

**Conference for Food Protection
2023 Issue Form**

Issue: 2023 III-013

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.

Title:

Report - Disinfectant Committee (DC)

Issue you would like the Conference to consider:

The Disinfectant Committee requests acknowledgement of their final report, thanking the committee members for their hard work, and that the committee be disbanded.

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 on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

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 a norovirus or other viral pathogen outbreak occurs, local and state regulatory agencies 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 recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but are not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

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 types of EPA-registered disinfectants which 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 due to their conformity to 40 CFR 180 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

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 use disinfectants on 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." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "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 hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address the use of disinfectants in food establishments along with a guidance document to provide detailed information on disinfectants and how they should be used would alleviate confusion and potential misuse of disinfectants in such settings.

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...:

1. Acknowledgement of the Disinfectant Committee Report.
2. Thanking the members of the Committee for their work.
3. The Committee be disbanded; all assigned charges have been completed.

Submitter Information 1:

Name: Dale Grinstead
Organization: Mountain Top Microbiology

Address: 230 Shadow Creek Ln
City/State/Zip: Highlands, NC 28741-7029
Telephone: 2626310719
E-mail: dale.grinstead626@gmail.com

Submitter Information 2:

Name: Anna Starobin
Organization: Food Safety/Antimicrobials Consulting, LLC
Address: 201 Kemp Rd. West
City/State/Zip: Greensboro, NC 27410
Telephone: 336-558-5359
E-mail: anna.starobin718@gmail.com

Content Documents:

- "Final report"
- "Committee roster"
- "Guidance for the Safe and Proper Use of Sanitizers and Disinfectants in Foo"

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.

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME *Disinfectant committee*

DATE OF FINAL REPORT: 12/26/2022

COMMITTEE ASSIGNMENT: Council I Council II Council III Executive Board

REPORT SUBMITTED BY: Dale A. Grinstead, Anna Starobin

COMMITTEE CHARGE(S):

Issue # 2020 III-035

1. Review current regulations related to disinfectant use
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 treat a surface exposed to 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 progress back to the next Biennial Meeting in 2023 and the committee findings and recommendations may be presented at subsequent Biennial Meetings if necessary.

COMMITTEE WORK PLAN AND TIMELINE:

1. Review current regulations on use of disinfectants and engage with EPA to understand any upcoming changes to those regulations
2. Review literature available to inform the guidance document
3. Draft a guidance document based on the best available information
4. Draft suitable language changes for the code to include appropriate use of disinfectants in food facilities and on food contact surfaces.

TIMELINE:

1. First Draft of Guidance to be completed by July 2022
 - a. Content of Guidance finalized by August 2022
 - b. Guidance document finalized by October 2022
2. First draft of recommended changes to the Code by September 2022
 - a. Recommended changes to the Code completed by October 2022
3. First draft of issues from the committee by end of October 2022
 - a. Issues finalized by mid December 2022
 - b. Issues submitted by first week of January 2023

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. Overview of committee activities:

The committee held by Bi-weekly calls through July 2022 and then changed to weekly calls until mid-November 2020 when the guidance and issue drafts were completed.

2. Charges COMPLETED and the rationale for each specific recommendation:

- a. Review current regulations related to disinfectant use. Completed and no recommendation for this charge. Work was completed to provide information for the guidance.
- b. 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. Work completed and recommendation to accept and post the guidance is included in Issue 2 from this committee
- c. Consider recommending changes to the FDA Food Code to clarify the use of disinfectants in retail food facilities on food-contact surfaces. Work completed and recommended changes to address the use of disinfectants and to suggest changes to the vomiting and diarrheal language in the code are in Issues 3, 4, and 5.
- d. Report progress back to the next Biennial Meeting in 2023 and the committee findings and recommendations may be presented at subsequent Biennial Meetings if necessary. Work is completed and Issue one recommends disbanding the committee as all charges have been met.

3. Charges INCOMPLETE and to be continued to next biennium:

None

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.

Board Action is required for some provision(s) of this report and therefore a verbal report needs to be presented at the Board Meeting.

1. The participation of EPA in this committee was very valuable. CFP should consider that EPA be present as a consultant to Council III deliberations at the biennial meetings.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. **Issue #1: Report – Disinfectant committee:** List of content documents submitted with this Issue: *Disinfectant committee final report and Committee member roster.*

b. **Committee Member Roster:**

See attached revised roster PDF No changes to previously approved roster

"Committee Members Template" (Excel) available at: www.foodprotect.org/work/ (Committee roster to be submitted as a PDF attachment to this report.)

(1) **Other content documents:**

c. List of supporting attachments: Not applicable

(1) **Guidance for the safe and proper use of sanitizers and disinfectants in food establishments**

1. **Committee Issue #2: Use of Disinfectants in a Food Establishment Guidance.** List of content documents submitted with this Issue: *Guidance for the safe and proper use of sanitizers and disinfectants in food establishment.* Supporting documents: *Disinfectant committee final report and Committee member roster.*
2. **Committee Issue #3: Recommended Food Code Changes to Address Use of Disinfectants in Food Establishments.** List of content documents submitted with this Issue: *None.* Supporting documents: *Guidance for the safe and proper use of sanitizers and disinfectants in food establishment*
3. **Committee Issue #4: Recommended Food Code Changes to correct unclear language in the annex on hand antiseptics.** List of content documents submitted with this Issue: *None.* Supporting documents: *Guidance for the safe and proper use of sanitizers and disinfectants in food establishment*
4. **Committee Issue #5: Updates to the code to address the use of disinfectants during body fluid clean-up.** List of content documents submitted with this Issue: *None.* Supporting documents: *Guidance for the safe and proper use of sanitizers and disinfectants in food establishment*

Committee Name: Disinfection of Food Contact Surfaces								
Voting Members								
Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Grinstead	Dale	Co-Chair	Emeritus	N/A	Highlands	NC	2626310719	dale.grinstead626@gmail.com
Starobin	Anna	Co-Chair	Industry - Support	N/A	Greensboro	NC	3365585359	anna.starobin718@gmail.com
Hanson	Patricia	Member	Regulatory- State	FDACS	Tallahassee	FL	8506669090	patricia.hanson@fdacs.gov
Hernandez	Cris	Member	Regulatory- State	Oregan Health Authority	Beaverton	OR	503-890-7637	crishernandez13@gmail.com
Culbert	Carol	Member	Emeritus	Southern Nevada Health District	Las Vegas	NV	7023761124	zosh1@cox.net
Collins	Alicia	Member	Industry - Support	Steritech	Charlotte	NC	7072084399	alicia.collins@steritech.com
Minjares	Christina	Member	Industry- Retail Foods	Whole Foods Market	Austin	TX	5129837592	christina.minjares@wholefoods.com
Foster	Amy	Member	Industry- Food Service	Chik-Fil-A	Smyrna	GA	7708232840	amy.foster@cfacorp.com
Hernandez	Jaime	Member	Industry- Food Service	Starbucks Coffee Company	Rockville	MD	4435188145	jaiherna@starbucks.com
Nicar	Dave	Member	Industry- Support	Publix Super Markets Inc.	McCalla	AL	9016283212	dave.nicar@publix.com
Frasier	Angie	Member	Academia	Clemson	Clemson	SC	8646563652	afrazier@clemson.edu
Dinauer	Lauren	Member	Regulatory- Local	Pima County Health Department	Tucson	AZ	5202795083	lauren.dinauer2@pima.gov
Buckley	David	Member	Industry- Support	Diversey	Fort Mill	SC	8034872058	david.buckley@diversey.com
Brandt	Matthew	Member	Regulatory- State	Colorado Department of Public Health and Environment	Denver	CO		matthew.brandt@state.co.us
Manuel	Chip	Member	Industry- Support	GOJO	Akron	OH	2164088658	manuelc@gojo.com
Farrell	Sharon	Member	Regulatory - State	Indiana Department of Health	Indianapolis	IN	3174093556	sfarrell@isdh.in.gov
Non-Voting Members								
Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Moore	Veronica	FDA Consultant	Regulatory - Federal	FDA			240-402-1409	Veronica.Moore@fda.hhs.gov
Liggans	Girvin	FDA Alternate	Regulatory - Federal	FDA			240-402-1382	Girvin.Liggans@fda.hhs.gov
Rodriguez	Luis	CDC Consultant	Regulatory - Federal	CDC			954-356-6677	ved8@cdc.gov
Holst	Meghan	CDC Alternate	Regulatory - Federal	CDC			404-498-1076	ows6@cdc.gov
Blackburn	Tajah	EPA Consultant	Regulatory - Federal	EPA			703-347-0260	blackburn.tajah@epa.gov
Black	Elaine	Alternate	Industry- Retail Food	ECOLAB	Eagan	MN	3025442393	elaine.black@ecolab.com
Jacobs	Darryl	Alternate	Industry- Food Service	Wendy's	Dublin	OH	6145467007	darryl.jacobs@wendys.com
Babekir	Amani	Alternate	Industry - Support	Ecolab	Greensboro	NC		amani.babekir@ecolab.com
Brady	Janice	Alternate	Industry - Food Service	Denny's Inc.	SPARTANBURG	SC	803-837-1337	jbrady@dennys.com
Carlson	Eric	Alternate	Regulator - State	New Mexico Environmental De	Las Cruces	NM	5753394657	eric.carlson@state.nm.us
Derr	Samuel	Alternate	Industry - Retail Food	Elite Food Safety Training, Inc.	Naperville	IL	6307763430	sderr@elitefoodsafety.com
Douglas	Amanda	Alternate	Industry - Retail Food	Wawa	Wallingford	PA	267 575 7881	amanda.douglas@wawa.com
Edelen	Jeffrey	Alternate	Industry - Retail Food	Whole Foods Market	Austin	TX	737-932-1143	jeff.edelen@wholefoods.com
Haller	W. Michael	Alternate	Industry - Support	UL Everclean	La Verne	CA	9095386410	Mike.Haller@ul.com
Leach	Katie	Alternate	Industry - Retail Food	Stop and Shop	Westfield	MA	413-563-1208	Katie.leach@retailbusinessservices.com
ONeal	James	Alternate	Industry - Food Service	Denny's	Spartanburg	SC	8034802079	joneal@dennys.com
Rivas	Rose	Alternate	Industry - Processing	Rivas	Pfafftown	NC	7073636032	april@rivasranch.com
Romo	Nela	Alternate	Industry - Food Service	El Pollo Loco	West Covina	CA	949-689-3101	NROMO@ELPOLLOLOCO.COM
Schwartz	James	Alternate	Industry - Retail Food	Alberstons Companies	Concord	CA	9254371741	james.schwartz@safeway.com
Thesmar	Hilary	Alternate	Industry - Support	FMI	Arlington	VA	12024949016	hthesmar@fmi.org
Wallingford	Shelly	Alternate	Industry - Food Service	First Watch Restaurants	Bradenton	FL	(720) 456-5702	swallingford@firstwatch.com
Whitlock	Lisa	Alternate	Industry - Retail Food	Lisa Whitlock Retail Food Safet	Loma Rica	CA	(530) 770-1953	kitchencooker63@gmail.com
Wijesekera	Dilshika	Alternate	Industry - Support	Instacart	Seattle	WA	4798793903	dilshika.wijesekera@instacart.com
ZENLEA	JEREMY	Alternate	Industry - Retail Food	EG America	Westboro	MA	6035832506	zenlea@cumberlandfarms.com
Oswald	Steve	Alternate	Industry - Processing	Wakefern Food Corp	Elizabeth	NJ	9085273624	steve.oswald@wakefern.com
Sheltron	Susan	Alternate	Regulatory - State	WA Dept of Health	Kennewick	WA	15092121206	susan.shelton@doh.wa.gov
Baroudi	Dr. Al	Alternate	Industry - Food Service	The Cheesecake Factory	Thousand Oaks	CA	8185198331	abaroudi@thecheesecakefactory.com

CONFERENCE FOR FOOD PROTECTION

GUIDANCE FOR THE SAFE AND PROPER USE OF SANITIZERS AND DISINFECTANTS IN FOOD ESTABLISHMENTS

Executive summary

NOTE: The guidance in this document does not create or confer any rights for, or on, any person and does not operate to bind public health officials or the public. This guidance does not have the force and effect of law and thus is not subject to enforcement. EPA, FDA and CDC served as advisors participating in committee discussions as the guidelines were developed. Further, this guidance does not establish regulatory requirements and the recommendations contained herein are not intended to supplant, or otherwise serve as, the rules and regulations applicable to food establishments in a given Federal, State, local, or tribal jurisdiction. The contents of this document are solely the responsibility of the authors and does not necessarily represent the views of their employers.

The Conference for Food Protection (CFP) convened the 2020 Biennial Meeting using a virtual format in August 2021; the meeting was originally scheduled for April 2020 but was delayed due to the COVID-19 pandemic.

Throughout the COVID-19 pandemic, the use of disinfectants significantly increased in food establishments; however, available guidance for safe and proper use of disinfectants at retail was limited and occasionally conflicting. It was not always clear to food industry and regulatory sectors which products were appropriate for use in order to reduce or inactivate microorganisms of concern.

