight seen in this study is a spurious effect and not indicative of immunotoxicity.

4-hydroxy-2,5,6-trichloroisophthalonitrile is a major metabolite of chlorothalonil in plants and the predominant residue in animals. Toxicology data available for this metabolite include acute oral and subchronic toxicity studies in rats, developmental toxicity studies in rats and rabbits, a reproduction toxicity study in rats, a chronic toxicity study in dogs and chronic/carcinogenicity studies in rats and mice. The results of these studies indicate that the toxicity of the 4-hydroxy metabolite is similar to that of parent chlorothalonil. Based on this determination, EPA has concluded that the chlorothalonil risk assessment adequately accounts for potential toxicity resulting from exposure to 4-hydroxy chlorothalonil, and a separate risk assessment is not needed.

Specific information on the studies received and the nature of the adverse effects caused by chlorothalonil and 4-hydroxy chlorothalonil, 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* in the document *Chlorothalonil. Petition For Tolerances on Brassica Head and Stem Subgroup 5A, Cucurbit Vegetable Group 9, Fruiting Vegetable Group 8, Ginseng, Horseradish, Lentil, Lupin, Okra, Persimmon, Rhubarb, Yam, Lychee, and Starfruit. Human-Health Risk Assessment*, page 15 in docket ID number EPA–HQ–OPP–2007–1106.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for chlorothalonil used for human risk assessment can be found at *http://www.regulations.gov* in the document *Chlorothalonil. Petition For Tolerances on Brassica Head and Stem Subgroup 5A, Cucurbit Vegetable Group 9, Fruiting Vegetable Group 8, Ginseng, Horseradish, Lentil, Lupin, Okra, Persimmon, Rhubarb, Yam, Lychee, and Starfruit. Human-Health Risk Assessment*, page 36 in docket ID number EPA–HQ–OPP–2007–1106.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to chlorothalonil and its 4-hydroxy metabolite, EPA considered exposure under the proposed tolerances as well as all existing chlorothalonil tolerances in 40 CFR 180.275. EPA assessed dietary exposures from chlorothalonil and its metabolite 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; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed 100% crop treated, tolerance-level residues and default processing factors for all foods except tomatoes (average field-trial residues and empirical processing factors used), peppers (average field-trial residues used) and snap beans (average field-trial residues used).

iii. *Cancer*. Because chlorothalonil's cancer effects are the result of chronic exposure, EPA is using the chronic exposure assessment to assess chlorothalonil's cancer risk.

iv. *Anticipated residue information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The residues of concern in drinking water include parent chlorothalonil and its 4-hydroxy metabolite. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for chlorothalonil and 4-hydroxy chlorothalonil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of chlorothalonil and 4-hydroxy chlorothalonil. 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*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of chlorothalonil and its 4-hydroxy

metabolite for chronic exposures are estimated to be 68.2 parts per billion (ppb) for surface water and 3.2 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 68.2 ppb was used to assess the contribution from drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Chlorothalonil is currently registered for the following uses that could result in residential exposures: As a fungicide on golf courses and as a preservative in paints. EPA assessed residential exposure using the following assumptions: There is potential for short-term or intermediate-term dermal exposure of adults and children on golf courses that have been treated with chlorothalonil. There is also potential for short-term/intermediate-term dermal and inhalation exposure of handlers of paints containing chlorothalonil and potential for short-term/intermediate-term postapplication dermal exposure of adults, as well as short-/intermediate-term postapplication dermal and episodic incidental oral exposures of children from the use of chlorothalonil-treated paints in residential buildings. Postapplication inhalation exposures to chlorothalonil on treated golf courses and in buildings from treated paint are expected to be negligible, and the Agency has not identified a hazard of concern for short-term or intermediate-term dermal exposures; therefore, EPA assessed only short-term and intermediate-term inhalation exposures of handlers using chlorothalonil-treated paints and episodic postapplication incidental oral exposures of children from the use of chlorothalonil-treated paints in residential buildings.

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

Chlorothalonil is a polychlorinated fungicide. Other members of this class include hexachlorobenzene (HCB), pentachlorophenol (PCP) and pentachloronitrobenzene (PCNB). This is a very loose classification of compounds related only in being polychlorinated and acting 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 the purposes of this tolerance action, therefore, EPA has assumed that chlorothalonil does not have 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicity database for chlorothalonil includes rat and rabbit developmental toxicity studies (two of each) and two reproduction toxicity studies in rats, as well as a subchronic neurotoxicity study in rats. In addition, there are developmental toxicity studies in rats and rabbits and reproduction toxicity studies in rats available for the 4-hydroxy metabolite as well as the major soil degradate, SDS–46851.

