

**Conference for Food Protection
2020 Issue Form**

Issue: 2020 III-035

Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Late Breaking Issue Title:

Amend Food Code: clarify language for disinfection of food-contact surfaces

Late Breaking Issue you would like the Conference to consider:

The 2017 Food Code does not address disinfection or the use of disinfectants on food-contact surfaces.

Retail food facilities have a need to use disinfectants to kill viruses on food-contact surfaces. Examples include disinfection following bodily fluid events, Norovirus or Hepatitis A illnesses or outbreaks, or COVID-19 cases. Most disinfectants are registered to kill viruses and other microorganisms on surfaces, whereas most commonly used food-contact surface sanitizers only reduce bacteria of food safety concerns and may not be effective and/or registered against viruses.

Due to the global SARS-CoV-2 pandemic, health orders from local and state regulatory agencies across the country have required disinfection in retail food facilities on a routine basis and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises. These various orders and recommendations have resulted in confusion for facility operators and regulators on how to correctly use disinfectants, especially while simultaneously meeting sanitization requirements.

The intent of this Issue is to clarify in the FDA Food Code the use of EPA-registered disinfectants on food-contact surfaces when there is a need to prevent the spread of a virus in a retail food facility.

Concerns related to the use of disinfectants on food-contact surfaces include several considerations, as summarized above, from regulatory and industry perspectives. Should the Council wish to consider an alternative to the Recommended Solutions presented in this Issue, an additional option to establish a CFP Council committee to further study this topic is outlined in an attached supporting document (Supporting Attachment #3).

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code in relation to disinfectants has led to various interpretations from regulators and industry and the potential for misuse. If these products are not used as registered the residue could impact human health and/or adulterate food

Retail food facility disinfection to stop the spread of Norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When an outbreak of Norovirus occurs, local and state regulatory agencies will require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have required disinfection in retail food facilities as needed and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises. Additionally, the Centers for Disease Control and Prevention (CDC) issued their own recommendations for disinfection of food-contact surfaces within retail food facilities. CDC's recommendation following disinfection includes rinsing and sanitizing. See Example #3 below.

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two ways EPA-registered disinfectants are used on food-contact surfaces in retail food facilities:

- 1) Disinfectants that require a rinse step prior to resuming regular operations; and
- 2) Disinfectants that do not require a post rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, do not require a rinse step prior to further use. (40 CFR 180.940)

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should approach the use of disinfectants for food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." To comply with this section, it is unclear if washing, rinsing, sanitizing, and air-drying are required following the use of a disinfectant.

Example #2

Within the hand antiseptic narrative of the 2017 Food Code Annex 3, Section 2-301.16, it states, "Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization" and "disinfection."

Example #3

The CDC has issued guidance on the use of disinfectants in a retail food facility.

(<https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/business-employers/bars-restaurants.html>). This guidance calls for rinsing and sanitizing following the

use of a disinfectant on a food-contact surface (see excerpt in next paragraph) and it does not appear to align with Section 4-702.11 of the 2017 Food Code (see Example #1 above).

“If a food-contact surface must be disinfected for a specific reason, such as a blood or bodily fluid cleanup or deep clean in the event of likely contamination with SARS-CoV-2, use the following procedure: wash, rinse, disinfect according to the label instructions with a product approved for food-contact surfaces, rinse, then sanitize with a food-contact surface sanitizer.”

This Issue submission does not include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

that letters be sent to the FDA and the CDC requesting they work together to develop final guidance on the use of disinfectants in a retail food facility to assure alignment between CDC guidance and FDA Food Code.

The Conference further recommends that a letter be sent to the FDA requesting the following:

1. Amend the most recent edition of Food Code to:

- a. Add a definition for the term “DISINFECTION” for food-contact surfaces to align with the definition of “disinfectant” in the Code of Federal Regulations, 40 CFR 158.2203.
- b. Add a requirement to use a disinfectant effective against a virus of a food safety/public health concern in section 2-501.11 Clean-up of Vomiting and Diarrheal Events.
- c. Add a requirement that if a chemical disinfectant applied to food-contact surfaces is EPA-registered for food-contact surfaces, it shall be used in accordance with the EPA-registered label use instructions.

2. Explain the appropriate use of disinfection in retail food facilities by adding narrative to the Food Code Annex or by posting an interpretation document to the FDA Food Code Reference System.

Attachments:

Content Documents: *(documents requiring Council review; approval or acknowledgement is requested in the recommended solution above) n/a*

Supporting Attachments: *(documents submitted to provide background information to Council)*

1. Supporting Attachment #1: EPA-Registered Disinfectants June 2021

2. Supporting Attachment #2: Food Protection Trends published article.

Sanitizers and Disinfectants: A Retail Food and Foodservice Perspective Angela M. Fraser, Jeffrey Anderson, Juan Goncalves, Elaine Black, Anna Starobin, David Buckley, Dale Grinstead, Chip Manuel, Jill Hollingsworth Bibliographic citation: Food Protection Trends, vol. 41, no. 3, pp. 358-367, May 2021 Volume 41, Issue 3: Pages 358–367

Permission granted by publisher (IAFP) to include article as an Issue supporting attachment.