This ongoing confusion resulted in the submission of late-breaking Issue 2020-III-035 pertaining to the use of disinfectants in retail food establishments and the concern that disinfection is not addressed in the 2017 FDA Food Code (Food Code). As a result of Council III deliberation in August 2021, a “Disinfection of Food-Contact Surfaces Committee” was formed with charges including charge 1) propose disinfection language for the Food Code, and charge 2) develop a guidance document for food establishments on when and how to safely apply disinfectants on food contact surfaces as needed to reduce or eliminate disease-causing microorganisms (e.g., bacteria, fungi, and viruses) during the clean-up of bodily fluid events, foodborne illness outbreaks, and the COVID-19 pandemic.

The committee was comprised of representatives from academia, local/state/federal regulatory agencies, and the food industry. Consultants from FDA, EPA and CDC were advising the committee throughout the entire process of guidance document preparation. The committee met weekly for approximately 9 months to fulfill its charges, including the completion of this guidance document.

The committee agreed it was critical to provide guidance on the use of sanitizers and disinfectants, to clarify differences between these categories of products, when and how it is appropriate to use them to control disease-causing pathogens. A review of important regulatory requirements and safeguards, such as EPA registration and product label information, is also provided in this document.

The purpose of this guidance document is to increase knowledge and awareness about the proper use of sanitizers and disinfectants in retail food establishments. When used

properly, sanitizers and disinfectants are powerful and complimentary tools that can keep consumers safe from pathogens that cause infectious disease.

INTRODUCTION

The COVID-19 pandemic heightened attention to the importance of cleaning, sanitizing, and disinfecting of surfaces in food establishments. In response, many governmental agencies governmental agencies, such as the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and United States Department of Agriculture (USDA) began emphasizing the need to frequently disinfect high-touch surfaces.^[1] In many instances, high-touch surfaces are classified as nonfood-contact surfaces, which according to the US FDA Food Code 2017 must be cleaned. Although the 2017 Food Code does not recommend disinfecting or sanitizing non-food contact surfaces, there are occasions when it is appropriate to use an antimicrobial treatment on those surfaces. Disinfectants are used less frequently in food establishments which has led to some observations of misunderstanding and misuse of these antimicrobials.

In addition to disinfectant use during unusual circumstances such as outbreaks and pandemics, there are other occasions when disinfectant use is appropriate in the retail food and food service industry (hereafter referred to as food establishments).

Disinfectants should be used during clean-up of bodily fluid spills as well as during foodborne outbreaks. Other occasions when disinfectant use is appropriate in food establishments is when the organism to be controlled is not controlled by available sanitizers or when a higher level of microbial control is desired.

Clearly, there are a number of occasions, some of them quite common, when disinfectant use is appropriate in food establishments. Although sanitization is a routine, common

practice defined in the U.S. Food and Drug Administration (FDA) Food Code, disinfection is not addressed in the Food Code. Sanitizers and disinfectants may both be present in food establishments, but sanitizers are more frequently used in those environments. It is important to emphasize that sanitizers and disinfectants are **not** interchangeable products and care must be taken to ensure they are not inadvertently misused. Consequently, end users need to understand the differences between sanitizers and disinfectants as well as when, why, and how both can be used in food establishments. The aim of this guidance is to increase knowledge about proper use of sanitizers and disinfectants in food establishments to facilitate proper use. When used properly, sanitizers and disinfectants are powerful and complementary tools that can keep food establishments safe from pathogens that cause infectious disease.^[1]

TABLE OF CONTENTS

- EXECUTIVE SUMMARY 1**
- INTRODUCTION 3**
- TABLE OF CONTENTS 5**
 - List of Tables* 6
 - List of Figures* 6
- DEFINITIONS 7**
- DIFFERENCES BETWEEN DISINFECTANTS, FOOD-CONTACT SURFACE (FCS) SANITIZER, AND NON-FOOD-CONTACT SURFACE (NFCS) SANITIZERS..... 10**
 - CONTACT TIME 10
 - CHEMICAL CONCENTRATION 10
 - CLEANER-DISINFECTANTS AND DETERGENT-SANITIZERS 11
 - SURFACE DISINFECTANT/ SURFACE SANITIZER COMBINATION PRODUCTS 11
 - Those with different concentrations and/or contact times for disinfection and sanitizing* 12
 - Those with the same concentration and contact time for disinfection and sanitizing* 12
 - PRODUCTS WITH BIOFILM CLAIMS 12
 - PESTICIDAL (ANTIMICROBIAL) DEVICES 13
- WHICH SURFACE SANITIZERS OR DISINFECTANTS TO USE? 13**
 - CONSIDERATIONS FOR CHOOSING TO USE A SURFACE SANITIZER OR DISINFECTANT: 14
 - Material Compatibility* 16
 - Dispensing Considerations* 17
- WHEN TO USE A SURFACE DISINFECTANT VS. A FCS SANITIZER? 18**
 - WHEN IS USE OF A DISINFECTANT THE RIGHT CHOICE? 18
 - Product user suspects surfaces are contaminated with a virus or fungus* 18
 - To achieve a higher level of antimicrobial efficacy* 18
 - When a surface sanitizer effective against the microorganism(s) of concern is not available.* 19
 - WHEN IS USE OF A SURFACE SANITIZER THE RIGHT CHOICE? 19
 - OTHER CONSIDERATIONS: 19
- HOW TO USE DISINFECTANTS IN FOOD ESTABLISHMENTS.....20**
 - READING EPA-REGISTERED PRODUCT LABELS 21
 - EPA registration number* 21
 - Format*..... 21
 - Directions for use* 22
 - Dilution*..... 22
 - Contact time*..... 22
 - Claims*..... 23
 - Surface type and compatibility* 23
 - Shelf life*..... 23
 - Storage and disposal*..... 24
 - Statutory precautionary statements* 24
 - Phone number*..... 24
 - FREQUENCY OF SURFACE SANITIZER AND DISINFECTANT USE 25

APPLICATION METHODS FOR SURFACE SANITIZERS AND DISINFECTANTS:	26
SURFACE SANITIZER AND DISINFECTANT CONCENTRATION VERIFICATION	31
DISINFECTION OF FOOD-CONTACT SURFACES	34
SAFETY.....	37
<i>Mixing:</i>	37
<i>Directions for use on different surfaces:</i>	37
<i>Storage and Disposal:</i>	37
WHERE TO USE DISINFECTANTS IN A FOOD ESTABLISHMENT	38
BODILY FLUID CLEAN-UP PROCEDURE	39
WHO PERFORMS CLEAN-UP?	40
CLEAN-UP KIT AND OTHER SUPPLIES NEEDED FOR CLEAN-UP	40
CLEAN-UP PROCEDURES.....	41
<i>Cleaning Launderable items</i>	43
ANNEX:.....	45
REGULATIONS ON DISINFECTANT AND SURFACE SANITIZER USE IN FOOD SERVICE ESTABLISHMENTS.....	45
<i>Oversight and registration of disinfectants and surface sanitizers in the USA</i>	<i>45</i>
<i>Regulatory process, testing, review, and approval</i>	<i>45</i>
<i>Antimicrobial chemical efficacy testing</i>	<i>47</i>
LABEL, LABELING AND ANTIMICROBIAL CLAIMS	48
ENFORCEMENT	49
THE ROLE OF STATE AND LOCAL AUTHORITIES IN REGISTRATION AND LAWFUL USE OF DISINFECTANTS AND SURFACE SANITIZERS	50
FDA OVERSIGHT OF FOOD CODE AND CONNECTION TO EPA/CDC	50
KEY SECTIONS OF FDA FOOD CODE ADDRESSING SURFACE SANITIZERS AND DISINFECTANTS.....	51
DEVELOPMENT OF DISINFECTION GUIDANCE FOR THE PUBLIC BY CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)	53
SUSTAINABILITY CONSIDERATIONS WHEN SELECTING DISINFECTANTS AND SURFACE SANITIZERS.....	53
SUPPLEMENTAL LABELING.....	55
DISTRIBUTOR LABEL	56
WHAT IS A RADIUS OF THE AREA TO BE CLEANED AND DISINFECTED?.....	57
<i>Introduction</i>	<i>57</i>
<i>Laboratory-Based Studies in Chronological Order</i>	<i>58</i>
<i>Select Outbreak Case Studies.....</i>	<i>58</i>
<i>Conclusions</i>	<i>59</i>
LITERATURE REFERENCES.....	60
ADDITIONAL RESOURCES	63
<i>Additional information for control of specific pathogens.</i>	<i>63</i>
AUTHORS	64

List of Tables

Table 1. Attributes of common SANITIZER and DISINFECTANT ACTIVE INGREDIENTS _____	14
Table 2. Food Code recommended FOOD-CONTACT SURFACE cleaning frequency _____	25

List of Figures

Figure 1. Example of a Product Label. _____	24
--	----

DEFINITIONS

Note: These definitions are intended for use only in this guidance document. They are not exact references of U.S. Environmental Protection Agency (EPA) or US Food and Drug Administration (FDA) definitions and are included here solely to aid the reader of this guidance document.

ACTIVE INGREDIENT: chemicals in a pesticide product (e.g., surface sanitizer or disinfectant) that act to control the pests.^[1]

ANTIMICROBIALS: substances or mixtures of substances used to destroy or suppress the growth of pathogens (e.g., bacteria, viruses, or fungi) on inanimate objects and surfaces. While hot water and steam can be used to treat surfaces, they are not legally defined as antimicrobials.

BACK OF THE HOUSE: any place that the customers cannot go within a FOOD ESTABLISHMENT, such as kitchens, food preparation areas and storage areas.

DETERGENT-SANITIZER: surface sanitizer that can also be used as a cleaner

DISINFECTANT: substance, or mixture of substances that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.^[3]

EPA ESTABLISHMENT NUMBER: the EPA assigns a unique number to each establishment that produces any pesticide, active ingredient, or pesticide device. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that each producing establishment must place its EPA ESTABLISHMENT NUMBER on the label or immediate container of each pesticide, active ingredient or device produced.^[4]

EPA REGISTRATION NUMBER: all EPA-registered DISINFECTANT and SANITIZERS must have an EPA REGISTRATION NUMBER (EPA Reg. No.). The EPA Reg. No. of a product can be more useful than its brand name for identifying the EPA-registered product. Alternative brand names have the same EPA Reg. No.

FOOD-CONTACT SURFACE: a surface of equipment or a utensil with which food normally comes into contact or a surface of equipment or a utensil from which food may drain, drip or splash into a food, or onto a surface normally in contact with food.^[5] Term is abbreviated as FCS in this document.

FOOD-CONTACT SURFACE SANITIZER: substance, or mixture of substances, that reduces the microbial population in the inanimate environment by significant numbers but does not destroy or eliminate all microorganisms.^[3]

Note: *The FDA defines the process of sanitization but does not provide a definition for SANITIZER. The EPA, however, does define a surface sanitizer. The abbreviated version of EPA definition (above) will be used in the context of this guidance document.*

FOOD ESTABLISHMENT: operation that stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption.^[5]

FRONT OF THE HOUSE: any place where customers can go within a FOOD ESTABLISHMENT, such as the dining room, bar, patio, areas open to shoppers, checkout counters and bathrooms.

INERT INGREDIENT: substances in addition to the ACTIVE INGREDIENT(s) referred to as “inert ingredients” or sometimes as “other ingredients.” An INERT INGREDIENT generally is any substance (or group of similar substances) other than an ACTIVE INGREDIENT intentionally included in a pesticide product. Examples include emulsifiers, solvents, carriers, aerosol propellants, fragrances, and dyes.^[3]

MASTER LABEL: contains claims and directions for all approved uses for a given product and all associated required labeling. All other labeling for a given product must not contain any text beyond that which is approved in the master label. This label goes on file with the EPA once it is stamped “accepted.”

NONFOOD-CONTACT SURFACE: surfaces that typically do not come in contact with food. Term is abbreviated as NFCS in this document.

NONFOOD-CONTACT SURFACE SANITIZER: substance, or mixture of substances that when evaluated for efficacy by the EPA, is sufficient to yield a reduction of 3 logs within 5 minutes on a NONFOOD-CONTACT SURFACE, which is equal to a 99.9% reduction.

PRODUCT LABEL: written, printed, or graphic matter on, or attached to, the pesticide container or device or any of its wrappers.^[4]

PESTICIDE: any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

DIFFERENCES BETWEEN DISINFECTANTS, FOOD-CONTACT SURFACE (FCS) SANITIZER, AND NON-FOOD-CONTACT SURFACE (NFCS) SANITIZERS

DISINFECTANTS, FCS and NFCS SANITIZERS are different classifications of ANTIMICROBIALS used for different purposes. Understanding those differences is important when selecting the correct antimicrobial product to achieve the desired outcome.

Contact Time

One common difference between surface SANITIZERS and DISINFECTANTS is contact time. Most FCS SANITIZERS are tested at 30- and 60- seconds contact time, but a 1- minute contact time is listed on the PRODUCT LABEL, whereas contact times for NFCS SANITIZERS are 5 minutes or less. DISINFECTANTS have a wider range of contact times – from less than 60 seconds up to 10 minutes. Moreover, some DISINFECTANTS have different contact times for different microorganisms and product use concentrations. For example, a DISINFECTANT may have one contact time against human norovirus, a different contact time when used against coronaviruses, and a third contact time when used against *E. coli*. The contact times can also vary depending on use concentrations as some DISINFECTANTS can be used at more than one concentration. DISINFECTANT manufacturers can assist in selecting the correct DISINFECTANT to ensure microorganisms of concern are controlled and the DISINFECTANT is properly used. It is important to review the PRODUCT LABEL to verify that the correct contact time and DISINFECTANT concentration are used to control microorganisms of concern.

