rule, we also requested comments on its collection of information provisions.

The rule's § 169.215 of 33 CFR requires ships to transmit position reports using long range identification and tracking (LRIT) equipment that has been type-approved by their Administration. Its § 169.230 of the same title requires ships' LRIT equipment to transmit position reports at 6-hour intervals unless a more frequent interval is requested remotely by an LRIT Data Center. And its § 169.245 requires a ship's master to inform his or her Flag Administration without undue delay if LRIT equipment is switched off or fails to operate. The master must also make an entry in the ship's logbook that states his or her reason for switching the LRIT equipment off, or an entry that the equipment has failed to operate, and the period during which the LRIT equipment was switched off or non-operational.

The LRIT NPRM and final rule are available electronically through the docket (USCG–2005–22612) at *www.regulations.gov*. On August 12, 2008, under 44 U.S.C. 3505(c), OMB approved the collection of information associated with the requirements in §§ 169.215, 169.230, and 169.245 of the LRIT final rule under OMB control number 1625–0112. A copy of the OMB notice of action is available in our online docket.

Dated: August 15, 2008.

Howard L. Hime,

Acting Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. E8–19307 Filed 8–19–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0573; FRL–8376–9]

Residues of Quaternary Ammonium Compounds, N-Alkyl (C_{12-18}) dimethyl benzyl ammonium chloride on Food Contact Surfaces; 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 n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride (CAS No. 68424–85–1) on food contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. The regulation will exempt from the requirement of tolerance residues in food resulting from contact with surfaces treated with antimicrobial solutions where the end-use concentration of active quaternary compound does not exceed 400 ppm.

DATES: This regulation is effective August 20, 2008. Objections and requests for hearings must be received on or before October 20, 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–2006–0573. 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: Velma Noble, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6416; 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 dairy cattle milk producer, food manufacturer, or beverage manufacturer. Potentially affected entities may include, but are not limited to:

- Dairy Cattle Milk Production (NAICS code 11212).
- Food manufacturing (NAICS code 311).
- Beverage Manufacturing (NAICS code 3121).

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

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

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

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–2006–0573. 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 October 20, 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–2006–0573., 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. Petition for Exemption

In the **Federal Register** of November 28, 2007 (72 FR 67299) (FRL–8141–1), 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 6F7071) by Edwards-Councilor Co., Inc, 1427 Baker Road Virginia Beach, VA 23455. The petition requested that 40 CFR 180.940(a) be amended by increasing concentration limits for n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride in end-use solutions eligible for tolerance exemption. That notice referenced a summary of the petition prepared by Edwards-Councilor Co., Inc, 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.

Based upon review of the data supporting the petition, EPA has created a new exemption n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride (CAS No. 68424–85–1) instead of amending the current exemption for the sake of clarity. The reason for this change is explained in Unit IV.B.

III. Aggregate Risk Assessment and Determination of Safety

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 . . . .''

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in section 408(c)(2)(B) 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 exemption from the requirement for a tolerance for residues of alkyl (C_{12-18}) dimethyl benzyl ammonium chloride on food contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. EPA's assessment of exposures and risks associated with amending the exemption from the requirement for a tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by alkyl (C_{12-18}) dimethyl benzyl ammonium chloride as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The alkyl dimethyl benzyl ammonium chlorides(ADBAC) chemical case is comprised of 24 compounds that are structurally similar quaternary ammonium compounds (quats) that are characterized by having a positively charged nitrogen covalently bonded to three alkyl group substituents (two methyls and R component) and a benzyl substituent. The R component represents the different number of hydrocarbon carbon moieties delineated by different percentages (i.e. Alkyl (50% $C_{14,}$ 40% $C_{12,}$ 10% C_{16}) dimethyl benzyl ammonium chloride. In finished form, these quats are salts with the positively charged nitrogen (cation) balanced by a negatively charged anion. The most common anion for the quats in this cluster is chloride. However, other anions, such as saccharide and bromide are also used. The Agency clustered these chemicals together because variance in the length and conformation of alkyl carbon chains between 12 and 18 does not appear to significantly affect the toxicity or fate of ADBAC compound.