3. Supporting Attachment #3: Alternative Recommended Solution for Consideration

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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Supporting Attachment #1: EPA-Registered Disinfectants

Late Breaking Issue Title: Amend Food Code: clarify language for disinfection of food-contact surfaces
(Submitted for the 2020 CFP Biennial Meeting, rescheduled 2021)

Issue Submittal Date: June 2021

Additional regulatory information regarding EPA-registered disinfectants for food-contact surfaces is available below:

- USDA’s Animal and Plant Health Inspection Service, Overview of the Regulation of Disinfectants. “Disinfectants are registered and regulated by the U.S. Environmental Protection Agency (EPA) under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (40 CFR 150-189).
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Cleaning-and-Disinfection/Regulation-of-Disinfectants>
- What does “Food Contact” mean for products included on EPA’s List N?
<https://www.epa.gov/coronavirus/some-products-list-n-say-food-contact-what-does-mean>
- EPA’s List N: A list of products EPA expects to kill SARS-CoV-2, the coronavirus that causes COVID-19. Tool:
<https://www.epa.gov/pesticide-registration/list-n-advanced-search-page-disinfectants-coronavirus-covid-19>
- Disinfectants used for food-contact surfaces must meet food-contact surface sanitization claims set forth by the EPA. To ensure equal protection against pathogens which may pose a public health risk on food-contact surfaces, disinfectants used at retail food facilities may be required to meet EPA requirements and Code of Federal Regulations (CFR) sections, including but not limited to:
 - 9 CFR 180 Subpart C Section 424.21(b)/Food Ingredients and Sources of Radiation;
 - 21 CFR 170-186/Food Additives, Generally Recognized as Safe;
 - 21 CFR Part 189/Prohibitions;
 - 40 CFR 158.2203/Definition;
 - 40 CFR 180/Tolerance for Pesticides; and 21 CFR Part 189/Prohibitions
- FDA Food Code Sections: 3-202.12/Additives

Sanitizers and Disinfectants: A Retail Food and Foodservice Perspective

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SUMMARY

The coronavirus disease 2019 (COVID-19) pandemic has brought heightened attention to the importance of cleaning, sanitizing, and disinfecting in retail food and foodservice establishments. In response, major governmental agencies have emphasized the need to frequently disinfect high-touch surfaces. While this recommendation may seem straightforward and achievable, it is far more nuanced and complex. In the retail food and foodservice industry, sanitization is a routine, common practice defined and recommended in the U.S. Food and Drug Administration (FDA) Food Code. Hence, sanitizers, rather than disinfectants, are the main antimicrobial products used in these settings. It is important to emphasize that sanitizers and disinfectants are not interchangeable products, so they may be inadvertently misused. Therefore, end users need to understand the differences of when, why, and how both can be used in retail food and foodservice settings. The aim of this paper is to increase end users' knowledge and awareness about the proper use of sanitizers and disinfectants in retail food and foodservice establishments. This paper is organized into six sections—Antimicrobial Products: Sanitizers and Disinfectants, FDA Food Code, Regulation of Sanitizers and Disinfectants, Understanding EPA-Registered Labels, Emerging Issues, and Current and Future Trends in Sanitizing and Disinfecting. When used properly, sanitizers and disinfectants are powerful tools that can keep retail food and foodservice operations safe from pathogens that cause infectious disease.

OVERVIEW

COVID-19 has brought heightened attention to the importance of cleaning, sanitizing, and disinfecting in retail food and foodservice establishments. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), is primarily transmitted through person-to-person contact via respiratory droplets from coughing, sneezing, talking,

and breathing. Based on what we currently know, it is not transmitted through food. Even so, concerns have been raised about its spread in retail food and foodservice establishments, resulting in changes in restaurant and grocery store operations, as well as contributing to the closure of thousands of restaurants across the United States (5, 17). In response, major U.S. government agencies (i.e., the Centers for Disease Control and Prevention, the Environmental Protection Agency [EPA], and the Food and Drug Administration [FDA]) published a series of recommendations, one of which promotes the frequent disinfection of high-touch surfaces (2, 12, 15). While this recommendation may seem straightforward and achievable, it is in fact far more nuanced and complex. In the retail food and foodservice industry, sanitization is a routine, common practice defined and recommended in the FDA Food Code. Hence, sanitizers, rather than disinfectants, are the main antimicrobial product used in the food industry. Sanitizers and disinfectants are not interchangeable products, but due to complex regulatory frameworks and lengthy labels, they may be inadvertently misused. Therefore, it is important to understand the differences in when, why, and how both can be properly used in retail food and foodservice establishments. The aim of this paper is to increase end users' knowledge and awareness about the proper use of sanitizers and disinfectants in retail food and foodservice establishments.

ANTIMICROBIAL PRODUCTS: SANITIZERS AND DISINFECTANTS

Sanitizers and disinfectants are often complex formulations that contain at least one or more active ingredient(s). These active ingredients provide the intended antimicrobial effect (i.e., reduction or elimination of targeted microorganisms). Characteristics of common active ingredients or their blends are presented in *Table 1*. While *Table 1* describes

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TABLE 1. Attributes of common sanitizer and disinfectant active ingredients

