on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: June 25, 2009.

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. In § 180.920, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * *	* *	* *
Sodium 1,4-dihexyl sulfosuccinate (CAS Reg. No. 3006–15–3).	.....	Surfactants, related adjuvants of surfactants
* * *	* *	* *
Sodium 1,4-diisobutyl sulfosuccinate (CAS Reg. No. 127–39–9).	.....	Surfactants, related adjuvants of surfactants
* * *	* *	* *
Sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5).	.....	Surfactants, related adjuvants of surfactants
* * *	* *	* *

* * * * *

[FR Doc. E9–16086 Filed 7–7–09; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0140; FRL–8417–4]

d-Phenothrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide d-phenothrin [(3-phenoxyphenyl)methyl] 2,2-Dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate in or on all food/feed crops at 0.01 parts per million (ppm) following wide-area mosquito adulticide applications. McLaughlin Gormley King Company requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 8, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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–2008–0140. 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., 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 Room S–4400, One Potomac Yard (South Building), 2777 S. Crystal Dr., Arlington, VA 22202–4501. 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: Carmen Rodia, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax number: (703) 308–0029; e-mail address: *rodia.carmen@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, those engaged in the following activities:

- 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 to provide 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 electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2008–0140 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 as required by 40 CFR part 178 on or before September 8, 2009.

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 this copy, identified by docket ID number EPA–HQ–OPP–2008–0140, 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 Avenue, NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Room S–4400, One Potomac Yard (South Building), 2777 S. Crystal Dr., Arlington, VA 22202–4501. 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.

II. Petition for Tolerance

In the **Federal Register** of September 28, 2007 (72 FR 55204) (FRL–8147–1) (EPA–HQ–OPP–2007–0880), 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 7F7251) by McLaughlin Gormley King Company, 8810 Tenth Avenue, North, Minneapolis, MN 55427–4319.

The petition requested that 40 CFR part 180 be amended by establishing permanent tolerances for residues of the insecticide d-phenothrin, [(3-phenoxyphenyl)methyl] 2,2-Dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate), in or on all food/feed crops at 0.01 ppm following wide-area mosquito adulticide applications. That notice referenced a summary of the petition prepared by McLaughlin Gormley King Company, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 the petitioned-for tolerances for residues of the insecticide d-phenothrin in or on all food/feed crops at 0.01 ppm following wide-area mosquito adulticide treatments. EPA's assessment of exposures and risks associated with establishing 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.

d-Phenothrin has low acute toxicity via the oral, dermal and inhalation routes of exposure, is only a mild eye irritant, is non-irritating to the dermis and tests negative for skin sensitization. The effects on the liver are the most systemically sensitive endpoint following repeated oral exposure based on acceptable subchronic and chronic toxicity studies in rodents and dogs, specifically, increased liver weight, hepatocellular vacuolization and hypertrophy and, at higher doses, increased liver serum enzymes. Based on a 90–day inhalation study in rats, the most sensitive effects from repeated inhalation exposure are portal of entry effects (histopathological changes in the nasal turbinates in both sexes). This inhalation study also indicated histological effects on the liver, thyroid and adrenal which are of borderline toxicological significance alone, but which are supported in part by the increased organ weights and histological findings of similar occurrence in some oral studies. d-Phenothrin was not associated with any systemic toxicity up to the limit dose of 1,000 mg/kg/day in a 3–week dermal toxicity study in rats.

Currently, d-phenothrin is lacking acceptable neurotoxicity studies and these studies are considered data gaps. The only available, but unacceptable/non-guideline, neurotoxicity study in

rats indicated piloerection in animals administered at 5,000 mg/kg for 5 consecutive days; however, the rabbit developmental study provides evidence of neurotoxicity. Indications of neurotoxicity from the rabbit developmental study include presence of spina bifida at the mid-dose of 100 mg/kg/day, microphthalmia at 300 mg/kg/day and hydrocephaly at the high-dose of 500 mg/kg/day. While these neurodevelopmental effects were seen in only a single fetus each, the observations of spina bifida and microphthalmia can be considered significant because they are uncommon in untreated rabbits, yet they occurred together in the d-phenothrin rabbit development study.