In all ADBACs, it is the positive entity (quaternized nitrogen) that is of relevance from toxicology and exposure perspectives. The negative part of ADBAC (counter ion) is a relatively non-toxic entity (chloride). Alkyl (50% $C_{14,}$ 40% $C_{12,}$ 10% C_{16}) dimethyl benzyl ammonium chloride (PC code 069105) was chosen by the Agency as the representative chemical for Group II, ADBAC, and the toxicology database for PC code 069105 is being considered representative of the hazard for the ADBAC class of quaternary ammonium compounds. The individual exposure scenarios in the ADBAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that an ADBAC 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 (a.i.) on the labels for all of the ADBAC compounds when used in combination.

ADBACs 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 human carcinogens based on negative carcinogenicity studies in both rats and mice. 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 2–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 ADBAC, can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2005–0339, *Alkyl dimethyl benzyl ammonium chloride (ADBAC)- Report of Antimicrobials Division Toxicity*

Endpoint Committee (ADTC) and the Hazard Identification Assessment Review Committee (HIARC).

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 highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (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. The Level of Concern (LOC) is a reference value expressed as either a reference dose/population adjusted dose (RfD/PAD) or margin of exposure (MOE). 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 uncertainty/safety factors. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing 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.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of a cancer occurrence greater than that expected in a lifetime. Generally, cancer risks are considered non-threshold. 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 ADBAC used for human risk assessment is shown in the Table in this unit.

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ADBAC FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General pop., females 13+, infants and children)	An acute dietary endpoint was not identified in the database.		
Chronic dietary (All populations)	NOAEL = 44 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.44 mg/kg/day cPAD = 0.44 mg/kg/day	Chronic toxicity/ carcinogencity-rat MRID 41947501 LOAEL = 88 mg/kg/day based on decreased body weight and weight gain
Incidental oral short-term (1 to 30 days)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity-Rat MRID 42351501 LOAEL = 30 mg/kg/day based on clinical signs and decrease body weight gain
Incidental oral intermediate-term (1 to 6 months)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity-Rat MRID 42351501 LOAEL = 30 mg/kg/day based on clinical signs and decrease body weight gain
Dermal short-term (1 to 30 days) (Formulated product (4% ai.))	Dermal study NOAEL = 20 mg/kg/day (333 $\mu g/cm^2$)[b] UF_A = 3 x UF_H = 3x FQPA SF = 1x	LOC for MOE = 10 [d]	21–day dermal toxicity-guinea pigs MRID 41105801 LOAEL = 40 mg/kg/day based on denuded non-vascularized epidermal layer
Dermal intermediate-term (technical grade a.i.) (1 to 6 months)	Dermal study NOAEL = 20 mg/kg/day (80 $\mu g/cm^2$)[c] UF_A = 3 x UF_H = 3x FQPA SF = 1x	LOC for MOE = 10 [d]	90–day dermal in rats MRID 41499601 LOAEL = 20 mg/kg/day based on highest doest tested before irritation became significant. Irritation not observed until day 43
Dermal Short-term (technical grade a.i)	No endpoint identified from the available data on dermal irritation. Dermal irritation in the 90–day dermal toxicity study was not evident until day 43 (MRID 41499601)[d]		
Long-Term Dermal (technical grade a.i.)	No appropriate endpoint identified. No systemic effects observed up to 20 mg/kg/day, highest dose of technical that could be tested without irritation effects.[d]		

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ADBAC FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Inhalation (all exposures)	Oral study NOAEL = 3 mg/kg/day 100%) UF_A = 10x UF_H = 10 x UF =10x[a] FQPA SF = 1x	LOC for MOE = 1,000	Developmental Toxicity-rabbit MRID 42392801 LOAEL = 9 mg/kg/day based on clinical signs of toxicity in maternal animals

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

[a] An additional uncertainity factor of 10x is applied for use of an oral endpoint for route-to-route extrapolation to determine if a confirmatory inhalation toxicity study is warranted.