Chemical Concentration

Another common difference between SANITIZERS and DISINFECTANTS is the ACTIVE INGREDIENT concentration which is often higher and sometimes different in DISINFECTANTS than in most surface SANITIZERS. This higher concentration is one of the reasons DISINFECTANTS can achieve a higher level of ANTIMICROBIAL efficacy compared

to surface SANITIZERS. In most cases this higher level of ACTIVE INGREDIENT exceeds the level that can be safely applied to a FCS without a follow-up rinse. Furthermore, some INERT INGREDIENTS that do **not** meet the statutory limit outlined in 40 CFR 180 might be used in a DISINFECTANT, making the DISINFECTANT inappropriate for a no-rinse FCS application.^[6] Therefore, **it is critical to carefully review PRODUCT LABELS for all registered surface SANITIZERS and DISINFECTANTS to ensure their safe and proper use.**

Cleaner-Disinfectants and Detergent-Sanitizers

Some DISINFECTANTS are designed to be used on surfaces without prior cleaning. These products are referred to as “cleaner- DISINFECTANTS” or “one-step DISINFECTANTS.” They contain ingredients that enhance product’s ability to remove soil from surfaces, often in a single cleaning and disinfection step. To ensure an additional soil load does not interfere with the DISINFECTANT’S antimicrobial performance, efficacy testing is done with 5% soil added to the test solutions.^[7]

FCS SANITIZERS are designed to be used on a clean surface. When using DETERGENT-SANITIZERS, often called cleaner-SANITIZERS, that can also be used as a cleaner, it is important to ensure the product is first used for cleaning, followed by a repeat application on the precleaned surface. FCS sanitization is always a multi-step procedure. The Food Code states that if a DETERGENT-SANITIZER is used to clean a FCS and the same DETERGENT-SANITIZER is used to SANITIZE the surface, then no rinse is required between cleaning and sanitizing that FCS (Food Code 4-501.115).^[5] However, it is important to remove soil during the cleaning process. Carefully review PRODUCT LABELS for all registered surface SANITIZERS and DISINFECTANTS to ensure safe and proper use.

Surface DISINFECTANT/ Surface SANITIZER Combination Products

Some products can be used as both a surface SANITIZER and a DISINFECTANT. These ANTIMICROBIALS come in two broad categories.

Those with different concentrations and/or contact times for disinfection and sanitizing

Many surface SANITIZER products have DISINFECTANT claims on the EPA-registered PRODUCT LABEL. Surface SANITIZERS and DISINFECTANTS may have different contact times and concentrations. For example, a quaternary ammonium-based product may be used at 200 PPM with a 60 second contact time and be an effective FCS SANITIZER. That same product, however, may be used at 600 PPM with the same or different contact time and be registered as a DISINFECTANT. While FCS SANITIZERS are meant to be used on FCS without a follow-up rinse, that is not always the case for DISINFECTANTS. Some DISINFECTANTS require a rinse step following application. Check the PRODUCT LABEL and consult with the chemical manufacturer to verify correct use of the chemical.

Those with the same concentration and contact time for disinfection and sanitizing

In recent years, a handful of DISINFECTANTS known as no-rinse DISINFECTANTS have been introduced to the market. These DISINFECTANTS have passed EPA Product Performance Test Guidelines as a DISINFECTANT and are designed within the limits outlined in 40 CFR 180, which permits them to be used on FCS without a follow-up rinse.^[6] These products may also have FCS SANITIZERS claims. Specific claims vary for these products and so do their contact times. Refer to the PRODUCT LABEL to ensure these products are used correctly. Manufacturers of these chemicals can provide guidance on appropriate use of these no-rinse DISINFECTANT products.

Products with biofilm claims

Biofilm kill claims are primarily allowed for DISINFECTANTS. Because these claims were only recently allowed, only a few DISINFECTANTS have that claim. A limited number of surface SANITIZERS have biofilm claims, some of which were granted prior to current, more strict requirements.

Pesticidal (antimicrobial) devices

Sometimes a device is used to sanitize or disinfect surfaces. In some cases, the device may generate sufficient chemical to kill microorganisms on a surface. In other cases, the device may inactivate microorganisms via a physical process. EPA refers to these devices as pesticide devices. Examples of generated chemical antimicrobial agents include hypochlorous acid, ozone and ozonated water, and chlorine dioxide. Devices that inactivate microorganisms via non-chemical means include UV light and high temperature. The EPA does not require registration of pesticide devices. However, these devices must be produced in EPA-registered establishments and some states do require registration of pesticide devices, and a few require efficacy data for submission.

The data plate on the device must list the establishment number. “Because there is no EPA registration of solutions generated and used on-site, the user of the equipment should look to the equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as well as the conditions for use of the solution” (Food Code Annex 3 7.204-11 Sanitizers, Criteria).^[5] There are several companies which choose to register end use solution, following EPA required efficacy test protocols.

Maintaining and cleaning devices used for on-site generation of sanitizing solutions in accordance with manufacturer specifications help ensure SANITIZERS are generated in the form and concentration for which their efficacy was assessed.

WHICH SURFACE SANITIZERS OR DISINFECTANTS TO USE?

The U.S. EPA is the regulatory authority for ANTIMICROBIALS like surface SANITIZERS and DISINFECTANTS used in FOOD ESTABLISHMENTS. Therefore, **only** EPA-registered surface SANITIZERS and DISINFECTANTS can be used in FOOD ESTABLISHMENTS.

Considerations for choosing to use a surface **SANITIZER** or **DISINFECTANT**:

When choosing a surface **SANITIZER** or **DISINFECTANT** multiple factors should be considered, such as:

- Microorganisms against which the surface **SANITIZER** or **DISINFECTANT** are effective against
- Contact time required for surface **SANITIZER** or **DISINFECTANT** to be effective
- Compatibility of surface **SANITIZER** or **DISINFECTANT** with surfaces being treated
- Safety
- Cost
- Tolerance to hard water
- Stability/shelf life
- Effectiveness in presence of soil

Table 1. Attributes of common **SANITIZER** and **DISINFECTANT** ACTIVE INGREDIENTS^[1]

ACTIVE INGREDIENT	SPECTRUM OF ACTIVITY^A	ADVANTAGES	DISADVANTAGES
Free available 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
Quaternary ammonium compounds (QAC)	Vegetative bacteria and enveloped and nonenveloped viruses	<ul style="list-style-type: none"> • Broad spectrum of activity • Compatible with most surfaces • Very stable with 	<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,

ACTIVE INGREDIENT	SPECTRUM OF ACTIVITY ^A	ADVANTAGES	DISADVANTAGES
		long shelf lives <ul style="list-style-type: none"> • Less reactive with soil 	reducing active levels in a solution <ul style="list-style-type: none"> • 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 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	<ul style="list-style-type: none"> • Can be used in 	<ul style="list-style-type: none"> • High flammability

ACTIVE INGREDIENT	SPECTRUM OF ACTIVITY ^A	ADVANTAGES	DISADVANTAGES
	bacteria and enveloped viruses	environments where aqueous SANITIZERS or DISINFECTANTS are undesirable <ul style="list-style-type: none"> • No residue • Limited impact on organic matter 	<ul style="list-style-type: none"> • Some alcohols display poor compatibility with certain plastic materials • RTU format only

Chlorine and quaternary ammonium compound-based (QAC) SANITIZERS are the most commonly used on FCS in FOOD ESTABLISHMENTS. The EPA-registered PRODUCT LABEL will include critical information (e.g., kill claims and contact times) for various use concentrations of the product.

Material Compatibility

Material compatibility profiles for SANITIZERS and DISINFECTANTS are important to consider when selecting a product. The material compatibility profile is highly dependent on not only the product's ACTIVE INGREDIENT, but also the total formulation, as well as an application method for the SANITIZERS and DISINFECTANTS. Over time, surfaces can become damaged if exposed to repeated use of a surface SANITIZER or DISINFECTANT incompatible with the surface. Repeated use of incompatible surface SANITIZERS or DISINFECTANTS can lead to micro-abrasions, cracks, and pitting that can make cleaning, sanitizing, and disinfecting more difficult to accomplish as microorganisms can "hide" in these imperfections and eventually form biofilms.^[8]

While every FOOD ESTABLISHMENT is unique, some generalizations can be made. Stainless steel, a common material used, is usually resistant to a variety of chemicals. However, repeated use of strong oxidizers (e.g., chlorine-based), may cause pitting to occur over time. Soft metals (e.g., aluminum, brass, bronze, copper) are highly sensitive

to pH extremes. Surface SANITIZERS and DISINFECTANTS with alkaline or acidic formulations may accelerate oxidation of these soft metals. Plastic materials found in FOOD ESTABLISHMENTS vary widely in their chemical composition and construction. Some solvents used in surface SANITIZER and DISINFECTANT formulations may be incompatible with various plastic materials. The chemical manufacturer is an excellent resource for determining the material compatibility profile of a surface SANITIZER or DISINFECTANT. Often, the material compatibility profile is listed on the PRODUCT LABEL.

Dispensing Considerations

DISINFECTANTS and surface SANITIZERS can be dispensed using three different dispensing platforms. The goal of the dispensing platform is to safely deliver the product in its registered use concentration.

Automatic dilution of concentrates. The most frequently dispensed solutions in FOOD ESTABLISHMENTS are concentrates. Concentrates are diluted at the point of use via automatic dispensers. These concentrates have a variety of advantages. Minimal packaging size provides cost savings during shipping to the FOOD ESTABLISHMENT and products are often less expensive when diluted at the point of use (versus ready-to-use products). It is extremely important that automated dosing and dispensing systems are set up and installed appropriately to consistently deliver an accurate chemical dose. Poor dosing control can lead to a variety of challenges, such as increased risk of health hazards related to exposure by employees, use of an ineffective product, and regulatory concerns (potentially even fines). Because these systems can degrade over time, periodic checks and/or servicing by a chemical provider are recommended.

Manual dilution of concentrates. Manual dosing systems are rarely used due to issues with under- and over-dosing. These systems are more prone to human error and typically used in unique situations, such as tight spaces and boil water advisories.

Ready-to-Use. Ready-to-use (RTU) surface SANITIZERS and DISINFECTANTS do not require dilution prior to use. Advantages of RTU products include ease of use, since they do not require mixing, and limited/reduced risk related to under- or overdosing of the

product. The main disadvantage of RTU products is cost - usually they are more expensive.

WHEN TO USE A SURFACE DISINFECTANT VS. A FCS SANITIZER?

When is use of a disinfectant the right choice?

Given the differences between surface SANITIZERS and DISINFECTANTS, it is reasonable to ask when use of a DISINFECTANT is the right choice for a FOOD ESTABLISHMENT.

There are several situations when a DISINFECTANT as opposed to a surface SANITIZER should be used:

Product user suspects surfaces are contaminated with a virus or fungus

As mentioned above, a key difference between surface SANITIZERS and DISINFECTANTS is that SANITIZERS are generally not approved for use against spores, mycobacteria, viruses and fungi, such as mold or mildew. Currently with few exceptions, the EPA does not allow these claims for surface SANITIZERS, which compels the user to control these types of microorganisms with a DISINFECTANT. The PRODUCT LABEL lists microorganisms and conditions of use (concentration, contact times, application methods, etc.) under which surface SANITIZERS and DISINFECTANTS are effective.

Note: the EPA is reviewing its policy, and, in the future, more SANITIZERS may have virucidal claims.

To achieve a higher level of antimicrobial efficacy

Another scenario when a DISINFECTANT may be used instead of a surface SANITIZER is when a higher level of efficacy is desired. Cleaning up bodily fluids is a common example of such situation. Many microorganisms of concern are viruses (e.g., HIV, norovirus, hepatitis, etc.) so a DISINFECTANT is likely to be a better choice than a surface SANITIZER. Use of a DISINFECTANT may be appropriate when cleaning restrooms due to the potential presence of high levels of human pathogens, such as viruses. Another

situation when DISINFECTANTS may be a better option is when cleaning high-touch surfaces, such as door handles, touch screens for credit card readers, push buttons for dispensers, chairs, light switches, etc.

When a surface SANITIZER effective against the microorganism(s) of concern is not available.

In addition to efficacy against viruses and fungi, there may be bacteria that need to be controlled that surface SANITIZERS are not commonly tested or effective against.

Examples include *Pseudomonas* spp. or *Mycobacterium* spp. Many DISINFECTANTS are effective against a broad range of bacteria. Similarly, when biofilm control is a priority, a DISINFECTANT (with few exceptions) is likely the correct choice. Check the PRODUCT LABEL for the complete list of organisms against which a DISINFECTANT is effective to verify correct product selection. Chemical manufacturers can assist with product selection.

Another instance when DISINFECTANTS should be used is when required by a regulatory authority. It is important to make sure the required use is in compliance with the EPA-registered PRODUCT LABEL.

When is use of a surface SANITIZER the right choice?

A FOOD-CONTACT SURFACE SANITIZER is recommended for use by the Food Code.^[5] A surface SANITIZER is the default option for most applications in FOOD ESTABLISHMENTS. Use a surface SANITIZER if (1) it is effective against the microorganisms of concern and listed on the EPA-registered label, and (2) it is required by a regulatory authority. Ensure product used is in compliance with the EPA-registered label. Select an FCS SANITIZER or NFCS SANITIZER depending on the nature of the surface being sanitized.