As noted, developmental effects were observed in the rabbit developmental study. Minimal adverse effects were observed at the highest dose treated in the rat developmental study. In two acceptable rat reproduction studies, both systemic and reproductive/offspring toxicity occurred at the same doses with similar effects for offspring and dams in each study (organ weight changes in the 1986 study and decreased body weight gain in the 1995 study).

Endocrine-related effects were observed in tests which indicated potential estrogen, androgen and/or thyroid-mediated toxicity. d-Phenothrin produced adrenal cortex vacuolation in the 1–year dog feeding study and 90–day inhalation toxicity study in rats. In addition, the 90–day inhalation toxicity study also resulted in follicular thyroid cell enlargement. Hepatocellular enlargement was produced in the 26–week dog feeding study, the 1–year dog feeding study and the 90–day inhalation study, but was not always associated with thyroid toxicity in these studies at the doses tested. The endpoints selected for chronic dietary, incidental oral and inhalation exposure are protective of endocrine-related effects.

d-Phenothrin has been classified as ''Not Likely to be Carcinogenic to Humans.'' Rat liver tumors, namely hepatocellular carcinomas, occurred only at excessively toxic doses (limit dose) and were; therefore, discounted and mouse liver hepatocellular adenomas, which are common, did not achieve statistical significance ($p < 0.01$). In addition, an acceptable battery of mutagenicity studies was negative for mutagenic potential.

More detailed information on the studies received and the nature of the adverse effects caused by d-phenothrin 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 in the document entitled, ''d-Phenothrin (Sumithrin®) Risk Assessment for Reregistration Eligibility Decision (RED) and Associated Section 3 Registration Action,'' dated July 2, 2008, by going to *http://www.regulations.gov*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2008–0140–0024 in that docket. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2008–0140. Double-click on the document to view the referenced information on pages 50–54 of 66.

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 d-phenothrin used for human risk assessment can be found in the document entitled, ''d-Phenothrin (Sumithrin®) Risk Assessment for Reregistration Eligibility Decision (RED) and Associated Section 3 Registration Action,'' dated July 2, 2008, by going to *http://www.regulations.gov*. The referenced document is available in the docket established by this action, which is described under ADDRESSES, and is identified as EPA–HQ–OPP–2008–0140–0024 in that docket. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2008–0140. Double-click on the document to view the referenced information on pages 23–24 of 66.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to d-phenothrin, EPA considered exposure under the petitioned-for tolerances and assessed dietary exposures from d-phenothrin 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. In estimating acute dietary exposure, EPA conducted a screening level acute dietary and drinking water exposure assessment for the proposed new food use of d-phenothrin for all commodities and incorporated the Agency's estimated surface water peak concentration of 1 part per billion (ppb). An acute dietary exposure analysis was performed for the population subgroup females 13–49 years old only as no acute endpoint was identified for the remaining population subgroups. The acute dietary assessment assumed tolerance-level residues in plant and livestock commodities and 100 pecent crop treated (PCT).

ii. *Chronic exposure*. In estimating chronic dietary exposure, EPA conducted a screening level chronic dietary and drinking water exposure assessment for the proposed new food use of d-phenothrin and incorporated the Agency's chronic or estimated surface water concentration of 0.0407 ppb. The assessment assumed tolerance-level residues in plant and livestock commodities and 100 PCT.

iii. *Cancer*. As explained in Unit III.A., d-phenothrin is considered to be ''Not Likely to be Carcinogenic to Humans.'' As a result, an exposure assessment to evaluate cancer risk is not needed for d-phenothrin.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue information in the

dietary exposure assessment for d-phenothrin.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for d-phenothrin in drinking water. These simulation models take into account data on the physical, chemical and fate/transport characteristics of d-phenothrin. 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 d-phenothrin for acute exposures are estimated to be 0.1002 ppb for surface water and 0.00600 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 0.0407 ppb for surface water and 0.00600 ppb for ground water. Chronic exposures for cancer assessments are estimated to be 0.0369 ppb for surface water and 0.00600 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the estimated surface water peak concentration value of 1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the chronic or estimated surface water concentration value of 0.0407 ppb was used to assess the contribution to 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). Based on a review of active labels and proposed new uses, 12 residential exposure scenarios have been assessed for d-phenothrin. Inhalation and incidental ingestion exposure assessments have been conducted for the residential scenarios. Short-term and intermediate-term exposures are expected and assessed for residential handler and post-application exposure scenarios based on use and expected exposure patterns.