[b] Formulated-based dermal endpoint = (20 mg/kg guinea pig x 0.43 kg guinea pig x 1,000 μg/mg)/ 25.8 cm^2 area of guinea pig dosed = 33 μg/cm^2.

[c] TGAI-based dermal endpoint = (20 mg/kg rat x 0.2 kg rat x 1,000 μg/mg)/ 50 cm^2 area of rate dosed = 80 μg/cm^2.

[d] For dermal exposures, irritation as the effect was selected for the short-term endpoint and a reduced margin of exposure (MOE) was used to characterize the risk. The use of irritation as a toxic endpoint for assessment of dermal risk is appropriate in this case, as dermal exposure that results in primarily an irritation response is considered a self-limiting type of exposure that is not expected to last for any length of time, and variability in the response is not expected to be as great as systemic toxic responses. For ADBAC, the MOE for short-term dermal risk is reduced to a total factor of 10x(3x for interspecies extrapolation, 3x for intraspecies variation

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to n-Alkyl (C_{12-18}) Dimethyl Benzyl Ammonium Chloride, EPA considered exposure under the petitioned-for exemption as well as all existing ADBAC exemptions or tolerances in (40 CFR 180.940(a), and (c)). EPA assessed dietary exposures from ADBAC in food as follows:

ADBACs are to be used as a sanitizer on counter tops, utensils, appliances, tables, refrigerators, food packaging, and beverage bottling. The use of these actives in antimicrobial products for use 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.

The Agency assessed chronic dietary exposures from the use of ADBAC as a disinfectant and food contact sanitizer on utensils, countertops, and in food/ beverage processing facilities. The assessment calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI) using modified FDA methodologies for utensils and Indirect Dietary Residential Exposure Model software (IDREAM) for countertops. IDREAM incorporates consumption data from USDA's Continuing Surface of Food Intakes by Individuals (CSFII) for 1994–1996, and 1998. The 1994–1996, and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days.

The Estimated Daily Intake (EDI) calculations presented in this assessment for treated indirect dietary exposures resulting from sanitizing utensils assumed that food would contact 4,000 cm^2 (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) and that the residual solution remaining on the surface or pesticide migration fraction is 1 milligram (mg) per square centimeter of treated area. The body weights used for this assessment were 70 kilogram (kg) for an adult male, 60 kg for an adult woman, and 10 kg for an infant. Based on data provided in a new residue study, Transferability Equivalence among Quats and Measured Food Surrogate Transfer Efficiency (MRID 46870703), a conservative transfer rate of 43% was used to estimate the amount of residues on the surface that will be transferred to food and subsequently ingested. The maximum application rate for ADBAC on utensils is 0.0033 lbs a.i per gallon of treatment solution.

There are two levels of refinement for assessing dietary exposure to antimicrobial products used on countertops. The three dimensional approach, Tier 2, was utilized for this assessment. This conservative approach uses food consumption and preparation patterns as well as data and assumptions that are not chemical specific. Food ingredients are separated into nine categories based on food preparation, food physical properties, and potential, or likelihood of contact with treated countertops. The nine food categories are liquids, fruit, bread, cheese, vegetable, meat, purees (e.g., pudding, oatmeal), pieces (foods normally consumed in small pieces), and powders (foods normally used in powder/granular forms). Assumed countertop residues are converted to estimated residues contacting the countertops using a translation factor for each food category, and default residue transfer efficiency for a representative food. Therefore, IDREAM combines the estimated countertop residues for surface treatment products, CSFII consumption data, food-specific conversion factors that relate the surface area contacting a countertop with corresponding weight of the food item, and the transfer efficiency of residues from countertops to food. Conservative assumptions for these analyses include: All disinfectants registered to disinfect kitchen countertops are included; all foods are prepared on treated countertops; all prepared foods will come in contact with treated countertops at the maximum active ingredient residues; these residues will not diminish over time (i.e. residue reduction will not occur from cooking or preparation processes); there is a 100% likelihood of contact to account for both commercial and residential scenarios; all commercial facilities and households use the same disinfectant product; all foods are prepared and consumed.