Sanitizer	Spectrum of activity ^a	Advantages	Disadvantages
Free available chlorine (chlorine, hypochlorous acid, sodium hypochlorite)	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Broad spectrum of activity • Good hard water tolerance 	<ul style="list-style-type: none"> • May be incompatible with some soft metals • Rapidly inactivated by soil • Limited shelf life that varies with pH • Can generate chlorine gas if mixed with acid or ammonia • Can be inactivated by organic matter
Quaternary ammonium compounds	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Broad spectrum of activity • Compatible with most surfaces • Very stable with long shelf lives • Less reactive with soil 	<ul style="list-style-type: none"> • Can be inactivated by hard water • Can be inactivated by some surfactants used in cleaners • May bind to cleaning cloths, reducing active levels in a solution • Food Code requires use above 24°C (75°F)
Peroxides	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Minimal residue • Formulated for good hard water tolerance 	<ul style="list-style-type: none"> • May require elevated levels to be effective against catalase-positive organisms. • May be incompatible with some soft metals
Peracids	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Broad spectrum of activity (note that antifungal activity may require a mixture of peracid) • Compatible with most surfaces • Minimal residue 	<ul style="list-style-type: none"> • Pungent odor • Limited shelf life • Inactivated by some types of soil • May be incompatible with some metals
Acid anionics	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Compatible with residual cleaners if rinsing is incomplete • Good cleaning performance • Good material compatibility • Good hard water tolerance 	<ul style="list-style-type: none"> • May be incompatible with some soft metals and some plastic surfaces • Can generate chlorine gas if mixed with chlorine products
Alcohol	Vegetative bacteria and enveloped viruses	<ul style="list-style-type: none"> • Can be used in environments where aqueous sanitizers or disinfectants are undesirable^b • No residue • Limited impact on organic matter 	<ul style="list-style-type: none"> • High flammability • Some alcohols display poor compatibility with certain plastic materials • RTU format only

^aNote that the specific spectrum of activity will vary depending on the formulation and will be reflected on the product and EPA approved labels. Consult the label and the supplier of the disinfectant or sanitizer for detailed information.

^bLow-water-activity food production areas.

limitations of common active ingredient(s), the final product formulation may include a blend of active ingredients, as well as additional inert ingredients, to help overcome these limitations. Inert ingredients can be added for various reasons (e.g., improved cleaning performance, aesthetics, formulation

stability, and hard water tolerance). Surfactants are added to improve the cleaning performance of both disinfectants and sanitizers in combination products (i.e., detergent-sanitizers and detergent-cleaners), which are described below. Chelating agents are added to some formulations to

improve product performance in the presence of hard water. Thickeners or solvents are sometimes used to control the flow of the formulation, affecting how the product is dosed or diluted for use. Both active and inert ingredients are carefully chosen by the manufacturer to meet the efficacy and usability needs of the end user.

Sanitizers

A sanitizer is defined as “a substance, or mixture of substances, that reduces the bacteria population in the

inanimate environment by significant numbers but does not destroy or eliminate all bacteria” (9). The testing and efficacy required for food-contact and nonfood-contact surface sanitizers are presented in *Table 2*. It is important to note that efficacy tests for sanitizers can only be performed with bacteria and not with other microorganisms, such as viruses, fungi, and yeast. Other bacteria can be added to claims on the product label based on proven efficacy and customer needs. Two categories of sanitizers will be discussed in this paper—food-contact surface sanitizers and nonfood-

TABLE 2. Definitions and regulatory requirements for disinfectants and sanitizers

Disinfectants			Sanitizers		
Agent that destroys or irreversibly inactivates bacteria, fungi, and viruses but not necessarily bacterial spores in the inanimate environment [40 CFR § 158.220(c) (9)]			Agent that reduces the number of bacteria in the inanimate environment by significant numbers, but does not necessarily destroy or eliminate all bacteria [40 CFR § 158.220(c)(9)]		
Product type	Requirements (organisms and time)		Product type	Requirements (organisms and time)	
Hospital	<i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i>	Must pass required disinfectant laboratory test (wipe, spray, and liquid versions exist); contact time can be no longer than 10 min	Food Contact	Halide-based products (i.e., products with active ingredients including chlorine, iodine, and bromides): <i>S. aureus</i> or <i>Salmonella enterica</i>	Halide-based products must demonstrate equivalency to 50, 100, or 200 ppm of available chlorine
				Nonhalide-based products (products with nonhalide active ingredients, e.g., peracids, quats and alcohol): <i>S. aureus</i> and <i>Escherichia coli</i>	Nonhalide-based products must achieve 5-log reduction in laboratory test in 30 s, although claim must be listed as 1 min (wipe version exists)
General	<i>S. aureus</i> and <i>P. aeruginosa</i> or <i>S. enterica</i>		Non-food contact	<i>S. aureus</i> and <i>Klebsiella pneumoniae</i> or <i>Klebsiella aerogenes</i>	Must achieve 3-log reduction in laboratory test within 5 min
Limited	<i>S. aureus</i> or <i>S. enterica</i>				

Note: Once the basic requirements have been met, a company may test and add a variety of additional microorganism kill claims to the label through the registration process.

contact surface sanitizers. The FDA Food Code specifically addresses sanitization for food-contact surfaces, whereas it does not address sanitization of nonfood-contact surfaces. Nonetheless, retail food and foodservice operators may choose to sanitize both surface types to minimize the risk of cross-contamination.

Disinfectants

A disinfectant is defined as a “substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment” (9). The testing and efficacy required for disinfectants are listed in *Table 2*. The EPA separates disinfectants into three categories—limited, broad, and hospital disinfectants. The broad and hospital categories of disinfectants are most often used due to their wider range of antimicrobial claims. The FDA Food Code only mentions the use of disinfectants in Section 2-501.11, “Clean-up of Vomiting and Diarrheal Events” (15).