Other considerations:

Several other factors can impact whether to use a DISINFECTANT or a SANITIZER:

- DISINFECTANTS tend to be more expensive than surface SANITIZERS because they are often used at higher concentrations than surface SANITIZERS and may

have more complex formulations. They typically have more microorganisms on the label, which are costly to test.

- Most DISINFECTANTS have a relatively complicated process for use on FCS. After DISINFECTANT application on an FCS, the surface must be rinsed if required by a PRODUCT LABEL. Surfaces must remain wet with SANITIZERS or DISINFECTANTS for the required contact time specified on the PRODUCT LABEL. Many DISINFECTANTS have longer contact times than surface SANITIZERS. Because of the long contact time during which the surface must remain wet with DISINFECTANT, multiple applications of DISINFECTANT to the surface may be needed.
- Most DISINFECTANTS and surface SANITIZERS are not interchangeable. Use patterns highlighted above create challenges regarding proper use of a product. When both surface SANITIZERS and surface DISINFECTANTS are available in a FOOD ESTABLISHMENT, it is easy to misuse them. This could result in an unintentional contamination or adverse health effects for the user or public. Therefore, employee training on proper use of SANITIZERS and DISINFECTANTS is important.
- The relatively high concentration of ACTIVE INGREDIENTS found in many DISINFECTANTS as well as other ingredients can present a safety profile different from FCS SANITIZERS. Proper Personal Protective Equipment (PPE) should be worn if required on the product Safety Data Sheet or the PRODUCT LABEL. For guidance on PPE requirements, contact the chemical manufacturer and provide training for employees as needed.

HOW TO USE DISINFECTANTS IN FOOD ESTABLISHMENTS

When using an EPA-registered DISINFECTANT, read the PRODUCT LABEL and follow the directions, including the application method.

The EPA regulatory process requires that all registered DISINFECTANTS legally sold in the United States include directions for use to ensure efficacy without resulting in adverse effects on the environment.^[9]

DISINFECTANT procedures and application types can vary based on the purpose of the procedure implementation, which is why it is important to read and follow the instructions on the PRODUCT LABEL. Deviating from the PRODUCT LABEL use instructions, including application methods, is illegal and could be unsafe.

Reading EPA-registered product labels

PRODUCT LABELS display the most relevant and useful information for the end user. It is important to note that a product can be sold under a different name than the one that appears on the MASTER LABEL. Key parts of the PRODUCT LABEL include:

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 EPA lists (e.g., List G or 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 specifies if the product is RTU (i.e., does not require any dilutions) or if it is a concentrate (i.e., liquid or powder requiring dilution as specified by the label before use).

Directions for use

Use instructions present valuable information on dilution, contact time (see below), and whether the product can be sprayed, wiped, mopped and so on. They also list cleaning steps and whether a potable-water rinse is required.

Dilution

A concentrated product will have precise instructions for use, listing ounces per gallon and parts per million (ppm) to help the end user achieve the correct concentration. The efficacy of some antimicrobial products, such as SANITIZERS and DISINFECTANTS, may be affected by the water hardness used to prepare diluted product. Because of this, which is why manufacturers test efficacy of the product in hard water. The label will indicate the water hardness level at which efficacy testing was done, indicating the highest water hardness to be used when the product is diluted. Water hardness varies throughout the United States. For information about a specific location, contact the local health agency or local water utility.

Contact time

The contact time indicates how long the surface must be in contact with a surface SANITIZER or DISINFECTANT. Similarly, to an FCS SANITIZER, for a DISINFECTANT to be effective, the surface must be wet with the product for the entire contact time. Importantly, some DISINFECTANTS with longer contact times may need to be applied more than once to achieve the full required contact time.

Contact times can vary based on product type, target microorganism, or specific use/application. Required contact time for FCS SANITIZERS is typically one minute, apart from sanitizing in a dish machine^[5]; required contact time for NFC surface SANITIZERS can be up to 5 minutes. DISINFECTANTS can have various contact times for different bacteria, viruses, or fungi but generally do not exceed 10 minutes. If a PRODUCT LABEL lists multiple contact times for the same application, it is recommended to use the longest contact time and the strongest dilution noted. When a specific microorganism is targeted, the contact time for that microorganism listed on the label must be used.

Claims

A claim is an EPA-approved statement about a product supported by data that has been approved by the EPA. Claims can range from simply naming a product as a surface SANITIZER or DISINFECTANT to specifics about its ability to kill a particular virus or bacterium or claims it will SANITIZE a particular surface type.

Efficacy claims are specific to the intended use as a surface SANITIZER or DISINFECTANT, and they are also specific to the concentration and contact time. Product marketing materials or associated literature are regarded as “labeling” by the EPA.^[10] Therefore, claims listed in these materials are subject to the same rules as claims on product packaging and physical labels. An emerging viral pathogen claim is another type of claim, such as one used during a COVID-19 pandemic. This type of claim will appear on a MASTER LABEL and can be used on marketing materials during an active outbreak, such as during the COVID-19 pandemic.

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 surfaces that could become damaged through use of the product. For example, peracid products should not be used on soft metals like copper and highly acidic or highly alkaline chemicals may damage aluminum.

Shelf life

The EPA requires shelf life (expiration date) to be listed on the PRODUCT LABEL only when the shelf life is less than one year. 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 in the FDA Food Code (Section 4-302.14).

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 hazards associated with misuse of the product and first aid procedures should injury occur.

Phone number

A phone number must be listed for the user to access additional information or file a complaint about the product as well as an emergency phone number in case of exposure.

An example of a PRODUCT LABEL is in

Figure 1.

Figure 1. Example of a Product Label.^[1]

Antibacterial All Purpose Cleaner

Danger
KEEP OUT OF REACH OF CHILDREN

ACTIVE INGREDIENTS

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

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 PHYSICIANS: Available 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.: 1234-567-8901

DISTRIBUTED BY:
Company
1234 Main Street
Anytown, USA 12345

EPA Reg. No. 1234-567-8900

Base Registrant Company Number | Product Number | Distributor or Manufacturing Number

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

Frequency of surface **SANITIZER** and **DISINFECTANT** use.

Section 4-702.11 of the Food Code states FOOD-CONTACT SURFACES shall be sanitized before use and after cleaning. Therefore, frequency of sanitizing is dependent on frequency of cleaning. Cleaning frequency for FOOD-CONTACT SURFACES is presented in section 4-602 and summarized below:

- When changing between types of food, such as fish, beef, chicken, pork
- When changing between raw and ready-to-eat foods
- Any time FCS and utensils may be contaminated
- Every 4 hours unless the equipment is held below room temperatures

The following table is provided in the Food Code to determine cleaning frequency at temperatures below room temperature:

Table 2. Food Code recommended FOOD-CONTACT SURFACE cleaning frequency^[5]

Temperature	Cleaning frequency
5.0°C (41°F) or less	24 hours
>5.0°C -7.2°C (>41°F -45°F)	20 hours
>7.2°C -10.0°C (>45°F -50°F)	16 hours
>10.0°C -12.8°C (>50°F -55°F)	10 hours

While the 2017 Food Code provides guidance for frequency of sanitizing, it does **not** address disinfection.

Frequency of disinfection varies depending on circumstances at the time of disinfection. During normal, routine conditions, surfaces should be disinfected at least daily. High-touch surfaces (e.g., door handles, dispensers, restroom surfaces) should be disinfected at least daily when the facility is open. During outbreaks surfaces should be disinfected at the frequency recommended by public health officials. Surfaces should also be disinfected immediately after a bodily fluid event.

Application methods for surface **SANITIZERS** and **DISINFECTANTS**:

- **Coarse Spray Application**

- Coarse spray is the most common application method where relatively large droplets are generated. Large droplets are not suspended in the air for very long and typically do not spread very far from the sprayer. According to the American Society of Agricultural and Biological Engineers, the volume median diameter (VMD) of a coarse spray is $>325\ \mu\text{m}$. Examples of coarse sprays include trigger sprayers, most hose-end sprayers, and wall-mounted dispensing systems with dispensing hoses. Unless otherwise specified on a label, if surface **SANITIZER** or **DISINFECTANT** use instructions say to “spray” the surface **SANITIZER** or **DISINFECTANT**, it is a coarse spray. Many dispensing systems can give somewhat inaccurate dosing if a very small amount of surface **SANITIZER** or **DISINFECTANT** is dispensed. For this reason, it is better to fill small containers from a larger volume. A good practice for surface **SANITIZERS** is to dispense a surface **SANITIZER** into the surface **SANITIZER** compartment of a sink **then** fill spray bottles from that compartment. A container used to dispense **DISINFECTANT** or surface **SANITIZER** must be clean and should never be used to hold any other chemical such as a cleaner. Residual cleaners may inactivate a **DISINFECTANT** or surface **SANITIZER** added to that container.

- **Wipe Applications**

- Cloth Immersed in surface **SANITIZER**
 - Surface **SANITIZERS** can be prepared in a bucket and a wiping cloth immersed into the solution, which can then be used to clean surfaces. However, as indicated in the Food Code, while wiping a surface with a surface **SANITIZER**-soaked cloth may be adequate for cleaning purposes, it does not constitute sanitizing the surface. “Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Wiping cloths that are

not dry (except those used once then laundered) must be stored in a surface SANITIZER solution of adequate concentration between uses. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the surface SANITIZER. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper surface SANITIZER concentration should be verified by monitoring the solution periodically with an appropriate chemical test kit. The sanitizing solution must stay on the surface for a specific contact time in accordance with the manufacturer's EPA-registered label (Food Code Annex 3-304.14 Wiping Cloths, Use Limitation).^[5] Surface SANITIZER concentration should be checked at least every 4 hours and whenever a fresh solution is dispensed into the container. The PRODUCT LABEL includes instructions of this use application. The manufacturer can also provide guidance on product use.

- Cloth Immersed in DISINFECTANT

- DISINFECTANT can be prepared in a bucket with a cloth immersed in the solution, which can then be used to disinfect surfaces. Ensure DISINFECTANT solution in the bucket is at the correct concentration. Soil can build up in buckets, inactivating the DISINFECTANT and reducing its concentration. Both dirty and clean cloths may inactivate DISINFECTANT solution, therefore the concentration in such containers must be verified at least every 4 hours. A surface being disinfected must remain wet with DISINFECTANT for the duration of the registered contact time. The PRODUCT LABEL includes instructions for this use application. The manufacturer can also provide guidance on product use.

- Disposable SANITIZER wipes

- Disposable wipes, single use wiping cloths or towelettes are popular application methods. Typically, they are pre-moistened with surface

SANITIZER in a container with a surface SANITIZER. These wipes are intended to be single use, then discarded. Wiping a surface with a disposable wet sanitizing cloth is an acceptable practice for wiping food spills and equipment surfaces. However, this practice does not constitute cleaning and sanitizing of FCS to satisfy the methods and frequency requirements in parts 4-6 and 4-7 of the Food Code. The sanitizing solution must stay on the surface for a specific contact time in accordance with the manufacturer's EPA-registered label.^[5] It should also be noted that the EPA does not currently allow wipes to be used on items that could be immersed in SANITIZER, e.g., utensils, cutting boards, glasses, etc. Wipes should be used on immobile surfaces or those that cannot be immersed in SANITIZER.

- It is important to make sure at least two wipes are used for an EPA-registered cleaner/surface SANITIZER wipe. The first wipe is used for a cleaning step, the second for a sanitizing step. If the wipes are not registered as a cleaner/surface SANITIZER, a three-step process should be followed (wash, rinse, sanitize), using at least one wipe for each step.
 - Disposable wipes may hold less solution than other wipes, therefore, make certain surfaces remain wet for the entire contact time listed on the PRODUCT LABEL.
- Disposable DISINFECTANT wipes.
- Disposable DISINFECTANT wipes, single use wiping cloths or towelettes have become popular in recent years. They are pre-moistened with DISINFECTANT at the correct concentration. These wipes are meant to be used once, then discarded. If FCS are wiped with a DISINFECTANT wipe, a rinse step may be required. The PRODUCT LABEL will provide use instructions and specify if rinse step is required.

- Disposable DISINFECTANT wipes may hold a limited amount of a product solution; therefore, make certain surfaces remain wet for the entire contact time listed on the PRODUCT LABEL.
- Mopping
 - This application method is always used on NFCS. The soil level in the mop bucket tends to be very high, therefore, the concentration of surface SANITIZER or DISINFECTANT in the bucket must be closely monitored to ensure its effectiveness.
- **Immersion**
 - In this application, items being treated are completely immersed in surface SANITIZER or DISINFECTANT for the required contact time. They may be immersed in a sink, bucket, specialized tank or other equipment containing surface SANITIZER or DISINFECTANT. Some equipment or utensils must be disassembled prior to immersion to ensure all treated surfaces have contact with a surface SANITIZER or DISINFECTANT. After items are sanitized or disinfected, care must be taken to prevent recontamination during reassembly. It may be necessary to disinfect or sanitize any tools used to reassemble the equipment or utensils. Chemical and equipment manufacturers can provide guidance on proper procedures for sanitizing or disinfecting equipment.
- **Clean In Place (CIP)**
 - CIP involves circulating cleaning, rinsing and sanitizing solutions through piping and flushing interior surfaces of equipment. The CIP process is specific to a piece of equipment. Equipment and chemical manufacturers can provide guidance on how to conduct the CIP process along with recommendations for selecting the best surface SANITIZER for CIP equipment. CIP processes can have some unique requirements for surface SANITIZER, such as low foam or a high-temperature tolerance.

