

determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have substantial direct effect on one or more Indian tribes, 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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office

of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction, from further environmental documentation considering that it relates to the promulgation of operating regulations or procedures for drawbridges. Under figure 2–1, paragraph (32)(e), of the instruction, an “Environmental Analysis Check List” and a “Categorical Exclusion Determination” are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

■ For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Section 117.217 is amended by revising paragraph (a) to read as follows:

§ 117.217 Norwalk River.

(a) The draw of the Washington Street S136 Bridge, mile 0.0, at Norwalk, shall operate as follows:

(1) The draw shall open on signal; except that, from 7 a.m. to 8:45 a.m., 11:45 a.m. to 1:15 p.m., and 4 p.m. to 6 p.m., Monday through Friday, except holidays, the draw need not be opened for the passage of vessels that draw less than 14 feet of water.

(2) The draw need not open for the passage of vessel traffic, from 10 a.m. to 12 p.m., on the first Saturday in December, to facilitate the running of the annual Norwalk River Fun Run. Should inclement weather force the postponement of the race the above bridge closure shall be implemented the next day, the first Sunday after the first Saturday in December, from 10 a.m. to 12 p.m.

(3) The bridge opening signal is three short blasts. Vessels drawing 14 feet of water or more shall add one prolonged blast after the three short blasts.

* * * * *

Dated: August 20, 2007.

Timothy S. Sullivan,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. E7–17567 Filed 9–5–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0572; FRL–8146–7]

Residues of Quaternary Ammonium Compounds di-n-Alkyl (C₈₋₁₀) dimethyl Ammonium chloride, Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends 40 CFR 180.940(a), the exemption from the requirement of a tolerance for residues of Quaternary Ammonium Compounds, di-n-Alkyl (C₈₋₁₀) dimethyl ammonium chloride, average molecular weight (in amu) 332 to 361 on food contact surfaces when applied/used in public eating places, dairy processing equipment, and food-processing equipment and utensils by increasing the allowable use solution concentrations of quaternary compounds. Lonza Inc. submitted a petition to EPA under the Federal Food,

Drug, and Cosmetic Act requesting an increase in the concentrations of quaternary compounds in end-use products eligible for the exemption. As amended, the regulation will exempt solutions from the requirement of a tolerance residues resulting from contact with surfaces treated with solutions where the end use concentration of the specific quaternary compounds does not exceed 240 parts per million (ppm) of active quaternary ammonium compounds, and the end-use concentration of all quaternary chemicals in the solution does not exceed 400 ppm of active quaternary compound.

DATES: This regulation is effective September 6, 2007. Objections and requests for hearings must be received on or before November 5, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0572. 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 web site 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 Building), 2777 S. Crystal Drive 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 telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Velma Noble, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(703) 308-6233; e-mail address: noble.velma@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 *Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)*, paragraph (a). 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 the FFDCFA, as amended by the Food Quality Protection Act (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-2006-0572 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 November 5, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0572, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of October 25, 2006 (71 FR 62458) (FRL-8099-6), EPA issued a notice pursuant to section 408(d)(3) of the FFDCFA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6F7045) by Lonza, Inc, 90 Boroline Rd, Allendale, NJ 07401. The petition requested that 40 CFR 180.940(a) be amended by increasing concentration limits for aliphatic alkyl quaternary compounds in end-use solutions eligible for the tolerance exemption for Quaternary Ammonium compounds: Di-n-Alkyl (C₈₋₁₀) dimethyl ammonium chloride, average molecular weight (in amu) 332 to 361) on food contact surfaces in public eating places, dairy processing equipment, and food

processing equipment and utensils from 150 ppm to 240 ppm and the total end use concentration of all quaternary chemicals in solution from 200 ppm to 400 ppm. The notice referenced a summary of the petition prepared by Lonza Inc., 90 Boroline Rd Allendale, NJ 07401, the registrant, which is available to the public in the docket at www.regulations.gov, Docket ID Number EPA-HQ-OPP-2006-0572. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the 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) 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), 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), 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 caused by the Aliphatic Alkyl Quaternaries are discussed in this unit.