Risk assessments were conducted for residential exposure pathways based on registered uses. Residential post-application exposure and risk to d-phenothrin was assessed using both deterministic and probabilistic modeling approaches.

The residential exposure assessment includes 2 handler and 10 post-application residential exposure scenarios. The term ''handler'' applies to individuals who mix, load and apply the pesticide product. The term ''post-application'' describes individuals who are exposed to pesticides after entering areas previously treated with pesticides. d-Phenothrin products for outdoor residential use are almost exclusively available as aerosol sprays. There are a small number of outdoor fogger products containing d-phenothrin (at least one); however, due to the absence of scenario-specific exposure data for outdoor foggers, the fact that there are very few fogger products for residential outdoor use and the fact that assessment of aerosol sprays and mosquito ultra low volume (ULV) applications are likely to address risks from foggers, residential use of outdoor foggers was not assessed separately for this analysis.

EPA assessed residential exposure using the following assumptions: Primary assumptions for assessing post-application exposure to use of foggers and aerosols in indoor residential settings were based on data provided by the Non-Dietary Exposure Task Force (NDETF). The NDETF was formed in 1996 by members of the Pyrethrin Joint Venture and Piperonyl Butoxide Task Force II to respond to reregistration needs and to produce scientifically sound data on non-dietary exposures to pyrethrins, the pyrethroids, piperonyl butoxide and MGK® 264 insecticide synergist.

EPA used the AGricultural DISPersal model (AGDISP), version 8.15.0.4, to calculate airborne concentrations of d-phenothrin from aerial ULV mosquito abatement spray applications. ULV sprayers disperse very fine aerosol droplets that stay aloft and kill flying mosquitoes on contact. ULV applications involve small quantities of the insecticide formulation in relation to the size of the area treated, typically less than 3 ounces per acre. AGDISP provides estimates of the 1–hour average concentration and the downwind deposition of spray material released from the aircraft equipment and predicts the motion of spray material released, including the mean position of the material and the position variance about the mean as a result of turbulent fluctuations, providing a prediction of spray drift.

For the AGDISP modeling for d-phenothrin, label recommendations were followed, but conservative assumptions were made. The resultant data were used to assess inhalation exposure resulting from aerial application of d-phenothrin as a mosquito adulticide. Deposition data from the AGDISP model were not used to assess post-application incidental oral exposure to d-phenothrin because residential application of d-phenothrin products outdoors to patios and lawn areas results in higher deposition. Therefore, post-application incidental oral exposures were assessed using estimated deposition from homeowner application of outdoor house and garden spray products.

Air concentrations from truck-mounted ULV spray applications are estimated based on the SOP for residential exposure assessment for inhalation exposure from use of an outdoor space spray for pest control. The approach was modified to assume that 1% of the highest application rate for a truck-mounted ULV sprayer is available in the breathing zone of the resident. It is assumed that the full application rates for a truck-mounted ULV sprayer (with a 1% dilution factor) is available in the breathing zone of the residential bystander, i.e., an application rate expressed as lbs. a.i./ft^2 is converted into a concentration expressed in a per cubic foot (ft^3) basis.

Scenario-specific data on pyrethrins and/or permethrin from the NDETF studies were used to determine deposition of d-phenothrin on vinyl and carpet flooring following use of a total release indoor fogger. Given the close structural similarity of pyrethrins, permethrin and d-phenothrin and the similarity of use patterns for these chemicals, EPA believes that the NDETF pyrethrins and/or permethrin data provide appropriate surrogate data for d-phenothrin. Permethrin data were used preferentially for this assessment, if available, since permethrin and d-phenothrin are both synthetic pyrethroids.

