12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 23, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDed]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.220 is amended by adding text to paragraph (d) to read as follows:

§ 180.220 Atrazine; tolerances for residues.

* * * * *

(d) *Indirect or inadvertant residues.* Tolerances are established for indirect or inadvertant residues of atrazine, 2-chloro-4-ethylamino-6-isopropylamino-s-triazine, in or on the following raw agricultural commodity when present therein as a result of application of atrazine to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Vegetable, leafy, except brassica, group 4	0.25

[FR Doc. E8–15010 Filed 7–1–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–1024; FRL–8368–1]

Residues of Quaternany Ammonium Compounds, Didecyl Dimethyl Ammonium Carbonate and Didecyl Dimethyl Ammonium Bicarbonate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the quaternany ammonium compounds, didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate (hereinafter cited jointly as DDACB), on food-contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. Lonza, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting to establish concentration limits of DDACB in end-use products eligible for the exemption from the requirement of a tolerance. As amended, the regulation will exempt solutions from the requirement of tolerance residues resulting from contact with surfaces treated with solutions where the end-use concentration of DDACB does not exceed 240 parts per million (ppm).

DATES: This regulation is effective July 2, 2008. Objections and requests for hearings must be received on or before September 2, 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–2006–1024. 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) 308–6233; 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 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–2006–1024 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 September 2, 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–2006–1024, 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 67300) (FRL–8141–2), 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 6F7131) by Lonza, Inc., 90 Boroline Rd., Allendale, NJ 07401. The petition requested that 40 CFR 180.190(a) be amended by establishing concentration limits for DDACB in end-use solutions eligible for tolerance exemption. That notice referenced a summary of the petition prepared by Lonza, 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.

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 DDACB on food-contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. EPA's assessment of exposures and risks associated with establishing 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 DDACB 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.

DDACB is a part of the aliphatic alkyl quaternaries chemical case which is comprised of six compounds that are structurally similar quaternary ammonium compounds (quats). This group of chemicals are characterized by having a positively charged nitrogen covalently bonded to two alkyl group substituents (at least one C^8 or longer)

and two methyl substituents. In finished form, these quats are salts with positively charged nitrogen (cation) balanced by a negatively charged molecule (anion). The anion for the quats in this group are chlorine, carbonate, bicarbonate, or bromine.

In 1988, EPA issued PR Notice 88–2 outlining ''Clustering of Quaternary Ammonium Compounds.'' In that PR Notice, quats were clustered into 4 groups as follows:

Group I: The alkyl or hydroxyalkyl (straight chain) substituted quats; otherwise referred to as the aliphatic alkyl quaternaries.

Group II: The non-halogenated benzyl substituted quats (including alkyl benzyl, dodecyhlbenzyl, hydroxybenzyl, hydroxyethylbenzyl, and naphylmethyl).

Group III: The di- and tri-chlorobenzyl substituted quats.

Group IV: Quats with unusual substitutes (charged heterocyclic compounds).

In all types of aliphatic alkyl ammonium chloride quaternaries, it is the positive entity (quaternized nitrogen containing the aliphatic alkyl and/or aromatic alkyl groups) that is of relevance from toxicology and exposure perspectives. The negative part of the aliphatic alkyl ammonium chloride quaternaries (counter ion) is relatively non-toxic entities (bicarbonate, carbonate, chloride). Aliphatic alkyl ammonium chloride quaternaries were originally formulated with chloride as the negative or the counter ion. However, one negative ion in the aliphatic alkyl ammonium chloride quaternaries can be replaced with another without disrupting the structural integrity of the chemical (i.e., quaternized nitrogen) and thereby without having a significant effect on toxicity. Accordingly, the toxicological profiles of the aliphatic alkyl ammonium chloride quaternaries are very similar and a toxicological assessment of any of the aliphatic alkyl ammonium chloride quaternaries is representative of the group. Didecyl dimethyl ammonium chloride (DDAC), was chosen as the representative chemical for aliphatic alkyl ammonium chloride quaternaries because it was registered first. On this basis, the toxicology database for DDAC is accepted as representative of the hazard for this class of quaternary ammonium compounds.

The aliphatic alkyl ammonium chloride 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 negative carcinogenicity studies in rats and mice feeding studies using doses above limit dose. 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 aliphatic alkyl quaternaries can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0338, Didecyl Dimethyl Ammonium Chloride (DDAC)—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 UFs. 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*.

