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, 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) 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 6, 2000) do not apply to this rule. In addition, This 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: December 28, 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 180.571 is amended by alphabetically adding the following commodities in the table in paragraph (a) to read as follows:

§ 180.571 Mesotrione; tolerances for residues.

(a) * * *

Commodity	Parts per million
Berry, group 13	0.01
* * *	* *
Cranberry	0.02
Flax, seed	0.01
Lingonberry	0.01
Millet, grain	0.01
Millet, forage	0.01
Millet, hay	0.02
Millet, straw	0.02

* * * * *

[FR Doc. E8–181 Filed 1–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0268; FRL–8345–8]

Poly(hexamethylenebiguanide) hydrochloride (PHMB); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the insecticide, Poly(hexamethylenebiguanide) hydrochloride (PHMB) on all food when residues are the result of lawful application of a food contact surface sanitizer containing PHMB as a sanitizer solution in food handling establishments when applied as a sanitizer. Arch Chemicals Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of PHMB.

DATES: This regulation is effective January 9, 2008. Objections and requests for hearings must be received on or before March 10, 2008, 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–2005–0268. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either in the electronic docket at *http://www.regulations.gov*, or, if only

available in hard copy, at the Office of Pesticide Programs (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: Adam Heyward, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6422; e-mail address: *heyward.adam@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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 180.940(a) Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions. 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*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by 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–2005–0268 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 March 10, 2008.

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–2005–0268, 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'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 December 21, 2005 (70 FR 75805) (FRL–7745-8), 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 tolerance petition (PP 5F6975) by Arch Chemical Inc.,1955 Lake Park Drive, Suite 100, Smyrna, GA 30080. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Poly(hexamethylenebiguanide) hydrochloride. This notice included a summary of the petition prepared by the petitioner Arch Chemical Inc. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which 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. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

A. Toxic Effects

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 and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The

nature of the toxic effects are discussed in this unit.

There are adequate toxicology data available to characterize the toxicity of PHMB. PHMB is a severe eye irritant and is a moderate dermal irritant and sensitizer. Acute oral, inhalation and dermal toxicity are acute toxicity, category III, which requires the signal word caution to appear on the product label as defined in 40 CFR 156.64(3).

B. Toxic Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (NOAEL) from the toxicology study identified as appropriate for the risk assessment is used to estimate the toxicological level of concern (LOC).

The Agency's level of concern for residential PHMB dermal, inhalation and oral exposures is 100 (i.e. a margin of exposure (MOE) less than 100 exceeds the Agency's level of concern). The level of concern is based on 10x for interspecies extrapolation and 10x for intraspecies variability. A summary of the toxic endpoints for PHMB is listed in the following table.

TABLE 1—TOXICOLOGICAL ENDPOINTS FOR ASSESSING OCCUPATIONAL AND RESIDENTIAL EXPOSURES/RISK*

ExposureScenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	NOAEL = 20 mg/kg/day UF = 100 Acute RfD = 0.2 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF= 0.2 mg/kg/day	Rabbit Developmental Study (MRID 42865901) LOAEL = 40 mg/kg/day based on a reduced number of litters and skeletal abnormalities.
Acute Dietary (General population including infants and children)	No appropriate single dose effect was identified for the general population.		
Chronic Dietary (All populations)	NOAEL = 20 mg/kg/day UF = 100 Chronic RfD = 0.2 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF= 0.2 mg/kg/day	Rabbit Developmental Study (MRID 42865901) LOAEL = 40 mg/kg/day Based on increased mortality, reduced food consumption, and clinical toxicity; Mouse Developmental Study (Report No. CTL/P/335, 1977 (cited in Report No. 003810, 1978. Section C-9)) LOAEL = 40 mg/kg/day Based on reduced body weight gain; and Rat Developmental Study (Report No. CTL/P/1262, 1976 (cited in Report No. 003810, 1978. Section C-11)) LOAEL = 50 mg/kg/day Based on reduced food consumption.
Short-Term Incidental Oral (1-30 days)	NOAEL = 20 mg/kg/day UF = 100	Residential LOC for MOE = 100	Rabbit Developmental Study (MRID 42865901) LOAEL = 40 mg/kg/day Based on the increased mortality, reduced food consumption, and clinical toxicity; Mouse Developmental Study (Report No. CTL/P/335, 1977 (cited in Report No. 003810, 1978. Section C-9)) LOAEL = 40 mg/kg/day;Based on reduced body weight gain; and Rat Developmental Study (Report No. CTL/P/1262, 1976 (cited in Report No. 003810, 1978. Section C-11)) LOAEL = 50 mg/kg/day Based on reduced food consumption.
Intermediate-Term Incidental Oral (1 - 6 months)	NOAEL = 20 mg/kg/day UF = 100	Residential LOC for MOE = 100	See Short-Term Incidental Oral Endpoint
Short-Term, Intermediate-Term and Long-Term Dermal Exposure	Dermal (or oral) study NOAEL= 150 mg/kg/day UF = 100 (Relative dermal absorption rate =100%)	Residential LOC for MOE = 100	80-Week Skin Painting Study – Mouse (MRIDs 00066475 and 00104796) LOAEL = 750 mg/kg/day based on decreased body weight and liver tumors.
Short-Term, Intermediate-Term and Long-Term Inhalation Exposure	An appropriate route-specific inhalation study is not available. The oral endpoint of 20 mg/kg/day with a target MOE of 100 (10x inter-species extrapolation, 10x intra-species variation) is used. An additional 10x route-to-route extrapolation is used to determine if a confirmatory inhalation toxicity study is warranted.		
Cancer (oral, dermal)	EPA has classified PHMB as having suggestive evidence of carcinogenicity but the evidence was too weak to warrant quantification of human cancer risk		

*UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = acute population adjusted dose (a = acute, c = chronic) RfD = reference dose, LOC = level of concern, MOE = margin of exposure

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

PHMB is an antimicrobial that is used as a hard surface sanitizer and may be in or on food processing equipment, premises of food processing plants, milk processing equipment, milk processing plants, eating establishments, food contact surfaces, adhesives, and slurries. The use of PHMB as an antimicrobial product on these various surfaces may result in pesticide residues in human food. Residues from treated surfaces can migrate to food that comes into contact with the treated surfaces which then can result in human ingestion.

1. *Food*. The Agency assessed acute and chronic dietary exposure from the use of PHMB as a disinfectant and food contact sanitizer on direct and indirect food-contact surfaces. This assessment calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI) using an FDA model (''Sanitizing Solutions: Chemical Guidelines for Food Additives Petition, January 1993''). The FDA model takes into account application rates, residual solution, area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight of the population exposed.

To calculate the EDI (estimated daily intake) values for PHMB when it is used as a sanitizer in public eating spaces, it was assumed that PHMB would be used at a concentration of 550 parts per million (ppm), the thickness of the PHMB residues on surfaces would be 1 mg per square centimeter of treated surface, and the surface area of the food contact surface being sanitized to which a person would be exposed on a daily basis is 4,000 cm^2 (which includes contact with treated silverware, china, and glass used by an individual who regularly eats three meals per day at an institutional or public facility). It was also assumed that 100% of the pesticide would migrate to food.

To calculate the EDI (estimated daily intake) values for PHMB when it is used in the food processing industry, it was also assumed to be used at a concentration of 550 ppm. However, specific to this scenario, the exposure estimates were calculated using the milk truck model that is described in the FDA document, ''Sanitizing Solutions: Chemistry Guidelines For Food Additive Petitions.'' This includes the assumption that estimates of sanitary exposure from use in dairy processing plants significantly exceed estimates based on other uses with food processing equipment and utensils. For the purpose of assessing risks stemming from food processing uses, parameters assuming a sanitized milk truck were used as the worst case scenario. The various input parameters, such as the size of the truck, internal surface area, residual thickness, and application rate of PHMB were used to calculate potential residues present in the truck per liter of food (i.e. milk).

For each dietary exposure assessment it was assumed that adults (both male and female) consume 3,000 grams of food a day and a child, 1,500 grams. This allowed for an estimation of the amount of PHMB that is anticipated to be present in an average adult's or child's daily intake from these uses, and in turn, the calculation of a daily dietary dose.

2. *Drinking water exposure*. The uses of PHMB are not expected to significantly contaminate drinking water sources. As provided in the PHMB Reregistration Eligibility Document, ''none of the uses associated with PHMB are expected to impact either surface or ground water resources.'' Therefore, the PHMB contributions for drinking water exposure are considered to be negligible and are not quantified.

B. Other Non-Occupational Exposure

The residential exposure assessment considers all potential non-occupational pesticide exposure, other than exposure due to residues in food or in drinking water. Exposures may occur during and after application as a hard surface disinfectant (e.g. walls, floors, tables, fixtures) and to swimming pools. Each route of exposure is assessed, where appropriate, and risk is expressed as a margin of exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL.

Residential exposure may occur during application of PHMB to indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays) and to swimming pools. The residential handler scenarios were assessed to determine dermal and inhalation exposures. Surrogate dermal and inhalation unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data and the Chemical Manufactures Association Anitmicrobial Exposure Assessment Study (USEPA, 1999) and the SWIMODEL 3.0 was utilized to conduct exposure assessments of pesticides found in swimming pools and spas (Versar, 2003). Note that for this assessment, EPA assumed that residential users complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The duration for most residential exposures is believed to be best represented by short-term duration (1 to 30 days). The short-term duration was chosen for this assessment because the residential handler and post-application scenarios are assumed to be performed on an episodic, not a daily basis.

Based on toxicological criteria and the potential for exposure, the Agency has conducted incidental oral, dermal and inhalation exposure assessments for PHMB residential use. As noted previously, MOEs greater than or equal to 100 are considered adequately protective for the residential exposure assessment.

Specific information on the residential exposure for PHMB can be found at *http://www.regulations.gov*, docket ID No. EPA–HQ–OPP–2005–0268.