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 ADBAC for bottling/packing of food is 0.0103 lbs a.i per gallon of treatment solution. EDI values were calculated

using an approach similar to that used for treated food utensils. Exposure was assumed to occur through the ingestion of three food products that might be packaged in 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. The calculated % cPADs for all population subgroups do not exceed 100% and therefore are not of a concern.

2. *Dietary exposure from drinking water.* ADBAC is applied to nursery ornamentals and turf as an bactericide and fungicide. The Tier 1 surface water and ground water model was used to assess Estimated Drinking Water Concentrations (EDWCs). EPA modeled the ornamental plant use because this use has the highest application rate of all labeled uses — 302 lbs. a.i/Acre, and a maximum of three applications per year. The EDWCs determined for the nursery ornamental use are also protective of all other uses with lower application rates. The EDWC for surface water is 331 microgram/Liter (µg/L) and ground water is 5.4 µg/L. There were no major degradates of ADBAC in the laboratory studies.

ADBAC is also used for mosquito control and as an algaecide in decorative ponds and pools. Because the mosquito control and algaecide uses are both periodic in nature and are restricted to a limited use area, EPA expects drinking water exposures from these uses to be minimal in comparison to the ornamental plant exposure estimate for drinking water using the tier I surface and ground water model. Additionally, antisapstain and cooling water tower uses for ADBAC are potential exposures to drinking water. These uses are also expected to result in minimal exposure in comparison to the modeled EDWCs for the ornamental use taking into account that the Tier 1 model assumed that ADBAC was applied at 302 pounds/acre across the entire watershed.

Specific information on the dietary and drinking water exposure assessments for ADBAC can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0339 *Dietary Risk Assessment on ADBAC and Tier 1 Drinking Water Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) and Didecyl Dimethyl Ammonium Chloride (DDAC).*

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

ADBAC is currently registered for the following residential non-dietary sites: Homes, swimming pools, humidifiers. EPA assessed residential exposure using the following assumptions: Residential exposure may occur during the application as well as post application of ADBAC to indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays), carpets, swimming pools, wood as a preservative, textiles (e.g., diaper treated during washing and clothes treated with fabric spray), and humidifiers. The residential handler scenarios were assessed to determine dermal and inhalation exposures. Residential post application scenarios such as children exposure to treated toys and floors were also assessed to determine dermal and incidental oral exposures. Surrogate dermal and inhalation unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data 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.

Specific information on the residential exposure assessment for ADBAC Quaternaries can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0339 *Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational and Residential Exposure Assessment.*

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.''

EPA's risk assessment for any individual ADBAC is based on an assessment of the cumulative exposure to all ADBACs. The individual exposure scenarios in the ADBAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that an ADBAC 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 ADBACs when used in combination. Thus, because the risk assessment for ADBAC accounts for exposures to all of the ADBACs, 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 ADBAC. 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 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 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 SF. 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 SF value based on the use of traditional UFs and/or FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence that ADBAC result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–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 SF to 1X. That decision is based on the following findings:

i. The toxicity database for ADBAC pertaining to the risks to infants and childrenis complete.

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

iii. There is no evidence that ADBAC results in increased susceptibility in *in utero* rats or rabbits in the prenatal

developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. Conservative ground water and surface water modeling estimates were used. Similarly conservative residential standard operating procedures (SOPs) were used to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by ADBAC.

E. Aggregate Risks and Determination of Safety

The chronic dietary aggregate risk assessment includes direct and indirect food contact uses as well as drinking water exposures. Based on the results of the chronic aggregate assessment, the estimated chronic risks for adults and children are 8.4% and 40.9% of the respective cPADs. Therefore, the chronic dietary aggregate risks are not of concern (i.e., less than 100% of cPAD).