The Aliphatic Alkyl Quaternaries are corrosive, highly irritating to the eye and skin, with moderate acute toxicity by oral, dermal, and inhalation routes of exposure. These chemicals are classified as "not likely" to be a human carcinogen based on a negative carcinogenicity study in rats and mice feeding studies using doses above the limit. There is no evidence of these chemicals being associated with increased susceptibility to developmental toxicity or reproductive toxicity based on two developmental toxicity studies and a two-generation reproductive study. Lastly, they are negative for mutagenicity and neurotoxicity. Specific information on the studies received and the nature of the toxic effects caused by Di-n-Alkyl (C₈₋₁₀) dimethyl ammonium chloride, average molecular weight (in amu) 332 to 361 (DDAC) 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>;

Docket ID Number EPA-HQ-OPP-2005-0338; *Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision (RED)*

for Didecyl Dimethyl Ammonium Chloride (DDAC).

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). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in variations in sensitivity among members of the human population as well as other unknowns.

The Agency's level of concern (LOC) for residential Aliphatic Alkyl Quaternaries' 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 extrapolation. However, the uncertainty factor or "target" MOE for Aliphatic Alkyl Quaternaries' dermal exposures is 10 for residential scenarios. The target MOE was chosen because the established endpoint is for dermal irritation, not a systemic toxic effect. In addition, dermal irritation is considered a reversible and short-term effect, thus supporting a 10x uncertainty factor (half a log (10.5) or approximately 3x for interspecies extrapolation and half log (10.5) or approximately 3x for intraspecies variation). It should be noted that the determination to reduce the 100x UF to 10X UF for irritation endpoints is made on a case-by-case basis.

Aliphatic Alkyl Quaternaries toxicological endpoint summary is listed in the following table.

TABLE 1.—SUMMARY OF TOXICOLOGICAL ENDPOINTS FOR DDAC

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE/UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50) NOAEL (developmental) = 10 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Parenatal Developmental Toxicity - Rat MRID 41886701 LOAEL = 20 mg/kg/day based on increased incidence of skeletal variations.	

TABLE 1.—SUMMARY OF TOXICOLOGICAL ENDPOINTS FOR DDAC—Continued

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE/UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population)	An acute dietary endpoint was not identified in the data base. This risk assessment is not required		
Chronic Dietary (general population)	NOAEL = 10 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Chronic Toxicity Study - Dog MRID 41970401 LOAEL = 20 mg/kg/day based on increased incidence of clinical signs in males and females and decreased total cholesterol levels in females
Chronic RfD = 0.1 mg/kg/day			
Incidental Oral (Short-Term)	NOAEL (developmental) = 10 mg/kg/day	Target MOE = 100 (10x inter-species extrapolation, 10x intra-species variation) FQPA SF = 1	Prenatal Developmental Toxicity - Rat MRID 41886701 LOAEL = 20 mg/kg/day based on increased incidence of skeletal variations.
Incidental Oral (Intermediate-Term)	NOAEL = 10 mg/kg/day	Target MOE = 100 (10x inter-species extrapolation, 10x intra-species variation) FQPA SF = 1	Chronic Toxicity Study - Dog MRID 41970401 LOAEL = 20 mg/kg/day based on increased incidence of clinical signs in males and females and decreased total cholesterol levels in females.
Dermal, Short-term (formulated product 0.13% a.i.)	No endpoint identified. No dermal or systemic effects identified in the 21-day dermal toxicity study (MRID 45656601) up to and including the limit dose of 1,000 mg/kg/day		
Dermal, Short-term ^a	NOAEL (dermal) = 2 mg/kg/day (8 µg/cm ²)	Target MOE = 10 (3x inter-species extrapolation, 3x intra-species variation)	90-day Dermal Toxicity - Rat MRID 41305901 LOAEL = 6 mg/kg/day based on increased clinical and gross findings (erythema, edema, exfoliation, excoriation, and ulceration)
Dermal, Intermediate- and Long-term	No appropriate endpoint identified		
Inhalation, Short-Term	NOAEL ^b = 10 mg/kg/day	Target MOE = 100 (10x inter-species extrapolation, 10x intra-species variation) FQPA SF = 1	Prenatal Developmental Toxicity - Rat MRID 41886701 LOAEL = 20 mg/kg/day based on increased incidence of skeletal variations.
Inhalation, Intermediate- and Long-Term	NOAEL ^b = 10 mg/kg/day	Target MOE = 100 (10x inter-species extrapolation, 10x intra-species variation) FQPA SF = 1	Chronic Toxicity Study - Dog MRID 41970401 LOAEL = 20 mg/kg/day based on increased incidence of clinical signs males and females and decreased total cholesterol levels in females.