The Agency's LOC for aliphatic alkyl ammonium chloride quaternaries' inhalation and oral exposures is 100 (i.e., a MOE less than 100 exceeds the Agency's level of concern). The LOC is based on an UF of 10x for interspecies extrapolation and 10x UF for intraspecies extrapolation. For dermal exposures, irritation as the effect was selected for the short-term endpoint and a reduced 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 aliphatic alkyl quaternaries, the MOE for short-term dermal risk is reduced to a total factor of 10x (3x for interspecies extrapolation, 3x for intraspecies variation).

A summary of the toxicological endpoints for aliphatic alkyl quaternaries used for human risk assessment is shown in Table 1 of this unit. Specific information on the studies received such as the NOAEL and the LOAEL from the toxicity studies caused by aliphatic alkyl quaternaries can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0338, Didecyl Dimethyl Ammonium Chloride (DDBAC)—Report of Antimicrobials Division Toxicity Endpoint Committee (ADTC) and the Hazard Identification Assessment Review Committee (HIARC).

TABLE 1. —SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ALIPHATIC ALKYL AMMONIUM CHLORIDE QUATERNARIES 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 (Females 13–50 years of age)	NOAEL = 10 milligrams/kilograms/day (mg/kg/day) UF_A = 10x UF_H = 10 x FQPA SF = 1x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Prenatal Developmental Toxicity—Rat (MRID 41886701) LOAEL = 20 mg/kg/day based on increased incidence of skeletal variations.
Chronic dietary (All populations)	NOAEL= 10 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	Chronic RfD =0.1 mg/kg/day cPAD = 0.1 mg/kg/day	Chronic Toxicity—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.
Incidental oral short-term (1 to 30 days)	NOAEL= 10 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Prenatal Developmental Toxicity—Rat (MRID 41886701) LOAEL = 20 mg/kg/day based on increased incidence of skeletal variations.
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	Chronic Toxicity—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 (1 to 6 months)	Dermal study NOAEL= 2 mg/kg/day ((8 micrograms (ug)/centimeters $(cm)^2$)[a] %when appropriate) UF_A = 3 x UF_H = 3x FQPA SF = 1x	LOC for MOE = 10	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 endpoint identified.		
Inhalation short-term (1 to 30 days)	Oral study NOAEL[b]= 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10 x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Prenatal Developmental Toxicity (MRID 41886701) LOAEL = 20 mg/kg/day based on increased incidence of skeletal variations.
Inhalation (1 to 6 months)	Oral) study NOAEL[b] = 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	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_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] Short-term dermal endpoint = (2 mg/kg rat x 0.2 kg rat x 1,000 ug/mg)/50 cm^2 area of rat dosed = 8 ug/cm^2.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to DDACB, EPA considered exposure under the petitioned-for exemption as well as all existing aliphatic alkyl quaternaries exemptions or tolerances in (40 CFR 180.940(a)). EPA assessed dietary exposures from DDACB in food as follows:

Aliphatic alkyl quaternaries are to be used as a sanitizer on appliances, beverage bottling, counter tops, food packaging, refrigerators, tables, and utensils. 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 appliances, countertops, equipment, and utensils can migrate to food coming into contact with the treated and rinsed surfaces and can be ingested by humans.

The Agency assessed acute and chronic dietary exposures from the use of DDACB 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 Food and Drug Administration (FDA) methodologies for utensils and Indirect Dietary Residential Exposure Model software (IDREAM) for countertops. IDREAM incorporates consumption data from United States Department of Agriculture (USDA) Continuing Survey of Food Intakes by Individuals (CSFII) for 1994–1996 and 1998. The USDA CSFII 1994–1996 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days.

The 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 china, glass, and silverware 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 mg/cm^2 of treated area. The body weights used for this assessment were 70 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 demonstrate the amount of residues on the surface that will be transferred to food and subsequently ingested. The maximum application rate for DDACB on utensils is 0.0020 lbs active ingredient (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., oatmeal, pudding), 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 those countertops; all prepared foods will come in contact with treated countertops at the maximum application rate and transfer residues do 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 and households use the same active ingredients; 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 DDACB for bottling/packing of food is 0.0020 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 with treated material: Beverages (alcoholic and non-alcoholic), egg products, and milk. 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 percent of an aPAD and a cPAD do not exceed 100% and therefore are not of a concern.

2. *Dietary exposure from drinking water*. DDACB outdoor uses are as an algaecide in wood preservative treatment and a slimicide in secondary oil field uses. The oil field uses are considered to be contained. The other uses are not expected to significantly contaminate drinking water sources. Therefore, the DDACB contributions for drinking water exposure are considered to be negligible and are not quantified.

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).