- **Misting/Fogging**

Application of surface SANITIZERS or DISINFECTANTS via fogging or misting should be approved by the EPA and must be specified on the PRODUCT LABEL along with use instructions and safety requirements. In these applications the surface SANITIZER or DISINFECTANT is dispensed via a device that delivers the liquid surface SANITIZER or DISINFECTANT via very small droplets. Fogging typically generates droplets with <50 µm VMD, whereas misting generates slightly larger droplets with a 50 to 100 µm VMD. The purpose of this application is to increase a treated surface coverage. The very small droplet size in mists and fogs compared to coarse spray application droplet size can significantly impact the safety of the surface SANITIZER or DISINFECTANT because small droplets are more easily inhaled deeply into lung tissue. When surface SANITIZERS or DISINFECTANTS are applied as a mist or fog, employees should vacate the area or wear respirators if their presence is required. In addition, for DISINFECTANTS which are registered for misting or fogging, PRODUCT LABELS are required to state that foods must be removed from the area of treatment or be covered up. Small droplets stay suspended in the air much longer than those applied using a coarse spray and may remain in the treated area for hours. Restricted access to the treated area may be required for entire application time as well as several hours after treatment.

- **ElectroStatic Spray (ESS)**

ESS is different from misting and fogging, even though it might seem to be similar. The primary difference is the device used for dispensing the surface SANITIZER or DISINFECTANT generates and applies a very small electrical charge to the products' droplets. The intent of this charge is to attract droplets to the surface being treated to ensure the surface SANITIZER or DISINFECTANT covers all treated surface areas. Mists and

fogs applied with ESS systems do not remain in the air for a long time, but due to the small droplet size, the use of respirators may be required in the areas being treated. Most ESS systems dispense small volumes of surface SANITIZER or DISINFECTANT; therefore, it is important to ensure enough product is dispensed to cover surfaces for the entire contact time specified on the PRODUCT LABEL. When surface SANITIZER or DISINFECTANT is registered for application via ESS, directions and safety precautions are provided on the PRODUCT LABEL.

- **Gaseous/Vaporized**

This application is similar to fogged or misted surface SANITIZER or DISINFECTANT except in this case the surface SANITIZER or DISINFECTANT is applied as a gas form, not in small droplets. PPE is required and employees or other personnel should vacate the area because many gaseous or vaporized surface SANITIZERS or DISINFECTANTS are highly toxic when inhaled. When a surface SANITIZER or DISINFECTANT is registered for this type of application, directions and safety precautions can be found on the PRODUCT LABEL and SDS.

Surface SANITIZER and DISINFECTANT Concentration Verification

Section 4-302.14 of the Food Code states, “A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided”, and section 4-501.116 states, “Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device.” A surface SANITIZER concentration needs to be measured to ensure it meets minimum concentration requirements for proper sanitization and does not exceed appropriate use levels.^[5]

Test strips are the most common test kits used in FOOD ESTABLISHMENTS. Acceptable test strips are usually specified by chemical manufacturers and are different for various surface SANITIZER and DISINFECTANT actives. Although some chemistries have similar actives, they may require different test strips.

It is important to read directions for each type of test strip or other measuring device. Accuracy of results may depend on the tested solution temperature, time required for the strip immersion in the solution, and time needed before comparing the color of the strip and the chart.

Test strips will change color in response to certain levels of the active chemical being measured and will cover a range of concentrations typical to the DISINFECTANTS or surface SANITIZERS the test strips are intended to measure. When using test strips, it is important to choose a test strip with a measurement range that brackets the expected active concentration. For example, if measuring an active concentration of 600 ppm, select a test strip with a range that is both above and below the target level, with the smallest increments possible.^[11]

Usually, surface SANITIZER concentrations are measured in three-compartment sinks, towel buckets, spray bottles, and warewash machines. Surface SANITIZER concentrations are measured immediately after dispensing surface SANITIZER and during use. It is customary to check the surface SANITIZER concentration at least every four hours, or more often if necessary. Frequency for measuring concentration could vary and depends on multiple factors, such as:

- Chemistry used
- Soil levels in the solution
- SANITIZER solution temperature
- Towels/surface SANITIZER ratio
- Type of towels used

Some wiping cloths when placed in quaternary ammonium chloride (QAC) surface SANITIZER solutions for storage, may bind the active to the wiping cloth material, leading to a quick drop of the ACTIVE INGREDIENT in the solution. QACs are known for this but other ACTIVE INGREDIENTS are also susceptible to binding of the active.

Residual cleaning chemical, soil or other materials in surface SANITIZER or DISINFECTANT solution containers can also inactivate the surface SANITIZER or DISINFECTANT. It is critical that any container that will be used to hold the surface SANITIZER or DISINFECTANT is clean and is never used to hold any other chemical.

For accurate measurement, test strips must be used correctly by following the directions on the strip dispenser. An example of a common error is measuring concentration of a surface SANITIZER solution that is too warm or too cold. Most test strips are designed for use at ambient temperature (approximately 75°F). Temperatures above 10°F or below 75°F can lead to inaccurate readings. Another source of an error when measuring detergent-based SANITIZERS, such as QAC is presence of a foam in the sample tested. It is important to ensure a sample tested has no foam on it. Many dosing systems can be slightly inaccurate if a small amount of surface SANITIZER is dispensed for concentration verification. If a small amount of surface SANITIZER (one quart or less) is needed, it is best to dispense a larger volume (one gallon or more) into a container such as a three-compartment sink and test that solution. Smaller containers can then be filled from the larger volume.

Test strips are calibrated for room temperature use and may provide inaccurate results if the surface SANITIZER solution is tested above or below that temperature. It may be necessary to take a smaller portion of surface SANITIZER from a larger volume and allow it to come to room temperature before it is tested. It is important to use test strips before their expiration date.

Other more complicated techniques can be used for measuring concentrations, such as titration kits, but they are seldom used in FOOD ESTABLISHMENTS. Chemical manufacturers may use them to calibrate dispensing equipment.

The FDA Food Code 2017 does not address the use of DISINFECTANTS (only mentioned in Annex 3), therefore, there are no Food Code recommendations for measuring their concentrations. Because all DISINFECTANTS are EPA-registered products, concentration of dilutable products should be tested. Measuring techniques discussed above can be used to verify DISINFECTANT concentration.

DISINFECTION of FOOD-CONTACT SURFACES

Review the PRODUCT LABEL to determine appropriate use as directions can vary.

Determine disinfection needs within the FOOD ESTABLISHMENT, then follow the PRODUCT LABEL instructions for specific use(s) of the chemical.

DISINFECTANTS can be used on an FCS; however, most DISINFECTANTS require rinsing after being applied to an FCS. Regular food preparation and cooking would follow the rinse step (if required) after a DISINFECTION step.

The procedure to clean and disinfect an FCS with a DISINFECTANT requiring rinsing after application is as follows:

- Clean the FCS using a cleaning product, or cleaner- DISINFECTANT.
- Rinse cleaner and soil from the FCS.
- Apply DISINFECTANT and allow FCS to remain wet for the required contact time of DISINFECTANT.
- Rinse off DISINFECTANT.

The procedure to clean and disinfect FCS with a no-rinse DISINFECTANT (i.e., one that does not require a rinse step after use) on an FCS is as follows:

- Clean the FCS using a cleaning product, or cleaner- DISINFECTANT.
- Rinse cleaner and soil from the FCS.
- Apply the DISINFECTANT according to use instructions making sure the FCS remains wet for the required contact time of the DISINFECTANT.

Note the following details on the PRODUCT LABEL:

- **Warning statements:**

Without proper precautions in place, exposure to many cleaning, SANITIZING, or DISINFECTING products can be risky to your health. The Occupational Safety and Health Administration (OSHA) requires any hazards associated with product use be clearly stated on the PRODUCT LABEL. Labels highlight required PPE, first aid procedures in case of a spill or other exposure, and disposal precautions (if necessary). The EPA categorizes products from I (highly toxic) to IV (very low toxicity). If possible, select products rated as category IV to reduce risk of harm.

- **Dilution/refilling and testing of chemical containers:**

The PRODUCT LABEL indicates if the product is in a ready-to-use (RTU) form (i.e., does not require any dilutions) or if it is a concentrate, such as liquid or powder. If the product is in a concentrated form, it will need to be diluted per label instructions before use. A concentrated product has precise instructions for use, listing ounces per gallon and final concentration of a use solution (ppm) to help the end user achieve the correct concentration. The efficacy of some diluted products may be affected by the hardness of the water used to prepare the product. For this reason, manufacturers commonly test product efficacy in hard water. The LABEL may indicate the water hardness level at which efficacy testing was done. Product efficacy may be negatively impacted if the product is diluted in water above the hardness stated on the PRODUCT LABEL. Water hardness varies throughout the United States. For information about a specific location, users should contact the local water utility.

Personal Protective Equipment (PPE):

- To determine PPE requirements, refer to the PRODUCT LABEL and the Safety Data Sheet (SDS), paying attention to how the product will be used. Once a surface SANITIZER or DISINFECTANT is diluted to use concentration,

PPE may not be required. SDS will sometimes recommend two sets of PPE, one for the concentrate and one for the use solution.

- PPE is designed to protect an individual from chemical exposures. Adequate PPE should address exposure risks to skin, eyes, lungs, face, hands, feet, and other parts of the body. Examples of PPE include safety glasses, goggles or eye shields to reduce eye damage resulting from splashing, chemical resistant gloves, long-sleeved garments (e.g., uniforms, closed-toe shoes, and respirators) to prevent accidental inhalation.

- **Contact time**

Contact times can vary based on product type, target organism, or specific use.

- The required contact time for food-contact hard surface SANITIZERS is typically 1 minute, with the exception of contact time for sanitizing in a dish machine.^[5]
- Contact time for nonfood-contact SANITIZERS can be up to 5 minutes.
- DISINFECTANTS can have various contact times which depend on the type of bacteria, viruses, or fungi but do not exceed 10 minutes.

If a product has multiple contact times for the same application, it is recommended to use the longest contact time **and** highest concentration. For additional guidance consult your local health department or the product manufacturer. In cases when a specific organism is targeted, the contact time for that organism listed on the PRODUCT LABEL should be used. For a DISINFECTANT to be effective, the surface must be wet with DISINFECTANT for the full duration of the contact time. Some DISINFECTANTS with longer contact times might need to be applied more than once to achieve the full required contact time.

Safety

Mixing:

Never mix multiple products! Mixing will not only negatively impact performance, but it is an extremely dangerous practice that could result in serious injury or death from the formation of toxic fumes. For example, mixing bleach-based solutions with vinegar or ammonia can generate chlorine and chloramine gases that could result in severe lung tissue damage if inhaled. In a recent CDC survey of chemical end users and consumers, a large percentage of people were unaware of the dangers of mixing chemicals, with only 35% of responders understanding that mixing bleach with vinegar is dangerous.^[12] This knowledge gap highlights the need to educate end-users on the potential dangers of mixing chemicals.

Directions for use on different surfaces:

The use instruction section of a PRODUCT LABEL provides information on use concentration, contact time (see below) and the product application type (product can be sprayed, fogged, misted, electrostatically sprayed, wiped, immersed or mopped). The instructions will also indicate if a pre-cleaning step or a potable water rinse is required. It is important to always adhere to product use instructions on LABEL instructions. Use of surface cleaner, surface SANITIZERS or DISINFECTANTS for tasks they are not designed for could result in damaged equipment or surfaces and lead to employee and/or guest exposure.

Storage and Disposal:

Always refer to the PRODUCT LABEL to determine chemical storage and disposal requirements. Store all products together by chemical type and hazard class code (if applicable). Do not store products together that could cause reactions if mixed. Follow PRODUCT LABEL instruction for ambient temperature storage requirements and do not expose to direct heat. Never store products on the floor and do not store higher than eye level. Storing products on top shelves is a dangerous practice and increases risk of a chemical spill. Be sure all products are properly LABELED so that all handlers are aware of instructions, risks, and safety precautions. Only store products in original packaging or

appropriate containers with correct labels. Re-using empty containers to store other products or chemicals is a risky practice and could result in accidental mixing or exposure as well as violations during safety inspections and is a violation of the Food Code.^[5]

WHERE TO USE DISINFECTANTS IN A FOOD ESTABLISHMENT

Most DISINFECTANTS used in FOOD ESTABLISHMENTS are intended for targeted interventions or specific areas. Typically, they are reserved for restrooms, high touch points, blood and bodily fluid clean up, pathogen remediation, outbreak control, or biofilm control. It is important to use DISINFECTANTS only when needed and **not** as a substitute for a surface SANITIZER.

The following are examples of when it is appropriate to use DISINFECTANTS:

- When the user is concerned about surfaces contaminated with a virus or fungus
- When a surface SANITIZER effective against the organism(s) of concern is not available.
- When required by a regulatory authority

If needed for bodily fluid clean up or pathogen remediation, DISINFECTANTS can be used on most surfaces within FOOD ESTABLISHMENTS, such as food equipment surfaces (food-contact and nonfood-contact), dining tables and chairs, counter tops, food display cases, mop sinks and cleaning tools, restrooms and other customer service areas. To ensure efficacy and safety of DISINFECTANTS, it is critical to use EPA-registered DISINFECTANTS and follow LABEL instructions. Post-rinsing may be required after a DISINFECTANT is used on FOOD-CONTACT SURFACES (this requirement is listed on the EPA-registered label).