Recently, disinfectants have become an increasingly important tool for retail food and foodservice operations because of their efficacy against microorganisms not claimed by sanitizers, such as noroviruses or coronaviruses. The product label identifies the specific microorganisms against which the disinfectant has been tested and approved by the EPA. In general, disinfectant use is confined to places or surfaces where there may be a greater risk of human or animal pathogen transfer, such as high-touch surfaces (door handles, light switches, dispenser buttons, dining room chairs, and tables) and bathrooms. In some instances, food-contact surfaces should be disinfected after certain contamination events. Examples include controlling the spread of pathogens associated with blood, vomit, or diarrheal events or cleaning up the facility for reopening after a suspected or confirmed foodborne disease outbreak. Traditional food-contact surface sanitizers are not designed to meet the decontamination challenges presented by viruses that may have contaminated surfaces during these events. If virus control or generally higher-level microbial control is required, it is necessary to disinfect (not sanitize) the contaminated food-contact surface. For surfaces that are visibly dirty, the general protocol is to clean, rinse with potable water, disinfect according to label instructions for the disinfectant, rinse again with potable water, and then sanitize with a food-contact sanitizer before reusing the surface. The rinse step before disinfection of a food-contact surface is essential to prevent reducing the efficacy of the disinfectant, and rinsing after disinfection is important to prevent chemical cross-contamination with foods attributed to disinfectant residue and to prevent potential inactivation of sanitizer with residual disinfectant. If the surface is visibly clean and the product is labelled as a one-step disinfectant, one can eliminate the cleaning step, so the general protocol is disinfect, rinse with potable water, and sanitize with a food-contact sanitizer.

Combination products

Up to this point, sanitizers and disinfectants have been discussed as separate products. However, many manufacturers often formulate products to function as both a food-contact surface sanitizer and a disinfectant. Additional functions, such as sanitizing nonfood-contact surfaces (e.g., textiles, floors, drains, and walls), can also be added to product claims through testing and EPA approval to meet market or customer needs. It is not unusual for one product to be approved for use as a sanitizer at one concentration and as a disinfectant at a higher concentration with different contact times. For example, some quaternary ammonium products can be used as a food-contact sanitizer at 200 ppm and as a disinfectant at 450 ppm. Other combination or multifunctional products include those designed to deliver benefits other than microbial control, such as a detergent-disinfectant or detergent-sanitizer (commonly called cleaner-disinfectants or cleaner-sanitizers). Both can be of benefit to the end user through process simplification.

Packaging

Sanitizers and disinfectants can be purchased in a range of formats—wipes, aerosols, sprays, concentrated liquids, and tablets. Wipes, aerosols, and sprays are typically ready-to-use (RTU) formats, and concentrates (liquids or tablets) require dilution with water. As the names imply, RTU products can be used as purchased, whereas concentrates need additional handling (e.g., dispensing, dilution, and concentration confirmation). Concentrates are advantageous because they require less storage, use far less packaging, and are easier to ship than RTU products. However, safety of concentrated chemicals and the equipment and training needed for proper dilution of these products should be considered. Some manufacturers have developed tamper-proof packaging to prevent workers from gaining access to chemical concentrates, as well as sophisticated dispensing equipment to ensure dilution accuracy and safety.

FDA FOOD CODE

The FDA publishes the Food Code to provide a comprehensive and uniform approach to food safety management for retail food and foodservice establishments in the United States (15). Among the goals of the Food Code is the creation of common and standardized food safety language to improve communication between regulators and industry operators. Retail food and foodservice operators need to familiarize themselves with the Food Code so effective cleaning and sanitizing procedures become an integral part of their operation, as the Code has been widely adopted throughout the United States as the basis for state and local regulations.

The objective of cleaning requirements outlined in the Food Code is to remove soil (e.g., food debris, proteins, fats, and carbohydrates) from both food-contact surfaces and nonfood-contact surfaces. Food-contact surfaces at

TABLE 3. Cleaning frequencies of food contact surfaces and utensils

Temp	Cleaning frequency
<5.0°C (41°F)	24 h
>5.0°–7.2°C (>41–45°F)	20 h
>7.2–10°C (>45–50°F)	16 h
>10–12.8°C (>50–55°F)	10 h
>12.8°C (>55°F)	4 h

room temperature (except for storage containers) should be cleaned as needed throughout the day and at least once every 4 hours. For cold rooms, such as a meat cutting room, food-contact surfaces can be cleaned and sanitized less frequently than every 4 hours (Table 3). Surfaces must be cleaned and rinsed with potable water before being sanitized to allow the sanitizer to achieve its expected efficacy. EPA-registered sanitizers must be used at the concentration and contact time (typically 1 minute) that are listed on the label instructions. It is important to note that shorter sanitizer contact times listed in the Food Code, which range from 7 seconds for chlorine-based products to 30 seconds for quaternary ammonium and iodine products, apply to dish machine applications, not to surface applications. Therefore, it is important to always follow the product label instructions.

Cleaning and sanitizing processes are addressed in several parts and subparts of Chapter 4 of the Food Code, which further elaborate the three-step process—cleaning, rinsing, and sanitizing of food-contact surfaces (i.e., equipment and utensils)—that is the foundation for procedures used in retail food and foodservice establishments. Below is a listing of where to find these procedural steps in the Food Code.