Short-term and intermediate-term aggregate risks were calculated using the total MOE approach. Only the short-term aggregate is presented here because the endpoints for incidental oral as well as inhalation are identical for the short- and intermediate-term durations. Moreover, EPA has not identified that aggregate risks are not of concern for adults for any of the three routes of exposure. The aggregate adult MOEs are 1,200 for oral, 480 for dermal, and 2,000 for inhalation, which are greater than the target MOE of 100 for the oral, 1,000 for inhalation, and 10 for dermal. For children, the aggregate risk estimate for each of the routes of exposure are also above the target MOEs of 100 for the oral, 1,000 for inhalation, and 10 for dermal (MOE = 140 for the oral route, 1,200 for the dermal route, and no co-occurrence for the inhalation route), and thus are not of concern.

Based on the toxicological and exposure data discussed in this preamble, EPA concludes that ADBAC will not pose a risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty of no harm will result to the general population, or to infants and children from aggregate exposure to ADBAC residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method for food is not needed for enforcement purposes. Food contact sanitizers are typically regulated by the State health departments to ensure that the food industry is using 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, rather than food items that may come into contact with 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 ADBAC and didecyl dimethyl ammonium chloride (DDAC), then High Pressure Liquid Chromatogram–Ultraviolet Visible (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.

B. Revisions to Petitioned-For Exemption

EPA has revised the exemption as proposed in the notice of filing. The petitioner proposed to amend the exemption for Quaternary Ammonium Compounds: N-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride by increasing the amount of quaternary chemicals that may be in end-use concentrations from 200 ppm to 400 ppm. There presently exists an exemption for Quaternary Ammonium Compounds: Alkyl (C_{12-18}) dimethyl benzyl ammonium chloride (CAS Reg. No. 8001–54–5) that limits the concentration of quaternary chemicals to 200 ppm; however, because the petitioner specifically sought an exemption for Quaternary Ammonium Compounds: N-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride (CAS Reg. No. 68424–85–1) with a limit for the concentration of quaternary chemicals at 400 ppm, EPA has not amended the existing exemptions but instead established a new exemption for Quaternary Ammonium Compounds: N-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride (CAS Reg. No. 68424–85–1).

V. Conclusion

Therefore, an exemption from the requirement of a tolerance under section 408 of FFDCA is established for residues of n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride (CAS No. 68424–85–1), on food contact surfaces resulting from use as an antimicrobial pesticide formulation applied to food-contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils, provided that the end-use concentration of all quaternary chemicals in solution does not exceed 400 ppm of active quaternary compound.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final 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 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, Alkyl Dimethyl Benzyl Ammonium Chloride Quaternaries, Food Additives, Food-Contact Sanitizers Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 7, 2008.

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 alphabetically adding a new entry in the table in paragraph (a) to read as follows:

§ 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: n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride	68424–85–1	When ready for use, the end-use concentration of all quaternary chemicals in solution is not to exceed 400 ppm of active quaternary compound.
* *	*	* *

* * * * *

[FR Doc. E8–19070 Filed 8–19–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 071106673–8011–02]

RIN 0648–XJ81

Fisheries of the Exclusive Economic Zone Off Alaska; Greenland Turbot in the Aleutian Islands Subarea of the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Greenland turbot in the Aleutian Islands subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2008 Greenland turbot total allowable catch (TAC) in the Aleutian Islands subarea of the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), August 15, 2008, through 2400 hrs, A.l.t., December 31, 2008.

FOR FURTHER INFORMATION CONTACT: Jennifer Hogan, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2008 Greenland turbot TAC in the Aleutian Islands subarea of the BSAI is 790 metric tons (mt) as established by the 2008 and 2009 final harvest specifications for groundfish in the BSAI (73 FR 10160, February 26, 2008) and the allocation from the non-specified reserves (73 FR 40193, July 14, 2008).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS, has determined that the 2008 Greenland turbot TAC in the Aleutian Islands subarea of the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 540 mt, and is setting aside the remaining 250 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Greenland turbot in the Aleutian Islands subarea of the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Greenland turbot in the Aleutian Islands subarea of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 14, 2008.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*