Inhalation following application of an indoor total release fogger was not modeled separately because the aerosol spray application scenario is likely to provide a more conservative exposure estimate and; therefore, be protective of exposures following use of a total release fogger. While application rates for total release foggers and aerosol sprays are comparable, labels for use of total release foggers require that the room be closed and vacated during release of the fogger and that the room be opened and thoroughly ventilated for a period of time (e.g. 30 minutes, 1 hour) prior to re-entry.

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.''

d-Phenothrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids interact with sodium channels, there are multiple types of sodium channels and it is currently unknown whether the pyrethroids have similar effects on all channels and there is also no clear understanding of effects on key downstream neuronal function e.g., nerve excitability, and how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by the Agency's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. When available, EPA will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. 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*. d-Phenothrin demonstrated qualitative and quantitative susceptibility in an acceptable rabbit developmental study. Specifically, developmental toxicity (spina bifida) occurred at a lower LOAEL (100 mg/kg/day) than the maternal LOAEL (300 mg/kg/day) for decreased body weight gain and food consumption. In rats, d-phenothrin was developmentally toxic only at a dose of 3,000 mg/kg/day. The NOAELs and LOAELs for maternal animals and fetuses were the same in this study. In the 1986 and 1995 rat reproduction studies, the NOAELs/LOAELs for both maternal and offspring/reproductive findings occurred at the same dose levels (both studies) and the types of offspring effects (organ weight changes (1986) and decreased mean pup weights (1995)) were also present in the respective maternal animals from the two studies.

3. *Conclusion*. The risk assessment and FFDCA safety finding for d-phenothrin are based on a well characterized but incomplete toxicity database. With the retention of the full FQPA SF of 10x, the toxicity database is considered adequate to evaluate the risks to infants and children based on the following findings:

i. The toxicity database for d-phenothrin is incomplete for a full hazard assessment. The toxicity database for d-phenothrin lacks acceptable acute, subchronic and developmental neurotoxicity studies and an immunotoxicity study. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by d-phenothrin. An immunotoxicity study is required, as a new data requirement under the 40 CFR part 158 data requirements for registration of a pesticide (food and non-food uses).

ii. The only available neurotoxicity study in rats is an unacceptable/non-guideline study which demonstrated clinical signs of piloerection but no axonal damage. The rabbit developmental study provides evidence of neurotoxicity. Spina bifida at the mid-dose and treatment-related presence of hydrocephaly, another serious neurodevelopmental effect, was seen at the highest dose tested in the rabbit developmental study. Generally, other specific neurotoxic clinical signs were absent in other acute, subchronic and chronic d-phenothrin studies in rats and dogs; however, d-phenothrin does not display the full spectrum of Type 1 clinical signs in rats and dogs up to the limit dose.

iii. There is qualitative and quantitative evidence of increased susceptibility for d-phenothrin in the rabbit developmental study in the form of spina bifida at doses lower than those causing maternal toxicity. There was no evidence of increased susceptibility in the 2–generation reproduction study in rats. There is low concern for quantitative and qualitative susceptibility observed in the rabbit developmental study because the NOAELs/LOAELs in this study are well characterized and are used to establish the acute Reference Dose (aRfD). The NOAEL (7.1 mg/kg/day) selected for the chronic Reference Dose (cRfD) is lower (14x) than the dose at which developmental effects were observed.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment utilizes proposed tolerance-level or higher residues and assumes 100 PCT for all commodities. Use of screening level dietary assessments ensures that acute and chronic dietary risks will not be underestimated. The Tier 1 drinking water assessment uses model parameters designed to provide conservative, health protective estimates of water concentrations. Post-application exposure to children was assessed using maximum application rates and established exposure assumptions. Based on standard assumptions, most residential scenarios were not of concern (MOEs > 1,000). For those assessments with MOEs < 1,000, a refined probabilistic analysis was carried out and all scenarios passed (all MOEs > 1,000) at the 99th percentile level.