There was no evidence of increased qualitative or quantitative susceptibility of fetuses or offspring in any of the submitted developmental or reproduction studies for chlorothalonil or its metabolites, except in one of the chlorothalonil developmental toxicity studies in rabbits. In the newer of the two rabbit studies, there was a slight increase in the incidence of two variations (13th rib and reduced sternebrae) in fetuses in the high-dose group. No maternal effects occurred at any dose in this study. EPA's concern for this equivocal evidence of quantitative susceptibility is low, and there are no residual uncertainties with regard to prenatal and postnatal susceptability, for the following reasons: The variations were only observed in one of the two developmental toxicity studies conducted in the same strain of rabbit at the same dose levels; these variations are known to occur spontaneously within this strain (New Zealand White) of rabbit, as evidenced by the fact that the concurrent controls had high incidences of both variations; and there is a well-defined NOAEL for the study that is protective of these effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for chlorothalonil is complete, except for acute neurotoxicity and immunotoxicity studies, and EPA has determined that an additional uncertainty factor is not required to account for potential neurotoxicity or immunotoxicity. The reasons for this determination are explained as follows:

a. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect after the tolerance petition was submitted, these studies are not yet available for chlorothalonil. In the absence of specific immunotoxicity studies, EPA has evaluated the available chlorothalonil toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. In a 90–day oral toxicity study in rats, a slight decrease in thymus weight was observed at the HDT, a possible indication of immunotoxicity. However, since there were no histopathological findings noted in the thymus and no effects on the thymus observed in other subchronic or chronic/carcinogenicity studies in rats, EPA has concluded that the slight effect on thymus weight seen in this study is a spurious effect and not indicative of immunotoxicity. Due to the lack of evidence of immunotoxicity for chlorothalonil, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the NOAEL of 2 milligrams/kilogram/day

(mg/kg/day) already established for chlorothalonil, and an additional factor (UFDB) for database uncertainties is not needed to account for potential immunotoxicity.

b. Acute neurotoxicity testing is also required as a result of changes made to the pesticide data requirements in December of 2007. Although an acute study has not yet been submitted, there is no evidence of neurotoxicity in any study in the toxicity database for chlorothalonil, including a subchronic neurotoxicity study. Therefore, EPA has concluded that an additional uncertainty factor is not needed to account for the lack of these data.

ii. Although there was equivocal evidence of increased quantitative susceptibility of fetuses to chlorothalonil exposure in one of two rabbit developmental toxicity studies, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments utilized tolerances or anticipated residues that are based on reliable field trial data. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to chlorothalonil in drinking water. EPA used similarly conservative assumptions to assess postapplication incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by chlorothalonil.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, chlorothalonil is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to chlorothalonil from food and water will utilize 94% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of chlorothalonil is not expected.

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

Chlorothalonil is currently registered for uses that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to chlorothalonil. Since the doses and endpoints selected for chlorothalonil to assess short-term and intermediate-term exposure are identical, the short-term and intermediate-term risk estimates for chlorothalonil are the same.

Using the exposure assumptions described in this unit for short-term/intermediate-term exposures, EPA has concluded the combined short-term/intermediate-term food, water, and residential exposures aggregated result in an aggregate MOE of 270 for adults. The MOE for adults includes food, drinking water and short-/intermediate-term inhalation exposure of individuals mixing, loading and applying chlorothalonil-treated paint with an airless sprayer, the handler exposure scenario resulting in the highest estimated exposure to chlorothalonil.

As discussed in Unit III.C.3., there is potential for short and intermediate-term post-application dermal exposure of children on golf courses and in residential areas where chlorothalonil-treated paints have been used; however, EPA has not identified a toxicological endpoint of concern for short or intermediate-term dermal exposures. Therefore, for children, the short and intermediate-term aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

EPA did assess incidental oral exposures of children from ingestion of paint chips containing chlorothalonil. The estimated incidental oral MOE for children is 1,200. Ingestion of paint chips is considered to be an episodic, rather than a routine behavior; therefore, EPA has determined that it is not appropriate to aggregate incidental oral exposures with chronic exposures from food and drinking water.

4. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., EPA classified chlorothalonil as a ''likely'' human carcinogen by all routes of exposure, based on the increased incidence of renal adenomas and carcinomas observed in both sexes of rats and mice, the rarity of the tumor response in the kidney, and the increased incidence of papillomas and/or carcinomas of the forestomach in rats and mice. EPA has determined that the mechanism of carcinogenicity of chlorothalonil is non-linear (i.e. not a non-threshold effect) and that the Point of Departure used in calculating the cPAD is protective of the cancer effects. Since there are no uses of chlorothalonil expected to result in chronic residential exposure, and since chronic dietary exposure for the overall U.S. population is less than the cPAD (43% of the cPAD), EPA concludes that aggregate cancer risk from exposure to chlorothalonil is below the level of concern.

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, or to infants and children from aggregate exposure to chlorothalonil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC) method with electron-capture detection (ECD)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no established or proposed Codex MRLs for residues of chlorothalonil on lychee or starfruit.

V. Conclusion

A tolerance is proposed for combined residues of chlorothalonil, tetrachloroisophthalonitrile, and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on lychee at 15 ppm and starfruit at 3.0 ppm.

VI. Statutory and Executive Order Reviews

This proposed 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed 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). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency hereby certifies that this proposed action will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities. 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 proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this proposed 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 9, 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: November 13, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be 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 commodities to the table in paragraph (a)(1) to read as follows:

§ 180.275 Chlorothalonil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Lychee	15
* * * * *	
Starfruit	3.0
* * * * *	

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