- Cleaning.** Part 4-6 describes cleaning procedures for food-contact surfaces (i.e., equipment and utensils). Included are objectives, recommended cleaning frequencies, and cleaning methods. It is recommended that nonfood-contact surfaces be cleaned as needed, but it is not required that they be sanitized.
- Frequency.** Section 4-602.11 describes how often food-contact surfaces need to be cleaned and sanitized under certain conditions, such as when handling food at room temperature or in a temperature-controlled room (i.e., a meat cutting room) (Table 3).
- Rinsing.** Section 4-603.16 recommends the rinsing of cleaned equipment and utensils so that abrasives and cleaning chemicals are removed or diluted to aid in the effectiveness of the sanitizing step. (See “Detergent-Sanitizer” below for exceptions to this recommendation.) Section 4-904.14 states two conditions under which equipment and utensils can be rinsed after cleaning and sanitizing: (1) when a rinse is applied directly from the potable-water supply by a dish machine and (2) when the EPA-registered label use instructions require a rinse after a sanitizer is applied in a commercial dish machine.
- Sanitizing.** The Food Code states in Part 1-2, Definitions, that “sanitization” means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, equal to a 99.999% reduction, of representative disease microorganisms of public health importance. This definition aligns with the performance standards for a nonhalogen-based food-contact surface sanitizer (i.e., products with active ingredients, such as chlorine, iodine, or bromides) that is registered by the EPA. Part 4-7 specifies the frequency and methods for sanitizing food-contact surfaces, the final step prior to reuse of a food-contact surface. It includes two options for sanitizing cleaned and rinsed surfaces (i.e., use of hot water or chemical sanitizers). Important criteria for using chemical sanitizers, along with examples of the most commonly used chemicals, are in Section 4-501.114. All sanitizers must be used in accordance with the EPA-registered label use instructions.
- Detergent-sanitizer.** This food-contact sanitizer product type is addressed in Section 4-501.115. These sanitizers can be used for both the cleaning and sanitizing steps and do not require a rinse between the two steps. Spray to clean the surface, which may include wiping if needed to remove soil, and then spray again with the same product to sanitize.
- Nonfood-contact surfaces.** The Food Code does not address using sanitizers on nonfood-contact surfaces and recommends only cleaning these surfaces as needed. However, retail food and foodservice operators often use sanitizers on nonfood-contact surfaces to minimize the possible risk of cross-contamination.
- Disinfectants.** Disinfectants are not defined in the 2017 Food Code, but their use is referenced in Section 2-501.11, “Clean-up of Vomiting and Diarrheal Events.” The Food Code specifically states that procedures to clean up after a vomiting or diarrheal event should

involve a more stringent process than routine sanitization: “It is therefore important that foodservice establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration.”

As stated above, disinfection is not a current regulatory requirement in retail food and foodservice establishments. However, when a disinfectant is used on a food-contact surface, special attention must be paid to the EPA-registered label use instructions (i.e., concentration, contact time, and application method), which typically includes a rinse step after use.

- **Concentration verification.** In Section 4-302.14, the concentration of the sanitizer is required to be measured to be sure it is used at a minimum concentration that ensures proper sanitization and that it does not exceed the level above which the sanitizer may not be safe. Therefore, “a test kit or other device that accurately measures the concentration in mg/L [ppm] of sanitizing solutions shall be provided.”

REGULATION OF SANITIZERS AND DISINFECTANTS

The U.S. EPA is the primary regulatory authority for antimicrobial products like sanitizers and disinfectants used in retail food and foodservice establishments. Antimicrobial products are identified as antimicrobial pesticides by the EPA, as they fit the statutory definition of products intended to reduce or eliminate microorganisms (7). Various physical and chemical attributes of sanitizers and disinfectants may differentiate them in the marketplace. Regardless of these differences, they all must meet certain regulatory standards to be legally sold in the United States. The EPA sets minimum levels of biocidal efficacy (i.e., the ability to reduce or eliminate targeted organisms under laboratory conditions) that must be met for a product to be called a disinfectant or sanitizer (11). Additional organisms can be added to the EPA-registered product label based on proven efficacy and shared in the marketing material of individual manufacturers. In addition, the EPA determines the human and ecological risks from exposure to antimicrobial products, which results in statutory precautionary and first aid labelling, including any personal protective equipment that may be required when the product is used. The EPA Antimicrobial Division manages the registration of antimicrobial products used on inanimate objects, such as sanitizers and disinfectants. Although not the focus of this paper, there are other regulated antimicrobial products used in retail food and foodservice establishments. For example, the FDA, not the EPA, has responsibility for regulating skin antiseptics (i.e., antimicrobial hand soaps and hand sanitizers).

A data package submitted to the EPA for the registration of an antimicrobial product must include microbiological data (i.e., efficacy data), chemistry data, stability (or

shelf life) data, and toxicology data (to help determine precautions and recommendations for personal protective equipment). The submission must also include a detailed master label containing first aid statements, precautionary language directions for use, efficacy claims (often a list of microorganisms and the contact times and product concentrations), and suitable marketing claims. The scientific experts at the EPA not only analyze the data submitted but make decisions on whether proposed marketing language is truthful and not “false and misleading.” Product ingredients are also reviewed carefully. In the case of food-contact sanitizers, all ingredients (i.e., active and inert) must be approved for food use, allowing the product to bear a “no rinse required” use instruction. Disinfectants do not have this requirement; therefore, disinfectants must be rinsed off if used on a food-contact surface, and then that same surface must be sanitized before reuse. If using a detergent-sanitizer or detergent-disinfectant, rinsing is not required if stated on the product label (8, 15). The EPA review process can take up to 4 months for the addition of a new claim or application and between 5 and 10 months for a new product. It might take several years if the product has been designed with a novel active ingredient.