UF = uncertainty factor, FQPA SF = special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = Level of concern, NA = Not Applicable.

^a Short-term dermal endpoint = (2 mg/kg rat x 0.2 kg rat x 1,000 µg/mg) ÷ 50 cm² area of rat dosed = 8 µg/cm².

^b An additional UF of 10x is used for route extrapolation from an oral endpoint to determine if a confirmatory study is warranted.

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

Aliphatic Alkyl Quaternaries are used as a sanitizer on counter tops, utensils, appliances, tables, refrigerators, food packaging, and beverage bottling. The use of Aliphatic Alkyl Quaternaries as

an antimicrobial product on food or feed contact surfaces, agricultural commodities, and application to food-grade eggs may result in pesticide residues in human food. Residues from treated surfaces, such as utensils, countertops, equipment, and appliances can migrate to food coming into contact with the treated and rinsed surfaces and can be ingested by humans.

1. *Food.* The Agency assessed acute and chronic dietary exposure from the use of Aliphatic Alkyl Quaternaries 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 (2003). 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.

The EDI calculations presented in this assessment are based on the assumption that food can contact 2,000 cm² of treated surface per day (which represents contact with a treated countertop surface area), 4,000 cm² of treated surface per day (which represents contact with treated silverware, china, and glass used by an individual who regularly eats three meals per day at an institutional or public facility), or 6,000 cm² of treated surface per day (which represents treated countertops, silverware, china,

and glass by an individual who regularly eats three meals per day at an institutional or public facility). It also assumes that 10% of the pesticide would migrate to food.

When assessing the food bottling/packaging use, EPA assumed a 100% transfer rate because the food is potentially in contact with the treated surfaces for very long periods of time. The maximum application rate for Aliphatic Alkyl Quaternaries for bottling/packaging of food is 0.0020 lbs active ingredient (a.i) per gallon of treatment solution. EDI values were calculated using an approach similar to that used for treated food-contact surfaces and food utensils. Exposure was assumed to occur through the ingestion of three food products that might be packaged with treated material: milk, egg products, and beverages (alcoholic and non-alcoholic). A calorie intake modification factor of 0.64 was applied to the EDI for a child to account for the differences between intake values among children and adults.

2. *Drinking water exposure.* The only Aliphatic Alkyl Quaternaries outdoor uses are an algacide in decorative/swimming pools, antisapstain wood preservative treatment, once-through cooling tower treatment, and oil field uses. The pond and oil field uses are considered to be contained. The other uses are not expected to significantly contaminate drinking water sources. Therefore, the Aliphatic Alkyl Quaternaries contributions for drinking water exposure are considered to be negligible and are not quantified.

It should be noted that the Agency estimated concentrations for exposure to aquatic animals resulting from the antisapstain and cooling tower uses. These levels were not considered appropriate for use in the drinking water assessment due to the very conservative nature of the models used, that the model estimates runoff/point source concentrations and not water body concentrations, and the fact that the models does not account for dilution.

Specific information on the dietary and drinking water exposure assessments for Aliphatic Alkyl Quaternaries can be found at <http://www.regulations.gov>; Docket ID Number EPA-HQ-OPP-2006-0338; *Dietary Risk Assessment on DDAC and Tier 1 Drinking Water Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC); Didecyl Dimethyl Ammonium Chloride (DDAC).*

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 surfaces disinfectant (e.g., walls, floors, tables, fixtures), to textiles (e.g., clothing, diapers) to swimming pools and to carpets. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a MOE, which is the ratio of estimated exposure to an appropriate NOAEL.

Residential exposure may occur during the application of Aliphatic Alkyl Quaternaries to indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays), carpets, swimming pools, wood as a preservative, textiles (e.g., diapers treated during washing and clothes treated with fabric spray), and humidifiers. The residential handler scenarios were assessed to determine dermal and inhalation exposures. Surrogate dermal and inhalation unit exposure values were estimated using data from the Pesticide Handler Exposure Database (PHED) and the Chemical Manufactures Association Antimicrobial 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 the 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 daily basis.

Based on toxicological criteria and the potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for Aliphatic Alkyl Quaternaries residential use. As noted previously, MOEs greater than or equal to 100 for the inhalation route of exposure and 10 for dermal exposure are considered adequately protective for the residential exposure assessment.