DDACB is currently registered for the following residential non-dietary sites: Homes and day-care nurseries. EPA assessed residential exposure using the following assumptions:

Residential exposure may occur during the application as well as post application of DDACB to indoor hard surfaces (e.g., mopping, trigger pump sprays, wiping). 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, inhalation, and incidental oral unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data and the Chemical Manufactures Association Antimicrobial Exposure Assessment Study (EPA, 1999). 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 DDACB can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–1024, Review of Petition to Amend 40 CFR 180.940 to add Didecyl Dimethyl Ammonium Carbonate/Bicarbonate.

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 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 Aliphatic Alkyl Quaternary (DDAC) Reregistration Eligibility Decision (RED)) were developed by assuming that a DDAC compound was used on 100% 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.

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*. Given the data on the aliphatic alkyl ammonium chloride quaternaries, there is no evidence that DDACB 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 aliphatic alkyl ammonium chloride quaternaries is complete.

ii. There is no indication that aliphatic alkyl ammonium chloride quaternaries are 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 aliphatic alkyl ammonium chloride quaternaries 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.

iv. There are no residual uncertainties identified in the exposure databases. Although EPA may, in the future, refine exposure estimates for aliphatic alkyl ammonium chloride 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 ammonium chloride quaternaries.

E. Aggregate Risks and Determination of Safety

1. *Dietary risks from food and feed uses*. EPA compares the estimated dietary exposures to an aPAD and a cPAD, 0.1 mg/kg/day, which are the same value for DDACB. Generally, a dietary exposure estimate that is less than 100% of the aPAD or the cPAD does not exceed the Agency's LOC.

The antimicrobial indirect food use acute and chronic risk estimates from exposure to treated utensils and countertops are below the Agency's LOC. For adult males, the acute and chronic dietary exposure risk estimates are 5.9% for utensils and 1. 92% for countertops. The aPAD and cPAD for adult females of child bearing age (13–49), the highly exposed group, is 6.9% for utensils and 1. 79% for countertops. For children ages 1–2, the most highly exposed population subgroup, the acute and chronic dietary risk estimates are 41. 3% for utensils and 6.21% for countertops. Therefore, dietary exposure estimates are below the Agency's LOC for all population subgroups. The antimicrobial indirect food use chronic risk estimates from exposure to treated food packaging and beverage bottles are below the Agency's LOC. The percent cPAD values exceeded 100% and are not of concern.

Specific information on the dietary exposure assessment for DDACB can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–2006–1024, Review of Petition to Amend 40 CFR 180.940 to add Didecyl Dimethyl Ammonium Carbonate/Bicarbonate.

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.

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

IV. Other Considerations

An analytical method for food is not needed. 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 not 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 DDACB, then high pressure liquid chromatogram with ultraviolet visible (HPLC-UV) is used to determine the amount of ADBAC. The amount of DDACB is determined by calculating the difference between the total amount of quaternary compounds and ADBAC.

V. Conclusion

Therefore, an exemption is established for residues of DDACB, regulated chemical, on food-contact surfaces in public eating establishments, on dairy processing equipment, and food processing equipment and utensils.

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, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply,*

Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Aliphatic alkyl quaternaries, Food-contact sanitizers, Pesticides and pests, Quaternary ammonium compounds, Reporting and recordkeeping requirements.

Dated: June 10, 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 an entry to 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, didecyl dimethyl ammonium carbonate/didecyl dimethyl ammonium bicarbonate	148788–55–0/148812–654–1	When ready for use, the end-use concentration of these specific ammonium compounds is not to exceed 240 ppm of active quaternary ammonium compound.
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[FR Doc. E8–14880 Filed 7–1–08; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261 and 266

[FRL–8687–6]

RIN 2090–AA15

US Filter Recovery Services, Inc., Under Project XL

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is withdrawing a final rule published on May 22, 2001 which modified the regulations under the Resource, Conservation and Recovery Act (RCRA) to enable the implementation of the US Filter Recovery Services, Inc. (USFRS) project that was developed under EPA's Project eXcellence in Leadership (Project XL) program. Project XL was a national pilot program that allowed state and local governments, businesses and federal facilities to work with EPA to develop more cost-effective ways of achieving environmental and public health protection. In exchange, EPA provided regulatory, policy or procedural flexibilities to conduct the pilot experiments.

DATES: The final rule is effective August 1, 2008.

FOR FURTHER INFORMATION CONTACT: Sandra Panetta, Mail Code 1870T, U.S. Environmental Protection Agency, Office of Policy, Economics and Innovation, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Ms. Panetta's telephone number is (202) 566–2184 and her e-mail address is *panetta.sandra@epa.gov*. Further information on today's action may also be obtained on the Internet at *http://*