DISINFECTANTS can be used on all surfaces listed on the EPA registered PRODUCT LABEL. Currently, there is a limited number of products with EPA registered claims for soft surface disinfection with virucidal claims.

BODILY FLUID CLEAN-UP PROCEDURE

In Section 2-501.11 Clean-up of Vomiting and Diarrheal Events states of Food Code 2017 “A FOOD ESTABLISHMENT shall have written procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter. *Pf.*” Guidelines for implementation of this regulatory provision are in Annex 3 Public Health Reasons/Administrative Guidelines for Section 2-501.11 Clean-up of Vomiting and Diarrheal Events^[5], which identifies what components need to be included in a written plan for clean-up of vomitus and fecal matter in FOOD ESTABLISHMENTS.

Based on these recommendations the following plan should include, but is not limited to:

- Contents of clean-up kit
 - Cleaning agent(s) and effective DISINFECTANT(S)
 - DISINFECTANTS should be an EPA-registered product with a stated claim against norovirus. Consult with your chemical provider to address the questions on product registration if not listed on the PRODUCT LABEL.
 - PPE
 - Cleaning tools
- Procedure for:
 - Preparing contaminated area(s) before clean-up which include:
 - Removing food (packaged and unpackaged), and all items that might have been contaminated (e.g., tablecloth, condiments, flatware, etc.).
Note: *Do not disinfect packaged food as currently there are no EPA-registered DISINFECTANTS approved for this application.*
 - Identifying and isolating areas that will be cleaned
 - Cleaning and disinfecting contaminated area(s)
 - Containing and removing vomit/diarrheal waste
 - Disinfecting pre-cleaned surfaces

- Instructions for post clean-up procedure, which include:
 - Handling PPE and tools used to clean-up vomitus or fecal matter (discarding or cleaning/disinfecting)
 - Discarding open food items which may have been contaminated
 - Cleaning and disinfecting cleaning equipment and tools which may have been contaminated
- Training program for workers on implementation of procedures
 - Training is highly recommended for all new and current employees at least once per year.

Who performs clean-up?

Ideally, nonfood workers should be responsible for cleaning-up vomit/diarrheal waste to prevent cross-contamination. (*This might not be feasible for FOOD ESTABLISHMENTS with limited staff*). Regardless, all workers tasked with clean up should be trained. Professional cleaning services can also be used.

Clean-up kit and other supplies needed for clean-up

Having a clean-up kit readily available ensures all tools needed to properly clean contaminated areas are readily available. Clean-up kits can be purchased or self-assembled.

At a minimum all clean-up kits must include:

- Personal protective equipment – PPE to be worn during cleaning.
 - Follow use directions and PPE requirements listed on a PRODUCT LABEL and SDS.
 - Provide a list of the PPE that must be worn when using the chemicals specified in the FOOD ESTABLISHMENT’S clean-up procedure.
 - At a minimum, anyone cleaning-up vomit/diarrheal waste should wear durable, single-use gloves, disposable eye protection and a disposable apron. Other PPE items may be required for the chemical used. PPE should protect an individual from the chemical used for disinfection as well as from pathogens that may be present in the bodily spill being cleaned and disinfected.

- Cleaning/disinfecting chemicals
 - EPA-registered SANITIZER or DISINFECTANT effective against norovirus.
 - Detergents if used in the clean-up procedure.
- Cleaning tools
 - Absorbent powder/solidifier (e.g., kitty litter or product provided by your kit supplier)
 - Disposable paper towels. Do not use cloth towels as they could be a source of cross-contamination.
 - Mop head if vomit/diarrheal waste are on the floor. If a mop is used, it must be thoroughly disinfected or discarded after use.
 - Bucket, if preparing DISINFECTANT solution.
- **Waste removal**
 - 1 disposable scoop/scrapper
 - 2 plastic bags with 2 twist ties
- **Tools to mark area to be cleaned, such as cones, tape, placard, among others.**

Clean-up procedures

- Before cleaning begins:
 - Direct everyone (i.e., employees and patrons) to vacate the area where the event occurred.
 - Block off the affected area.
 - Put on PPE.
 - At a minimum, personnel assigned to clean should wear, durable, single-use gloves and a disposal apron. Refer to the SDS to determine if additional PPE needs to be worn.
- Cleaning Hard Surfaces
 - Place sufficient absorbent powder/solidifier to completely cover the body fluid waste.
 - Completely cover solidified waste with disposable paper towels.
 - Apply DISINFECTANT (i.e., spray, pour over) so paper towels are saturated.

- Remove the covered waste, which includes solidified matter and paper towels, using a scoop or a scraper. Place covered waste and the scoop/scraper into the first trash bag.
- Spray DISINFECTANT over the area from which the waste was removed.
- Make sure all treated surfaces are wet for the entire contact time listed on the PRODUCT LABEL. Use the contact time for norovirus listed on the PRODUCT LABEL, if the cause of body fluid contamination is unknown.
- Wipe or rinse off the disinfected area with clean paper towel(s).
- Put paper towels and disposable cleaning tools into the first trash bag and tie with a twist tie, then place into second trash bag. Secure the second trash bag with a second twist tie.
 - If non-disposable cleaning tools are used (e.g., mops, buckets), disinfect them after clean-up is complete, before returning them to storage area.
- Remove PPE and place it into the second trash bag tying with the second twist tie.
- Discard the double-bagged waste into a dumpster.
 - Never place contaminated waste in a regular trash receptacle located inside the establishment.
- Wash hands and forearms with soap and warm water for 20 seconds^[5]
 - Wipe hands with a paper towel and turn off the faucet using this paper towel
- Cleaning soft surfaces, such as upholstered furniture, and draperies.
 - Place sufficient absorbent powder/solidifier to completely cover the body fluid waste.
 - Completely cover solidified waste with disposable paper towels.
 - Remove the covered waste, which includes solidified matter and paper towels, using a scoop or a scraper. Put into the trash bag, along with the scoop/scraper used in to the first trash bag.
 - Use DISINFECTANTS with claims against norovirus designed to be used on soft surfaces.
 - Apply (i.e., spray, pour over) so paper towels are saturated.

- A. Spray DISINFECTANT over the area from which the waste was removed.
- *Make sure that the DISINFECTANT used is registered for use on soft surfaces.*
 - *Make sure all treated surfaces are wet for the entire contact time listed on the PRODUCT LABEL.*

Use steaming for disinfection if EPA registered DISINFECTANTS are not available for the soft surface of interest, such as carpet.

- B. “Steam clean (heat inactivation) at 158°F for 5 minutes or 212°F for 1 minute for complete inactivation. Disinfecting with bleach may discolor carpets and/or upholstered furniture”
- Wipe or rinse off the disinfected area with clean paper towel(s).
 - Put paper towels and disposable cleaning tools into the first trash bag and tie with a twist tie then place into the second trash bag. If non-disposable cleaning tools are used, disinfect them after clean-up is complete.
 - Remove PPE and place it into the second trash bag tying with the second twist tie.
 - Discard the trash bag into a dumpster.
 - Never place it in a regular trash receptacle located inside the establishment. If non-disposable cleaning tools are used, disinfect them after clean-up is complete and before returning them to a storage area.
- Wash hands and forearms with soap and warm water.
 - Wash the faucets along with washing hands.
 - Wipe hands with a paper towel and turn off the faucet using the same paper towel.

Cleaning Launderable items

Wash laundry thoroughly

If possible, remove and wash clothes or linens that may be contaminated with vomit/diarrheal waste as soon as possible.

- Handle soiled items carefully without agitating (shaking) them.
- Wear rubber or disposable gloves while handling soiled items.

- Wash the items with detergent (cleaning agent) and hot water at the maximum available cycle length and then machine dry them at the highest heat setting.
- Wash hands and forearms with soap and warm water for at least 20 seconds.^[5]
 - Wipe hands with a paper towel and turn off the faucet using the same paper towel.

ANNEX:

REGULATIONS ON DISINFECTANT AND SURFACE SANITIZER USE IN FOOD SERVICE ESTABLISHMENTS

Oversight and registration of DISINFECTANTS and surface SANITIZERS in the USA

The EPA is the primary regulatory authority for environmental surface SANITIZERS and DISINFECTANTS used in FOOD ESTABLISHMENTS (i.e., retail and foodservice operations). Surface SANITIZERS and DISINFECTANTS are identified as ANTIMICROBIAL PESTICIDES by the EPA, as they fit the statutory definition of products intended to reduce or eliminate microorganisms.^[1] The FIFRA gives the EPA the authority to regulate the distribution, sale, and use surface SANITIZERS and DISINFECTANTS.

The EPA requires laboratory testing to verify manufacturers' antimicrobial activity claims for their surface SANITIZERS and DISINFECTANTS. In addition, the EPA requires extensive data on the potential health and environmental effects of all these products, before granting a registration, which is a license to market a product in the United States.

Regulatory process, testing, review, and approval

The EPA has developed criteria to substantiate acceptable levels of microbial kill or "efficacy" for a product to be registered as a surface SANITIZER or DISINFECTANT. Minimum testing requirements mandate efficacy against specific bacterial strains. Additional microorganisms can be added to the registration if the manufacturer of the DISINFECTANT or surface SANITIZER submits additional lab testing for these microorganisms. Based on data provided by the manufacturer, the EPA determines the human and ecological risks from exposure to products reviewed. Based on this review, precautionary language such as "Caution", "Warning", or "Danger" as well as PPE and first aid labelling. Scientific experts at the EPA analyze the data submitted and make decisions on whether proposed marketing language from the manufacturer is truthful and not "false and misleading." Once data have been evaluated and deemed

acceptable, the EPA approves a product MASTER LABEL and assigns an EPA REGISTRATION NUMBER.

A MASTER LABEL includes all approved uses for a surface SANITIZER or DISINFECTANT, use directions, safety information and an approved marketing language. The PRODUCT LABEL is the label attached or associated with the product as it is distributed and sold. Note the following differences between the two labels:

- PRODUCT LABEL
 - May only contain a subset of the information provided on the MASTER LABEL
 - Is not required to include all information from the MASTER LABEL
 - Cannot contain information not included on the MASTER LABEL
 - Users must comply with this label
- MASTER LABEL
 - Contains all claims approved for use on a registered product
 - Contains all claims approved for use on a registered product for multiple settings, such as household, food service, hospitals, etc.
 - multiple settings such as household, food service, hospitals, etc.

The Occupational Safety and Health Administration (OSHA) has direct authority over Safety Data Sheets (SDS), formerly called Material Safety Data Sheets (MSDS) for surface SANITIZERS and DISINFECTANTS. When an SDS is distributed with a product, it becomes a part of its labeling because it is accompanying the product (FIFRA 2(p)(2)(A)). Therefore, if an SDS includes warnings, precautions or any other information that conflict with the FIFRA-approved label, it could be misleading to end users, resulting in the product to be considered misbranded and unlawful for sale or distribution. For example, in 2012 OSHA adopted a revised Hazard Communication Rule for SDSs which utilizes the criteria for signal words, (e.g., Danger or Warning) adopted by multiple countries under the Globally Harmonized System (GHS) for hazard

communication language and symbols. The EPA has not adopted the GHS criteria; thus, an OSHA SDS may have a signal word that differs from the one the EPA requires for a surface SANITIZER or DISINFECTANT PRODUCT LABEL. PR Notice 2012-1 explains how a company can explain and justify such a difference if it occurs in order to prevent users from being misled by the inconsistencies. If there is a conflict that prevents compliance with both, the chemical manufacturer should be contacted to clarify the conflict.

The data package submitted to the EPA to register surface SANITIZERS and DISINFECTANTS must include:

- Microbiological data (i.e., efficacy data)
- Chemistry data (ingredients and their concentration)
- Stability (or shelf life) data
- Toxicology data (to help determine precautions and recommendations for PPE)
- Food-contact tolerances for each ingredient (FOOD-CONTACT SURFACE SANITIZERS and DISINFECTANTS)

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)
- Approved marketing language

Antimicrobial chemical efficacy testing

DISINFECTANTS, FCS and NFCS SANITIZERS can be tested for antimicrobial efficacy in various ways. The methods are standardized, and some have been validated through multi-lab collaboration.

Although the test methods vary, most of the performance standards show a reduction of test microorganisms. Test methods vary, for example in some test methods test culture is added to the antimicrobial product's use solution (suspension method) or to a test surface (carrier test).

FCS SANITIZERS are generally tested using a 30-second contact time, but the shortest contact time that can be claimed on the PRODUCT LABEL is 60 seconds. Note that FCS SANITIZERS for use in dish machines could claim shorter contact times if the data submitted to the EPA supports that claim. NFCS SANITIZERS and DISINFECTANTS have multiple contact times which could vary for different microorganisms.

Label, labeling and antimicrobial claims

Companies selling or distributing EPA-registered surface SANITIZERS and DISINFECTANTS may not make ANTIMICROBIAL efficacy claims on PRODUCT LABELS or any other written or graphic material, including literature, marketing materials and websites, unless the data supporting the claims were reviewed and approved by the EPA. Surface SANITIZER and DISINFECTANT LABELS provide critical information about how to safely and legally handle and use these products.