Specific information on the residential exposure assessment for Aliphatic Alkyl Quaternaries can be found at <http://www.regulations.gov>; Docket ID Number EPA-HQ-OPP-2006-0338; *Didecyl Dimethyl Ammonium Chloride (DDAC)*

Occupational and Residential Exposure Assessment.

V. Cumulative Effects

Another factor EPA must consider in making a section 408 reasonable certainty of no harm determination is any "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

The Aliphatic Alkyl Quaternaries are a group of structurally similar quaternary ammonium compounds that are characterized by having a positively charged nitrogen covalently bonded to two alkyl group substituents (at least one C₈ or longer) and two methyl substituents. In finished form, these quats are salts with the positively charged nitrogen (cation) balanced by a negatively charged molecule (anion). The anion for the quats in this cluster is chloride or bromide. Didecyl dimethyl ammonium chloride, or DDAC, was chosen as the representative chemical for this class in PR notice 88-2. On that basis, the toxicology database for DDAC is accepted as representative of the hazard for this class of quaternary ammonium compounds. However, the toxicologic responses observed from animal toxicity studies with DDAC are generalized responses to treatment and are difficult to attribute to any one mechanism.

EPA's risk assessment for the Group I Cluster is based on an assessment of the cumulative exposure to all aliphatic alkyl quaternary compounds. The individual exposure scenarios in the DDAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that a DDAC compound was used on 100 percent of the surfaces authorized on the label that could result in human exposure and summing the percent active ingredients on the labels for all of the aliphatic alkyl quaternary compounds when used in combination. Thus, because the risk assessment for DDAC accounts for exposures to all of the aliphatic alkyl quaternary compounds, there is no need for a separate cumulative risk assessment for those compounds. The Agency has not identified any other substances as sharing a common mode of toxicity with DDAC.

VI. Safety Factor for Infants and Children

1. *In general.* Section 408 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 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 evidence that Aliphatic Alkyl Quaternaries result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

3. *Conclusion.* 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 Aliphatic Alkyl Quaternaries is complete for assessing risk to infants and children under the FFDCa.

ii. There is no indication that Aliphatic Alkyl Quaternaries are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. There is no evidence that Aliphatic Alkyl Quaternaries result 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. Although EPA may, in the future, refine exposure estimates for Aliphatic Alkyl Quaternaries based on more sophisticated modeling techniques, the current exposure assessment is based on a combination of conservative assumptions that is likely to overstate exposure from food to Aliphatic Alkyl Quaternaries.

VII. Aggregate Risks and Determination of Safety

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, 0.1 mg/kg/day, which are the same value for the aliphatic alkyl quaternaries. 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 are below the Agency's level of concern. For adults, the acute and chronic dietary exposure risk estimates are 3.32% of the aPAD and cPAD for adult females of child bearing age (13 to 50), the highly exposed adult group. For children ages 3 to 5, the most highly exposed population subgroup, the acute and chronic dietary risk estimates are 13.3% of the aPAD and cPAD. Therefore, dietary exposure estimates are below the Agency's level of concern for all population subgroups. The antimicrobial indirect food use acute/chronic risk estimates from exposure to treated food packaging and beverage bottles are below the the Agency's level of concern. Neither the percent aPAD or percent cPAD values exceeded 100% and are not of concern.

Specific information on the dietary exposure assessment for Aliphatic Alkyl Quaternaries can be found at <http://www.regulations.gov>; Docket ID Number EPA-HQ-OPP-2006-0338; *Dietary Risk Assessment on DDAC*.

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 10 for dermal exposure; therefore, are not of concern.

3. *Aggregate cancer risk for U.S. population.* Based on the carcinogenic data, the EPA concludes that there is reasonable certainty that Aliphatic Alkyl Quaternaries do not pose an aggregate cancer risk to the U. S. population.

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 Aliphatic Alkyl Quaternaries residues.

VIII. 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 recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a 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 FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCa 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 appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruption Screening Program (EDSP) have been developed, the Aliphatic Alkyl Quaternaries (DDAC) 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 the 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. A titration method is used to determine the total amount of quaternary compound. If the use solution is a mixture of DDAC and alkyl dimethyl benzyl ammonium chloride (ADBAC), then High Performance Liquid Chromatography using Ultra

Violet Detection (HPLC-UV) is used to determine the amount of ADBAC. The amount of DDAC is determined by calculating the difference between the total amount of quaternary compounds and ADBAC.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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).