V. Cumulative Effects

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 PHMB and any other substances and PHMB 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 PHMB has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

VI. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10x'') 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. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no quantitative or qualitative evidence of increased susceptibility to the fetus following *in utero* exposure to PHMB in the prenatal developmental toxicity studies, and no quantitative or qualitative evidence of increased susceptibility to the offspring when adults are exposed to PHMB in the two-generation reproductive study. In each study, any development/reproductive effect observed occurred at doses equal to or higher than the doses at which maternal toxicity was observed. This, together with the nature of the effects seen in the studies has led the Agency to conclude that there is no evidence of increased susceptibility.

EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1x. That decision is based on the following findings:

i. The toxicity database for Poly(hexamethylenebiguanide) hydrochloride (PHMB) is complete for assessing risk to infants and children under the FFDCA.

ii. There is no indication that PHMB is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. There is no evidence that PHMB results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level residues and will not underestimate the exposure and risk. Conservative ground and surface water modeling estimates were used. Similarly conservative Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by PHMB.

VII. Determination of Safety for U.S. Population, Infants and Children

Safety is assessed for acute and chronic risks by comparing aggregate 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 LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute and chronic risk*. EPA compares the estimated dietary exposures to an aPAD and a cPAD, both of which are 0.2 mg/kg/day for PHMB. Generally, a dietary exposure estimate that is less than 100% of the aPAD or cPAD does not exceed the Agency's levels of concern.

The antimicrobial indirect food use acute/chronic risk estimates from exposure to treated utensils and countertops as well as from food processing facility sanitation are below the Agency's level of concern. For adults females of child bearing age (13 to 49 years old), the cumulative (food utensils and food processing) acute and chronic dietary exposure risk estimates are 18.8% of the acute and chronic PADs. For children ages 3 to 5 years old, the most highly exposed population subgroup, the cumulative chronic dietary risk estimates are 37.2% of chronic PAD (there are no effects anticipated for the acute exposures). Therefore, dietary exposure estimates are below the Agency's level of concern for all population subgroups. Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues. Accordingly, EPA finds that exempting from the requirement of a tolerance will be safe.

2. *Non-occupational risk*. Aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Using the exposure assumptions described in this unit for other non-occupational exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs greater than or equal to 100 for the inhalation route of exposure and 100 for dermal exposure. Therefore, these levels of exposure are not of concern.

3. *Aggregate cancer risk for U.S. population*. EPA has classified PHMB as having no greater than suggestive evidence of carcinogenicity. The weight-of-the-evidence considerations for this classification are as follows:

i. A treatment-related statistically significant increase (trend and pair-wise) in vascular tumors (mainly benign) was seen in female rats at an oral dose that was considered to be adequate, but not excessive. This was considered the strongest evidence on the Agency's evaluation of PHMB.

ii. Oral exposure to male and female mice also resulted in treatment-related vascular tumors seen at an excessive dose. However, at the next highest dose level, which was considered adequate but not excessive, there was a slight, but not statistically significant, increase in this same tumor, which added to the Agency's concern for this tumor type.

iii. It is noted that dermal exposure to female mice resulted in an equivocal increase in vascular tumors seen at only an excessive dose.

iv. No treatment-related increase in any tumors was seen in male rats via the oral route or in male mice via the dermal route of exposure.

Based on the findings above, the Agency has determined that PHMB posed no greater than a negligible cancer risk.

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 PHMB. Accordingly, EPA finds that exempting PHMB from the requirement of a tolerance will be safe.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also

adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA has authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, PHMB may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

B. Analytical Method(s)

An analytical method for food is not needed. Food contact sanitizers are typically regulated by state health departments to ensure that the food industry is using these products in compliance with regulations in 40 CFR 180.940. The end use solution that is applied to the food contact surface is analyzed not food items that may come into contact with the treated surface. An analytical method is available to analyze the use dilution that is applied to food contact surfaces. The solution can be analyzed by use of the spectrophotometric method.

C. Existing Tolerances

There is no existing tolerance or exemption from tolerance for PHMB.

D. International Tolerances

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for any food uses at this time.

VIII. 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 final rule has been exempted from review under Executive Order 12866, 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) 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 6, 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).

IX. 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: December 18, 2007.

Betty Shackleford,

Acting Director, Antimicrobials 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 180.1280 is added to subpart D to read as follows:

§ 180.1280 Poly(hexamethylenebiguanide) hydrochloride (PHMB) exemption from the requirement of a tolerance.

Poly(hexamethylenebiguanide) hydrochloride (PHMB)(CAS Reg. No. 32289–58–0) is exempt from the requirement of a tolerance for residues of the antimicrobial in or on all food commodities when the residues are the result of the lawful application of a food contact surface sanitizer containing PHMB at 550 parts per million (ppm).

[FR Doc. E8–189 Filed 1–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0300; FRL–8346–3]

Zeta-cypermethrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of zeta-cypermethrin and its inactive R-isomers in or on Citrus (dried pulp, fruit and oil); oilseed commodities (seeds of borage, castor oil plant, Chinese tallow tree, crambe, cuphea, echium, euphorbia, evening primrose, flax, gold of pleasure, hare's-ear mustard, jojoba,