Once the basic requirements have been met (Table 2), a manufacturer may test and add a variety of additional microorganism kill claims to the label through the registration process. Companies manufacturing sanitizers and disinfectants typically market claims that resonate with the retail food and foodservice industry (e.g., norovirus, *Listeria monocytogenes*, and *E. coli* O157:H7). Importantly, only additional bactericidal claims can be added to a sanitizer label, whereas additional bactericidal, virucidal, fungicidal, tuberculocidal, and sporicidal claims can be added to a disinfectant label. It should be noted that many products have proven efficacy as both food-contact and nonfood-contact surface sanitizers, in addition to disinfectant efficacy, often at different concentrations and contact times, so a product might have a long menu of efficacy claims listed on its master label. Therefore, it is important to read the label carefully to understand which claims apply when using the product as a food-contact surface sanitizer and which apply when using the product as a disinfectant. The labels of all EPA-registered sanitizers and disinfectants are listed in a searchable database available in the EPA Pesticide Product Labeling System (PPLS) (14) and at the National Pesticide Retrieval Information System (NPRIS) (1). In addition, to help users select an appropriate sanitizer or disinfectant to control microorganisms of interest, the EPA maintains specialized lists (13). Examples include List G, the EPA’s Registered Antimicrobial Products Effective Against Norovirus, and List N, Disinfectants for Use against SARS-CoV-2 (COVID-19). The latter (List N) will be described in greater detail later in this paper.

Antibacterial All Purpose Cleaner

ACTIVE INGREDIENTS

Active Ingredient	A X.YZ%
Active Ingredient	B X.YZ%
Active Ingredient	C X.YZ%
Active Ingredient	D X.YZ%
OTHER INGREDIENTS:	X.YZ%
TOTAL:	100.00%

Danger
KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective (rubber or chemical resistant) gloves. Harmful if swallowed or if absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

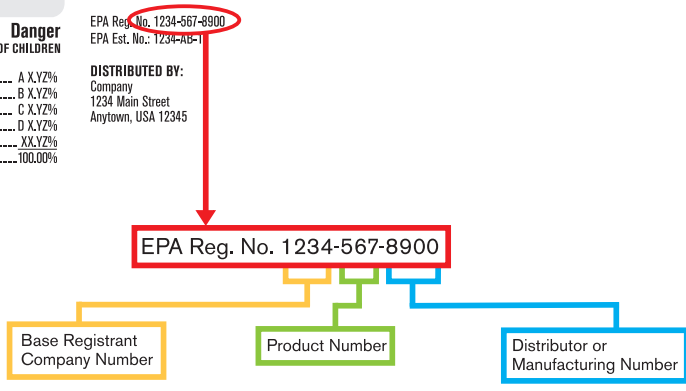
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling poison control center or doctor or going for treatment.
FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-XXX-XXXX OUTSIDE NORTH AMERICA, CALL 1-XXX-XXX-XXXX

EPA Reg. No. 1234-567-8900
EPA Est. No.: 1234-AB-1

DISTRIBUTED BY:
Company
1234 Main Street
Anytown, USA 12345



Not all products have a two-part EPA Registration Number.
Sub-registered products are three-parts.

FIGURE 1.

UNDERSTANDING EPA-REGISTERED LABELS

Once a product is registered with the EPA, its master label is accessible to the public through the PPLS or the NPRIS (see Regulation of Sanitizers and Disinfectants, above). The master label is a comprehensive document that contains a great deal of information about the product, such as functions, safety information, use directions, use sites, efficacy claims, and marketing claims. Commercial, package, or market labels are developed from the master label and are what the end users see on sanitizer or disinfectant containers. The label on the product container has the most relevant and useful information for the end user. This information cannot deviate from the language on the master label, which is registered with the EPA. Additional information from the master label may be used in marketing materials, such as brochures, websites, and other advertising forms. It is important to note that a product can be sold under a different name than the one that appears on the master label. The most important parts of a commercial antimicrobial product label are presented in *Figure 1* and are also described below.

- **EPA registration number.** On the product label, the registration number is displayed as “EPA Reg. No.” followed by two or sometimes three sets of numbers. Because products may be marketed and sold under different brand names, they might have the same EPA registration number. Products made by a supplier or distributor (i.e., not a manufacturer) have three sets of

numbers; the last set of numbers identifies the supplier, who is not the same as the manufacturer. If the first two sets of numbers match a registration number that is on one of the EPA lists (e.g., List N), the product is equivalent to the listed product. For example, if “EPA Reg. No. 12345-12” is on List N, then all products labeled EPA Reg. No. 12345-12-#### are an equivalent product, because the last set of numbers identifies the supplier or distributor.

- **Format.** The product label indicates if the product is in an RTU format (does not require any dilutions) or if it is a concentrate (liquid or powdered) that needs to be diluted as specified by the label before being used.
- **Directions for use.** The use instruction section presents valuable information on dilution, contact time (see below), and whether the product can be sprayed, wiped, mopped, and so on. It also lists precleaning steps or whether or not a potable-water rinse is required.
- **Dilution.** A concentrated product will have precise instructions for use, listing ounces per gallon and ppm to help the end user achieve the correct concentration. The efficacy of some antimicrobial products may be affected by the hardness of the water used to prepare the diluted product. For this reason, manufacturers test the efficacy of the product in hard water. The label will indicate the water hardness level at which efficacy testing was done, such as an instruction to dilute 2 oz/gal of sanitizer in

water up to 500 ppm hardness. The efficacy of the product will be negatively impacted if the product is used in water above the hardness stated on the product label. Water hardness varies throughout the United States. For information about a specific location, one should contact the local health agency or local water utility.