EPA-registered MASTER and PRODUCT LABELS are legally enforceable, and all include the statement, *"It is a violation of Federal law to use this product in a manner inconsistent with its LABELING."* **In other words, the LABEL is the law.**

If the intended users of a product are in FOOD ESTABLISHMENTS, companies manufacturing surface SANITIZERS and DISINFECTANTS typically develop data and claims that are most relevant for the product's intended use (e.g., norovirus, *Listeria monocytogenes*, *Salmonella* spp., *Shigella* spp., *E. coli* O157:H7 control, etc.). Many products have proven efficacy as FCS and NFCS SANITIZERS, as well as DISINFECTANTS. It is common for these product categories to be used at different concentrations and contact times.

PRODUCT LABELS generally contain a subset of the claims and use instructions that appear on the MASTER LABEL. A PRODUCT LABEL will often only contain those claims and use instructions appropriate for a specific use setting, such as FOOD ESTABLISHMENTS, health care or other settings. As a result, a product might have a long list of efficacy claims on its MASTER LABEL, but a much shorter list on a PRODUCT LABEL. The user of any surface SANITIZER or DISINFECTANT is required to comply with the PRODUCT LABEL and use the chemical as instructed on that label.

MASTER LABELS of all EPA-registered surface SANITIZERS and DISINFECTANTS are listed in a searchable database available in the EPA PPLS^[13] and in the National Pesticide Retrieval Information System (NPRIS).^[14] To help users select an appropriate surface SANITIZER or DISINFECTANT to control microorganisms of interest, the EPA maintains multiple specialized lists of ANTIMICROBIAL products registered by the EPA.^[15] 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 EPA's newest lists include searchable tables for ease of use. Lists may not be updated regularly therefore; it is important to follow the PRODUCT LABEL use instruction to ensure that the proper surface SANITIZER or DISINFECTANT is used correctly.

Enforcement

The EPA enforces requirements under FIFRA, which governs the distribution, sale and use of surface SANITIZERS and DISINFECTANTS. The EPA is authorized to take enforcement action under the following circumstances:

- Distribution or sale of unregistered surface SANITIZERS and DISINFECTANTS
- Composition of registered surface SANITIZERS and DISINFECTANTS that differ from the formulation submitted at registration

- Registered surface SANITIZERS and DISINFECTANTS that are misbranded or adulterated
- Registered surface SANITIZERS and DISINFECTANTS that are applied using an unapproved method (e.g., fogging)

Enforcement can include fines, stop sale orders, and/or seizure of products not meeting EPA requirements. Additionally, EPA's enforcement program aims to ensure surface SANITIZERS and DISINFECTANTS entering the United States meet EPA requirements.

End users can report suspicious products or individual surface SANITIZER and DISINFECTANT incidents by contacting pesticidequestions@epa.gov. Efficacy of registered products is occasionally confirmed by regulators or manufacturers. Manufacturers are required to review reports of adverse effects or efficacy issues for their registered products and comply with the EPA incident reporting requirements.^[16]

The role of state and local authorities in registration and lawful use of DISINFECTANTS and surface SANITIZERS

Surface SANITIZERS and DISINFECTANTS that are sold, distributed, or used must be registered by each state. States have a variety of requirements for registration which can include all or a subset of the information submitted to EPA and in the case of some states can include additional data requirements. Refer any additional questions to your chemical supplier.

FDA oversight of Food Code and connection to EPA/CDC

The FDA Center for Food Safety and Applied Nutrition, Retail Food Protection Staff, Retail Food Police Team (CFSAN/RFPS/RFPT) produces the model FDA Food Code. It represents the FDA's recommendations for a uniform system of regulation to ensure food at retail is safe for consumers. The Food Code is offered for adoption by local, state and federal governmental jurisdictions for administration by various health agencies with delegated compliance responsibilities for FOOD ESTABLISHMENTS.

FDA partners with federal internal and external agencies who have a stake in food safety (CDC, USDA/FSIS, EPA, FDA-Office of Food Additive Safety, FDA-Office of Food Safety/Division of Seafood Safety and Division of Milk/Dairy Products, etc.) and work together to harmonize regulatory provisions and recommendations where applicable.

The federal government is committed to enhanced coordination of food safety efforts with state, local, and tribal agencies, and the food industry to protect the food supply. Establishing uniform and enforceable standards of food safety in FOOD ESTABLISHMENTS is an important part of strengthening the U.S. food protection system. The FDA, EPA, and USDA partner with food safety stakeholders and are committed to reducing the incidence of foodborne illness in the United States.

Key sections of FDA FOOD CODE addressing surface SANITIZERS and DISINFECTANTS

The use of surface SANITIZERS is addressed in the Food Code in several places. 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. 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 surface SANITIZERS). Important criteria for using chemical surface SANITIZERS, along with examples of commonly used chemicals, are in Food Code Section 4-501.114, 4-703.11(C), 7-204.11.^[5] All surface SANITIZERS must be used in accordance with the EPA-registered label use instructions.

DETERGENT-SANITIZERS are addressed in FDA Food Code Section 4-501.115.^[5]

These combination products can be used for both cleaning and sanitizing steps and do

not require a rinse between the two steps. Apply to clean the surface, which may include wiping if needed to remove soil, then apply again with the same product to sanitize. Refer to the PRODUCT LABEL for use pattern information. Contact your chemical manufacturer to answer any questions.

NFCS SANITIZERS are not directly addressed in the Food Code. The Code recommends only cleaning these NFCS as needed. However, operators often use surface SANITIZERS and/or DISINFECTANTS on NFCS SANITIZERS to minimize the possible risk of cross-contamination.

DISINFECTANTS are not defined in the 2017 Food Code, but their use is referenced in Annex 3 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 FOOD 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."^[5] As stated above, disinfection is currently not a regulatory requirement in FOOD 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 and requirement for post-disinfection rinse).

The Food Code addresses surface SANITIZER use concentration verification. In Section 4-302.14, the code specifies that "a test kit or other device that accurately measures the concentration in mg/L [ppm] of sanitizing solutions shall be provided."

The code further goes on to say in section 4-501.116 that the "Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device".^[5]

Development of disinfection guidance for the public by Centers for Disease Control and Prevention (CDC)

The CDC is the nation's leading science-based, data-driven, service organization that protects the public's health. The CDC is one of the government agencies where recommendations during a public health crisis could be found. In tandem with government agencies, including the FDA and EPA, the CDC makes evidence-based recommendations to the public on the control of pathogens that pose a public health concern. These recommendations often come in the form of guidance documents, such as those released during the COVID-19 pandemic. The CDC takes into consideration the risk factors related to transmission of disease-causing microorganisms as well as the availability of EPA registered products effective against the target microorganism. The CDC provides guidance documents to assist manufacturers or distributors of DISINFECTANTS and surface SANITIZERS in their communication with end users on suitability of products for control of the target pathogen.

During outbreaks caused by a new emerging pathogen, for which effective antimicrobial products might not be registered with the EPA, the CDC can provide recommendations for surface SANITIZER or DISINFECTANT use. In anticipation of such situations, the EPA has published a guideline which helps to register products against new emerging viral pathogens.^[17]

Sustainability considerations when selecting DISINFECTANTS and surface SANITIZERS

In recent years, consumer demand for more sustainable and environmentally friendly products and processes has increased. This demand for more “eco-friendly” and/or “green” products has also carried over to both cleaning and ANTIMICROBIAL products.

The US EPA has programs to help consumers make informed purchases for environmentally friendly products. The EPA's Safer Choice program^[18] helps

consumers, businesses, and purchasers find products that perform and contain ingredients that are safer for human health and the environment. ANTIMICROBIAL products are not within the scope of the EPA Safer Choice program. Instead, EPA maintains a program called Design for the Environment (DfE).^[19] Similar to the Safer Choice program, the DfE program helps purchasers make informed decisions when selecting environmentally friendly ANTIMICROBIAL products, such as surface SANITIZERS and DISINFECTANTS.

The DfE program is optional and there is no regulatory requirement that any surface SANITIZER or DISINFECTANT be certified under this or any other sustainability program. Products approved under the DfE program have been certified by EPA and are ones that:

- minimize any possible risks to human health by excluding ingredients that might have the potential to negatively impact young children, cause cancer, or have other negative effects
- further protect fish and other aquatic life
- minimize pollution of air or waterways and prevent harmful chemicals from being added to the land
- ensure products have no unresolved compliance, enforcement, or efficacy issues

Importantly, the EPA does not consider the DfE logo to be a product endorsement. The DfE logo indicates the product has been certified by the EPA, but these products do not meet the Safer Choice Standards.

Although DfE provides a certification for sustainability of certain attributes of ANTIMICROBIALS, many other products, particularly some concentrates do not meet the DfE certification criteria. However, concentrated ANTIMICROBIALS products have additional sustainability benefits, utilizing less packaging and less carbon associated with transportation, and have the same efficacy and hazard profile as products that are sold as ready to use, when diluted as directed. When choosing a SANITIZER or

DISINFECTANT, it is important to understand the full picture of sustainability of the product and which sustainability attributes matter to you, rather than looking for a certification or seal as this may not be aligned with you/your companies' goals for sustainability.

It should also be noted there are other sustainability programs such as Greenseal and EcoLogo, which offer certifications for cleaning products as well as guidelines for sustainable disinfection. These programs are independent of the EPA DfE and Safer Choice certification but are intended to achieve a similar purpose, i.e., allow users of chemicals to better understand the sustainability and environmental impact of those chemicals. However, it is critical to note that DfE is the only on label certification allowed by the EPA for SANITIZERS and DISINFECTANT. It is also important to understand that all of these programs are completely optional and that a FOOD ESTABLISHMENT is not required to use surface SANITIZERS or DISINFECTANTS that have been certified in any sustainability program, and that sustainable sanitizing and disinfection can be achieved by selecting products with key sustainability attributes in alignment with company goals, independently and regardless of third-party certification.

Supplemental Labeling

Supplemental labeling contains modifications to the pesticide label since the last MASTER LABEL approval (e.g., new use, change application timing). Supplemental labels must be submitted for EPA and state approval, stamped "ACCEPTED" and placed in the official record. Supplemental labels are partial labels distributed with the product by the registrant or distributors in addition to the complete PRODUCT LABEL. Because these are partial labels, they must bear a statement referring the user to the PRODUCT LABEL for complete directions, precautions, and a statement that both the PRODUCT LABEL and supplemental labeling must be in the possession of the user. Compliance with both the PRODUCT LABEL and supplemental labeling is required to safely and effectively use the product.

Supplemental labeling must include the following:

- Product Name
- EPA REGISTRATION NUMBER
- Restricted use classification statement (if applicable)
- “It is a violation of Federal law to use this product in a manner inconsistent with its labeling.”
- “This labeling must be in possession of the user at the time of application.”
- “Read the label affixed to the container for [product name] before applying.”
- “Use of [product name] according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for [product name].”

Typically, supplemental labeling will be incorporated into the MASTER LABEL at the next printing of the PRODUCT LABEL (final printed label) or within 18 months, whichever comes first. There are circumstances when these updates may not be completed. For example, if directions for use on the supplemental labeling are subject to continual, frequent change (e.g., California aerial application county restrictions can change every six months). Supplemental labeling must be approved prior to distribution. Supplemental labeling also includes state registration of special local need (SLN) under FIFRA 24(c).

Distributor label

A distributor label is used when a product is registered to one company but is distributed or sold (known as “supplemental distribution”) by another company (known as the “distributor” or “sub-registrant”). (40 CFR 152.132). Distributor labels are not submitted for approval, but a Notice of Supplemental Distribution must be submitted to EPA and states before supplemental distribution of the product.

The registrant is responsible for the contents of both the distributor product and the distributor label.

A distributor label must be the same as the registered PRODUCT LABEL except for:

- Product name
- Distributor name and address
- EPA ESTABLISHMENT NUMBER
- EPA REGISTRATION NUMBER (a third set of numbers is added at the end denoting the distributor's company number, e.g., EPA Reg. No. 1234-56-7890)
- Product claims (specific claims may be deleted as long as no other changes are necessary, but new claims cannot be added)
- Warranty statements (if allowed by contract between the registrant and the distributor and such change is not false or misleading)

The term “supplemental distributor labeling” is sometimes used but is not proper EPA terminology and is often confused with the term “supplemental labeling.” The correct term is “distributor label.” A supplemental label is used to add new uses or directions for a product, while a distributor label cannot include any uses or directions that differ from the registered product's labeling.

WHAT IS A RADIUS OF THE AREA TO BE CLEANED AND DISINFECTED?

Introduction

Vomiting is a hallmark symptom of a norovirus infection. Infectious norovirus particles can spread in the environment via droplets or aerosol formed during vomiting episodes. Hence, proper environmental disinfection is critical to disrupt its spread. At present, no conclusive evidence is available to support a cleaning radius for vomitus because the extent of contamination and quantity of aerosol formed during vomitus emission and cleanup is still unknown. In fact, most cleanup procedures rarely include a cleaning radius, leaving this to the discretion of the cleaner.