The FQPA 10x SF is to be retained primarily due to the absence of needed acute, subchronic and developmental neurotoxicity studies in conjunction with a finding of increased sensitivity for a neurological effect in the rabbit developmental study. EPA finds that an additional 10x SF will protect the safety of infants and children because the neurotoxic effects were generally not seen in the d-phenothrin toxicity database and when those effects were seen it was at comparatively high doses.

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.

The aggregate risk assessment integrates the assessments conducted for dietary/drinking water and residential exposure. Since there is potential for concurrent exposure via the food, water and residential pathways, all routes of d-phenothrin exposure have been considered.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Acute dietary exposure analysis was performed for the population subgroup females 13–49 years old only. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected for the general population or other population subgroups. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to d-phenothrin will occupy 1.3% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to d-phenothrin from food and water will utilize 13% of the cPAD for children 1–2 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 d-phenothrin is not expected.

3. *Short-term risk*. The short- and itermediate-term aggregate risk is the estimated risk associated with combined risks from average food exposures, average drinking water exposures, incidental oral exposures and inhalation exposures. Exposure from oral and inhalation exposure pathways is not aggregated for d-phenothrin because the toxicity endpoints for these exposure routes are not based on common specific target organ toxicity effects. Aggregate risk from exposure to d-phenothrin residues from food, drinking water and incidental oral exposures do not present risks of concern.

4. *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 d-phenothrin residues.

For more detailed information on non-dietary (residential) exposure, including the use of the AGDISP and CARES models and the NDETF data as part of assessing residential exposure to d-phenothrin, please refer to the document entitled, ''d-Phenothrin (Sumithrin®) Risk Assessment for Reregistration Eligibility Decision (RED) and Associated Section 3 Registration Action,'' dated July 2, 2008, by going to *http://www.regulations.gov*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2008–0140–0024 in that docket. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2008–0140. Double-click on the document to view the referenced information on pages 31–42 of 66.

In addition, for more detailed information on the refinements incorporated as part of the probabilistic assessment of d-phenothrin, please refer to the document entitled, ''d-Phenothrin (Sumithrin®): Addendum to Residential Exposure Assessment,'' dated August 19, 2008, by going to *http://www.regulations.gov*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2008–0140–0029 in that docket. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2008–0140. Double-click on the document to view the referenced information.

IV. Other Considerations

A. Analytical Enforcement Methodology

No multiresidue monitoring protocol data were submitted by the registrant for d-phenothrin. No analytical method was recommended by the registrant for enforcement. However, the United States Food and Drug Administration (FDA) has tested d-phenothrin through their multiresidue protocols. d-Phenothrin is completely recovered through protocol 302, but only 60% remains after florisil cleanup, which is rarely used any more. No additional data are needed from the registrant.

Adequate enforcement methodology is available to enforce the tolerance expression. FDA's Pacific Regional Laboratory Northwest has developed a gas chromatography/mass spectrometry detection (GC/MSD) method that recovers d-phenothrin. 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 currently no established CODEX, Canadian or Mexican maximum residue limits (MRLs) for residues of the insecticide d-phenothrin in or on all food/feed crops following wide-area mosquito adulticide applications.

V. Conclusion

Therefore, tolerances are established for residues of the insecticide d-phenothrin ([(3-phenoxyphenyl)methyl] 2,2-Dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate).

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: June 19, 2009.

Steven Bradbury,

Acting Director, 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 180.647 is added to read as follows:

§ 180.647 d-Phenothrin; tolerances for residues.

(a) *General.* A tolerance of 0.01 parts per million is established for residues of the insecticide d-phenothrin in or on all food/feed crops following wide-area mosquito adulticide applications.

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

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

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

[FR Doc. E9–15937 Filed 7–7–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0478; FRL–8423–6]

Pyrimethanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation replaces existing tolerances for residues of pyrimethanil on fruit, citrus, group 10 postharvest; and fruit, stone, group 12, except cherry with tolerances for residues of pyrimethanil in or on fruit, citrus, group 10, except lemon, postharvest; fruit, stone, group 12; and lemon, preharvest and postharvest. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 8, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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–2008–0478. 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., 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 Bldg.), 2777 S. Crystal Dr., 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: 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 those engaged in the following activities:

- 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 to provide 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 electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite 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 FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those