X. 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, Food contact sanitizers, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 29, 2007.

Frank Sanders,

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 180.940 is amended by revising the following entry to the table in paragraph (a):

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *
(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
*	* * *	* * *
Quaternary Ammonium Compounds, Di-n-Alkyl (C ₈₋₁₀) dimethyl ammonium chloride, average molecular weight (in amu) 332 to 361	None	When ready for use, the end-use concentration of these specific in quaternary ammonium compounds is not to exceed 240 ppm of active quaternary ammonium compound; the end-use concentration of all quaternary chemicals in the solution is not to exceed 400 ppm of active quaternary compound.
*	* * *	* * *

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Chapter 2

RIN 0750-AF56

Defense Federal Acquisition Regulation Supplement; Emergency Acquisitions (DFARS Case 2006-D036)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has adopted as final, without change, an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to provide a single reference to DoD-unique acquisition flexibilities that may be used to facilitate and expedite acquisitions of supplies and services during emergency situations.

EFFECTIVE DATE: September 6, 2007.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Benavides, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301-3062. Telephone (703) 602-1302; facsimile (703) 602-7887. Please cite DFARS Case 2006-D036.

SUPPLEMENTARY INFORMATION:

A. Background

DoD published an interim rule at 72 FR 2631 on January 22, 2007, to provide a single reference to the acquisition flexibilities that may be used to facilitate and expedite DoD acquisitions of supplies and services during emergency situations. The rule supplements the Governmentwide acquisition flexibilities found in Part 18 of the Federal Acquisition Regulation.

DoD received no comments on the interim rule. Therefore, DoD has adopted the interim rule as a final rule without change.

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*,

because the rule is a compilation of existing authorities, and makes no change to DoD contracting policy.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply, because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Chapter 2

Government procurement.

Michele P. Peterson,
Editor, Defense Acquisition Regulations System.

Chapter 2—Amended

Interim Rule Adopted as Final Without Change

■ Accordingly, the interim rule amending 48 CFR Chapter 2, which was published at 72 FR 2631 on January 22, 2007, is adopted as a final rule without change.

[FR Doc. E7-17432 Filed 9-5-07; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202 and 252

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is making technical amendments to the Defense Federal Acquisition Regulation Supplement (DFARS) to update the list of Air Force and Navy contracting activities and to remove obsolete text.

EFFECTIVE DATE: September 6, 2007.

FOR FURTHER INFORMATION CONTACT: Ms. Michele Peterson, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301-3062. Telephone (703) 602-0311; facsimile (703) 602-7887.

SUPPLEMENTARY INFORMATION: This final rule amends DFARS text as follows:

- *Section 202.101.* Updates the list of Air Force and Navy contracting activities.
- *Section 252.219-7009.* Removes an obsolete date within a reference to a

partnership agreement between DoD and the Small Business Administration.

List of Subjects in 48 CFR Parts 202 and 252

Government procurement.

Michele P. Peterson,
Editor, Defense Acquisition Regulations System.

■ Therefore, 48 CFR Parts 202 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR Parts 202 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR chapter 1.

PART 202—DEFINITIONS OF WORDS AND TERMS

■ 2. Section 202.101 is amended in the definition of “Contracting activity” as follows:

- a. In the list with the heading “NAVY”, by removing “Deputy, Acquisition Management, Office of the Assistant Secretary of the Navy (Research, Development, and Acquisition)” and adding in its place “Office of the Deputy Assistant Secretary of the Navy (Acquisition & Logistics Management)”; and
- b. By revising the list with the heading “AIR FORCE”.

The revised list reads as follows:

202.101 Definitions.

* * * * *

AIR FORCE

- Office of the Assistant Secretary of the Air Force (Acquisition)
- Office of the Deputy Assistant Secretary (Contracting)
- Air Force District of Washington
- Air Force Operational Test & Evaluation Center
- Air Force Special Operations Command
- United States Air Force Academy
- Air Force Materiel Command
- Air Force Reserve Command
- Air Combat Command
- Air Mobility Command
- Air Education and Training Command
- Pacific Air Forces
- United States Air Forces in Europe
- Air Force Space Command
- Program Executive Office for Aircraft Systems
- Program Executive Office for Command and Control & Combat Support Systems
- Program Executive Office for Combat and Mission Support
- Program Executive Office for F/A-22 Programs
- Program Executive Office for Joint Strike Fighter