A pattern of viral particles spread is influenced by an array of factors (i.e., viscosity and volume of vomitus, air flow in the room, height of vomiter and type of vomit and establishment layout among others). Given the complexity of each individual factor and

their interaction, it is very difficult to recommend a single radius for clean-up of vomitus. A brief summary of the state of the science regarding norovirus spread in vomitus is below. Multiple studies showed different results regarding the radius of vomit clean-up. This summary is intended to help individual FOOD ESTABLISHMENTS to make a decision on the clean-up radius to be used after a vomiting episode.

Laboratory-Based Studies in Chronological Order

Few laboratory-based studies aim to investigate norovirus spread induced by vomiting. In 2013, U.S. researchers investigated droplet spread during vomiting by conducting a “tipping bucket” experiment.^[20] In these experiments, various volumes of artificial vomit (either artificial saliva or oatmeal) were dropped from a height of 3.5 ft and the amount of splatter across the room was evaluated. The maximum travelling distance of the droplets was 14.5 ft, leading to recommendation for this distance to be a minimum radius for vomit clean-up procedures. Airborne particles may spread further than 14.5 ft.

In a 2014 study, researchers created “vomiting Larry” a vomiting machine designed to replicate realistic vomiting episodes so the droplet spread could be studied.^[21] In this study, water with a fluorescent dye was used to track spread of droplets during vomiting episodes. In a conclusion of this study an area of approximately 84 ft² was recommended to be decontaminated after a vomiting episode. It was emphasized that this area does not take into consideration airborne particles, since they could not be visualized in the experiments.

In 2015, these same researchers published results from aerosolization experiments using a “vomiting machine” which anatomically mimicked a scaled down version of a vomiting episode.^[22] In this study, simulated vomitus and MS2 bacteriophage, a surrogate virus for human norovirus were used. Less than 0.03% of total virus was aerosolized in all experiments, which corresponds to >13,000 norovirus particles aerosolized during a typical vomitus event. This study did not assess total particle spread.

Select Outbreak Case Studies

There are many outbreak investigations where environmental spread of norovirus was documented. In 1998, 58 out of 129 dinner guests became ill at a hotel after a guest

vomited on the wooden floor of the restaurant.^[23] Analysis of attack rates by dining table showed an inverse relationship with the distance from the person who vomited, providing strong evidence for norovirus spread by aerosolization during the vomiting incident. The authors also noted the presence of ceiling fans near the incident, which likely promoted norovirus particle spread throughout the restaurant. No distances between tables were given in the research article, although every table in the restaurant had guests who later became ill from the incident.

In 1999, more than 300 people became sick over a five-day period after a concert attendee vomited multiple times during the concert.^[24] Many of the individuals sickened did not sit in the same section as the index case. This study resulted in the widespread use of 25 feet as a recommended radius for cleaning up suspected norovirus incidents, since there were cases within a 25-foot radius of the index case who became ill.

Conclusions

In summary, there is convincing evidence that vomiting can spread norovirus particles through droplets as well as aerosols. While a facility will need to determine the appropriate practical clean-up radius for their own establishment, there are several best practices that should always be used. Any surface with visible vomitus or diarrhea needs to be cleaned and disinfected during the clean-up procedure. EPA-registered DISINFECTANTS with norovirus claims must be used in these procedures. Since EPA DISINFECTANTS are not registered for decontaminate inanimate packaging materials, packaged foods suspected to be impacted by the norovirus incident should be discarded not disinfected. Airflow should be considered when determining the appropriate area for clean-up. For example, an indoor environment with multiple ceiling fans will likely spread virus further than an environment without fans.^[23] The establishment should consider all affected areas besides the floors such as table legs, table surfaces, shelves, display cases, etc. during cleanup as norovirus particles can spread in all directions during an incident. Consider cleaning other areas which sick individual may have touched.

Literature References

- [1] Fraser A.M., J. Anderson, J. Goncalves, E. Black, A. Starobin, D. Buckley, D. Grinstead, C. Manuel and J. Hollingsworth. 2021. Sanitizers and Disinfectants: A Retail Food and Foodservice Perspective. *Food Prot. Trends*. 41:3 358-367
- [2] U.S. Environmental Protection Agency. 2022. Basic Information about Pesticide Ingredients. Available at: <https://www.epa.gov/ingredients-used-pesticide-products/basic-information-about-pesticide-ingredients#:~:text=Active%20ingredients%20are%20the%20chemicals,with%20its%20percent%20age%20by%20weight.>
- [3] U.S. Environmental Protection Agency. 2022. Pesticide Registration Manual: Chapter 4 - Additional Considerations for Antimicrobial Products. Available at <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
- [4] US. Government. 2012. Federal Insecticide, Fungicide, and Rodenticide ACT. Available at: <https://www.agriculture.senate.gov/imo/media/doc/FIFRA.pdf>
- [5] U.S. Food and Drug Administration. 2017. FDA Model Food Code. Available at: www.fda.gov/FoodCode.
- [6] U.S. Environmental Protection Agency. 2004. 40 CFR 180.940. Title 40—Protection of environment, part 180—Tolerances and exemptions for pesticide chemical residues in food, sec. 180.940—Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions). Available at: www.law.cornell.edu/cfr/text/40/180.940
- [7] U.S. Environmental Protection Agency. 2018. Series 810—Product performance test guidelines: 810.2000—General considerations for testing public health ANTIMICROBIAL pesticides, guide for efficacy testing. Available at: www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines.
- [8] Grinstead, D.A. 2009. Chapter 12: Sanitation for prevention of biofilm formation and biofilm removal. *In* *Biofilms in the Food and Beverage Industry*. P. Fratamico, B. Annous and J. Guenther eds. Woodhead Publishing. pp 331-358
- [9] U.S. Environmental Protection Agency. 2022. Can I apply a product using a method that is not specified in the directions for use? Available at: <https://www.epa.gov/coronavirus/can-i-apply-product-using-method-not-specified-directions-use>.
- [10] U.S. Environmental Protection Agency. 2016. Label Review Manual. Available at: https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm_2-22-21.pdf
- [11] 3M Corporation. 2021. Measuring Disinfectants and Sanitizers. Available at: <https://multimedia.3m.com/mws/media/801225O/measuring-DISINFECTANT-SANITIZER-concentration-tech-talk.pdf>
- [12] Gharpure R, Hunter CM, Schnall AH, et al. Knowledge and Practices Regarding Safe Household Cleaning and Disinfection for COVID-19 Prevention — United States, May 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:705–709. DOI: <http://dx.doi.org/10.15585/mmwr.mm6923e2>
- [13] U.S. Environmental Protection Agency. 2020. Pesticide product and label system. Available at: <https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1>

- [14] Anonymous. 2020. National Pesticide Information Retrieval System. Center for Environmental and Regulatory Information Systems, Purdue University, West Lafayette, IN. Available at: <http://npirspublic.ceris.purdue.edu/ppis/default.aspx>.
- [15] U.S. Environmental Protection Agency. 2020. Antimicrobial Products Registered with EPA for Claims Against Common Pathogens. Available at: <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>.
- [16] U.S. Environmental Protection Agency. 2022. Reporting Unintended Exposure and Harm from Pesticides (Incidents). Available at: <https://www.epa.gov/pesticide-incidents>
- [17] U.S. Environmental Protection Agency. 2016. Guidance to registrants: process for making claims against emerging viral pathogens not on epa-registered disinfectant labels. Available at: https://www.epa.gov/sites/default/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf
- [18] U.S. Environmental Protection Agency. 2022. Safer Choice. Available at: <https://www.epa.gov/saferchoice>.
- [19] U.S. Environmental Protection Agency. 2022. Learn About Design for the Environment (DfE) Certification. Available at: <https://www.epa.gov/pesticide-labels/learn-about-design-environment-dfe-certification>.
- [20] Libera, Dominic A. (2013). Initial Studies Characterizing the Fate of Vomitus During a Projectile Vomiting Episode (Accession No. 1840.16/9038) [Master of Science Thesis, North Carolina State University, Raleigh NC]. Available at <https://repository.lib.ncsu.edu/>.
- [21] Makison Booth C. Vomiting Larry: a simulated vomiting system for assessing environmental contamination from projectile vomiting related to norovirus infection. *J Infect Prev.* 2014 Sep;15(5):176-180. doi: 10.1177/1757177414545390. PMID: 25419239; PMCID: PMC4230971.
- [22] Tung-Thompson G, Libera DA, Koch KL, de Los Reyes FL 3rd, Jaykus LA. Aerosolization of a Human Norovirus Surrogate, Bacteriophage MS2, during Simulated Vomiting. *PLoS One.* 2015 Aug 19;10(8):e0134277. doi: 10.1371/journal.pone.0134277. PMID: 26287612; PMCID: PMC4545942.
- [23] Marks PJ, Vipond IB, Carlisle D, Deakin D, Fey RE, Caul EO. Evidence for airborne transmission of Norwalk-like virus (NLV) in a hotel restaurant. *Epidemiol Infect.* 2000 Jun;124(3):481-7. doi: 10.1017/s0950268899003805. PMID: 10982072; PMCID: PMC2810934
- [24] Evans MR, Meldrum R, Lane W, Gardner D, Ribeiro CD, Gallimore CI, Westmoreland D. An outbreak of viral gastroenteritis following environmental contamination at a concert hall. *Epidemiol Infect.* 2002 Oct;129(2):355-60. doi: 10.1017/s0950268802007446. PMID: 12403111; PMCID: PMC2869894.

Additional Resources

Additional information for control of specific pathogens.

COVID-19

- Cleaning and Disinfecting Your Facility Every Day and When Someone Is Sick
<https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>
- Cleaning, Disinfecting, and Ventilation Plan, Prepare, and Respond
<https://www.cdc.gov/coronavirus/2019-ncov/community/clean-disinfect/index.html>
<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/disinfecting-your-home.html>
- Healthcare
<https://www.cdc.gov/hai/pdfs/resource-limited/environmental-cleaning-RLS-H.pdf>
<https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>

Norovirus

- <https://www.cdc.gov/norovirus/about/prevention.html>
- [Guidelines for Norovirus cleaning – Michigan DOH and Dept of Ag](#)
- [Norovirus: step-by-step clean up of vomit and diarrhea | UMN Extension](#)
- [Norovirus Response and Cleanup \(U.S. National Park Service\) \(nps.gov\)](#)
- [Microsoft Word - Steritech White Paper - Guidelines for Response to Vomiting and Diarrheal Incidents in Foodservice Establishments-Revisions.docx](#)
- [Preventing Norovirus | CDC](#)
- <https://www.osha.gov/sites/default/files/publications/norovirus-factsheet.pdf>
- [General Information about Norovirus | HAI | CDC](#)
- [Food Safety Resources | EHS Activities | EHS | CDC](#); CDC helped this partner: [NorovirusIncident 8.5x11 Eng Clr Concentrated v4 \(waterandhealth.org\)](#).
- [Norovirus Response and Cleanup \(U.S. National Park Service\) \(nps.gov\)](#)

Hepatitis A

<https://www.cdc.gov/hepatitis/hav/index.htm>

Authors

Committee Co-Chairs

Grinstead, Dale. *Mountain Top Microbiology, LLC*
Starobin, Anna. *Food Safety/Antimicrobials Consulting, LLC*

Committee Voting Members

Brandt, Matthew. *Colorado Department of Public Health and Environment*
Buckley, David. *Diversey*
Collins, Alicia. *Steritech*
Culbert, Carol. *Southern Nevada Health District (retired)*
Dinauer, Lauren. *Pima County Health Department*
Farrell, Sharon. *Indiana Department of Health*
Foster, Amy. *Chick-fil-A*
Fraser, Angie. *Clemson University*
Hanson, Patricia. *Florida Department of Agriculture and Consumer Services*
Hernandez, Cris. *Oregon Health Authority*
Hernandez, Jaime. *Starbucks Coffee Company*
Manuel, Chip. *GOJO*
Minjares, Christina. *Whole Foods Market*
Nicar, Dave. *Publix Super Markets Inc.*

Committee Non-Voting Members

Babekir, Amani. *Ecolab*
Baroudi, Al. *The Cheesecake Factory*
Black, Elaine. *Ecolab*
Brady, Janice. *Denny's Inc.*
Carlson, Eric. *New Mexico Environmental Department*
Derr, Samuel. *Elite Food Safety Training, Inc.*
Douglas, Amanda. *Wawa*
Edelen, Jeffrey. *Whole Foods Market*
Haller, W. Michael. *UL Everclean*
Jacobs, Darryl. *Wendy's*
Leach, Katie. *Stop and Shop*
O'Neal, James. *Denny's*
Oswald, Steve. *Wakefern Food Corp*
Rivas, Rose. *Rivas Ranch*
Romo, Nela. *El Pollo Loco*
Schwartz, James. *Alberstons Companies*
Shelton, Susan. *Washington Department of Health*
Thesmar, Hilary. *FMI, The Food Industry Association*
Wallingford, Shelly. *First Watch Restaurants*
Whitlock, Lisa. *Lisa Whitlock Retail Food Safety Consultant*
Wijesekera, Dilshika. *Instacart*
Zenlea, Jeremy. *EG America*

Federal Advisors to the Committee with Alternates

Blackburn, Tajah. *EPA*
Holst, Meghan. *CDC/DDNID/NCEH/DEHSP*
Liggans, Girvin. *FDA*
Moore, Veronica. *FDA*
Rodriguez, Luis. *CDC/DDNID/NCEH/DEHSP*
Williams, Juhi. *FDA*