- **Contact time.** Antimicrobial products have minimum contact times listed on their product labels. These contact times can vary based on the product type, the target organism, or a specific use. The required contact time for food-contact hard surface sanitizers is typically 1 minute, with the exception of sanitizing in a dish machine (see FDA Food Code), and for non-food-contact sanitizers, it can be up to 5 minutes. Disinfectants can list various contact times for different bacteria, viruses, or fungi but generally do not exceed 10 minutes. If a product has multiple contact times for the same application, it is recommended to use the most conservative contact time for routine disinfection, meaning the longest contact time and the strongest dilution. In cases when a specific organism is targeted, the contact time for that organism listed on the label should be used. Note that for a disinfectant to be effective, the surface must be wet with the disinfectant for the full duration of the contact time. It is important to note that some disinfectants with longer contact times might need to be applied more than once to achieve the full required contact time.
- **Claims.** A claim is a statement about a product supported by evidence or data and has been approved by the EPA. Claims can range from simply naming a product as a sanitizer or disinfectant to specifics about its ability to kill a particular virus or bacterium or claims that it will sanitize a particular surface type. An example is an efficacy claim, which lists organisms for which the product has been shown to have efficacy.
- These claims are specific to the intended use as a sanitizer or disinfectant, and they are also specific to the concentration and a contact time. Any product marketing materials or associated literature are regarded as “labelling” by the EPA, and therefore, claims listed on these materials are subject to the same rules as claims on product packaging and physical labels. Another type of claim to note is an emerging viral pathogen claim, used during a pandemic, such as the COVID-19 pandemic. This type of claim will only appear on a master label (this will be discussed below in Emerging Issues).
- **Surface type and compatibility.** Some products may have information about surfaces for which the product is intended (e.g., stainless steel, glazed tile, cabinets, or floors). Product labels may also mention the surfaces that may become damaged through use of the product; for example, peracid products should not be used on soft metals like copper.

- **Shelf life.** The EPA requires that shelf life (expiration date) be listed on the label of a product only when the shelf life is less than 1 year. The shelf life is determined for an unopened container by the product manufacturer. For products that are in use (e.g., wiping cloth solution), the concentration must be checked according to Section 4-302.14 in the FDA Food Code.
- **Storage and disposal.** Any specific instructions regarding storage or disposal are listed on the EPA-registered product label.
- **Statutory precautionary statements.** These statements alert the user to the hazards associated with misuse of the product and necessary first aid procedures if injury should occur.
- **Phone number.** A phone number must be listed for the user in order to access additional information or file a complaint about the product.

EMERGING ISSUES

Antimicrobial resistance

Discussions about the increased use of antimicrobial products, such as disinfectants and sanitizers, have centered around the potential risks associated with the misuse of these products. In particular, concerns have been raised about the possibility of the development of reduced antimicrobial susceptibility, often described in the scientific literature or media as antimicrobial resistance. The current research evaluating antimicrobial resistance of bacterial isolates recovered from food environments has focused on methodology and concentrations which are not relevant to the food industry (3). These studies are typically run following test methods common in antibiotic research, where use concentrations are very low and close to the minimum inhibitory concentration (MIC). The concentrations of sanitizers and disinfectants used in the food industry are typically hundreds of times higher than the MIC. Currently, no empirical data exist to indicate that the proper use of sanitizers or disinfectants leads to antimicrobial resistance under conditions present in food handling environments as part of a comprehensive sanitation program (4).

It is imperative that sanitization or disinfection processes be easy to follow. Sanitizer rotation has been discussed as a way to mitigate resistance development, without consideration of whether it is truly needed. This could bring additional challenges to an already complicated world of sanitizers, which may in turn further reduce cleaning and sanitization compliance.

Emerging viral pathogens

In August 2016, the EPA released guidance on disinfectant claims against emerging viral pathogens (EVP). The guidance allows companies to make EVP claims against new and emerging viruses during an outbreak by relying on historical data on similar or harder-to-kill viruses. In the

event of an outbreak of an EVP, there is an immediate need for disinfection solutions against this pathogen. However, there may be a lack of virus availability or laboratory expertise for testing disinfectant efficacy against this new virus. Therefore, in the interest of public health, the EPA developed a hierarchical approach to predict the effectiveness of disinfectants against EVP (10).

Viruses can be categorized into three groups based on their structure. The organisms that are the hardest to kill (most resistant) are the small nonenveloped viruses, followed by large nonenveloped viruses, and the easiest to kill (less resistant) are enveloped viruses. If a product is registered for use against a virus in a more resistant category, it can be assumed it will be effective against viral pathogens in a less resistant category. However, this is a temporary measure until the virus becomes available for testing and products can be tested to determine their true efficacy against the new pathogen.

In the case of SARS-CoV-2, a coronavirus which is an enveloped virus (easiest to kill), it is logical to assume that it will be inactivated with common disinfectants with proven, registered efficacy claims against viruses that are harder to kill, such as the nonenveloped virus type (e.g., norovirus, poliovirus, or rhinovirus). However, products that have small or large nonenveloped viruses listed on their labels cannot claim efficacy against less resilient viruses identified as emerging or reemerging pathogens until the EPA has granted an EVP claim. For example, to claim SARS-CoV-2 control based on this assumption, one needs either an EVP claim or a human coronavirus claim. The EVP guidance was “triggered” early in 2020 as COVID-19 quickly became a public health threat, which allowed manufacturers to communicate the expected effectiveness of certain disinfectant products that were preapproved by the EPA. In addition, the EPA compiled a searchable list of products with EVP claims that are appropriate for environmental disinfection and control of SARS-CoV-2. As the pandemic took hold, the EPA added products based on additional criteria, such as efficacy against viruses similar to SARS-CoV-2, to help alleviate shortages of effective products. This list is known as List N (12). Meanwhile, the EPA, testing laboratories, and manufacturers have been working to test the efficacy of many products specifically against SARS-CoV-2. As this publication was being prepared, the first few products tested against SARS-CoV-2 were becoming available on the market. The EPA has added these products to List N and continues to promote the use of any products on the list for disinfection of SARS-CoV-2.

Two points need to be emphasized. First, under pandemic conditions, such as the COVID-19 pandemic, it is imperative that antimicrobial products be used according to the viricidal disinfection directions and not the sanitization directions if the product can be used as both a sanitizer and a disinfectant. Second, it is highly recommended that, during the COVID-19 pandemic, those within the retail food and

foodservice industry should continue to use their sanitizers for routine procedures and use disinfectants where necessary, such as treating high-touch surfaces, cleaning bathrooms, and decontaminating the facility when there is known exposure.

CURRENT AND FUTURE TRENDS IN SANITIZING AND DISINFECTING

The SARS-CoV-2 pandemic has emphasized the importance of sanitizing and disinfecting unlike anything seen before in the retail food and foodservice industry. Even before the pandemic, efforts were underway to enhance cleaning, sanitizing, and disinfecting through innovative formulation and application. Retail food and foodservice establishments can be challenged by the complexities of sanitization programs, including multistep processes, the availability or need for multiple products with different use instructions, and low-moisture cleaning processes. The additional pressures of limited time and space for complicated procedures, high staff turnover, and the necessity for frequent training make time saving or simplification of sanitization (and disinfection) very desirable. Novel products are continually being developed and introduced to the market to help overcome some of these challenges by reducing risk, simplifying procedures, and helping to ensure compliance.

The recent development of procedures for reopening establishments that have been closed during the pandemic or for enhanced cleaning during operation have led to an increase in the availability and popularity of large area application techniques, such as fogging, misting, and electrostatic spray. However, the efficacies of these are unknown at this time, so there is some uncertainty and confusion about their usability. One of the greatest concerns is the potential for their misuse. The safety of workers and bystanders, in addition to effectiveness, should be paramount in decision making around these application options. Moreover, the regulatory requirements for products used through these systems are evolving.

In times of crisis, novel technologies and applications become very visible in the marketplace. It is important to note that pesticidal devices like UV and other nonchemical technologies do not go through the same regulatory rigor as traditional chemical products, and no standard efficacy methods exist for these products. Unlike chemical pesticides, the EPA does not routinely review the safety or efficacy of pesticidal devices and, therefore, does not confirm whether or under what circumstances such products might be effective against the spread of SARS-CoV-2 or other organisms. Some devices have limitations in how they are used and in general should only be used as an adjunct to routine sanitation practices. It is illegal to make false claims about the effectiveness of a pesticidal device, so any supporting science for such products should be carefully and critically assessed before adoption.

CONCLUSIONS

Historically, sanitizers have been the most commonly used antimicrobial product in retail food and foodservice establishments. That is changing as a result of the COVID-19 pandemic. Moving forward, we presumably will see disinfectants play a more important role in retail food and foodservice settings. Sanitizers and disinfectants are designed for different purposes, and these products must be used properly in order to achieve the desired public health outcomes. Therefore, it is important that industry professionals clearly understand when and how

to use a sanitizer and when and how to use a disinfectant. Most importantly, retail and foodservice industry training programs should emphasize the importance of proper use of sanitizers and disinfectants. When used properly, sanitizers and disinfectants are powerful tools that can keep retail food and foodservice operations safe.

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Supporting Attachment #3: Alternative Recommended Solution for Consideration

Late Breaking Issue Title: Amend Food Code: clarify language for disinfection of food-contact surfaces
(Submitted for the 2020 CFP Biennial Meeting, rescheduled for 2021)

Issue Submittal Date: June 2021

The following outlines an alternative to the Recommended Solutions included in the Late-Breaking Issue titled “Amend Food Code: clarify language for disinfection of food-contact surfaces” to establish a CFP Council committee to further study the topic of disinfectant use in retail food facilities.

Recommended Committee charges include:

1. Review current regulations related to disinfectant use (as outlined in attachment to this Issue titled, “Supporting Attachment – EPA-Registered Disinfectants June 2021”).
2. Develop a guidance document for posting on the CFP website for use by retail food facility operators (chain and independent operators), food safety trainers, and regulators to explain the appropriate use of disinfectants on food-contact surfaces in a retail food facility. Suggested topics include, but are not limited to:
 - a. Why to use, including an explanation of the difference between sanitization and disinfection.
 - b. When to use to protect against viruses (e.g., vomiting and diarrheal events, foodborne illness outbreaks, COVID-19 illness(es)).
 - c. What to use (e.g., EPA-registered products).
 - d. How to use (e.g., in accordance with EPA-registered label use instructions).
 - e. Recommended protocols for clean-up of vomiting and diarrheal events as specified in FDA Food Code section 2-501.11.
 - f. List of existing resources, such as federal agency guidance documents, federal regulations (referencing specific, applicable sections), and other publicly available resources to prevent information duplication or contradiction.
3. Consider recommending changes to the FDA Food Code to clarify the use of disinfectants in retail food facilities on food-contact surfaces.
4. Report Committee findings and recommendations back to the next CFP Biennial Meeting.